Risks of non-food consumer products 2021

Contents

1. Introduction

Risks of non-food consumer products 2021 is part of a programme of the Office for Risk Assessment & Research (BuRO) that provides a periodic overview of and insight into the risks to public health and other public interests for all the domains and production chains monitored by the Netherlands Food and Consumer Product Safety Authority (NVWA). The purpose of this report is to specifically identify the hazards and assess the risks to public health associated with the use of consumer products. This document forms the basis for an advisory report that was presented to the Inspector-General of the NVWA on July 14, 2021

1.1. Non-food consumer products

Non-food consumer products or, in short, consumer products, are divided into 16 subdomains based on specific legislation:

- Amusement devices
- Child use and care articles
- Biocidal products and plant protection products
- Chemical substances in consumer products
- Cosmetic products
- Portable climbing equipment
- Electrical equipment
- Gas appliances
- Machinery (for private purposes)
- Food contact materials
- Personal protective equipment
- Toys
- Playground equipment
- Tattoo and piercing supplies
- Textiles
- Other consumer products

The 'Other consumer products' subdomain includes products that do not fit into any of the other 15 subdomains mentioned above. The demarcation of the consumer products domain and subdomains is further described in Section 1.2.

The consumer products domain covers a wide and diverse area. There are hardly any overlaps between the various product groups. Product-related risks are usually introduced during production, e.g. due to an incorrect chemical composition, an unsafe design or a wrong choice of material. The ingredients or components come from a variety of suppliers; the assembler or producer combines them into a product and packages it.

Some of these products are produced in the Netherlands. The NVWA monitors the end product that is placed on the market, but it usually has no insight into production domains, as compared to the domains in food production. The supervision of the production of consumer products is essentially limited to cosmetic products, biocidal products and household chemicals.

The majority of consumer products are imported from outside the Netherlands. It is estimated that 75% are imported from outside the EU (NVWA, 2016f). If the producer is located within the EU, the NVWA can call on market surveillance authorities in other Member States if an unsafe product is found. If the producer is located outside the EU, the only option is to stop an unsafe product is at the border. The point of contact for this is the EU importer.

The domain assessment of consumer products has, therefore, been carried out with a focus on the product type. The physical, chemical and microbiological hazards have been identified for each subdomain and the risks to public health have been assessed.

1.2. Scope

The consumer products domain assessment covers the trading of all product groups that are described in the Commodities Act (*Warenwet*) as 'technical products', including food contact materials. Trading of products is understood to mean offering a product for sale, displaying,

exhibiting, selling or delivering a product or having the product available or in stock. In addition, this domain assessment covers:

- Products used by consumers or offered via sales channels accessible to consumers, e.g. retail or internet
- Products not initially designed for consumers but that are made available to consumers or to which consumers are exposed, e.g. rubber tiles placed under playground equipment
- Products that are used for providing services or that are made available to the consumer, e.g. tanning studios, DIY equipment rental or the application of tattoo inks by tattooists[1]

Exposure to chemical substances may involve aggregate exposure, including from other sources such as food or the indoor environment. In cases where this has a significant impact on the risk, the domain assessment will indicate this.

Products that are subject to other legal regimes or other regulatory authorities include the following:

- Medicines
- Medical devices
- Rubber granulate on sports fields
- Radio equipment: including Wi-Fi and Bluetooth-enabled products
- Vehicles
- Alcohol and tobacco (including e-cigarettes)
- Fireworks
- Pressure equipment
- Professional use of products

The demarcation between product groups is sometimes problematic, and this may lead to a lack of clarity regarding the responsibility of regulatory authorities. In April 2018, the scope was coordinated internally within the NVWA with the Policy, Planning and Instrument Development Department, the Communications Department and the NVWA Intelligence and Investigation Service.

1.3. BuRO assessment framework

The Office for Risk Assessment & Research (BuRO) of the NVWA performed the risk assessment of the consumer products domain in accordance with the Netherlands Food and Consumer Product Safety Authority Independent Risk Assessment Act (*Wet Onafhankelijke Risicobeoordeling Nederlandse Voedsel- en Warenautoriteit*)[2]. For this, two criteria, i.e. scientific substantiation and independence, are important. To fulfil the second criteria, BuRO set up and performed the risk assessment independently. No other organisational units of the NVWA were permitted to be involved, unless they were doing so at the initiative of BuRO, for the purpose of obtaining additional information.

Scientific articles and other reports published before 1 November 2019 were used for the scientific substantiation.

The recommendations resulting from this risk assessment for the monitoring of consumer products are aimed at the risk management activities performed by the NVWA Directorates. BuRO does not set any priorities or make any assessments based on, for example, feasibility and costs. An assessment of how the consumer products will be monitored is explicitly a risk management task.

This report is a risk assessment, where BuRO applies the definition of risk as formulated by Rosa (Rosa, 1998):

Risk is a situation or event where something of human value (including humans themselves) is at stake and where the outcome is uncertain.

1 In legal terms, there is also a question of trading if the product is rented to a specific consumer.
2 Act of 26 April 2006 laying down the rules for an independent risk assessment by the Netherlands Food and Consumer Product Safety Authority. Bulletin of Acts and Decrees 2006, 247.

Under the concept of risk, BuRO therefore distinguishes between the *likelihood* of a human value being threatened and the *effect* of the threat. In the consumer products domain, the *effect* relates to public health. In case of many risks, and in particular, risks arising from the use of consumer products, the interaction between the bearer of the threat (agent, product, chemical, microorganism, etc.) and the target of the threat (humans, animals, nature, etc.) plays an important role. The consumer product risk assessment is an attempt to assess whether the risk is primarily determined by the product or by consumer behaviour. It is often difficult to distinguish this clearly from records of accidents, incidents or other high-risk situations. However, it is important to make this distinction to ensure compliance with laws and regulations and monitor the risks to public health arising from the use of consumer products.

2. Laws and regulations

The risk assessment of the consumer products domain has been carried out within, but not limited by, the existing framework of laws and regulations. Standards have been established for a large number of consumer products. Some of these are harmonised under the General Product Safety Directive.

The chapters on the physical, chemical and microbiological risk assessment of consumer products explore the specific legislation, regulations and standards for each subdomain in greater detail. This chapter presents a general overview. It includes an overview of the laws and regulations identified as relevant to this risk assessment, but this should not be considered a comprehensive overview of all applicable legislation.

2.1. European laws and regulations

With regard to risks in the consumer products domain, the following EU laws and regulations are relevant:

Table 1 Overview of European directives and regulations for consumer products

Directive or Regulation	Scope
Directive 2001/95/EC	General product safety
Regulation (EC) No 528/2012	Biocidal products
Regulation (EU) No 1107/2009	Plant protection products
Regulation (EC) No 1907/2006	Chemical substances and mixtures (registration, evaluation and authorisation)
Regulation (EC) No 1272/2008	Chemical substances and mixtures (classification, labelling and packaging)
Regulation (EC) No 648/2004	Detergents
Regulation (EC) No 850/2004	Persistent organic pollutants
Regulation (EG) No 1223/2009	Cosmetic products
Regulation (EC) No 1935/2004	Food contact materials (framework regulation)
Regulation (EC) No 2023/2006	Food contact materials (good manufacturing practices)
Regulation (EU) No 10/2011	Plastic food contact materials
Regulation (EC) No 450/2009	Active and intelligent food contact materials
Regulation (EC) No 282/2008	Recycled plastic food contact materials
Regulation (EC) No 1895/2005	Epoxy derivatives in coatings (food contact materials)
Directive 84/500/EEC	Ceramic food contact materials
Directive 2007/42/EC	Regenerated cellulose film (food contact materials)
Regulation (EU) No 2018/213	Bisphenol-A in coatings (food contact materials)
Directive 93/11/EEC	Nitrosamines and nitrosatable compounds in rubber teats and soothers
Regulation (EU) No 284/2011	Polyamide and melamine kitchenware from China and Hong Kong
Directive (EU) 2019/904	Single-use plastic
Directive 2009/48/EC	Toys
Directive 2006/42/EC	Machinery
Directive 2014/35/EU	Electrical equipment

Directive or Regulation	Scope
Directive 2014/53/EU	Radio equipment
Regulation (EU) No 2016/426	Appliances burning gaseous fuels
Regulation (EU) No 2016/425	Personal protective equipment

2.2. National legislation

In addition, consumer products in the Netherlands are subject to national legislation. The following national laws and regulations are relevant to the risks associated with consumer products.

- Commodities Act Regulation on Food Contact Materials (*Warenwetregeling verpakkingen en gebruiksartikelen*)
- Commodities Act Decree on Tattooing Colourants (*Warenwetbesluit tatoeagekleurstoffen*)
- Commodities Act Decree on tattoos and piercings (*Warenwetbesluit tatoeëren en piercen*)
- Commodities Act Decree on Formaldehyde in textiles (*Warenwetbesluit formaldehyde in textiel*)
- Commodities Act Decree on Chipboard (*Warenwetbesluit spaanplaat*)
- Commodities Act Decree on Amusement Devices and Playground Equipment (*Warenwetbesluit Attractie- en speeltoestellen*)
- Specific Rules for Amusement Devices and Playground Equipment (*Nadere regels attractive en speeltoestellen*)
- Commodities Act Decree on Portable Climbing Equipment (*Warenwetbesluit draagbaar klimmaterieel*)
- Commodities Act Regulation on (*Warenwetregeling draagbaar klimmaterieel*)
- Commodities Act Regulation on Inspection Methods for Portable Climbing Equipment (*Warenwetregeling methoden van onderzoek draagbaar klimmaterieel*)
- Commodities Act Regulation on Strength Requirements for Soft Drink Bottles (*Warenwetregeling sterkte-eisen frisdrankflessen*)
- Enforcement Agreements for Fire Safety of Clothing in accordance with the Commodities Act (*Handhavingsafspraken brandveiligheid kleding conform de Warenwet*)
- Covenant on the Fire Safety of Nightwear (*Convenant brandveiligheid nachtkleding*)
- Buildings Decree 2012 (*Bouwbesluit 2012*)
- Regulation on Basic Safety Standards for Radiation Protection (*Regeling basisveiligheidsnormen stralingsbescherming*)
- Working Conditions Decree (*Arbeidsomstandighedenbesluit*)

2.3. Standards

A standard contains the agreements made between the producers, traders, users, governments and consumer organisations about a particular product, service or process. A large number of standards have been published in the area of product safety. Chapter 9 contains an overview of all the standards referred to in this risk assessment.

A designated or harmonised standard is a European standard developed by a recognised European standards organisation: CEN, CENELEC or ETSI. It is created following a request from the European Commission to one of these organisations. Manufacturers, other economic operators or conformity assessment bodies can use harmonised standards to demonstrate that products, services or processes comply with relevant EU legislation.

The references of harmonised standards are published in the Official Journal of the European Union.[3] For example, standards have been referenced under the Cosmetic Products Regulation, REACH Regulation, General Product Safety Directive, Toy Safety Directive, Machinery Directive, Electrical Equipment Directive, Gas Appliances Directive, Personal Protective Equipment Directive and Radio Equipment Directive.

[3] https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en

3. Approach

Under the instructions of BuRO, the Dutch consumer safety institute VeiligheidNL and the National Institute for Public Health and the Environment (RIVM) have conducted studies to gather knowledge on the hazards to public health in the consumer products domain. In addition to the reports from these assignments, which were created specifically for the domain assessment, BuRO has also made use of other data sources. These include reports from VeiligheidNL and the RIVM; fact sheets and reports from the NVWA; reports from joint EU market surveillance projects, coordinated by PROSAFE[4]; reports from institutes in other countries, such as the Danish Environmental Protection Agency (Danish EPA), the German Federal Institute for Risk Assessment (BfR), the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) and Health Canada; online databases of the Rapid Alert System for non-food products (Safety Gate) and the Rapid Alert System for Food and Feed (RASFF); reports from the Dutch Poisons Information Centre (NVIC)[5]; and scientific literature (the current domain assessment does however not involve a systematic literature review). Data up to 1 November 2019 have been included in this risk assessment of the consumer products domain.

The draft report was prepared by a multidisciplinary team at BuRO. Divisions of the NVWA's Enforcement Directorate were invited to provide additional information and check for any factual inaccuracies. Subsequently, representatives of sector organisations were requested to assess the draft report for factual inaccuracies.

BuRO has presented the preliminary findings and recommendations of the risk assessment to the Inspector-General of the NVWA and the NVWA directorates, to allow them to formulate a management response. The findings and recommendations were then presented to the relevant policy directorates of the Ministry of Health, Welfare and Sport (Ministerie van VWS).

The risk assessment method used follows the usual steps of such an assessment[6]:

- Hazard identification: separate assessments were made for the different hazard categories (chemical, microbiological, physical and mechanical/electrical) based on information available in different databases, such as Safety Gate. What hazards are relevant to consumer products? In other words, which physical and mechanical/electrical hazards are related to consumer product accidents? What chemical substances or microorganisms are present in/on consumer products that are associated with adverse health effects?
- Hazard characterisation: relevance of the threats to public health (Laux et al., 2016). Physical hazards are characterised based on biomedical knowledge or reported incidents, where a statement is made about the type of injury that may occur and its maximum severity (if possible, with the dose-response relationship). The identified chemical hazards have been characterised based on available toxicity information. At what dose does an effect occur? For the characterisation of microbiological hazards, the following factors have been considered: the way in which potential microbial hazards can enter the consumer products, whether they can survive in these products, whether growth or accumulation occurs, and whether they can cause disease along the route in question.
- Exposure estimation: estimation of the extent to which the consumer is effectively exposed to the microbiological, chemical and physical hazards of consumer products (likelihood).
- Risk characterisation: assessment of the risk in terms of likelihood (exposure) and severity (degree of hazard). For physical and chemical hazards, this has only been done for those subdomains where the relevant hazards are known; for microbiological hazards, all

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4 Product Safety Forum of Europe: a collaboration between market surveillance authorities throughout the European Economic Area (EEA). See http://www.prosafe.org/.

5 The NVIC may only be approached by healthcare providers (e.g. GPs or A&E doctors). The number of requests for advice received by the NVIC only gives an indication of the number of potential poisoning incidents caused due to exposure to a consumer product. This is because healthcare providers only approach the NVIC when they lack knowledge regarding the treatment. After all, if they have the necessary knowledge about the poisoning incident, they will not contact the NVIC immediately when a case presents itself.

6 Act of 26 April 2006 laying down the rules for an independent risk assessment by the Netherlands Food and Consumer Product Safety Authority. Bulletin of Acts and Decrees 2006, 247, last amended by Bulletin of Acts and Decrees 2018, 488.

subdomains have been included, because the risks for this category have been systematically identified for the first time in this risk assessment. These assessments are appended to this risk assessment report.

In the comprehensive risk assessments, the four steps described above have been followed for the identified hazards.

3.1. Physical risks

At the request of BuRO, VeiligheidNL performed an analysis of accident data in the period 2014-2017 and a review of the literature on accidents involving consumer products (Krul et al., 2019). An important source for this is the Injury Surveillance System (*Letsel Informatiesysteem, LIS*), managed by VeiligheidNL, in which a number of Dutch hospitals record all injuries treated at Accident and Emergency (A&E) departments. Other databases with possible information on accidents involving consumer products were also examined. VeiligheidNL organised an expert session to discuss the extent to which accidents and injuries can be attributed to product failure or consumer behaviour. It is often difficult to distinguish between these factors, and the available registration systems offer limited insight into this aspect.

3.2. Chemical risks

It is difficult to assess the chemical risks of consumer products because information on the exposure to chemical substances present in consumer products is not collected in a structured manner in the Netherlands or in Europe. The RIVM has published a report on the chemical substances present in a specific group of consumer products available in DIY stores (Woutersen et al., 2019a). It decided to prepare this report because there is a database available that is primarily focused on this sector: Information System on Consumer Articles (*Informatie Systeem Artikelen, ISA*)[7]. The ISA database contains information on nearly 2 million articles and products from 2,500 different suppliers and retailers, as well as information on the presence of chemical substances in products for sale at DIY stores. The information in the database is based on legally required documents, such as Safety Data Sheets (SDS). The ISA database are mainly DIY products, although it also contains information on cleaning products, adhesives and cosmetic products. Therefore, the RIVM report does not cover the entire product safety domain. In its report, the RIVM has classified substances and products based on hazard classification and exposure in accordance with a methodology developed by it. The products selected from this database are those containing one or more substances with a harmonised classification as hazardous to health, according to the CLP Regulation[8], or substances included in the list of the Dutch Ministry of Social Affairs and Employment[9] or the list of hormone disruptors (internal RIVM list). BuRO has used this selection from the ISA database to identify the chemical hazards.

In addition, BuRO also used other sources of data, particularly for subdomains falling outside the scope of the ISA database. The aim was to identify, for each subdomain, the substance groups or individual substances that occur frequently and pose a hazard. For this, various data sources on the occurrence of substances in consumer products were used, i.e. the priority list from the RIVM report 2015-0194 (Woutersen et al., 2015), NVWA fact sheets, reports from the NVWA laboratory, Danish EPA, Safety Gate, the RASFF and the NVIC and scientific literature.

3.3. Microbiological risks

For microbiological risks, the hazard identification consists of a description per microorganism. The necessary data were collected from Safety Gate notifications, RASFF notifications, RIVM research (De Jonge, 2019), the Source Document on Product Safety (*Brondocument Productveiligheid*) (NVWA, 2016f), the NVWA website (inspections), regulations, contingency plans of the RIVM's

[7] https://www.isa-quintens.nl/product

[8] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1-1355

[9] List of carcinogenic substances and processes, Ministry of Social Affairs and Employment, Government Gazette 2019, 38.

National Coordination Centre for Communicable Disease Control (*Landelijke Coördinatie Infectieziektenbestrijding, LCI*), the RIVM website, the Bad Bug Book (US FDA, 2012) and Canada Public Health's fact sheets. If any information for completing the four steps of the risk assessment was missing, e.g. information on whether there were any known cases of disease involving humans along a particular route, an additional specific literature search was performed in Pubmed and Google Scholar using search terms (e.g. pathogen, product, outbreak or infection).

3.4. Consumer risk perception

To get an idea of how consumers perceive the risks of consumer products, a survey was carried out in 2020 by a research agency under the instructions of BuRO (Motivaction, 2020). The buying behaviour of consumers was examined. What do consumers do with the safety information on the label and what kind of information do they find reliable? Questions were also asked about trust in government and the monitoring of consumer products. For some product categories, specific questions were asked about the assessment of the severity of the risk and confidence in the safety of the product. The perceived risks of the various subdomains were compared with the risks assessed by BuRO.

4. Assessment of the physical risks of consumer products

4.1. General

Physical risks arise due to the way the products are constructed (entrapment, suffocation, sharp edges, moving parts) and due to energy sources (e.g. heat, UV radiation, electric voltage).

Physical risks often result in acute injuries, which can range from superficial (cuts or abrasions) to fatal (suffocation, drowning, severe bleeding, serious head injury) injuries. However, the consequences may also occur gradually and/or emerge later, e.g. hearing damage due to noise or skin cancer due to UV radiation.

Hazard identification relating to the physical risks requires the identification of those product characteristics that may cause injury if the product is used in the reasonably foreseeable manner. The shape of a product may be important (sharp points, sharp edges). The dimensions relative to the anthropometric dimensions are relevant for determining whether a child can get stuck between bars and whether part of a toy could fit into the mouth.

The hazard characterisation encompasses that, based on biomedical knowledge or reported incidents, a statement is made about the type of injury that may occur and its maximum severity; if possible, this is accompanied by the dose-response relationship. The extent of injury - and hence the severity - often relates to the amount of energy released: a fall from a significant height, a collision at high speed or touching a red-hot object results in relatively serious injuries.

The exposure estimation can, theoretically, be derived from the usage data of the product, after assessing the various scenarios via which individuals may come into contact with the product-related hazard. However, as far as BuRO is aware, there are no accessible sources of information about the use of all consumer products; hence, scenarios must be devised by experts, possibly inspired by accident descriptions.

The risk characterisation results from combining information about the likelihood of a scenario and the severity of the resulting injury.

In view of the expected acute effects of physical risks, it seems logical that information on these risks should be sought from accident registrations. Various such registrations are available both in the Netherlands and in Europe. In the Netherlands, this mainly concerns the Letsel Informatie Systeem (LIS, Injury Information System, managed by VeiligheidNL) database, which contains information about victims who have been treated at the accident and emergency (A&E) department of a hospital (Lanting & Hoeymans, 2008); Prismant's National Medical Registration (*Landelijke Medische Registratie, LMR*) of hospital admissions; statistics on the causes of death compiled by Statistics Netherlands (CBS); and data from burn centres. The Survey of Injuries and Physical Activity in the Netherlands (*Enquêteonderzoek Ongevallen en Bewegen in Nederland*) (Urbanus et al.) also presents an overall picture (Hertog et al., 2013). In Europe, the EU Injury Database is managed by Eurosafe[10]. Some of the data are publicly available[11].

The analysis made by VeiligheidNL for the consumer products domain (Krul et al., 2019) covers the period from 2014 to 2017. During this period, an estimated 685,000 victims visited an A&E department annually in the Netherlands due to injuries. Of these, 78% (536,000) had sustained injuries as a result of a personal accident, sports-related accident or single-bicycle accident. The descriptions of the circumstances for the A&E visits contained details of the products that had caused the accident or injury or that had been involved in some other way. Only product groups that were relevant for the NVWA have been selected for the analysis by VeiligheidNL. Of the A&E visits resulting from a personal accident, sports-related accident or single-bicycle accident (536,000), at least one consumer product was mentioned in the description of the circumstances in almost half the cases. Twelve percent of the cases involved at least two consumer products and 1% involved at least three consumer products.

Subsequently, the analyses looked at those A&E visits in which at least one consumer product was in some way involved in causing the injury. Due to the low numbers of A&E visits per consumer

[10] http://www.eurosafe.eu.com/key-actions/injury-data
[11] https://webgate.ec.europa.eu/idb/public-access/

product, the analyses are based only on the total *registered* numbers at the 14 LIS hospitals in the period from 2014 to 2017 (n=110,673); this amounts to 239,000 accidents involving at least one consumer product on a national level (for all hospitals).

At the time of registration, the severity of the injury is indicated by the AIS score. AIS stands for Abbreviated Injury Scale[12]. The value of the Maximum AIS (MAIS) represents the most serious injury to a victim. The MAIS ranges from 1 (minor injury) to 6 (maximum/death). The AIS is recommended by the EU as an indicator of injury severity in traffic accidents. Injuries with a score of 2 or more on this Maximum Abbreviated Injury Scale (MAIS2+) are considered serious injuries.

There is a difference between the severity according to the AIS classification and that determined in the Safety Gate notifications. The AIS describes the threat to life associated with the injury, with a view to immediate treatment. Since the scale has been derived based on casualties from road traffic accidents, it refers to acute injuries. Long-term effects are not taken into consideration. Safety Gate is based on the product, and therefore it considers both the short- and long-term injuries that can be caused by the product. Whereas the AIS is only suitable for the classification of acute physical injuries, Safety Gate can be used for the entire domain of product safety.

A limitation of accident records is that a large proportion of the accidents are not product-related. For example, there are many children or elderly people who fall without any product being involved. Insofar as a consumer product is recorded as the 'Cause of accident' or 'Product involved', the exact role of the product must be critically examined: was it a specific hazard presented by this product, such as a sharp edge or moving part, that caused the fall or could it also have been caused by another product? Therefore, what needs to be looked at is the combination of the products with the type of accident and injury. It should be noted that there is no (European) database available that specifically focuses on incidents involving consumer products.

4.2. Exposure to physical hazards

A consumer is usually exposed to physical hazards through direct contact with a product, which results in transfer of energy to human tissues. The skin will be the first tissue affected, and this can lead to cuts, abrasions or stab wounds. In addition, bones, muscles, tendons and joints can absorb energy; if their load-bearing capacity is exceeded, this can lead to fractures, muscle tears or luxations.

Internal organs are generally only damaged at higher loads, since they are protected by the skin and the skeletal structure. Injuries such as brain damage or impaired breathing can be life-threatening. Impaired breathing may occur in various ways: external obstruction (due to e.g. a piece of clothing wrapped around the neck or a product that covers the mouth and nose), blockage of the pharynx (by an object in the mouth) or closing up of the trachea due to an object blocking the oesophagus.

Exposure to physical hazards is also possible without direct contact. This occurs when the energy is in the form of UV radiation, laser light, thermal radiation, radioactivity or loud noises. These types of physical hazards mainly affect the eyes, skin and ears, but radioactivity in particular can penetrate further and cause internal damage.

This chapter describes the physical hazards in detail: what kind of injuries can they cause, how severe can these injuries be, which product properties determine the effects and severity, which population is most sensitive?

4.2.1. Entrapment

The size of various openings in products can lead to the entrapment of body parts, clothing or hair. In situations where the victim falls or is in motion and cannot stop, this can lead to amputations of, for example, the fingers. If a piece of clothing that is wrapped around the neck (drawstring of a hoodie, scarf, etc.) gets caught somewhere, this can lead to strangulation. This can have potentially fatal consequences. Whether an opening poses a risk or not depends on the interaction

[12] www.aaam.org

between the person and the product, in combination with anthropometric data such as the shape and circumference of the head. In this context, the relevant dimensions are, e.g. the distance between the bars of the baby cot, stair gates and platform guards on playground equipment, the mesh size of climbing nets or the size of chain links (swings). Sharp V-shapes in critical places (e.g. at the top of a slide) are also a hazard. The CEN Technical Report CEN/TR 13387-3 provides an overview of this.

Requirements for preventing entrapment are included in the Toy Safety Directive 2009/48/EC[13] and in various European standards. A recent Australian publication (Vallmuur et al., 2018) noted that, despite these mandatory standards, accidents are still reported with these products; however, these records have several limitations, as indicated in the introduction to this chapter.

4.2.2. Moving parts

Products with moving parts (rotating, reciprocating, parts moving alongside or towards each other) can cause various injuries. Preferably these moving parts should be shielded off, but this is not always possible due to the function of the product. These may include products moved solely by muscular effort, such as playground equipment or bicycles, and collapsible products as well as powered devices such as DIY equipment or amusement devices. The latter categories may involve high amounts of energy. Many types of injuries are possible, such as cuts, broken bones or head injuries. Hair or clothing getting wound around a rotating part can have serious consequences.

Little biomedical research has been done on the amount of force or energy that leads to injury in humans. Most of the research in this area has been performed for the purpose of road safety. One of the few relevant articles is by Hohendorff et al. (Hohendorff et al., 2012). The authors found that, in case of entrapment, damage to a child's finger (aged eight months) occurs at a force of approximately 80 N. This is considerably lower than the legal requirement for the closing force exerted by automatic car windows (100 N).

Requirements for the prevention of injuries caused by moving parts are set out in the Toy Safety Directive 2009/48/EC[13] and in various European standards, such as those for toys, playground equipment, and a technical report on childcare articles (see Chapter 9).

4.2.3. Collision and impact

For a stationary product, collision is usually related to behaviour and is not product-specific. For moving products, impact (a high force or shock exerted over a short period of time when two or more bodies - in this case an object and a person - collide) is an intrinsic hazard, although the likelihood of being hit depends to a large extent on behaviour.

On products such as trampolines or bouncy castles, there is a chance of users colliding with each other; this is difficult to prevent due to the product design and hence user behaviour is an important factor for safe use. Another product-specific hazard with such products is that users may fall off these devices. In that case, the assessment for falls from heights, as covered elsewhere in this risk assessment, applies: setting up protective screens can help prevent a fall and limiting the height of the fall and installation of surrounding shock-absorbing surfacing can help reduce the consequences of a fall.

Moving products include playground equipment such as swings or projectiles such as toy parts, a bow and arrow or a ball. The degree of injury will depend on the body part affected, the shape and material of the projectile, and the energy. Face and eye injuries, in particular, have received quite a lot of attention (Alphonse & Kemper, 2013). Duma et al. (Duma et al., 2005) have established parameters for the degree of eye damage caused by projectiles. They concluded that normalised energy (energy per unit area) is the best predictor of eye injury.

[13] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys. OJ L 170, 30.6.2009, p. 1-37

4.2.4. Fire hazard

A number of different scenarios have been combined under the collective term 'fire'. For consumer products, this can be broken down into the following scenarios.

- A product as a cause of fire. Here the product is a source of ignition, causing flammable or combustible substances to start burning. This requires a certain minimum amount of energy, which is substance-dependent. Some products combine a source of ignition and combustible substance in one product. A product can be a source of ignition if it emits sparks or generates a high temperature, whether or not due to product failure. Examples of this include short circuits in electrotechnical equipment or machine friction.
- A product as a combustible substance (gas, liquid, solid). Consumer products can serve as fuel. For a fire to ignite, the three elements of the fire triangle must be brought together: fuel, oxygen (oxidiser) and ignition source. For products in the consumer products domain, oxygen will mainly come from the air (products containing an oxidising agent, such as fireworks, are excluded from the scope). Flammable substances may contain flammable gases and liquids with a flash point low enough to release enough flammable vapour to flare up on ignition.
- A product is affected by fire and the product catches fire (solid substance). This scenario covers products that present a hazard due to the impact of fire or heat on that product. This may also occur within a single product, e.g. in an electrical appliance in the event of a short circuit. Subsequently the product may catch fire. In case of some solids, such as plastics, the products may melt, creating a hot mass that can leak or stick to the skin.

Exposure to fire may occur in different ways. People can get burned and sustain burns due to the direct effect of the fire in the above scenarios. Another exposure route is a fire in one's home resulting from any of the described scenarios. In such cases, the availability of an escape route from the burning house is important.

Other effects of fire include asphyxiation and poisoning, as a result of the gases released through incomplete combustion. A well-known example of this is poisoning by carbon monoxide.

The use of combination smoke and carbon monoxide alarms in homes reduces the risk in case of fire.

On behalf of the Dutch Association of Insurers (in Dutch: Verbond van Verzekeraars), the Salvage Foundation (in Dutch: Stichting Salvage) provides first aid and shelter after fire, storm and water damage. In the Netherlands, 5,117 house fires occurred in 2018 for which the Salvage Foundation was called in for assistance, which represents an increase of more than 500 compared to 2017. Of these house fires, 100 were caused by a battery or battery pack[14]. The total number of notifications to the Salvage Foundation has been increasing steadily since 2014, and the majority involve house fires.[15]

4.2.5. Electrical voltage

Every household has a range of consumer products that run on electricity. The power required for operating these appliances can be generated by connecting them to a power source. The European electricity network has a standard alternating voltage of 230 Volts at 50 Hz.

Alternating current is suitable for supplying power to motors (such as vacuum cleaners) and some types of lighting. Most electronic circuits operate on direct current. Batteries and so-called stabilised power supplies provide the necessary stable direct current suitable for electronic circuits. Conversion of alternating current into direct current is done with the help of a transformer. A power supply often contains a capacitor to ensure that the current is stable (Kuphaldt, 2006).

How an alternating current affects the body depends mainly on the voltage and frequency. Low-frequency alternating current from the normal electricity grid causes an uncontrolled contraction of the muscles, which can prevent the live wire from being released and thus prolong the exposure. This makes the mains current three to five times more dangerous than direct current with the same voltage and amperage. On contact with direct current, there is a single convulsive

[14] https://www.verzekeraars.nl/publicaties/actueel/risicomonitor-woningbranden
[15] https://www.stichtingsalvage.nl/stichting-salvage/feiten-cijfers/

contraction of the muscles, which generally causes the person to be knocked away from the source of the current.

For both alternating and direct current, the higher the voltage and the greater the current, the greater the resulting injury. The current enters the body at the point of contact with the source of the current and will leave the body via the path of least resistance. An electric current can affect the heart. Alternating current at a frequency of 50 Hz flowing through the chest for only a short period of time at a strength of as low as 60 to 100 milliamperes (mA) can cause ventricular fibrillation, necessitating resuscitation. In case of direct current, this is 300 to 500 mA. In individuals wearing a heart catheter or pacemaker, the current required is much lower due to the direct route to the heart. At high voltages (>1000 Volt), the extent of damage to the brain is so great that respiratory arrest occurs.

Damage to tissue from exposure to electricity is primarily caused by the conversion of electrical energy into heat. The tissue offering the greatest resistance suffers the most damage. In case of skin, there will be burns on the surface of the skin, but at the same time, there will be fewer internal injuries. Low resistance of the skin when exposed to electricity results in few or no burns, while a greater amount of electrical energy is passed on to the internal tissues (Runde, 2018; Zemaitis et al., 2019).

A low-resistance connection in an electrical circuit may lead to a short circuit. The current that flows through can be so strong as to release a lot of heat. Sparks may also be generated. Protection against short circuiting is usually provided by installing safety fuses. If the load is too high, this protection interrupts the circuit.

A secondary hazard is fire. Many house fires and injuries as a consequence of electrical hazards are often due to the resulting fire or associated smoke (Holtrop, 2019). Short circuiting can cause fire.

Exposure to electricity due to consumer products is possible when live parts are accessible and can be touched. This is possible when a product is not designed or constructed properly or when damage occurs, for example, if a wire is pulled loose. Short circuits can occur when the distance between the live parts is too small. Short-circuits in large-capacity batteries, such as lithium-ion batteries, can result in a current so great that it causes an explosion.

4.2.6. Sound

Loud noises can lead to various forms of hearing damage, in particular temporarily or permanently impaired hearing, deafness and tinnitus. Much of the knowledge in this area has been gathered from the working environment at noisy workplaces and in orchestras, but it is becoming increasingly clear that exposure to noise during leisure time can also significantly contribute to hearing loss. Examples may include situations like attending pop concerts, but also the use of specific products such as headphones, toys and portable music devices. Sound also has cardiovascular effects and it can distract one’s attention from other hazards or mask these (e.g. failure to hear an approaching vehicle or an alarm).

The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of the EU has assessed the risks posed by products that can produce music, such as mobile phones and personal music players (PMPs) (SCENIHR, 2008). The degree of hearing loss is determined by the noise level and duration of exposure. It is assumed that an equivalent noise exposure of 80 dB(A) during an eight-hour working day (or a 40-hour working week) poses a negligible risk to hearing. The eight-hour equivalent level ($L_{equ, 8h}$) can be used to quantify noise exposure. SCENIHR concluded that there are many gaps in the data on noise exposure, patterns of PMP use, long-term effects and risk groups.

The European standard for toys EN 71-1 specifies requirements for the sound level that a toy may produce.

The RIVM has derived health-based guidance values for the indoor environment (Dusseldorp & Bruggen, 2007). For this, the health effects on adults were examined. The authors concluded ‘that there is sufficient evidence of the occurrence of hearing damage due to extremely high noise levels and of health and welfare effects, such as experiencing annoyance and sleep disruptions. There is

some, albeit inconsistent, evidence of an increased prevalence of cardiovascular conditions, such as hypertension and ischaemic heart disease. The limit value at which annoyance is experienced is a noise level of 42 dB(A), while a value of 35 dB(A) was found to have an influence on sleep parameters. Hence, these are the proposed guidance values for daytime and nighttime loads, respectively. Measured values for the actual noise levels in Dutch homes are not available.

4.2.7. Hot surfaces

Products that produce heat can cause burns. The severity of these injuries depends on the temperature, contact time and the material that touches the skin (Viglianti et al., 2014). The contact time for adults should be no more than 0.5 to 1 second; for children and the elderly, the response time when touching a hot surface may be longer - up to 15 seconds for children under 24 months.

Heating the products may also lead to breakages, e.g. glass objects. This may lead to cuts or contact with hot liquids.

4.2.8. Small parts

See also under choking as a mechanism of injury.

Small parts of products can cause choking. This is especially a hazard in case of young children who put all kinds of things in their mouths and do not understand how to reverse an action. There is an additional risk if the product is sharp and can lead to perforation of the digestive tract or can cause a chemical or electro-chemical reaction internally, such as a small battery or button cell (Marom et al., 2010; Draisma, 2015).

Choking is a leading cause of morbidity and mortality in children, particularly among children aged three years or younger. Food, coins and toys are the main causes of injury or death that are associated with choking (Committee on Injury Violence and Poison Prevention, 2010). Certain characteristics such as shape, size and consistency are significant with respect to the potential risk of choking.

4.2.9. Cuts

Sharp points or edges on a product can lead to cuts. The hazard is determined by the accessibility of the sharp point or edge, the sharpness as well as the force with which the skin comes into contact with the point or edge.

A criterion for the sharpness of an edge is specified in the European standard for toys EN71-1. If a piece of PTFE tape moved with a certain force along the edge is cut along more than 50% of its length, the edge is considered sharp.

Sharp points can be detected using a testing device, also described in EN 71-1. The point is inserted into a rectangular opening in the device with dimensions 1.02 x 1.15 mm; if this point can reach a depth of 0.50 mm in the device, the point is considered sharp.

4.2.10. Stability

Unstable products can cause injury in a variety of ways if they topple over. This can happen if someone sits or stands on the product and falls along with it; if the product falls on someone; or if the product contains a hot liquid, a hazardous substance, an open flame or moving parts.

In case of a fall involving a product, the severity of the injury depends on the height of the fall and the speed, if applicable. If someone is hit by a toppling product, the mass of the product is an important factor; at the same time, however, a heavy product is generally less likely to tip over or be blown over, because its centre of gravity usually has to rise before a tipping point is reached.

The likelihood that a product that can stand upright on its own will fall over can be determined in two ways: by measuring the energy required to push the product over or by measuring the angle at which a product is no longer stable on an inclined plane (van Aken et al., 1994). In some cases

(e.g. bouncy castles), it is necessary to anchor the product for safe use; for this, proper equipment and instructions should be supplied with the product.

The European standard for toys EN 71-1 includes a criterion for the stability of toys intended to bear the mass of the child and for heavy immobile toys. For the first category, the toy is loaded with a mass of 25 or 50 kg (depending on the intended age group) and placed on an inclined plane with an inclination of 10 degrees. For the second category, the toy is placed on an inclined plane with an inclination of 5 degrees. The toy must not fall over during this test.

4.2.11. Strength

Products or parts of products that are not strong enough may collapse and this may lead to injuries.

The severity of the injury depends on the function of the product and how it is used. If someone is sitting or standing on the product, the height of the fall is important and, if it concerns a moving product, speed is also a determining factor.

The likelihood of a product collapsing depends on the expected loads and the resistance of the structure. In the Netherlands, the Buildings Decree 2012, which applies to built structures, bases its calculation on an ultimate limit state and a serviceability limit state[16]. Although most consumer products are not considered built structures (apart from amusement devices and playground equipment), the same methodology can be applied to them. The expected permanent and changeable loads, dynamic or otherwise, are multiplied by load factors (>1) to take into account unfavourable conditions; when calculating resistance, the calculated strength (resistance) is divided by factors (>1) to take into account unfavourable deviations of, for example, the material properties.

Products whose strength is of great importance are, for example, stairs and ladders, amusement devices and playground equipment or different types of seats. It is also important that small parts of toys or child care products should not be easily detachable. The European standard for toys contains requirements that are based on the force that children can potentially exert on the various parts.

Lack of maintenance, wear-and-tear and ageing can also affect the strength of a product.

4.2.12. Radiation

Products may emit both desired and undesired radiation. Radiation can be divided into ionising and non-ionising radiation. Ionising radiation is radiation with sufficient energy to knock an electron out of the outer shell of an atom. Ionising radiation is mainly associated with nuclear applications in the industrial and medical care sectors. A limited number of applications is present in consumer products. The type of applications permitted in the Netherlands are laid down in the Radiation Protection (Basic Safety Standards) Decree (*Regeling basisveiligheidsnormen stralingsbescherming*)[17]. Examples of such consumer products are luminescent light sources used for escape route signage or emergency lighting. Until 31 December 2005, it was permitted to make ionisation smoke detectors available to consumers. Although the radiation risk is limited, sale for household use has been prohibited, also because of the availability of good alternatives[18].

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[16] Decree of 29 August 2011 laying down regulations for the construction, use and demolition of buildings, Section 2.1. Bulletin of Acts and Decrees 2012, 125, last amended by Bulletin of Acts and Decrees 2019, 178 and the standard NEN-EN 1990 referenced therein. See also: https://www.studeersnel.nl/nl/document/technische-universiteit-delft/beton-staalconstructies/samenvattingen/beton-en-staal-vsb/1203405/view

[17] Regulation of the State Secretary for Infrastructure and Water Management, the State Secretary for Social Affairs and Employment and the Minister for Medical Care of 9 January 2018, no. IENM/BSK-2017/291098, laying down further rules for the protection of persons against the dangers of exposure to ionising radiation. Bulletin of Acts and Decrees 2018, 7, last amended by Government Gazette 2019, 6053.

[18] https://www.autoriteitnvs.nl/onderwerpen/rookmelders

Non-ionising radiation can be divided into two main areas - optical radiation and electromagnetic fields. Optical radiation mainly affects the eyes and skin. The skin becomes red and can become pigmented, while exposure of the eyes can lead to cataracts and damage to the retina and cornea.

Invisible ultraviolet light poses the greatest risks, especially in the long term, and sunlight is the largest contributor to the burden of disease. UV light associated with consumer products is for example the usage of UV lamps in sunbeds, but the sun can also be the source of the rays (sunglasses, clothing). UV radiation can cause skin burns and possibly lead to skin cancer. Skin cancer is the most common form of cancer in the Netherlands[19]. In the development of skin cancer, excessive exposure (especially at a young age) to UV radiation from the sun and/or a sunbed plays an important role. How the skin reacts to this also depends on the skin type. According to the KWF Dutch Cancer Society, the number of people with skin cancer is increasing at an alarming rate. In 2018, nearly 70,000 Dutch people were diagnosed with skin cancer[20].

Lasers emit a specific form of optical radiation. In contrast to other, non-coherent sources, the light is monochromatic and coherent. The biological effects of laser radiation are essentially the same as in the case of other types of optical radiation, but lasers deliver more power on a small area and can cause localised pieces of tissue to heat up to the point of rapid burning.

Table 2 provides an overview of the biological effects of radiation.

Table 2 Biological effects of different forms of electromagnetic radiation

Radiation		**Energy, wavelength, frequency**	**Biological effects**
Ionising radiation	X-ray and gamma radiation	>12 eV	Skin erythema, *cataracts*, sterility, death from acute high doses, *cancer in radiosensitive organs, hereditary effects*
Optical radiation	UVC	100 nm	
Ultraviolet	UVB	280 nm	Skin - erythema (redness), increased pigmentation Eye - photokeratitis (corneal inflammation, also known as welder's flash, snow blindness) *Skin cancer*
	UVA	315 nm	Skin - erythema (redness), increased pigmentation Eye - photochemical cataract
		400 nm	*Skin ageing (photoaging), skin cancer*
Visible	Visible		Eye - photochemical and thermal retinal injury
	IRA	780 nm	Thermal retinal injury, cataract
Infrared	IRB	1.4 µm	Skin burns Eye - corneal burns, cataract

[19] https://www.iknl.nl/kankersoorten/huidkanker
[20] https://www.kwf.nl/kanker-voorkomen/zon-uv-straling-en-huidkanker/de-zon-en-huidkanker

Radiation		Energy, wavelength, frequency	Biological effects
	IRC	3 µm 1 mm	Skin burns Eye - corneal burns, cataract Heating of the body surface
	Microwaves	300 GHz	Heating of the body surface
		1 GHz	Heating with a penetration of 10 mm Increased body temperature
Electromagnetic fields		<100 kHz	Charge accumulation on the body surface Disruption of nerve and muscle response
	Static	0 Hz	Magnetic field - dizziness, nausea Electric field - charge on body surface

Italics indicate long-term effects

4.2.13. Risk of falling

Based on the accident records in the LIS database, falling is a common type of accident. In the context of the consumer products domain, we do not take into account falls from fixed stairs, due to slippery floors or tripping on the street. The risk of falling in connection with consumer products arises, for example, due to the height of the product (climbing apparatus, ladder) or due to the fact that you have to balance yourself on the product (roller skates, wakeboards).

The consequences of a fall are mainly determined by the height of the fall, the surface on which someone falls, and the extent to which the victim can cushion the fall. Limiting the fall height is a logical measure if the product function allows this (Chalmers et al., 1996); otherwise, installing a shock-absorbing surface for cushioning the fall is sometimes possible. Furthermore, in some situations, personal protective equipment should be used (fall arrest belts, body protectors, wrist guards, helmets, etc.).

Quantitative biomechanical criteria for injury severity have been developed mainly for head injuries. The Head Injury Criterion (HIC), developed for measuring the crashworthiness of vehicles (Hutchinson et al., 1998; Cory et al., 2001), has been used to determine the safe height for falling from playground equipment and the shock-absorption capacity of various surfacing materials (Norton et al., 2004), although there are doubts whether the criterion used (HIC<1000) is sufficient to prevent arm fractures as well (Sherker & Ozanne-Smith, 2004). The HIC has also been used to formulate requirements for bicycle and ski helmets (Cripton et al., 2014). This criterion is suitable for characterising this type of injury but, for the overall risk assessment, a methodology analogous to the Safety Gate risk assessment has been used.

Moreover, a lot of research has been done on falls among the elderly, particularly focused on various fractures. But such incidents are usually related to the surfacing or slippery floors in combination with the person's physical condition.

4.2.14. Asphyxiation

Various properties of products can lead to choking (Rider & Wilson, 1996). These may include small objects that can block the windpipe, parts that can form a loop around the neck or products that do not allow air to pass through and can cover the mouth and nose.

Small parts are a particular hazard for young children, who put all kinds of things into their mouths and do not know how to reverse an action; the age limit in this respect is 36 months (3 years).

In the worst case, choking on a part of a product, whether small or large, can be fatal. The possibility of choking is mainly determined by the size and shape of the object. A mould, based on the dimensions of a young child's pharynx, can be used to check whether the object poses a risk. However, Milkovich et al. (2008) have shown that about one-fifth of the reports of choking involve objects that meet this criterion. These could be avoided by using a different mould and extending the requirements to also include toys intended for children above the age of three.

A factor that also contributes to this risk is whether a part of a product can be detached by a child. The toy standard NEN-EN 71-1 prescribes a test during which parts are tested by pulling with a force not exceeding 90 N.

Objects such as cords, strings or scarves that can form a loop around the neck and forcefully pulled can lead to strangulation. Here, the length and strength of the object are of significance. In the European toy standard, a length of more than 30 cm is considered a hazard. According to the European Child care articles - General safety guidelines NPR-CEN/TR 13387-3, loose cords may not exceed 22 cm in length and a loop - even if it can be formed from loose cords - must not have a circumference exceeding 36 cm.

Products that do not allow air to pass through them pose a hazard to young children who are not yet able to remove a covering placed over their mouths and noses; this may lead to suffocation. Such products could include plastic bags, mattresses or pillows on which the child can lie face down. For objects into which the head can be fully inserted, the circumference of the opening is important in terms of the hazard: if this opening is greater than 36 cm, it must be ensured that it cannot be drawn close with a cord. Materials more than 10 cm x 10 cm large that can be pressed against the face must be thicker than 0.038 mm or perforated and 1% of every 30 mm x 30 mm of the surface area must consist of openings.

4.3. Physical risks per subdomain

This chapter describes, for each subdomain and as far as relevant, the specific physical hazards that consumers may be exposed to, the route or mechanism by which such exposure may occur and the indications of actual exposure. Conclusions regarding the risks are drawn based on this. It is difficult to make a statement for a subdomain as a whole about the likelihood of an adverse health effect. Both the accident-related statistics and Safety Gate notifications present a distorted picture. In the case of the accident records, while it is certain that something has gone wrong, it is not clear whether this is because the product has failed or, for example, it has been used incorrectly. The Safety Gate notifications indicate the products that are classified by EU market surveillance authorities as risks, serious or otherwise, but the tested products are largely selected based on suspected deviation from the standard and experiences from previous investigations.

As far as biocidal products, tattoos, and piercings are concerned, the physical risks have not been taken into consideration.

4.3.1. Physical risks of amusement devices

Amusement devices refer to a large number of installations intended for amusement purposes, such as roundabouts, roller coasters, Ferris wheels, etc. The following definition has been provided in the relevant regulations: a structural device, either temporarily or permanently installed, designed to propel people for the purpose of amusement or recreation, powered by a non-human energy source. Amusement devices therefore involve movement, enjoyment and a power source, usually an engine. This means that trampolines with an electrically driven bungee (and therefore with an electric motor) also fall under this definition.

Amusement devices can be divided into two categories. On the one hand, there are devices that are permanently installed, such as in amusement parks. On the other hand, there are amusement devices that are installed temporarily, such as fairground attractions that are assembled and dismantled each time.

Amusement devices are owned by commercial companies. Consumers pay to use these devices. Safe use of these devices depends on how the operator handles the device and how the consumer is instructed and informed.

For operators of amusement devices, there is a strong incentive to ensure safety. An accident has no direct link with the actual risk but, after accidents, a clear decline in visitor numbers has been observed, not only for the amusement device in question but also for comparable devices. Accidents affect consumer confidence and therefore determine whether an amusement device or amusement park is profitable. At the same time, it has repercussions on the entire sector (Woodcock, 2019).

Legal framework

In Europe, amusement devices fall under national regulations. The European Machinery Directive[21] explicitly excludes amusement devices. Only small, electrically powered devices for up to three children are covered under this Directive.

The Commodities Act Decree on Amusement Devices and Playground Equipment[22] has been in effect in the Netherlands since 1997. This Decree sets forth requirements for the various stages of the life span of an amusement device: design, construction and management. This is further elaborated in the Specific Rules for Amusement Devices and Playground Equipment[23] in which the relevant standards have been referenced. For amusement devices, this is the NEN-EN 13814:2004 standard. A new version, updating the 2004 standard, has been published in 2019. The new

[21] Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC. OJ L 157 of 9.6.2006, pp. 24-86.

[22] Decree of 3 September 1996 establishing a general order in council for the implementation of the Dangerous Equipment Act (*Wet op de gevaarlijke werktuigen*). Bulletin of Acts and Decrees 1996, 474, last amended by Bulletin of Acts and Decrees 2016, 189.

[23] Specific Rules for Amusement Devices and Playground Equipment. Government Gazette 1997, 33, last amended by Government Gazette 2017, 4901.

standard consists of three sections that separately describe the requirements relating to design, use and maintenance, and monitoring and inspection. There is a transition period of three years during which both standards may be applied, although it is advised to use the new standard.

The legal framework provides for the mandatory inspection of amusement devices. This inspection must be carried out by a designated inspection body (*aangewezen keuringsinstantie, AKI*). The Ministry of Health, Welfare and Sport appoints these bodies and the conditions to be fulfilled by them are laid down in the Commodities Act Decree on Amusement Devices and Playground Equipment and the associated Specific Rules.

Amusement devices are inspected at various stages of their life span. Before the amusement device is put into use, the design is tested based on safety requirements. After the construction of the amusement device is complete, there is a commissioning inspection, which is the final check. After the amusement device has been put into operation, it is subject to periodic inspection.

Amusement devices that are permanently installed must be inspected once a year or once every two or three years, depending on their speed, acceleration and direction of movement.

The number of AKIs has decreased in recent years. At the end of 2019, there was one AKI in the Netherlands and two AKIs located abroad.

Identification of relevant physical hazards

There are many types of installations that fall under the heading of amusement devices. This makes it impossible to draw up a complete list of hazards applicable to every amusement device. Based on the definition in the regulations and in line with the standard, a certain number of hazards can be identified. The hazards relate to the movement that is made possible due to a power source.

According to the report from VeiligheidNL (Krul et al., 2019), there were 471 notifications in the LIS database for the fixed installations/objects in amusement parks and fairgrounds product group. This is a limited number compared to the total of approximately 110,000 notifications in the LIS database. The percentage of serious injuries with a MAIS2+ score is relatively high (44.1%). Contact with object was the mechanism of injury in 50% of the cases (235 times). Falling as the mechanism of injury was mentioned 187 times (40%).

According to research conducted by VeiligheidNL, approximately 600 people were treated at the A&E department per year between 2009 and 2013 following accidents involving an amusement device. Bumper cars accounted for the largest share of this (34%, 200) and the merry-go-round was reported as the second-most common cause (15%, 90). Six percent of the victims were admitted to hospital after treatment at the A&E department (40). This is a lower percentage than after a personal accident in general (18%), or after a personal accident involving children younger than 15 years (10%), which is the most common age group for victims of an accident with an amusement device. In the LIS database, there are no known fatalities in the period 2009-2013 following an accident with an amusement device.
According to the reports, injuries are caused by contact with a moving object (impact), entrapment and falling (Draisma, 2014).

A search in the NVWA's Notification Support System (*Meldingenondersteuningensysteem, MOS*) with the search term 'amusement device' mainly results in notifications about fairground attractions. This is the same for the notifications regarding injuries. For fairground attractions, in a few cases it has been indicated that the power supply (electricity) was not safe. The outcome of investigations following individual notifications to the NVWA has not been described in detail.

Woodcock and colleagues report a difference between amusement devices that consumers can steer themselves, such as bumper cars, and those that they cannot (Woodcock, 2019). If the consumer is able to influence the operation of the device, the number of accidents appears to be higher.

Based on the inspection results of amusement parks (NVWA, 2015f), the NVWA concluded that compliance with legal requirements and the level of safety guaranteed by amusement parks is relatively high. However, they noted that it is difficult for the smaller parks to set up a proper risk management system. As far as technical defects are concerned, it is reported that such defects

were mainly found in playground equipment. No defects were found in any of the amusement devices. This is attributed to the inspection regime.

To summarise, the most significant physical hazards for amusement devices are falls and impact (collision).

Exposure

There are approximately 1,000 fairground attractions in use in the Netherlands (NVWA, 2017g). These attractions are situated in different locations. According to figures from the Chamber of Commerce, there were 923 fairground operators in 2017. In 2012, 1,370 fairs were organised in the Netherlands, which was several hundred less than 20 years earlier (Deen, 2017). No data are available on the use of these attractions. Large fairs attract numerous visitors. The number of visitors can reach over a million.

As far as permanently installed amusement devices are concerned, in 2016, there were 150 amusement parks that collectively attracted 21,120,000 visitors (CBS, 2019b). The number of amusement devices present in each park and how often they are used is not reported for the Netherlands.

In North America, the IAAPA (International Association of Amusement Parks and Attractions) reports 370 million guests, accounting for a total of 1.7 billion rides on amusement devices. Analogous to the American figures, more than 100 million rides would have been taken on permanently installed amusement devices in the Netherlands.

Research by VeiligheidNL indicates that one-third of the people treated at the A&E department, following an accident involving an amusement device, were between the ages of 10 and 15.

Risks

In discussing the risks, a distinction is made between permanently and temporarily installed amusement devices.

The number of accidents with permanently installed amusement devices is low. In Europe, the accident rate for permanently installed amusement devices is 5.7 cases of injury per million visitors (CEN, 2019). Woodcock (Woodcock, 2019) reports the same number, but as a total for Europe, Africa and the Middle East. The rate of incidence in North America and Asia is only half of this. In North America, 2.1 cases of injury per million visitors have been reported. In Europe, 72% of accidents are attributed to consumer behaviour, 19% to operational causes and 9% to technical causes (CEN, 2019). Avoiding damage to their reputation is an important driver for operators to ensure that the amusement devices remain safe. There is a system of mandatory inspections in the Netherlands. Supervision by the NVWA has shown that there is a difference in the application of risk management systems between small and large amusement parks.

Based on the number of notifications, it appears that there is a greater risk of injury in the case of temporarily installed amusement devices. Due to the repeated process of assembly and dismantling, there is a greater chance of technical defects than in the case of permanently installed amusement devices. A few types of fairground attractions account for a large proportion of the accidents (bumper cars, merry-go-rounds). What plays a role here is that consumers can influence the operation of the device.

Surveillance by the NVWA in 2016 revealed deficiencies in 16% of the fairground attractions inspected, despite the mandatory inspection regime (NVWA, 2017g).

At the time of writing, there is only one inspection body (AKI) in the Netherlands. The NVWA supervises this AKI. In principle, operators have no choice if they want an inspection to be carried out.

Visitor numbers to fairgrounds are declining. Hence, operators are looking for new sources of income, etc., and the income of fairground operators is under pressure. It is not clear if this will affect the safety of the attractions.

Conclusion

The risks of amusement devices are not only related to the device itself, but also to the actions of the user (the consumer) and the operator of the device. When these parties act in a manner not foreseen by the manufacturer of the amusement device, the use of the amusement device becomes riskier. A point for special attention in this respect is the large percentage of young users (10-15-year-olds) that appear in the accident records.

Based on the frequency of treatments at A&E departments, it appears that the main mechanism of injury is impact (contact with object, collision). The severity of injury after impact is assessed at the maximum level of long-term effects that are possibly irreversible (Severity Category 3). Impact occurs more frequently in amusement devices where the consumer can influence the operation of the device, such as in the case of bumper cars. Considering the limited opportunities for consumers to do this, particularly regarding temporarily installed amusement devices, and the number of incidents, the likelihood is assessed as occasional. The combination of the likelihood and severity result in a medium to high risk, which is largely attributable to consumer behaviour.

Falls may occur with amusement devices. A fall from an amusement device operating at high speed or at a height can, in the most serious cases, result in injuries that can be fatal (Severity Category 4). Falls from amusement devices operating at high speed or at a height that are caused by the failure of the device itself are estimated as occurring very rarely, and therefore the likelihood is assessed as rare in the context of this assessment. This applies, in particular, to permanently installed amusement devices. Temporarily installed amusement devices are more likely to fail. The combination of severity and likelihood results in a low to medium risk from falls.

The fact that there is only one AKI in the Netherlands makes the system of inspection of amusement devices vulnerable. Private supervision of amusement device operators can contribute significantly towards reducing the risk of injury.

4.3.2. Physical risks of child use and care articles

Child use and care articles are products intended for young children aged up to 48 months to help them sleep, to feed or carry them or products for them to suck on. Examples include teats, soothers, drink bottles, children's high chairs, cots, baby bouncers, prams, baby mattresses and stair gates. These items are made from a variety of materials, including plastic, wood and metal. Given the particular vulnerability of this group, the safety of child use and care articles is of high priority.

Legal framework

In contrast to other product groups, there are no specific regulations for child use and care articles. Child use and care articles must comply with the General Product Safety Directive[24]. This Directive sets out general safety requirements for products. In view of their intended purpose and expected use, products should not pose any particular hazards to the safety or health of the user, in this case children. More than 30 European standards have been published to ensure the safety of child use and care articles, 13 of which are referenced under the General Product Safety Directive. Examples of these are EN 1400 (soothers), EN 14372 (mainly focused on the physical and mechanical safety of children's cutlery and feeding utensils), EN 14350-2 (drinking equipment) and EN 12586 (soother holders). The CEN Technical Committee (TC 252, Child Care Articles) has also provided a number of technical reports. Part 3 (NPR-CEN/TR 13387-3) explains the mechanical hazards of articles for infants and toddlers.

[24] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. OJ L 11, 15.1.2002, p. 4-17
Commission communication within the framework of the implementation of the Directive 2001/95/EC of the European Parliament and of the Council on general product safety (Publication of titles and references of European standards under the Directive). OJ C 267, 11.8.2017, p. 7-15

Identification of relevant physical hazards

VeiligheidNL's assessment (Krul et al., 2019) shows that the 'articles for transporting babies and children' product group scores low among the most frequently occurring injuries (281 times; 0.3% of a total of approximately 110,000 injuries); child bike seats seem to be the most significant individual product within this group (151 times; 54% of the total). The baby and children's furniture product group occurs even less frequently (246 times) and the baby care articles product group considerably less frequently (22 times). Chests of drawers occur quite frequently as an individual product (174 times). In this subdomain, the consumer products with the highest proportion of serious injuries are the baby bouncer (75%), baby carrier (73%) children's high chair (66%), bunk bed (66%) changing table (66%) and bed (57%). It should be noted that the baby bouncer was mentioned only 20 times and the baby carrier 11 times; also, a bed is not always a cot.

If we look at the mechanisms of injury, falling is by far the most common: 225 times for the articles for transporting babies and children product group and 212 times for the baby and children's furniture product group. Falling is also the most common mechanism of injury for individual products: children's high chair (173 times), child bike seat (94 times), pram (88 times), baby carrier (10 times). In the case of both children's high chairs and child bike seats, the injuries after a fall are often relatively serious: in 73% of the cases.

Contact with object as the mechanism of injury also occurs frequently: 43 times for the articles for transporting babies and children product group, 18 times for the baby and children's furniture product group and 55 times for child bike seat as an individual product. Other mechanisms of injury are rarely mentioned in the LIS database. In 2016, the US Consumer Product Safety Commission (US CPSC) published a report on approximately 59,000 injuries (in 2015) and 300 fatalities (in three years) among children under the age of five involving child care products (Chowdhury, 2016). The products most frequently mentioned for the injuries treated at A&E departments in the United States were cots/mattresses, baby carriers, prams and children's high chairs. Fatalities mainly involved cots/mattresses, cribs, playpens, carriers, baby baths/bath seats and baby bouncers. Injuries were often caused by a fall (from the product). Among the fatal accidents, the cause was often impeded breathing due to an unfavourable sleeping position (positional asphyxia), strangulation or drowning. US CPSC specifically states that the involvement of a product does not mean that the product itself was the cause of injury or death.

An overview has been made of the Safety Gate notifications from 2014 to 2018 relating to the physical safety of child use and care articles. In Safety Gate, the product category of childcare articles and children's equipment was selected.

The selected risk types were asphyxiation, burns, choking, cuts, damage to hearing, damage to sight, drowning, electric shock, entrapment, fire, health risk/other, injuries, strangulation and other, or combinations thereof.

For the sake of conciseness, Table 3 only includes the notifications that occurred more than once a year.

Table 3 Safety Gate notifications relating to the physical safety of child use and care articles in the period from 2014 to 2018

	2014	2015	2016	2017	2018
Total number of notifications	62	67	77	86	54
Choking	11	19	13	18	18
Injuries	34	27	23	32	13
Injuries, suffocation		3			
Entrapment, injuries		3	3		3
Choking, injuries	5		2		
Strangulation	2		10	3	2
Injuries, strangulation		2	6	4	3
Choking, strangulation	2	4		4	
Entrapment, injuries, strangulation			5		

	2014	2015	2016	2017	2018
Suffocation				5	2
Entrapment	2	2	4	2	3
Cuts				3	
Choking, entrapment, injuries			2		
Entrapment, strangulation				3	
Strangulation, suffocation				2	

It is noticeable that the naming of the risks varies greatly. The terms 'choking' and 'injuries' (including injuries from falling) occur every year; the term 'strangulation' also occurs but often together with another term.

Exposure

Exposure to hazards via child use and care articles is possible during transport or sleep and while caring for babies and children. This subdomain includes many different products. A common feature is that a child is often in contact with the product for long periods of time, as in the case of cots or soothers. For the items listed below, sufficient information was found via surveillance or literature to better understand the extent of exposure for the purpose of the risk assessment.

Cots, baby mattresses and mattress covers

Babies and small children spend a lot of time sleeping and therefore have prolonged contact with their cot and mattress.

Suffocation while sleeping among children below the age of one has been studied based on incidents reported to the US CPSC (Gaw et al., 2017). The products most frequently mentioned as being involved in fatal injuries were blankets and pillows. Also, children were often found wedged between a mattress and a wall, highlighting the importance of suitable cots with raised edges. Risks relating to the structure of the bed include the bars that a child can slip through or a gap between the edge of the bed and a - sometimes too small - mattress.

Mouth shields for soothers

Soothers are fitted with a so-called mouth shield. This prevents the soother from being swallowed by a baby or small child. For this reason, requirements have been specified regarding the size of the mouth shield and the ventilation holes.

In 2017, a study on the safety of soothers and soother holders was conducted as part of a PROSAFE Joint Action project (PROSAFE, 2018c). Eleven Member States (including the Netherlands) and Iceland participated in this project. The focus was on carrying out physical and mechanical studies A total of 73 soothers were tested; inspectors looked specifically for potentially deviating products. Of these selectively sampled products, six (8%) did not meet the construction requirements and six (8%) did not meet the mechanical requirements. The shortcomings related to the shield, ventilation holes, impact resistance and tensile strength.

Soother holders

Soother holders are made of various materials, such as textile, metal, plastic and wood. The biggest safety concern for soother holders relates to physical and mechanical safety. In particular, the maximum length (related to strangulation) and strength (related to choking on small parts) is of great significance. Some soother holders have a dual function and also serve as toys. In that case, the product must also meet the requirements for toys.

In 2009, the NVWA carried out a market study on the safety of soothers and soother holders (VWA, 2010a). The soothers were only subjected to a chemical analysis. Thirteen soother holders were examined, five of which did not meet the mechanical requirements. Four of these products had an excessively low tensile strength (one of them was also too long and had a clip that did not meet the requirement for ventilation) and one demonstrated an excessively low impact resistance.

In the above-mentioned PROSAFE Joint Action project from 2017, a total of 122 soother holders were tested, 45 of which also served as toys. Here, the inspectors were trying to specifically

identify potentially deviating products. Of these selectively sampled products, 86 (70%) did not meet the general requirements and 54 (44%) did not meet the mechanical requirements. Of the cords that also served as toys, 31 (69%) did not meet the requirements of the standard for toys. Common failures related to the length (sometimes too long), impact resistance, ventilation holes and, in the case of toys, size and shape (PROSAFE, 2018c).

Children's high chairs

Mainly physical and mechanical requirements are defined for children's high chairs. The NVWA studied the safety of children's high chairs in 2015 (NVWA, 2015e). The sample size consisted of 24 such chairs. Of these, 10 did not meet the requirements:

- One chair was unstable and could tip over backwards (4.2%)
- Three chairs could lead to finger entrapment (12.5%)
- Three chairs had gaps through which a child could fall (12.5%), although these chairs were equipped with a safety belt and, if a parent always made sure to use this belt, there was no risk.
- Three chairs did not carry the warning to make parents aware that a child should not be left alone in the children's high chair (12.5%)

Collapsible children's high chairs can lead to entrapment

Prams and pushchairs for carrying children

In products intended for carrying children, falling is the most common injury scenario (Fowler et al., 2016). A child can either fall out of the product or the product itself can fall over. Collapsible products can lead to entrapment.

Grynkiewicz-Bylina and Rakwic recently studied the strength of 43 carrier products (Grynkiewicz-Bylina & Rakwic, 2019). All the products remained intact during the static test (loading with a 9 to 27 kg child dummy for 24 hours), but 16% and 37% of the products respectively failed the attachment system test (90 cycles, 12.5 cm vertical movement, 2 Hz) and the dynamic test (50,000 cycles with the same movement).

Stair gates

From 2015 to 2018, there were 35 notifications in Safety Gate about stair gates that posed a hazard. The shortcomings often related to bar spacing, strength, attachment, climbability and failure to close automatically. However, there is insufficient information to adequately assess the risks.

Risks

When child use and care articles fail, serious injuries can occur. For example, certain scenarios that result in choking or a fall from a certain height can have serious consequences.

The likelihood of damage to health is not easy to determine for the subdomain as a whole. Virtually all young children will come in contact with one or more products from this subdomain and there is a high likelihood of exposure to the hazards present. There will often be a very minor health effect. However, it can be deduced from the accident records that tall products (high children's high chair, high sleeper bed, changing table) pose a considerable risk of certain injuries, since children can fall out of them or fall off them. There is a slightly less but still considerable likelihood of baby carrier products not being sufficiently strong. Products with cords often do not comply with the stipulated requirements, but apparently this does not often lead to incidents that are reported (few notifications of accidents and damage to health).

Conclusion

Falls can have long-term and permanent effects (Severity Category 3). A fall is the most commonly reported mechanism of injury, especially for children's high chairs, bicycle seats and changing tables. Almost all children up to approximately the age of three regularly sit in a children's high chair (3% of the population). Bicycle seats and changing tables are also widely used. The danger of falling is always present with the above-mentioned products because of the

elevated sitting or other position, but the likelihood of falling can be reduced through measures such as straps to secure the child. The likelihood of exposure (occurrence of the fall scenario) probably depends only to a small extent on the failure of the product; instead, behaviour such as inattention or failure to secure the child are important factors that increase the risk. Insofar as the product plays a role (such as the stability of the children's high chair), failures are rare, as is evident from the accident figures: in absolute terms, the number of reported fall injuries is limited. However, it should be noted here that minor incidents may occur often, without being reported. The overall likelihood of serious injury is assessed as rare, but the likelihood of limited injury is considerably higher. The risk depends to a large extent on the behaviour of parents/caregivers, which is difficult to influence via market surveillance. However, some of the child use and care articles do not meet the safety requirements. There appears to be a low to medium risk for consumers due to defective child use and care articles.

Suffocation due to obstructed breathing can be fatal (Severity Category 4). Several types of child use and care articles can cause suffocation: cots/mattresses, soothers, cords and products with bars such as stair gates. Baby cots and soothers are widely used, and stair gates and soother holders are also commonly used. The danger of suffocation only occurs if the product does not comply with the applicable standards. If caregivers do not notice the risky situation in time and intervene appropriately, very young children may not be able to remove the object obstructing their breathing on their own. However, there is a low likelihood of suffocation actually occurring: this mechanism of injury is almost non-existent in the LIS records. Nevertheless, suffocation in baby cots with a fatal outcome has been reported in the literature. The overall likelihood is assessed as rare. The combination of the likelihood of suffocation due to defective child use and care articles and the severity of damage to health due to suffocation results in a low to medium risk for consumers. Supervision by parents/caregivers of babies and children can help reduce product-related risks.

An insufficiently strong product can cause a fall with serious consequences (Severity Category 3). This scenario is especially likely in case of products such as baby carriers, children's high chairs and stair gates. There is a high likelihood of these products being used. Falls from a baby carrier sometimes occur, but it is not certain whether this is due to the carrier being insufficiently strong. Therefore, the likelihood is assessed as rare. The combination of the likelihood of an insufficiently strong baby and children's article and the severity of damage to health due to a fall results in a low to medium risk for the consumer, where the parent/caregiver can play an important role in reducing the risk.

The detachment of small parts that can fit into the child's mouth may cause choking (Severity Category 4). This scenario is especially likely in the case of products such as baby carriers, soothers and soother holders. There is a high likelihood of these products being used. The likelihood of obstructed breathing due to small parts is assessed as low, but if this occurs, there is a high risk of injury, particularly if caregivers do not intervene immediately when small parts are involved. Therefore, the likelihood is assessed as rare. The combination of the likelihood of insufficiently strong child use and care articles and the severity of damage to health due to choking results in a low to medium risk for consumers. Ageing products and wear and tear can increase the likelihood of injury.

4.3.3. Fire risk due to chemical substances in consumer products

In case of a chemical burn after contact with a caustic/corrosive substance, the skin becomes red and swollen, sometimes with blistering (as with thermal burns). Burns can also be caused by products made of flammable mixtures.

Legal framework

The CLP Regulation[25] (classification, labelling and packaging) is based on the Globally Harmonised System (GHS) of the United Nations. The Regulation lays down detailed criteria for labelling

[25] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures, amending and repealing Directives

elements: pictograms and standard warning sentences for hazards, prevention, response, storage and disposal for each hazard class and category. Corrosive chemicals are indicated by a hazard symbol for corrosive substances displayed on the packaging; for such chemicals, contact with the skin must be avoided by wearing suitable gloves. Similarly, the packaging of flammable gases and vapours, liquids, aerosols and solids display a hazard symbol for flammable substances.

Substances or mixtures classified under Category 1 (skin corrosion), sub-categories 1A, 1B and 1C, according to the CLP Regulation must be fitted with a Child Resistant Fastening (CRF). Substances or mixtures classified as flammable gases Categories 1 and 2, flammable liquids Categories 1 and 2 and flammable solids Categories 1 and 2 according to the CLP Regulation must be marked with a Tactile Warning of Danger (TWD). This enables blind and visually impaired people to determine whether a product contains a hazardous substance or mixture.

Under the CLP Regulation, companies in the Netherlands that make mixtures (mixture or solution consisting of two or more chemical substances) available on the market are obliged to notify the Dutch National Poisons Information Center (NVIC, Nationaal Vergiftigingen Informatie Centrum) of the composition of these products and of the relevant safety information. The NVIC uses this product-specific information to assess the severity of exposure and inform professional care providers about the health effects and treatment options for cases of poisoning involving these mixtures.

Hazard identification

Chemicals can catch fire and therefore cause burns. Some of the most common products that could cause chemical burns at home are battery acid from car batteries, cleaning products, bleach, ammonia, toilet cleaners, drain unblockers, paint strippers, denture cleaners, teeth whitening products, chlorine products for swimming pools or cement mix. Contact usually occurs by accident or because the safety rules are not properly followed. Babies, elderly and disabled persons are at higher risk of chemical burns (Mekkes, 2017).

Exposure

Chemical burns occur when the skin comes into contact with aggressive chemicals, especially strong acids (including hydrochloric acid, sulphuric acid, nitric acid and hydrogen fluoride) or strong bases (including sodium hydroxide, calcium hydroxide, barium hydroxide, and potassium hydroxide). Chemicals that are swallowed or inhaled can also damage the oesophagus or lungs or other organs (Mekkes, 2017). Burns can also be caused by a flammable mixture catching fire, e.g. the use of methylated spirits on the BBQ.

Risks

For the period 2014-2018, there are Safety Gate notifications for 274 products that are classified as chemical products. Out of these, if one searches specifically for the terms 'fire' and 'burns', four notifications fit the criteria. Three of these notifications relate to incorrect labelling, which creates a potential fire risk. One notification relates to an unsafe product (decalcifier) that can potentially lead to chemical burns, because the product foams when applied to a kettle or coffee machine.

Research by VeiligheidNL shows that, in a quarter of all visits to the A&E department in the Netherlands where the victim had an injury due to the effect of chemicals, a fire was involved in 24% of the cases and a cleaning product in 11% of the cases. The victims mainly suffered from poisoning, allergic reactions or superficial injuries as a result of chemical exposure. Bleaches/chlorine were mentioned in 4% of A&E visits and hair care products in 3% of the visits (Krul et al., 2019).

The NVIC receives tens of thousands of questions each year about cases of poisoning of humans and animals. By recording these information requests, it is possible to identify trends in the frequency of poisonings with specific substances. Figure 1 summarises the number of reported

67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1-1355

exposures (%) to household and DIY products across various product groups from 2014 to 2018 (NVIC, 2015;2016;2017;2018).

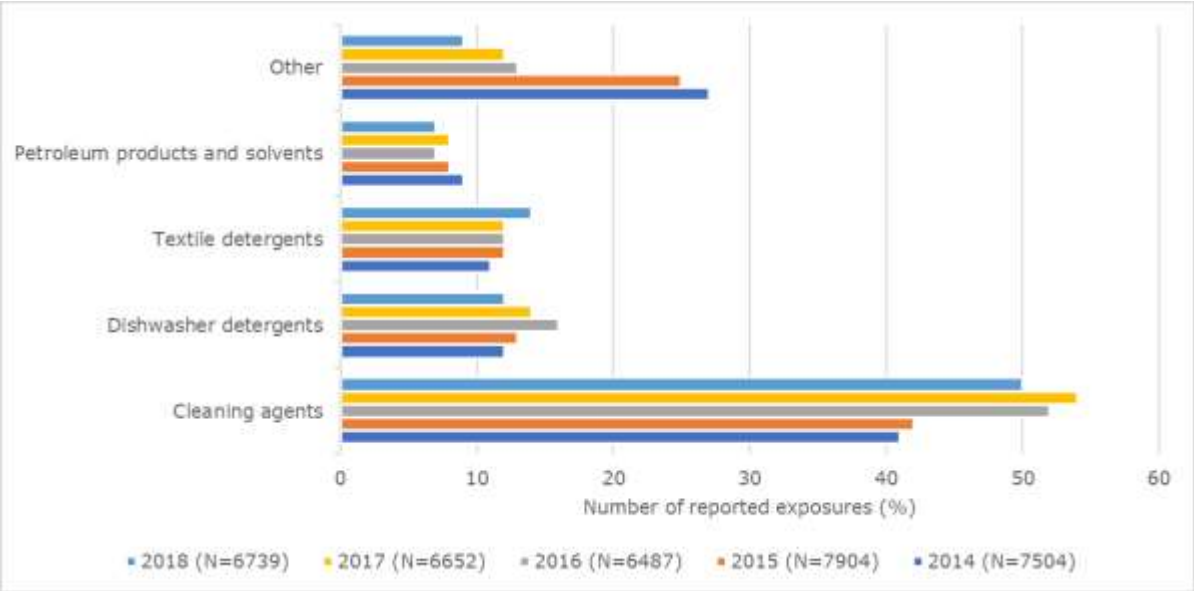

Figure 1 Overview of the number of reported exposures (%) to household and DIY products across the different product groups in the household and DIY products category from 2014 to 2018.

The breakdown by different product groups was more extensive in the NVIC annual overviews of 2014 and 2015 than in the later annual overviews. For the sake of clarity, only the reported exposures to product groups that recur in all the annual overviews have been displayed. The product groups that do not appear in all the annual overviews have been added to the group called 'Other'. This also explains why the size of this group was relatively large in 2014 and 2015. Most exposures to household products occurred in children aged 0 to 4 years (NVIC, 2015;2016;2017;2018;2019b).

In 2015, compared to 2013 and 2014, there was an increase in the number of notifications involving people aged 13 and above relating to unblockers. Most case of exposure were via skin contact, although ingestion, inhalation and eye contact have also been reported. Unblockers often contain sodium hydroxide or sulphuric acid. Both of these compounds are highly corrosive and cause tissue damage in case of exposure (NVIC, 2015).

The industrial products category includes chemical substances that can be used in or released from industrial processes. Exposure is mostly work-related and occurs via accidents in factories, refineries and laboratories. Consumers may also be exposed (e.g. chlorine in swimming pools or strong acids in cleaning products).

Figure 2 shows the number of reported exposures (%) to industrial products from 2014 to 2018. The group 'Other' consists of cases of exposure to smoke during fire and to combinations of chemicals (NVIC, 2015;2016;2017;2018;2019b).

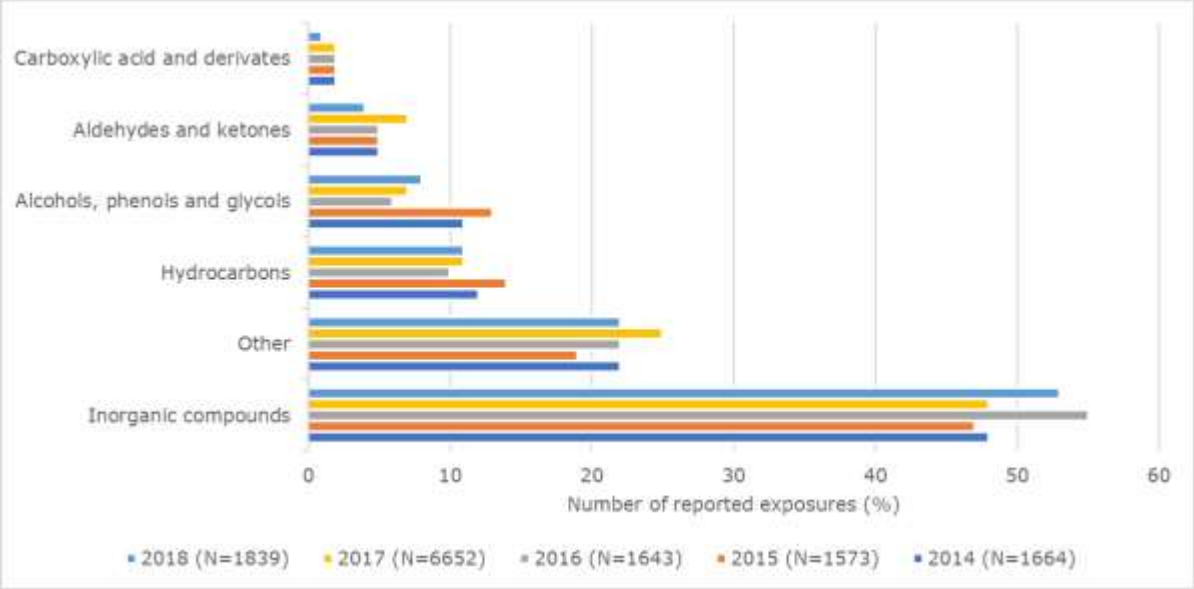

Figure 2 Overview of the number of reported exposures (%) to industrial products across different product groups in the industrial products category from 2014 to 2018.

Inhalation of gases or vapours is the main route of exposure for industrial products, followed by skin and eye contact. Most exposures to industrial products occurred in adults aged 18 to 65 years. Exposure to inorganic compounds was most frequently reported. This includes metals and strong acids and bases. Within the home environment, children aged 0 to 4 years are sometimes exposed to alcohols, phenols and glycols.

In 2014, nitric acid is a new entrant on the list of industrial products with the highest number of exposures. Nitric acid is a corrosive acid that can cause severe tissue damage at high concentrations (NVIC, 2015).

Conclusions

There are sufficient safeguards in place to warn consumers against the use of products that are flammable or corrosive. It is likely that the accidents that occur with flammable or corrosive products are mainly the result of incorrect behaviour on the part of the consumer. No indications were found of products not fulfilling the purpose for which they had been designed or for which they were meant to be used.

Flammable or corrosive products (e.g. DIY products and household and cleaning products) are used by many consumers. The likelihood of a health effect due to exposure to these products is assessed as rare, provided that proper precautions are taken. The damage to health resulting from the use of flammable or corrosive products is assessed as long-term effects that are possibly irreversible. The combination of likelihood and severity results in a low risk for the consumer if the product is used correctly. Despite this, health effects are sometimes reported, which may be the result of improper or incorrect use. It is therefore important that consumers are properly informed about the correct manner of use and warned against misuse or improper use. Illiterate people (such as small children) or non-Dutch speaking persons, who are unable to read and understand the instructions, are at an increased risk.

4.3.4. Physical risks of cosmetic products

Sunscreen products protect the skin from harmful exposure to the sun’s rays. The indicated SPF (Sun Protection Factor) is a measure of protection primarily against UVB radiation. The SPF is defined as the ratio of the minimal erythemal dose on skin protected by a sunscreen product to the minimal erythemal dose on the same skin without any protection. Besides sunscreen products, regular cosmetic products also contain SPF, e.g. day creams or hair masks. Other physical risks associated with the application of cosmetic products have not been taken into consideration.

Legal framework

Cosmetic products must comply with the Cosmetic Products Regulation (Regulation (EC) No 1223/2009)[26]. Article 3 stipulates that cosmetic products must be safe for human health when used under normal or reasonably foreseeable conditions of use. The European Commission has published a recommendation on the efficacy of sunscreen products and the claims made by them[27]. Sunscreen products must offer protection against both UVB and UVA radiation. The recommended test method to be used for determining the SPF value (measure of UVB protection) is the International Sun Protection Factor Test Method. This standard for the *in vivo* determination of SPF has since been replaced by ISO 24444. There is also an *in vitro* procedure for determining the SPF of UVA protection: ISO 24443.

According to this recommendation, the SPF should be indicated on the label of sunscreen products as shown in Table 4.

Table 4 SPF claim and protection in accordance with Commission Recommendation 2006/647/EC

SPF according to the label	Measured SPF	Protection
6	6-9.9	Low
10	10-14.9	Low
15	15-19.9	Medium
20	20-24.9	Medium
25	25-29.9	Medium
30	30-49.9	High
50	50-59.9	High
50+	>60	Very high

In addition to the SPF, the label should also indicate whether the product provides low, medium, high or very high protection. If a product also offers protection against UVA radiation, this should be indicated by means of the logo below. The UVA protection should be at least one-third of the UVB protection.

Commission Recommendation 2006/647/EC also states that sunscreen products should display warnings indicating that these products do not provide total protection and should include advice on other precautions to be observed. The label should also carry instructions for use that will ensure that the claim regarding the effectiveness of the product can be achieved.

Exposure

If there is insufficient protection from the sun, the skin will be exposed to increased solar radiation. In addition to immediate consequences such as skin burns (reddening), long-term effects such as skin cancer (melanomas) are a serious risk to public health.

Risks

The Safety Gate system was searched for notifications in the period from 2014 to 2018 for cosmetic products and the terms 'SPF' and 'UV'. This search resulted in 10 Safety Gate

[26] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59-209.

[27] Commission Recommendation 2006/647/EC of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto. OJ L 265, 26.9.2006, p. 39-43

notifications. However, eight of these notifications were related to the presence of chemicals (e.g. too much preservative) in sunscreen products or cosmetic products with SPF (day cream). One product label contained no indication of UV filters but had an SPF of 30. On another product, there was an error in the translation of the warning sentence on the label.

In 2014, the NVWA carried out a study on SPF in sunscreen products (NVWA, 2015c). In all, 176 sunscreen products of different brands, price categories, types (cream, milk, oil, gel and spray) and with high and low declared SPF values were sampled. The products were examined for N-nitrosodiethanolamine (NDELA) and UV filters (see: Chemical risks of cosmetic products). Based on the assessed UV filters, 58 products were selected, and their SPF was determined *in vitro* and *in vivo*. No proper statements can be made about the reliability of the SPF value on the basis of the SPF *in vitro* measurements. The SPF *in vivo* measurements show that the majority (86%) of the SPF values listed on the label is correct. For eight products, the measured *in vivo* SPF is lower than claimed. Here, the deviation was greater than 25%.

Conclusions

Excessive exposure to UV radiation can cause damage to the skin and sometimes lead to skin cancer (Severity Category 4). Some of the sunscreen products on the Dutch market provide significantly lower protection than claimed. Consumers may potentially expose themselves to the sun for longer than the period of time for which the product provides protection. A large part of the Dutch population uses sunscreen products during the summer and during holidays in sunny locations. Proper application of sunscreen plays an important role in protecting the skin from UV radiation. In addition to the SPF, the frequency of application and quantity of product applied are important. Figures from the KWF Dutch Cancer Society reveal that skin cancer due to overexposure to UV radiation is on the rise in the Netherlands. Taking all factors into account, the likelihood of skin cancer occurring due to a sunscreen product with insufficient SPF is assessed as occasional. Consumers are dependent on the market surveillance authority for mitigating this risk. In addition, consumers can reduce the risk themselves by limiting their exposure to UV radiation and using sufficient sunscreen. The combination of the likelihood of adverse effects on the skin, including skin cancer as a result of using sunscreen products with a significantly lower level of protection than claimed, and the severity results in a medium to high risk. Given the high likelihood of exposure to UV radiation, the provision of adequate information is important for limiting the risks.

4.3.5. Physical risks of portable climbing equipment

Portable climbing equipment is intended to allow one person at a time to bridge a height difference or to offer a means to assume an elevated or lowered position. Such equipment is intended to be transported without mechanical aids.

Since the ability to move the piece of equipment is a feature of portable climbing equipment, the structure is light and compact. At the same time, the structure must be sufficiently rigid, stable and strong for safety reasons. Different materials are used for this, e.g. metal, plastic and wood.

Portable climbing equipment sold to the consumer is not always specially designed for private use. The same products may also be intended for professional use.

Legal framework

From a European perspective, portable climbing equipment is subject to the General Product Safety Directive 2001/95/EC. This states, in general terms, that a product must be safe and must not, under normal or reasonably foreseeable conditions of use, present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons.

In the Netherlands, specific regulations have been in effect for a long time. Portable climbing equipment must comply with the Commodities Act Decree on Portable Climbing Equipment[28]. This

[28] Decree of 29 January 1986 laying down rules for certain types of ladders and steps; Commodities Act Decree on Portable Climbing Equipment. Bulletin of Acts and Decrees 1986.

includes Commodities Act Regulation on Specific Requirements for Portable Climbing Equipment and the Commodities Act Regulation on Inspection Methods for Portable Climbing Equipment [29].

In addition, there are European non-harmonised standards for portable climbing equipment. The NEN-EN 131 standard describes requirements for ladders and steps and NEN-EN 14183 covers step stools.

Identification of relevant physical hazards

VeiligheidNL's assessment (Krul et al., 2019) shows that five percent of the victims visiting the A&E department did so after a fall from a step or ladder, fixed staircases excluded. It is likely that these cases mainly relate to portable climbing equipment. The household step appeared among the top 30 most common consumer products as well as the highest proportion of serious injuries (MAIS2+ 68%). As stated by VeiligheidNL, it is not easy to indicate which of the injuries from accidents involving consumer products are caused by product failure. However, it does appear that a combination of factors is often involved: product failure combined with foreseeable and unforeseeable behaviour. With respect to product failure, it is not possible to make a distinction between, on the one hand, factors relating to the design and manufacture of the product, and on the other hand, the consequences of use and ageing.

During the expert session described in the VeiligheidNL assessment, ladders and steps were included in the main product groups with product-related physical hazards.

An overview has been made of the Safety Gate notifications from 2014 to 2018 relating to the physical safety of portable climbing equipment. Since there is no specific category for recording this type of equipment, it was decided to search using the search terms 'ladder(s)' and 'step(s)'.

The results of this assessment are presented in Table 5.

Table 5 Safety Gate notifications relating to the physical safety of portable climbing equipment in the period from 2014 to 2018.

Year	Total number of notifications in Safety Gate	Risk types	Number per risk type
2014	5	Injuries	4
		Cuts, entrapment, injuries	1
2015	8	Injuries	8
2016	8	Injuries	8
2017	5	Injuries	5
2018	2	Injuries	2

A market surveillance project has been carried out for ladders under the coordination of PROSAFE. During JA2012 (PROSAFE, 2015c), 28 bodies from 18 EU and EEA Member States conducted a joint study. After drawing up an extensive inventory focused on 66 ladders available on the market, 18 ladders were selected for further investigation. This was not a random sample, but a targeted search for products with potential problems. The ladders were tested in accordance with the version of the EN-131 series in effect at the time. None of the ladders tested passed the entire testing programme. The researchers report that, in their opinion, the standard in effect at the time also had certain shortcomings, especially with regard to slipping from the base and sliding sideways.

The European EN 131 series of standards are being revised and a number of parts have been published. The adjustments focus among other things on use and misuse. The base of ladders over

[29] Inspection Methods for Portable Climbing Equipment (Commodities Act) Regulation. Government Gazette 1986, 231.

3 metres high has been widened and higher ladders consisting of multiple sections may no longer be taken apart. This way the design of ladders should promote safe use.

Exposure

There is a high level of exposure to portable climbing equipment. Household stepladders are high on the list of most commonly used consumer products and step stools can be found in almost every household. The use of portable climbing equipment is variable and depends on the person. Steps are more often used by short persons. Ladders are mainly used for DIY activities.

Risks

Falling from heights is the main hazard when using portable climbing equipment. In addition, there is a risk of entrapment when using collapsible equipment. Although it is foreseeable that this mechanism of injury may occur, no literature has been found about such injuries.

Portable climbing equipment is relatively frequently involved in accidents with injuries. At the same time, the number of notifications about defective equipment on the market is limited. Therefore, the risk seems to be mainly limited to the use phase.

The greater the difference in the height bridged, the greater the risk. For accidents involving employees, the Health Council of the Netherlands (*Gezondheidsraad*) has established a link between the height from which a person falls and the extent of the injury or likelihood of death (Gezondheidsraad, 2013). A safe limit for the fall height could not be established, and neither was it possible to assess the health risk. The Dutch working conditions regulations[30] state that, from a height of 2.5 metres onwards, there is by definition a serious hazard, however, depending on the circumstances, the hazard may also be present below this value.

Conclusion

There have been few notifications of unsafe portable climbing equipment under the Commodities Act where the injury was caused by equipment failure. Moreover, there are few known test results. However, the number of accidents involving portable climbing equipment is quite high. Attempts have been made to make the use of portable climbing equipment safer by formulating standards. Expert judgement ranks portable climbing equipment high in terms of product-related hazards.

There is a link between the severity of the consequences of a fall and the height of the fall. This makes serious injuries more likely in case of a fall from steps or ladders than from step stools, although this need not be true in individual cases. The severity for the entire subdomain is assessed as long-term effects that are possibly irreversible (Severity Category 3).

It is likely that a consumer will be exposed to the inherent hazard posed by portable climbing equipment due to the bridging of height differences. If the hazard is caused by the product under normal conditions of use and maintenance, the likelihood is assessed as rare.

The combination of the likelihood of injury due to product failure and the severity of the consequences results in a low risk with respect to the product. Improper use leads to an increased likelihood of injury, resulting in a medium to high risk.

4.3.6. Physical hazards of electrical equipment

The term ‘electrical equipment’ formally includes objects used for the generation, conversion, transmission, distribution or use of electrical energy. This includes machinery, inverters, switchgear and control gear and energy-using appliances. Incidentally, the term ‘Electrotechnical Products’ was used in earlier NVWA publications, such as ‘Product Safety Status’ (*De Staat van Productveiligheid*) (NVWA, 2016f).

For consumer products, there is a somewhat narrower demarcation. This is based on the regulations, i.e. the Low Voltage Directive (see: Legal framework). This Directive applies to all

[30] Working Conditions Decree (*Arbeidsomstandighedenbesluit*), Article 3.16, Bulletin of Acts and Decrees 1997, 60, article amended by Bulletin of Acts and Decrees 2007, 525.

electrical equipment designed for use with an alternating current ranging from 50 to 1000 volts and a direct current from 75 to 1500 volts. This refers to the input or output voltage, but internally there may be higher voltages.

Products powered by batteries do not fall into this category when operated outside the voltage band. But the chargers that are used to charge the battery with mains current are included. In principle, a product may be considered both machinery as well as electrical equipment. In the Machinery Directive, a number of products are specifically designated as electrical equipment:

- Household appliances intended for domestic use
- Audio and video equipment
- Information technology equipment
- Ordinary office machinery
- Low-voltage switchgear and control gear
- Electric motors

The most common products in the electrical equipment category operate on 230 Volt mains voltage. Products that intentionally receive or emit radio waves are excluded.

Legal framework

The Low Voltage Directive 2014/35/EU applies to electrical equipment placed on the market in the European Union[31]. This Directive also includes safety requirements. In the context of the Directive, European standards have been harmonised, which means that conformity with the Directive and its safety requirements is presumed when the standards are applied to the product. This applies to a large number of standards from the NEN-EN 60335 series.

Directive 2014/35/EU has been implemented in Dutch law via the Electrical Equipment (Commodities Act) Decree (*Warenwetbesluit elektrisch materiaal*)[32].

Electrical or electronic products that intentionally transmit and/or receive radio waves for the purpose of radio communication and/or radiodetermination fall under the scope of the Radio Equipment Directive 2014/53/EU[33], for which Radiocommunications Agency Netherlands (*Agentschap Telecom*) is the regulatory authority for the Netherlands. In practice, this includes mobile and cordless phones as well as appliances with Wi-Fi connectivity, and the latter increasingly include household appliances such as refrigerators and washing machines. In the Netherlands, rules for such products are laid down in the Radio Equipment Decree 2016 (*Besluit radioapparaten 2016*)[34].

Identification of relevant physical hazards

VeiligheidNL's analysis (Krul et al., 2019) reveals a number of product groups. These groups are displayed in Table 6, together with the number of recorded accidents. It should be noted that, apart from the general remarks at the time of recording the accident, it is not clear to what extent the product groups fall, either wholly or partly, under electrical equipment or whether electrical equipment is present in other product groups. From 2014 to 2017, there were a total of approximately 110,000 visits to A&E departments in hospitals that record data for the LIS database.

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[31] Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits. OJ L 96, 29.3.2014, p. 357-374

[32] Decree of 20 June 2016 laying down rules for electrical equipment. Bulletin of Acts and Decrees 2016, 244.

[33] Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC. OJ L 153, 22.5.2014, p. 62-106

[34] Decree of 12 December 2016 laying down rules for radio equipment for implementing Directive 2014/53/EU. Bulletin of Acts and Decrees 2016, 535.

Table 6 Number of injury notifications in the LIS database involving electrical equipment

Product group	Number of notifications
Audio and communication equipment	316
Lighting (electric)	247
Other household appliances	229
Refrigerators and freezers	212
Washing and drying machines	162
Imaging equipment	106
Computer and accessories	104
Audio and video and communication equipment Other/unspecified	28

The number of notifications is limited in relation to the total. However, the injury is often relatively serious (MAIS2+ score between 30% and 45%) for these product groups (with the exception of other household appliances).

Each year, the Fire Service Academy (*Brandweeracademie*), part of the Institute for Safety (*Instituut Fysieke Veiligheid*), publishes an overview of fatal house fires in the Netherlands. These are sub-divided based on the causes, and electrical equipment (under the heading of electrical appliances) is a recurring category. Table 7 displays an overview of fatal fires that occurred from 2014 to 2018.

Table 7 Overview of fatal fires in the Netherlands from 2014 to 2018

Year	Number of fatal house fires[1]	Number of fires caused by electrical equipment[2]
2014	30	5 (17%)
2015	27	3 (11%)
2016	32	3 (9%)
2017	27	3 (9%)
2018	30	7 (23%)

1. Excluding arson and suicide
2. Every year, there are a number of fires for which the cause cannot be determined with certainty. These are the fires for which the cause has been established with certainty.

In its publication 'House Fires Risk Monitor 2019' (*Risicomonitor Woningbranden 2019*), the Dutch Association of Insurers (*Verbond van Verzekeraars*) has published figures obtained from a foundation,Stichting Salvage (Verbond van Verzekeraars, 2019). This foundation provides help and guidance after a fire or other damaging incident on behalf of the insurers. The Risk Monitor contains information on the number of fires caused by batteries or battery packs. There is an increase in this category from 72 fires in 2017 to 100 in 2018. Of these 100 fires, 40 involved loose batteries, battery packs or chargers.

An overview has been made of the Safety Gate notifications from 2014 to 2018 relating to the physical safety of electrical equipment. In Safety Gate, the product category of electrical appliances and equipment was selected.

The selected risk types were asphyxiation, burns, choking, cuts, damage to hearing, damage to sight, drowning, electric shock, entrapment, environment, fire, health risk/other, injuries, strangulation and other, or combinations thereof. Environment as a risk type was only taken into account in combination with one of the other risk types.

The most important results of this analysis are presented in Table 8.

Table 8 Safety Gate notifications relating to the physical safety of electrical equipment in the period from 2014 to 2018

	2014	2015	2016	2017	2018
Total number of notifications	209	179	138	133	169
Electric shock	143	115	83	89	110
Burns	19	11	6	3	5
Electric shock, Fire	14	14	23	21	15
Fire	14	22	7	5	11
Burns, Electric shock, Fire					9
Burns, Electric shock	5			6	5
Burns, Fire	3				
Health risk/Other		4			
Cuts			3		
Injuries			3		9

(1) The notifications for the 'Health risk/Other' risk type refer to electric blankets reported by Cyprus that could potentially overheat if connected directly to the mains voltage without a transformer. In this way, someone covered by the blanket could get injured.

In addition, an overview has been made of the Safety Gate notifications from 2014 to 2018 relating to the physical safety of lighting. In Safety Gate, the product categories of lighting equipment and lighting chains were selected.

The selected risk types were asphyxiation, burns, choking, cuts, damage to hearing, damage to sight, drowning, electric shock, entrapment, environment, fire, health risk/other, injuries, strangulation and other, or combinations thereof. Environment as a risk type was only taken into account in combination with one of the other risk types.

The main results of this analysis are presented in Table 9.

Table 9 Safety Gate notifications relating to the physical safety of lighting in the period from 2014 to 2018

	2014	2015	2016	2017	2018
Total number of notifications	90	87	111	116	104
Electric shock	61	58	73	84	68
Electric shock, Fire	18	19	30	25	28
Burns, Electric shock	5	3	2	1	
Fire	1	1	2	2	5

The NVWA has conducted a study of USB chargers in 2015. This study specifically looked at chargers sold separately (not included as an accessory with a product). The sampling was not done in a random manner. Since the analysis of the notified incidents showed that counterfeit chargers, universal models and cheap chargers appeared to have more safety defects, the study focused on these articles. Both physical and online shops were included in the sampling. Of the chargers tested (N=41), 59% did not meet the safety requirements, 25% had serious technical defects with a likelihood of electric shock or fire (NVWA, 2016e).

Sunbeds are electrical equipment that involve both an electrical hazard as well as a radiation hazard. To reduce the risk of using sunbeds, the European Union has adopted a package of measures that has been in effect since 2007. One of these measures is to ensure that the strength of the UV radiation emitted by sunbeds does not exceed 0.3 W/m^2. This value roughly corresponds to the maximum UV radiation from the sun in the Mediterranean area. In 2016, the NVWA conducted an extensive study of the radiation limits of sunbeds in tanning studios. At 154 tanning studios, the UV radiation from at least two sunbeds in each studio was measured. In 22 studios (14%), the radiation was found to be higher than 0.3 W/m^2. After intervention, the radiation was reduced to below the limit (NVWA, 2016c). The study focuses on the power of the sunbed rather than its use. There is a risk of harm to the consumer from radiation when using the device. The Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) concludes that,

given the strong evidence of skin cancer due to sunbed exposure (and with no indication of a safe threshold), there is no safe limit for exposure to UV radiation from sunbeds (SCHEER, 2016).

In the period 2014-2016, a number of market surveillance projects in the area of electrical equipment were carried out under the coordination of PROSAFE. These projects are called Joint Actions (JA) and they involve the participation of market surveillance authorities from different countries of the European Union and European Economic Area.

During Joint Action 2014, LED and CFL lamps were tested (PROSAFE, 2018b). The report clearly states at the start that inspectors tried to specifically identify the high-risk products and did not take a random sample. Of the tested lamps (N=211), 39% had faults that posed a risk to the safety of the user. In 17 cases, a Safety Gate notification was deemed necessary. The lamps ordered via the internet had more deviations, but the difference was not considered sufficient to be considered significant.

Joint Action 2015 (PROSAFE, 2018a) focused on home appliances, blenders, mixers and toasters. Of the 134 appliances tested, 32% were found to have major defects. Serious faults were identified in 21% of the appliances, implying a high level of risk. This resulted in 24 Safety Gate notifications.

Joint Action 2016 (PROSAFE, 2019a) dealt with hair styling appliances. Hair dryers (N=36), curling irons (N=36) and straighteners (N=37) were tested. The results showed that 44% of the appliances tested were low risk, 5% medium risk, 2% high risk and 7% serious risk. A total of nine Safety Gate notifications were made.

Exposure

Each Dutch household has about 100 electrical devices at home (Huisman et al., 2012). Not all of these appliances fall under the heading of electrical equipment, such as mobile and cordless phones and Wi-Fi devices. On the other hand, a charger for a mobile device is regarded as electrical equipment, which is why 100 is considered acceptable as a rough estimate. There are almost 8 million households in the Netherlands (CBS, 2019a). That amounts to 800 million electrical appliances. Every resident of the Netherlands comes into contact with electrical equipment on a daily basis.

In its recommendation, the SCHEER has looked into studies on the use of sunbeds. Based on this, it concludes that 35.7% of the adult population has used a sunbed at some point in their lives and 14% have done so in the last year (SCHEER, 2016). The prevalence in the Netherlands is not expected to deviate too much from this.

Risks

Considering the large number of products that fall into the electrical equipment category, the number of recorded incidents of injuries due to use is limited. However, the severity of injuries from these incidents is high relative to other consumer products. Every year, at least 1 in 10 fatal house fires is attributed to electrical equipment (Brandweeracademie, 2019). When the human body is exposed to electric current, this can lead to tissue damage (burns) and heart failure. The voltage and frequency of the European power network are hazardous for humans. Direct contact with live parts of electrical equipment must be avoided. If electrical current has a direct pathway to the heart, via e.g. a heart catheter or pacemaker electrodes, even a current of less than 1 milliampere can cause cardiac fibrillation (Runde, 2018). In homes in the Netherlands, the current goes up to 16 amps, which is many times higher. Based on the available data, no scientific distinction can be made between the percentage attributable to incorrect use and that attributable to product failure.

The risk of fire involving batteries or chargers is increasing (according to the Dutch Association of Insurers). This is due to the increase in the use of portable power banks. At the same time, there are indications that the likelihood of portable power banks causing a fire increases with the age of the product (Verbond van Verzekeraars, 2018). Lithium-ion batteries can be damaged by external impact. Chargers that are not specifically designed for a product increase the risk of fire and electrical shock (Verbond van Verzekeraars, 2017).

Targeted market surveillance actions show that a significant proportion of the tested devices have serious shortcomings. The limited number of market surveillance reports available do not provide a complete picture of the market. The notifications in the Safety Gate system mainly refer to electric shock as the predominant type of risk.

In the case of sunbeds, there is a risk to consumers even when the equipment meets the standard. No safe level of exposure can be established for UV radiation from a sunbed.

Conclusion

Use of electrical equipment is part of everyday life. A large number of products in this category are available to households in the Netherlands. Given this fact, there are relatively few notifications of A&E treatments relating to electrical equipment. It should also be noted that the scenarios that have led to the occurrence of these injuries are not known.

The main risks associated with electrical equipment are fire and electric shock. In case of fire, the electrical equipment acts as the source of ignition. If the product fails, is used incorrectly or not maintained properly, this may subsequently lead to a fire. Persons exposed to fire or its consequences may die from suffocation, poisoning or burns. This places it in the category of an injury or consequence that is or could be fatal (Severity Category 4). Electrical equipment is a major cause of house fires, with portable power banks playing a large role. The extent to which design, construction, use and ageing play a role in this is not known. Electrical equipment can cause fire but, given the amount of electrical equipment involved, the likelihood is assessed as occasional. The combination of the likelihood of fire caused by electrical equipment and the severity of the consequences results in a high to severe risk for the consumer through the use of the product.

Electrical shock can cause tissue damage and heart failure. It is possible that, under certain circumstances, this could lead to death. This also places it in the category of an injury or consequence that is or could be fatal (Severity Category 4). The likelihood of an electric shock, caused by a product that has been used and maintained normally, is assessed as rare. The combination of the likelihood of an electric shock and the severity of the consequences results in a low to medium risk for consumers.

Sunbeds are designed to irradiate consumers' skin with UV light. High exposure to UV radiation can lead to skin cancer. This falls into Severity Category 4. The likelihood is assessed as occasional, as a result of which the risk for the entire population is high to severe. Apart from encountering a product with an excessively high radiation intensity, consumer behaviour (frequency and duration of exposure) plays a primary role in the possible occurrence of an adverse health effect. Consumer behaviour and adequate monitoring by sunbed operators can help reduce the risk, in addition to market surveillance to ensure compliance with the prevailing safety requirements, such as the radiation limit.

4.3.7. Physical risks of gas appliances

Gas appliances generate energy by burning gaseous fuels. Consumers use gas appliances for cooking, heating their homes and heating water.

A distinction can be made between appliances that are connected to the gas network and those that operate on separate gas cylinders. Appliances connected to the gas network include gas cookers, central heating boilers, geysers and water heaters. In gas appliances with a separate gas supply, we see products for outdoor use, such as camping equipment (cooking stoves), heaters, gas barbecues and patio heaters.

Gas appliances sold to consumers are not always specially designed for private purposes. The same products may also be used for professional purposes.

This section also deals with carbon monoxide detectors, since these are recommended for the timely detection of problems with gas appliances.

Legal framework

Since 21 April 2018, the Gas Appliances Regulation has been in effect (Regulation (EU) 2016/426)[35]. It replaced the Gas Appliances Directive 2009/142/EC. The aspects of the Regulation relevant to the Netherlands are laid down in the Gas Appliances (Commodities Act) Decree 2018 (*Warenwetbesluit gastoestellen 2018*)[36].

The European regulations for making gas appliances available on the market state that a manufacturer may assume normal use. This includes the correct installation of an appliance and maintenance in accordance with the manufacturer's instructions. In addition, this implies use in accordance with the intended purpose or under reasonably foreseeable conditions of use. That is also the basic assumption for the underlying standards, i.e. the NEN-EN 15502 series, and the risk assessment to be performed by the manufacturer. In this way, it is possible for the manufacturer to control the risks not related to normal use via the instructions for use or maintenance and to classify these risks lower. This largely places the responsibility during the use phase on the consumer. At the time of the transition from the Gas Appliances Directive to the Gas Appliances Regulation, a hierarchy of measures was introduced under the essential safety requirements, i.e. Annex I, article 1.3. According to this hierarchy, the first step must be to eliminate or reduce risks as far as possible to ensure an inherently safe design and construction, the second step is to take the necessary protective measures, and the third step is to inform users. The NEN-EN 15502-1 and NEN-EN 15502-2(-2) standards applicable to the design of central heating boilers do not enforce an inherently safe design. Gas appliances manufactured before 21 April 2018 are not subject to the above-mentioned article 1.3.

On 28 May 2019, the House of Representatives of The Netherlands (Tweede Kamer) voted to amend the Housing Act (*Woningwet*). In view of the risks of carbon monoxide (OVV, 2015), once the amendment comes into force, it shall be prohibited to carry out works on gas combustion installations without a valid certificate. The requirements applicable to the certification of companies and persons permitted to perform such works are laid down in the Buildings Decree 2012 (Bouwbesluit 2012). The amendment to the Housing Act shall take effect at a date to be determined by Royal Decree. Based on Minister Ollongren's Letter to Parliament dated 27 May 2019, this is expected to be 1 July 2020. Subsequently, there will be a transition period of one year.

Identification of relevant physical hazards

The main hazards of gas appliances include the formation of carbon monoxide, fire and explosion, and burns due to hot surfaces.

Every year in the Netherlands there are, on average, five to ten fatalities and several hundred injuries due to accidents involving carbon monoxide in the household environment (OVV, 2015). According to the report of the Dutch Safety Board (OVV), a large proportion of this can be attributed to gas appliances, particularly those connected to the gas network. In the period 2012-2014, 46% of the cases involved central heating boilers, 32% involved tankless water heaters and another 10% involved fireplaces and room heaters, where it should be noted that not all the appliances in this group falls under the heading of gas appliances.

The OVV recognises the importance of correct installation and maintenance of the appliances connected to the gas network. A large number of incidents have been attributed to shortcomings in this area (OVV, 2015).

In the report entitled 'Records of gas installation-related accidents during use, Annual Overview 2017' (*Registratie van gasinstallatieongevallen achter de meter, jaaroverzicht 2017*) (KIWA, 2018), the research methodology was based on obtaining the necessary information via media reports, targeted questions to the parties involved, existing contacts and studies. There is no central record of incidents. For 2017, the Dutch testing, inspection and certification company Kiwa arrives at 56 gas installation accidents, 42 poisoning accidents, seven fire accidents and seven

[35] Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC. OJ L 81 of 31.3.2016, pp. 99-147.
[36] Gas Appliances (Commodities Act) Decree 2018. Bulletin of Acts and Decrees 2018, 217.

explosions, where six of these explosions were followed by fire. Two people died in these accidents and 170 were injured, with 119 people being seriously injured. Here, the majority of accidents are related to CO poisoning.

Krul (Krul et al., 2019) describes 652 notifications relating to the heating appliances product group. Out of a total of over 110,000, this is a limited number. The proportion of serious injuries is relatively high at just over 35%. It is not clear from the report to what extent the notifications involving carbon monoxide (126 times) and smoke from fire (352 times) can be attributed to the heating appliances product group.

An overview has been made of the Safety Gate notifications from 2014 to 2018 relating to the physical safety of gas appliances. In Safety Gate, the product category of gas appliances and components was selected.

The selected risk types were asphyxiation, burns, choking, cuts, damage to hearing, damage to sight, drowning, electric shock, entrapment, environment, fire, health risk/other, injuries, strangulation and other, or combinations thereof. Environment as a risk type was taken into account only if it occurred simultaneously with another risk type.

The results of this assessment are presented in Table 10. Combinations are displayed separately.

Table 10 Safety Gate notifications relating to the physical safety of gas appliances in the period from 2014 to 2018

Year	**2014**	**2015**	**2016**	**2017**	**2018**
Total number of notifications	***16***	***3***	***3***	***11***	***2***
Burns	8	2	1	1	1
Asphyxiation	5			2	
Burns, fire	2				
Fire	1	1	2	8	
Injuries (professional product)					1

From 2008 to 2011, the NVWA carried out annual studies on gas appliances for cooking and barbecues in the garden or at campsites. The results of these studies showed a clear reduction in the number of gas appliances that did not comply with the legal requirements laid down in the Gas Appliances Decree that was in effect at the time (NVWA, 2012).

In 2013, the NVWA carried out a study on portable flat gas stoves, which were commonly used at campsites and on boats (NVWA, 2014d). The study concluded that, assuming reasonably foreseeable conditions of use, none of the 27 portable flat gas stove models tested in this study met the relevant essential safety requirements set out in the regulations. The gas canisters that supplied the gas to the stove became excessively hot, resulting in the risk of fire and explosion.

In 2016, the NVWA carried out a study on large cooking burners, also known as wok burners (NVWA, 2016b). None of the 15 large cooking burners examined met the legal safety requirements. In 13 of the 15 cases, there was a serious safety risk, such as a lack of flame protection. Meanwhile the sale of the tested cooking burners has been prohibited.

The European Administrative Cooperation Group for gas appliances (GAD ADCO, called GAR ADCO after 2018) carried out a market surveillance study in 2016 on gas appliances for recreational use not connected to the gas network which had two or more burners and were installed in caravans, motorhomes and boats. Of the 43 appliances tested, less than 50% met all the requirements (ADCO, 2017).

A product associated with gas appliances are carbon monoxide detectors (CO detectors). The OVV report identifies (OVV, 2015) gas appliances as a cause of carbon monoxide poisoning and CO detectors can provide a timely warning of this. However, the prerequisite for this is that the

detector should work properly. A number of projects have been undertaken to check whether the detectors on the market meet the quality requirements.

A project was conducted and coordinated by PROSAFE in the period 2013-2015. This was the Joint Action on CO detectors or the Joint Market Surveillance Action on GPSD Products – JA2012, in which market surveillance authorities from different countries of the European Union and European Economic Area participated (PROSAFE, 2015a). In total, 81 models of CO detectors were inspected, and of these 25 were tested in a laboratory. In selecting the CO detectors for testing, potentially unsafe products were targeted. Although all the follow-up actions were not recorded in the report, the testing of the detectors resulted in nine cases involving a serious risk and 15 involving a high risk. There were only seven models in which no risks were detected. In 36 cases, the risk assessment was not disclosed by the market surveillance authority.

Following the PROSAFE project, the NVWA carried out a study in 2016 on CO detectors on the Dutch market (NVWA, 2016d). In this study, 29 different CO detectors with battery power were purchased from DIY shops and via the internet which, according to the report, included almost all the different types of CO detectors available to Dutch consumers at the time. Of the 29 CO detectors that were examined, 16 did not comply with the established requirements. Six of the CO detectors examined did not give an error signal in case of a faulty sensor. In eight of the CO detectors examined, the alarm was not activated by one of the different CO concentrations and ambient conditions. The outcome of the study was that the sale of 16 CO detectors was prohibited on account of a serious safety risk.

For 2018 and 2019, BuRO issued two advisory reports on central heating boilers, prompted by the risks associated with certain types of central heating boilers sold under the Nefit brand (BuRO, 2018d) (BuRO, 2019). These advisory reports make it clear that the use of central heating boilers is, in general, associated with risks of carbon monoxide poisoning and fire. These risks are not fully covered by the design of central heating boilers. In addition to the advice provided on the specific types of Nefit central heating boilers, there are also recommendations regarding the design, maintenance and information to be provided to consumers about appliances that are connected to the gas network. Without regular and adequate maintenance, the risks to consumers remain present.

Exposure

A large proportion of Dutch households are connected to the gas network and make use of it. There are about 6.2 million central heating boilers in use in buildings in the Netherlands. In 2017, approximately 430,000 new domestic central heating boilers were installed (both in newly constructed buildings and as replacement of older systems in existing buildings).

The number of gas appliances in use with a separate gas supply is more difficult to estimate. Given the diversity of products intended for recreational use, it is to be expected that many Dutch people use such appliances, even if it is often for only part of the year.

Carbon monoxide detectors are used in a large proportion of Dutch homes. In new buildings, it is compulsory to install a fire/CO detector in every enclosed space. In existing buildings the use of CO detectors is encouraged.

Risks

Gas appliances connected to the gas network can cause serious damage to health. A significant proportion of carbon monoxide poisonings are caused by gas appliances and can have fatal consequences. Gas appliances can also lead to house fires. A large part of the Dutch population may be exposed to these hazards. The likelihood of defects depends only partly on the construction of the gas appliance; installation and maintenance also play an important role.

Gas appliances that are not connected to the gas network can cause fires and explosions, resulting in serious injuries. A large part of the Dutch population may be exposed to these hazards during camping or recreational sailing. Research shows that a large number of the devices tested did not meet the requirements established in the regulations. In addition, the likelihood of fire depends on

how the appliance is used. If these appliances are used in a confined space, such as a caravan, motorhome or boat, there is an even higher risk.

If a CO detector is not working properly, it can have serious consequences. In case of an incomplete combustion process in the home, occupants do not receive a timely warning; as a result, they may be unknowingly exposed to carbon monoxide for a long period of time, possibly with fatal consequences. The likelihood of such a scenario depends on how the combustion equipment and CO detector in the home.

Conclusion

Defects in gas appliances connected to the gas network can lead to fatal consequences (Severity Category 4). The likelihood is assessed as rare. Less serious effects are more frequent. The combination of likelihood and severity results in a medium to high risk for the consumer, where good maintenance and compliance with regulations reduces the risks. The likelihood of accidents depends, to a large extent, on the manner of use by the consumer and the maintenance, e.g. by an installer.

Accidents involving gas appliances not connected to the gas network can cause serious injuries (Severity Category 3). Based on accident records, the likelihood seems to be rare. However, product research shows that many appliances do not meet the safety requirements. The combination of likelihood and severity results in a medium to high risk for the consumer due to the product.

Failure of a CO detector to function properly can have serious consequences, with potentially fatal exposure to carbon monoxide (Severity Category 4). This likelihood of this is assessed as rare, although many CO detectors do not meet safety requirements and consumers are unable to check these requirements themselves. The combination of likelihood and severity results in a medium to high risk for the consumer due to the product.

4.3.8. Physical risks of machinery

Machinery refers to products with moving parts that are mechanically driven. The power is supplied by a motor (running on electricity or fuel) or by compressed air. Machinery used for private purposes are intended to relieve human labour or effort. Examples of such machinery are drills, saws and lawn mowers.

There are also certain household appliances that could be considered as machinery according to the above definition, such as washing machines, tumble dryers and kitchen appliances. However, in the European regulations, it has been decided to consider these devices as electrotechnical appliances.

Electric bicycles, electric scooters and self-balancing scooters belong to the machinery product group, as do motorcycles or cross-country motorcycles that are not intended for use on public roads or are used specifically in competitive sports.

Machinery sold to consumers are not always specially designed for private purposes. The same products may also be used for professional purposes.

Legal framework

Machinery placed on the market in the European Union must comply with the Machinery Directive (2006/42/EC)[37]. This Directive is implemented in the Netherlands via the Machinery (Commodities Act) Decree (*Warenwetbesluit machines*).[38].

[37] Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC. OJ L 157, 9.6.2006, p. 24-86

[38] Decree of 30 June 1992 laying down rules on the safety of machinery. Bulletin of Acts and Decrees 1992, 379, last amended by Bulletin of Acts and Decrees 2018, 465.

The Directive sets out essential health and safety requirements. Machinery must comply with these requirements, not only when used as intended by the manufacturer but also when used under foreseeable abnormal conditions.

Identification of relevant physical hazards

A number of product groups have emerged from the assessment performed by VeiligheidNL's (Krul et al., 2019). The main groups are shown in Table 11, together with the number of recorded accidents. It should be noted that, apart from the general remarks at the time of recording the accident, such as those relating to the behaviour of the user, it is not clear to what extent the product groups fall, either wholly or partly, under machinery or whether machinery is present in other product groups. An example of this is the garden tools category. From 2014 to 2017, there were a total of approximately 110,000 visits to A&E departments in hospitals that record data for the LIS database.

Table 11 Product groups belonging to the machinery subdomain, mentioned in the LIS database as the product involved

Product group	Number of notifications
Bicycles, total (electric)	24499 (668)
Other tools (machinery)	2857 (>900)
Motorcycles and mopeds, total (cross-country)	1461 (988)
Garden tools (machinery)	672 (> 167)
Cleaning equipment	446

If we consider the products, the specific articles that emerge are displayed in Table 12.

Table 12 Products belonging to the machinery subdomain, mentioned in the LIS database as the product involved

Product	Number of notifications
Cross-country motorcycle	988
Electric bicycle*	668
Circular saw	458
Power drill/drill bit	249
Angle grinder	234
Self-balancing scooter (hoverboard)	208 (from mid-2016)
Lawn mower, electric/manual	167
Staple/nail gun, power/hand tool	42

* Products such as bicycle handlebars, pedals and wheels are recorded separately (640, 537 and 292 notifications respectively), where no distinction is made between normal and electric bicycles.

An increasing number of electrically powered machinery have a rechargeable battery or battery pack as their power source and are cordless (Kreule, 2018). This also applies to machinery intended for the transport of persons. The NVWA has studied the safety of self-balancing scooters (hoverboards) on the Dutch market. None of the 29 self-balancing scooters examined met the safety requirements. In the cases where this could be tested, the battery protection circuit failed. In addition, 27 cases involved sharp edges and a non-fireproof casing (NVWA, 2019d).

In its publication 'House Fires Risk Monitor 2019', the Dutch Association of Insurers has published figures obtained from the Salvage Foundation of the number of fires caused by a battery or an battery pack (Verbond van Verzekeraars, 2019). There is an increase in this category from 72 fires in 2017 to 100 in 2018. Of these 100 fires, 40 involved loose batteries, battery packs or chargers.

An overview has been made of the Safety Gate notifications from 2014 to 2018 relating to the physical safety of machinery. In Safety Gate, the product category of machinery was selected.

The selected risk types were asphyxiation, burns, choking, cuts, damage to hearing, damage to sight, drowning, electric shock, entrapment, environment, fire, health risk/other, injuries, strangulation and other, or combinations thereof. Products designated for professional use were omitted. Environment as a risk type was taken into account only if it occurred simultaneously with another risk type.

The results of this assessment are presented in Table 13. Combinations are displayed separately.

Table 13 Safety Gate notifications relating to the physical safety of machinery in the period from 2014 to 2018

Year	**2014**	**2015**	**2016**	**2017**	**2018**
Total number of notifications	***23***	***9***	***13***	***30***	***17***
Injuries	14	6	4	9	9
Cuts	3			7	4
Cuts, Injuries	1	1		1	
Electric shock	2		4	4	2
Cuts, Fire	1				
Burns	1		1		
Electric shock, Injuries			1	2	
Fire, Injuries	1				
Burns, fire		1	1		
Burns, injuries		1			1
Fire			2	3	1
Burns, cuts				1	
Electric shock, fire				1	
Burns, electric shock				1	
Entrapment, injuries				1	

In the period 2015-2018, a number of market surveillance projects relating to handheld power tools were carried out under the coordination of PROSAFE. These projects are called Joint Actions (JA) and they involve the participation of market surveillance authorities from different countries of the European Union and European Economic Area. Handheld power tools fall under the definition of machinery.

During Joint Action 2014, the Power Tools 1: Handheld Electric Angle and Straight Grinders activity examined 60 grinders (PROSAFE, 2017). The report clearly states at the start that inspectors tried to specifically identify the high-risk products at the lower end of the market and did not take a random sample. There were 34 Safety Gate notifications, four of which were classified under serious risks.

Joint Action 2015, Power Tools 2, focused on Handheld Electrical Circular Saws (PROSAFE, 2018-2019) . A total of 100 saws were tested, based on the EN IEC 60745 series (this series has since been partially replaced by the EN-IEC 62841 series). Of the 49 samples with shortcomings, 25% only concerned administrative requirements. Eighteen products had technical shortcomings and six related to both technical and administrative requirements. Fifty-one samples met all criteria. Eight Safety Gate notifications were made, two of which involved a serious risk.

Joint Action 2016, Power Tools 3 was aimed at Impact Drills (PROSAFE, 2019b). In a sample of 100 drills, shortcomings related to administrative requirements (use instructions, marking and declaration of conformity) were found in 47 samples and technical shortcomings in 14 samples. For six drills, the risk was assessed as medium to serious, where the serious risks in case of two of the drills were due to exposed live parts after the drop test. Fifty-one samples met all criteria.

Exposure

There are various subdomains within the machinery domain, such as equipment for DIY activities (for odd jobs and working in the garden). A large proportion of Dutch households will own one or more items of DIY equipment, which include handheld power tools, such as drills, as well as electric lawnmowers. Such equipment can be expected to be used for an extended period of time. Insurers use depreciation periods of between 6 and 10 years for handheld tools (Allianz, 2019; Klaverblad, 2019). It is suspected that such items of equipment are only replaced when they no longer work. Usually, the equipment in this category is not used on a daily basis. Also, use of this equipment will often be limited to adults.

Another specific subdomain consists of devices intended for transport of people (e.g. electric bicycles). According to research by industry associations RAI and BOVAG, 409,400 new electric bicycles were sold in 2018, compared to 294,000 in 2017 (BOVAG RAI, 2019). Exposure to this type of device has increased significantly and is expected to increase further. Among young people (school-age children), there is an increase in the use of electric bicycles (Berendsen, 2018).

Despite the uncertainties, exposure can be considered high for the entire subdomain.

Risks

The figures available from the review of A&E data do not provide a sufficient basis for further analysis. It is usually not possible to make firm statements about the factors that have contributed to these injuries, such as normal (intended) use of the product, ageing of the product, foreseeable unintended use and unforeseeable user behaviour.

Market surveillance activities have revealed a lot of shortcomings related to administrative requirements. It is not clear what influence this has on consumer risk, e.g. on consumer behaviour during use. The number of products actually tested as part of the market surveillance activities during the period is limited. The number of products found to have technical shortcomings is limited, on average only a few percent.

The risk of fire involving batteries, battery packs or chargers is increasing. This is due to the increase in the use of mobile energy supplies. At the same time, there are indications that the likelihood of mobile energy supplies causing a fire increases with the age of the product (Verbond van Verzekeraars, 2018). Lithium-ion batteries can be damaged by external impact. Chargers that are not specifically designed for a product increase the risk of fire and electrical shock (Verbond van Verzekeraars, 2017).

For a better assessment of the risk for the consumer, greater insight into the scenarios leading to injuries is needed.

Conclusion

Consumers use various types of machinery for private purposes, from tools to means of transport. This diversity makes it difficult to form an unambiguous picture of the risks. In proportion to the number of products reported as unsafe by market surveillance authorities, the number of first aid treatments for injuries caused by machinery is high. This may indicate that the consumer's behaviour when using the machine plays an important role in the occurrence of injuries. However, further insight into the occurrence of injuries cannot be gained from the current literature.

Three mechanisms of injury emerge from the assessment.

First of all, the increase in the use of battery packs and batteries, which leads to the risk of fire. Persons exposed to fire or its consequences may die from suffocation, poisoning or burns. This places it in the category of an injury or consequence that is or could be fatal (severity category 4).

The likelihood of this mechanism is assessed as rare. The combination of likelihood and severity results in a low to medium risk for the consumer.

Moreover, machinery have moving parts that may be accessible. Coming in contact with these may cause injury. This includes hazards caused by moving parts, sharp parts and impact, which cannot be clearly separated in this domain. In Safety Gate terminology, these are described as injuries and cuts. This mechanism can cause serious injuries (severity category 3). The likelihood of this occurring as a result of product failure is assessed as rare. The combination of likelihood and severity results in a low risk for the consumer, if the product is used correctly.

Finally, for machinery powered by electricity, there is a risk of electric shock. Contact with exposed live parts can be fatal, especially for vulnerable groups. Hence, this mechanism of injury falls into severity category 4. The likelihood of this occurring as a result of product failure is assessed as rare. The combination of likelihood and severity results in a low to medium risk for the consumer, if the equipment is not used correctly or if wear and tear has occurred.

4.3.9. Physical risks of food contact materials

Food contact materials may present physical risks. A well-known example from quite some time ago are the exploding soft drink bottles. These glass bottles had an insufficient burst pressure and could therefore spontaneously break. Another risk is when, for example, a tea glass bursts, the hot liquid can spill on someone, causing burns.

Legal framework

Requirements for glass bottles for carbonated drinks are outlined in Commodities Act Regulation on Strength Requirements for Soft Drink Bottles (*Warenwetregeling sterkte-eisen frisdrankflessen*)[39]. have been set out for the minimum wall thickness and burst pressure.

There is no legislation specifically for tea glasses. Section 18 of the Commodities Act[40] states that it is forbidden to trade in goods, other than food and beverages, where the person trading in these goods knows or should reasonably suspect that, in view of their intended use, these goods may pose particular risks to human safety or health. In 2004, the Director of the Nutrition, Health Protection and Prevention Department at the Ministry of Health, Welfare and Sport wrote a letter to the participants in the Commodities Act Consultative Framework (*Regulier Overleg Warenwet*), in which he stated that the test method used by the former Food and Consumer Product Safety Authority (VWA) offers the required level of protection (Ministerie van VWS, 2004).

Exposure

When glass bottles burst, there may be shards of glass flying around. This can cause injuries. If a tea or coffee glass explodes, hot liquid can spill on someone, causing burns. The assessment of injury data by VeiligheidNL (Krul et al., 2019) shows that tea and hot water are the most frequently reported causes for thermal exposure as the mechanism of injury; coffee also scores high in this respect. Some of these injuries may be caused by the exploding glass; this could be examined further by assessing these accidents.

Risks

For the identification of the risks the studies the NVWA has carried out are evaluated.

Soft drink bottles have been made from plastic rather than glass for some time now. The soft bottles still made of glass are usually small (e.g. 0.33 l). These glass bottles generally have a very thick wall and also have sufficient burst pressure. There are also other carbonated drinks that come in glass bottles, such as premixes and certain wines. Complaints about exploding bottles were investigated, based on which the NVWA determined that the explosions had been caused by

[39] Commodities Act Regulation on Strength Requirements for Soft Drink Bottles . Government Gazette 1997, 138. Last amended by Government Gazette. 2013, 32282.

[40] Act of 28 December 1935 containing regulations regarding the quality and marking of commodities. Bulletin of Acts and Decrees 1935, 822, last amended by Bulletin of Acts and Decrees 2018, 416.

insufficient wall thickness and/or burst pressure. No complaints have been recorded in recent years.

The study on the thermal shock resistance of tea glasses was prompted by an incident in 2003 in which a young child suffered second-degree burns when the hot water fell on her. The NVWA has developed a research method, which has been subsequently used during various studies. The last study was reported in 2010 (VWA, 2010b). Glasses made of tempered glass or borosilicate glass generally offer sufficient thermal shock resistance. The percentage of violations for tea and coffee glasses made of non-tempered glass decreased from approximately 45% to 21% in the period from 2003 to 2008. But, despite the decrease, this is still very high.

No targeted studies have been carried out since then. The thermal shock resistance of tea and coffee glasses falls within the scope of NVWA's regular research programme. Tea and coffee glasses with insufficient thermal shock resistance can still be found on the market. There is no clear standard or designated test method. This makes it more difficult for businesses to ensure that their product is safe. In the period 2011-2019, the NVWA studied a total of 25 consumer complaints relating to exploding tea and coffee glasses. Five of these complaints were found to be justified after lab research: the glasses did not provide sufficient thermal shock resistance.

In 2009, the thermal shock resistance of other glass utensils was also examined (VWA, 2010b). Oven dishes and tea and coffee pots made of glass are sufficiently shockproof. Almost all of them are made of tempered glass or borosilicate glass. Glass pudding bowls made of non-tempered glass are not thermally shock resistant when tested for a thermal shock of 95-100°C. These bowls are probably not intended to come into contact with boiling or hot liquids, so the question arises as to whether these test conditions were appropriate. This also applies to Weck jars/storage jars made of non-tempered glass. Weck jars that are specifically intended to be used as preserving jars should meet the standard applicable to tea glasses to ensure sufficient safety.

Conclusion

Breakage of tea and coffee glasses due to insufficient thermal shock resistance may result in serious burns with scarring (severity category 3). Exploding soft or other drink bottles can cause considerable injury due to the flying shards of glass (severity category 2). Both tea and coffee glasses (including double-walled ones) and soft drink bottles are frequently found in households and hospitality establishments. A significant part (about a fifth) of the glasses did not provide sufficient thermal shock resistance. If hot liquid is spilled on a person, there is a significant risk of burns. There is little data on the burst pressure of bottles. The likelihood of actually being exposed to hot liquid, when a glass explodes as a result of insufficient thermal shock resistance, is assessed as rare. This also applies to the likelihood of someone being hit by glass shards. The risk of burns or injury from shards of glass is therefore assessed as low.

4.3.10. Physical risks of personal protective equipment

Personal protective equipment refers to products designed to protect a person during activities involving a risk of injury. The basic principle is that the product actually protects the person who is wearing or carrying the product.

Consumers use personal protective equipment primarily for DIY and recreational activities such as sports. In addition, consumers may use personal protective equipment in emergency situations, such as life jackets to avoid drowning.

The personal protective equipment product group is very diverse, as it covers a wide range of applications and a variety of risks for which it offers protection. This may include impact protection (helmets, safety shoes, shin guards), respiratory protection (face masks), eye protection (safety goggles), dental protection (dentures), and so on.

Personal protective equipment sold to consumers are not always specially designed for private use. The same products may also be used for professional use.

Legal framework

Since 21 April 2018, Regulation (EU) 2016/425 is in effect with respect to the marketing of personal protective equipment in the European Union[41]. This Regulation has replaced Directive 89/686/EEC. In the Netherlands, this Directive was incorporated into the Personal Protective Equipment (Commodities Act) Decree (*Warenwetbesluit persoonlijke beschermingsmiddelen*). With the introduction of the Regulation, this Decree has been withdrawn and replaced by the Personal Protective Equipment (Commodities Act) Decree 2018[42].

Personal protective equipment that complies with the Personal Protective Equipment (Commodities Act) Decree as in effect on 20 April 2018 and that had been placed on the market before 21 April 2019 may be made available on the market at any time.

Annex I of the Regulation provides a breakdown of the risk categories for personal protective equipment. Category I must protect users against the in the annex listed minimal risks (e.g. damage to eyes from sunlight, temperatures up to 50°C). Category III covers only those risks that can lead to very serious consequences, such as death or irreversible damage to health, and includes some 13 named examples such as falls from great height or drowning. Category II includes personal protective equipment not in scope ofcategories I and III. Manufacturers must use a notified body when they wish to place category III personal protective equipment on the market.

Several standards have been harmonised under the Regulation. For example, the EN 352 series deals with hearing protectors, EN 166 with eye protection devices and EN 174 specifically deals with ski goggles. Various standards against fall protection have been harmonised (EN 353, 354, 355, 358, 360. 361, 362 and 365) and there are standards for helmets for different sports. A complete overview is available on the European Commission website[43].

Not all products that provide protection are covered under the above regulations. Ordinary rainwear, gloves and reflectors on sports clothing and clothing for animals fall under general product safety.

Identification of relevant physical hazards

In identifying the hazards, it should be noted that personal protective equipment is a special category of consumer product. For most consumer products, it is about the hazard potentially posed by the product or the use of the product. In case of personal protective equipment, the danger lies in the product not doing what it is intended to do.

From 2014 to 2017, there were a total of approximately 110,000 visits to A&E departments in hospitals that record data for the LIS database.

In VeiligheidNL's assessment (Krul et al., 2019), 463 accidents are reported for the personal protective equipment product group. In addition, there are 287 notifications relating to the horse-riding equipment product group. This product group was also taken into consideration because, according to the regulations, equipment such as the riding helmet (Madani et al.) falls under personal protective equipment. Among the products, helmet/cap was ranked the highest with 428 notifications. In addition, there were 67 notifications for the sport climbing gear product group. The same applies to this as for horse riding: not just helmets but also safety hooks fall under personal protection equipment.

An overview has been made of the Safety Gate notifications from 2014 to 2018 relating to the physical safety of personal protective equipment. In Safety Gate, the product category of protective equipment was selected.

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[41] Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC. OJ L 81, 31.3.2016, p. 51-98

[42] Decree of 11 April 2018 establishing the Personal Protective Equipment (Commodities Act) Decree and amending the Administrative Fines (Commodities Act) Decree (*Warenwetbesluit bestuurlijke boeten*), the Working Conditions Decree and the Pressure Equipment (Commodities Act) Decree 2016 (*Warenwetbesluit drukapparatuur 2016*). Bulletin of Acts and Decrees 2018, 104.

[43] https://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment_en

The selected risk types were asphyxiation, burns, choking, cuts, damage to hearing, damage to sight, drowning, electric shock, entrapment, environment, fire, health risk/other, injuries, strangulation and other, or combinations thereof.

Table 14 displays the most frequently recurring risk types. Other risk types are also reported, but not on a regular basis. These include the following risk types: chemical, damage to sight, choking, fire and burns.

Table 14 Safety Gate notifications relating to the physical safety of personal protective equipment in the period from 2014 to 2018

Year	2014	2015	2016	2017	2018
Total number of notifications	22	9	15	31	14
Injuries	12	3	12	25	13
Drowning	1	3	1	3	1
Cuts	1	1	1	2	0
Damage to sight	1	1	1	0	0

The Safety Gate notifications relate to safety helmets or other helmets, safety gloves, safety shoes, safety vests and sunglasses. These are products that do not provide the protection for which they are intended. The same also applies to the notifications with drowning as a risk type, where inflatable armbands and life jackets do not provide sufficient buoyancy. In a few cases relating to safety gloves and safety shoes, the Safety Gate notification is prompted by an excessive concentration of chromium VI in the leather from which the product is made.

In 2016, the NVWA carried out a study on hearing protection intended to provide protection against loud music (NVWA, 2016h). On average, the 16 earplugs that were examined offered sufficient protection against loud music. The fit and method of use were found to be important for the proper functioning of the earplugs.

Also in 2016, a European market surveillance project personal protective equipment was carried out under the coordination of PROSAFE. The Joint Market Surveillance Action 2016, Personal Protective Equipment (PPE) - Climbing Equipment (PROSAFE, 2019c) took place with the participation of market surveillance authorities from different countries from the EU and EEA. The report clearly states at the start that inspectors tried to specifically identify the high-risk products and did not take a random sample.

A total of 185 models were tested, including products that are used to a limited extent in the Netherlands (climbing halls), but are commonly used by mountaineers. All the tested personal protective equipment provide protection against Category III risks, i.e. risks that can have very serious consequences. Of the 30 ropes tested, 5 (16%) were found to have insufficient dynamic strength and 16 (33%) of the harnesses failed the static strength test. Among the energy absorbing devices, 41% failed during one or more tests and 17% of the helmets were not sufficiently resistant to impact or penetration. This resulted in 11 Safety Gate notifications involving serious risks. Administrative violations and shortcomings in markings or documentation occurred for 47% of all the products tested.

Exposure

Personal protective equipment is used in different ways by consumers. In order to display the extent of exposure, three types of uses have been distinguished: general use, use for sports and outdoor activities and use for DIY activities.

General use includes products such as sunglasses. A large part of the population owns one or more pair of sunglasses. Safety helmets used in traffic is another example. In the Netherlands, use of this is mainly limited to children. Helmets for use on motorcycles, scooters and mopeds do not fall under personal protective equipment, but motorcycle clothing does.

During sporting activities, personal protective equipment is primarily used for protecting the person against impact. According to a survey conducted by Dutch Olympic Committee and Sports Federation (NOC-NSF), 10 million Dutch people engage in some form of physical activity per week (NOC*NSF, 2019). The majority of these people go to the gym or run, activities for which the use of personal protective equipment is limited. Twenty-five percent of them are members of an association. This includes most team sports. The number of people playing football as well as doing competitive cycling is over one million. In both these sports, personal protective equipment against impact is normally used (shin guards and helmets, respectively). With this, the weekly exposure amounts to more than two million.

During DIY activities, certain items of personal protective equipment are used that are also used for professional purposes. This includes safety shoes and gloves as well as respiratory and hearing protection equipment and safety goggles. Although use of such equipment is recommended for DIY activities as well, there are no data on actual use.

Risks

Risks associated with personal protective equipment arise primarily when a consumer relies on the protective or mitigating effect of a product and the product fails to do what it is intended to do. When this occurs, the consequences can be serious if the protective equipment in question belongs to Category III. This category lists 13 risks, some of which are highly relevant to consumers, such as falling from a height and drowning. However, Category II also covers significant risks that are not further specified; for example, bicycle helmets fall into Category II.

If a product does not offer the necessary protection, a consumer is exposed to the risk against which the product is supposed to protect him or her. An injury scenario therefore consists of two types of likelihood: the likelihood of an undesirable event occurring, combined with the likelihood of product failure. It is only in a few cases that the likelihood of product failure is the sole risk involved, such as in the case of a mountain climber taking a rest while suspended from his or her equipment.

In view of the exposure compared to the number of incidents, the risk for consumers is low. The number of notifications of non-compliant products is also small. Moreover, it should be noted that the number of tests reported by market surveillance authorities is limited.

Conclusion

Within consumer products, personal protective equipment is a special category. Risks associated with personal protective equipment arise primarily when a consumer relies on the protective effect of a product and the product fails to do what it is intended to do. Other scenarios relate to user behaviour, such as using a product for a different application than intended and misuse (not using it as intended). Depending on the impact, the consequences can be serious. The risk of injury to consumers due to failure of personal protective equipment is estimated as low, provided the product is used as intended. The risk is medium if the product is used for a purpose other than intended or if it is misused.

The severity of the consequences depends on the category of personal protective equipment; but it can be said that Category III products could lead to a potentially fatal injury or consequence (severity sategory 4), while Category II products may lead to long-term effects that are possibly irreversible (severity category 3). It is believed that Category I personal protective equipment could only lead to easily reversible injuries that allow for recovery without medical treatment (severity category 1).

There is little evidence of consumers coming into contact with defective personal protective equipment. Given the use of this equipment, the likelihood of exposure to these products is assessed as rare. The combination of likelihood and severity results in a low to medium risk (in case of Severity Category 4) for the consumer. Furthermore, the consumer must be able to rely on the fact that the market surveillance authority monitors compliance with the safety requirements.

4.3.11. Physical risks of toys

Toys can be made of various materials, such as plastic, wood, textile, rubber and paint. Toys can also come in all sorts of shapes, ranging from blocks to balance bikes. Another categorisation of toys is by age. It is generally believed that children up to the age of three often put their toys in their mouths and suck on them. This should be taken into account in the risk assessment. Important categories of toys involving physical hazards are small blocks and parts as well as mobile toys (scooters, go-karts). Fire risks caused by toys are addressed separately in Section 4.3.12.

Legal framework

The safety of toys is regulated by the Toy Safety Directive 2009/48/EC[44]. In general, toys should not present a health hazard. In addition, Chapter 1 of Annex II contains particular safety requirements for the physical and mechanical properties. Standard EN 71-1 lays down in greater detail the mechanical and physical properties regarding the safety of toys. For toys intended for children up to 36 months, there are additional stringent requirements in connection with the behaviour of young children (sucking).

Identification of relevant physical hazards

VeiligheidNL's assessment (Krul et al., 2019) shows that the product groups mentioned in Table 15 are relatively commonly involved in injuries recorded at A&E departments, compared to the total number of recorded accidents involving products (over 100,000).

Table 15 Number of injuries recorded in the LIS database relating to toys

Product group	Number of recorded injuries involving the product group
Balls	10363
Equipment for roller skating/inline skating/rollerblading/skateboarding	2970
Toys (on wheels) that bear the child's weight	1817
Other toys	652
Construction toys	60
Games	39
Toy weapons	26

Individual products that were mentioned frequently were balls (10342 times), trampolines (4322 times), inline skates/skates (1171 times), skateboards (741 times), scooters (568 times) and other toys (401 times).

Products mentioned more than 50 times and the ones most frequently involving serious injury (MAIS2+) were the longboard (72%), roller skates (69%), waveboard (66%), space scooter (66%), self-balancing scooter (65%) and inline skates/skates (65%); the trampoline had the highest frequency of serious injury (51%) among the toys without wheels.

An overview has been made of the Safety Gate notifications from 2014 to 2018 relating to the physical safety of toys. In Safety Gate, the product category of toys was selected. This is a common category in Safety Gate, indicating that market surveillance authorities pay close attention to toys and regularly detect products with shortcomings.

[44] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys. OJ L 170, 30.6.2009, p. 1-37

The selected risk types were asphyxiation, burns, choking, cuts, damage to hearing, damage to sight, drowning, electric shock, entrapment, environment, fire, health risk/other, injuries, strangulation and other, or combinations thereof.

Table 16 displays the 10 most important physical risk types per year for toys.

Table 16 Safety Gate notifications relating to the physical safety of toys in the period from 2014 to 2018

	2014	2015	2016	2017	2018
Total number of notifications	***349***	***282***	***302***	***419***	***379***
Choking	193	167	160	243	224
Injuries	41	47	38	48	42
Chemical, Choking	12	10	4	12	19
Damage to hearing	11	4	26	20	14
Choking, Injuries	21	11	12	7	13
Strangulation	15	4	13	10	12
Burns	19	8	6	16	9
Choking, Strangulation	4	3	4	7	6
Suffocation	2	2	3	8	3
Choking, Suffocation	2	3	9	4	2

The high score for choking (caused by small parts) is notable; this is possibly a type of hazard that close attention is paid to and is also found to occur frequently. Furthermore, toys that make too much noise are an area of focus. Self-balancing scooters (hoverboards) are categorised in Safety Gate as hobby/sports equipment or sometimes as machinery, but not as toys. In this assessment, they are dealt with under machinery. The Safety Gate data relating to them are therefore presented in the chapter entitled 'Physical risks of other products'.

Exposure

Although the VeiligheidNL records do not provide detailed information on exposure scenarios, it can be concluded from the products concerned that there are frequent cases of children falling off toys on wheels. This is not surprising, since the function of such toys is often not as much propulsion as practising one's balance.

Balls may not be used simply as toys but also as sports products. A foreseeable scenario could be that someone is hit by a ball: contact with object is the most common mechanism of injury relating to balls according to Krul et al. (2019). In addition, it is possible that someone could trip or stumble over a ball.

In case of the trampoline, contact with object (110 times) and physical strain (41 times) were not mentioned very often; this suggests that children collide with each other more often than with parts of the trampolines. Trampolines can be considered toys if they are placed by a consumer in his or her own garden. Trampolines in indoor or outdoor playgrounds fall under playground equipment.

In the case of construction toys and toy weapons, a variety of scenarios may be involved; the data records on this are inconclusive. Contact with object as a mechanism of injury plays a limited role with respect to both construction toys and toy weapons. In case of foreign body as a mechanism of injury, the above-mentioned toy categories do not occur or occur rarely, but for the 'Other toys' category, this mechanism causes approximately 10% of the injuries (61 times); here, the foreign body may be an object that wholly or partly obstructs the airway. Under obstructed breathing as a mechanism of injury, toys were almost never mentioned.

Risks

Failure of toys may lead to serious injuries. Possible serious scenarios are choking due to obstruction of the airway and a fall from or due to a moving product.

It is difficult to make a statement for the subdomain as a whole about the likelihood of damage to health. The likelihood of children actually being exposed to choking hazards is low; injury records do not indicate choking as a frequently occurring problem. The fact that choking hazards from toys are reported relatively often in Safety Gate suggests that products are far from being compliant with the standards. Falls are much more frequent. There is a considerable risk of a fall from a toy on wheels, but behaviour can play a major role in this, and it is questionable whether this risk can be reduced via the product requirements. For powered products such as self-balancing scooters, the likelihood probably increases with the maximum speed.

Conclusion

Choking due to obstruction of the airway can be fatal (severity category 4). A fall from or due to a moving product can lead to serious injuries (severity category 3). All children come in contact with toys at some time in their lives, but the type of toys varies with age. The percentage of toys that pose a hazard, e.g. hazards relating to small parts or fall hazards, is unknown. No data are available for the entire subdomain and about the role of products. According to the accident records, choking does not appear to be a frequent problem. Falls are much more frequent. The risk of a fall from a toy on wheels is significant, but probably difficult to limit through the product requirements. The likelihood of the failure of toys is assessed as rare, but the likelihood of accidents may significantly increase as a result of consumer behaviour, particularly in case of falls with mild injuries. The combination of likelihood and severity results in a low to medium risk for the consumer.

4.3.12. Fire risk of toys

Toys may be made of various materials such as plastic, wood, textile, rubber or paint. These materials can be a fire hazard. Examples of textile toys are soft-filled toys (stuffed toys), toy disguise costumes (fancy dress costumes) and play tents. There are also specific chemical toys, e.g. chemistry sets, model building kits or cosmetic kits. These may contain chemicals or mixtures that are flammable. In addition, electric toys can also be a source of fire in the event of a short circuit.

Legal framework

The safety of toys is regulated by the Toy Safety Directive 2009/48/EC[45]. Annex II, Section IV, Point 5 states that electric toys must offer adequate protection against fire hazards. A standard has been published for the safety of electric toys: EN 62115. Annex II, Section II, Point 1 of the directive states the following about toy materials:

Toys must not constitute a dangerous flammable element in the child's environment. They must therefore be composed of materials which fulfil one or more of the following conditions:
(a) they do not burn if directly exposed to a flame or spark or other potential source of fire;
(b) they are not readily flammable (the flame goes out as soon as the fire cause disappears);
(c) if they do ignite, they burn slowly and present a low rate of spread of the flame;
(d) irrespective of the toy's chemical composition, they are designed so as to mechanically delay the combustion process.
Such combustible materials must not constitute a risk of ignition for other materials used in the toy.
Points 2, 3 and 4 specify requirements for the substances and elements present in toys. Chemical toys (for example, model building chemicals, chemistry sets or chemistry board games), must not contain, as such, any substances or mixtures that may become flammable due to the loss of non-flammable volatile components. In addition, toys other than toy percussion caps must not be

[45] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys. OJ L 170, 30.6.2009, p. 1–37.

explosive or contain elements or substances that are likely to explode. Furthermore, toys must not contain any substances or mixtures that, when mixed together, may explode through chemical reaction or through heating; or which may explode when mixed with oxidising substances; or which contain volatile components that are flammable in air and liable to form a flammable or explosive vapour/air mixture.

A harmonised standard has been published for testing the fire safety of toy materials in accordance with the requirements set out in Point 1: EN71-2. This standard sets out requirements and test methods for textile toys, i.e. soft-filled toys, toy disguise costumes, wigs and toys that can accommodate a child.

Specific standards have been drawn up for chemical toys. EN 71-4 describes the requirements for chemistry sets. Requirements for other chemical toys are specified in EN 71-5. A standard has also been drawn up for olfactory board games and cosmetic kits (EN 71-13), although the presence of flammable substances in these toys is rare.

Hazard identification

For identifying the hazards, the Safety Gate overview for the period from 2014 to 2018 (category: toys, risk: fire and burns) was examined. In addition, results from NVWA studies and other publications were examined. Nothing was found in the literature. The search terms used were 'toys', 'flammability', 'fire safety' and 'burns'.

Hazard characterisation

Burns may occur if a child comes in contact with burning textile toys. This can happen when the child is wearing the textile or holding a burning soft-filled toy, but also through the formation of molten droplets that can cause burns on the skin.

Risks

A total of 77 Safety Data notifications have been published relating to toys that involve a risk of burns or fire. This concerns 15 sets of toy disguise costumes where it was indicated that they do not comply with EN 71-2 in regards to the flammability. There is also a Safety Gate notification for a play tent that does not comply with EN 71-2. There are 46 Safety Gate notifications about masks, wigs and beards that are highly flammable and therefore pose a risk of burns. There are also 14 reports of electric toys, where there may be a risk of overheating due to a short circuit. For these, it is often stated that they do not comply with EN 62115. There are no notifications concerning fire hazards and chemistry sets or other chemical toys.

In 2004, the VWA examined the fire safety of textile toys, such as doll clothes, soft-filled toys, toy disguise costumes and play tents (VWA, 2004a). Four of the 48 samples tested did not comply with the requirements of EN 71-2, i.e. the flame speed was more than 33 mm/s. In 2005, the VWA carried out a specific study on textile toys intended to accommodate a child (VWA, 2005b). Five of the 19 tents examined were found to be self-extinguishing or non-combustible. In four tents, the flame propagation speed exceeded the prescribed maximum speed of 30 mm/s. In 2006, the VWA performed a market study on the fire safety of toys (VWA, 2006), which also examined the presence of flame retardants. A total of 95 toys from various categories were sampled and examined. The play tents and toy disguise costumes categories show the greatest number of deviations from EN 71-2. Most play tents are made of polyester. In the event of a fire, this will result in molten droplets, placing the child at risk of serious burns. The examined soft-filled toys (n=53) met the requirements of EN 71-2 with regard to flammability, except for one requirement. The study of the regulated flame retardants did not reveal any further findings.

It should be noted here that the scope of EN 71-2 is limited to soft-filled toys, toy disguise costumes, wigs and toys intended to be entered by a child. Toys that fall outside this scope are generally not tested for fire safety. No fire safety data are available for this category of toys.

Conclusion

If soft-filled toys catch fire, they can cause burns (severity category 3). If toy disguise costumes, wigs or play tents catch fire, severe second or third degree burns may occur; this may also be due to the formation of molten droplets (severity category 4).

Some older children may come in contact with flammable toys or electric toys that may be a source of ignition. The proportion of toys that present this hazard and do not comply with the requirements is unknown. Safety Gate notifications and NVWA studies show that there are toys on the market that do not meet the safety requirements. However, the study data of the NVWA are somewhat dated. The likelihood of a product catching fire is assessed as small. Soft-filled toys catching fire can cause burns in children. However, a child will normally let go of the soft-filled toy if it starts burning. Naturally, this is more difficult in the case of toy disguise costumes and play tents. If a child comes into contact with flames or molten droplets, there is a high likelihood of burns.

The overall likelihood of exposure to flammable toys is assessed as rare for soft-filled toys, electric toys, toy disguise costumes and play tents. The combination of likelihood and severity results in a low risk for consumers in the case of soft-filled toys and electric toys. As far as toy disguise costumes and play tents are concerned, likelihood and severity result in a low to medium risk.

4.3.13. Physical risks of playground equipment

Playground equipment consists of structures or elements designed for human recreation and enjoyment that only make use of gravity or the physical force exerted by a person. Examples include air cushions, water and other types of slides, climbing frame, swings, seesaws, sandboxes, trampolines and combinations of these elements in a single piece of equipment. Playground equipment intended for private purposes are regarded as toys.

Since there is a fall hazard involved, requirements are also established for the surfacing. The surfacing material may consist of sand, grass, gravel, bark, rubber tiles or another shock-absorbing material.

Legal framework

The Commodities Act Decree on Amusement Devices and Playground Equipment[46] lays down the requirements to be met by playground equipment. For playground equipment, a type approval test must be performed by an appointed inspection body. A technical construction file must be available. Complex items of equipment may also require a periodic inspection. The Specific Rules for Amusement Devices and Playground Equipment[47] references the European standards for playground equipment, surfacing materials and water slides.

Identification of relevant physical hazards

The Commodities Act Decree on Amusement Devices and Playground Equipment is aimed at covering a number of relevant hazards, such as instability, entrapment and falls.

In 2017 and 2018, VeiligheidNL examined records of accidents at indoor play facilities (Stam, 2017; Krul & Nijman, 2018). There are several hundred accidents per year involving indoor playground equipment that result in injuries requiring treatment in an A&E department. The extent of the problem is probably being underestimated, because it is not always clear from the description of the circumstances provided in the LIS database whether the accident took place indoors or outdoors. The assessment by VeiligheidNL has shown that the descriptions of circumstances in the LIS database are insufficient to make a statement about the role of product failures in accidents involving indoor play equipment.

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[46] Decree of 3 September 1996 establishing a general order in council for the implementation of the Dangerous Equipment Act. Bulletin of Acts and Decrees 1996, 474, last amended by Bulletin of Acts and Decrees 2016, 189.

[47] Specific Rules for Amusement Devices and Playground Equipment. Government Gazette 1997, 33, last amended by Government Gazette 2017, 4901.

It appears (Krul et al., 2019) that the fixed installations/objects at the playground/playpark category are mentioned relatively frequently in the injury records at A&E departments (9,278 out of a total of approximately 110,000 injuries). Individual products that were mentioned frequently were the trampoline (4,322 times), climbing frame/climbing apparatus (2,115 times), slide (1,069 times), other playground equipment (605 times), slide, swimming pool (239 times) and aerial cableway (110 times). Several products that were mentioned more than 50 times led to serious injuries relatively often: climbing frame (72%), swing (68%), other playground equipment (59%), slide (56%) and aerial cableway (56%).

From 2014 to 2018, there were no notifications in Safety Gate relating to the physical safety of playground equipment. Safety Gate also has no product category for playground equipment. The few swings and slides mentioned are classified as toys and based on the descriptions, these are generally intended for use in people's private gardens. This lack of notification may be due to the absence of European legislation in this area; however, European standards are available, as indicated under the 'Legal framework' section.

Exposure

The equipment frequently mentioned in accidents can be found in many places. Therefore, there is a high level of exposure to these items of equipment. All children up to at least 14 years of age come in contact with playground equipment. Some information on exposure scenarios can be derived from the recording of the mechanisms of injury.

Falling is, by far, the most common mechanism of injury for products in general (nearly 69,000 recorded falls out of a total of about 110,000 A&E treatments). According to (Krul et al., 2019), 13% of all falls resulting in the need for A&E treatment involve a climbing frame, 4% a swing, 4% a trampoline and 4% a slide.

For contact with object as the mechanism of injury, the slide is the most frequently mentioned piece of equipment (189 times), followed by the trampoline (110 times), water slide (89 times), other playground equipment (74 times) and climbing frame (64 times).

Physical strain as the mechanism of injury occurred 41 times with the trampoline, 17 times with the slide and 15 times with the climbing frame. This may be associated with unfortunate falls where, for example, an ankle is sprained.

Obstructed breathing as a mechanism of injury is generally rare. It is notable that this is mentioned for four types of playground equipment, i.e. for the slide, swing, other playground equipment and water slide, where each is mentioned once and where three of these accidents resulted in serious injuries. A possible scenario could be that a cord or drawstring on clothing got caught somewhere when the person slid or fell off.

Risks

There is always a risk of falling from playground equipment, since the height and climbing activity are part of the challenge of playing. The likelihood of a fall depends on whether there are railings built around a platform, the positioning of suitable handrails and handholds, as well as the child's skills and behaviour. The possible severity of the injury depends to a large extent on the height of the fall and the surfacing material. In view of the frequency of A&E treatments after a fall from playground equipment, it can be concluded that the current equipment as well as the surfacing material underneath it are not always designed to prevent injuries; the primary purpose of shock-absorbing surfacing material is to limit the severity of the injuries.

Although there are only a limited number of cases of obstructed breathing, if a child's head or neck or a cord or drawstring on clothing gets stuck somewhere on the equipment, this can be fatal.

Conclusion

A fall from playground equipment can lead to serious injuries (severity category 3). All children up to at least 14 years of age come into contact with playground equipment and a large proportion of playground equipment presents fall hazards as part of the challenge. A&E treatments after a fall from playground equipment are common. Factors that determine the likelihood of a fall are the

construction of railings around a platform, the positioning of suitable handrails and handholds and the child's skills and behaviour. The likelihood of a serious fall injury depends on the height of the fall and the shock absorbing qualities of the surfacing material and is assessed as occasional. The risk of a fall can be classified as medium to high. Supervision of playground equipment can help reduce the risk of serious injury.

If the head, neck or a cord or drawstring on clothing gets trapped during a movement, the injury can be fatal (severity category 4). There is little data on the presence of entrapment hazards. The likelihood of exposure to entrapment hazards depends on many factors, such as clothing and behaviour; there is no evidence that this occurs frequently. The overall likelihood of entrapment is assessed as rare. The combination of likelihood and severity results in a low to medium risk of entrapment for a consumer. The role of the market surveillance authority in mitigating this risk is likely to be limited.

4.3.14. Physical risks of textiles

The most relevant physical risks with respect to textiles are discussed here. Flammability will be addressed in a separate paragraph.

The word 'textile' literally means 'that which is woven'. A piece of textile consists of long or short threads that have been woven, knitted, knotted, braided or felted. It may be used as a raw material on the roll from which an end product is made, such as clothing, or the end product itself. It includes a range of consumer products such as clothing, linen, bed linen, home textiles, furnishing fabrics, carpets and rugs. It also includes haberdashery, yarns and knitting yarns. The term 'clothing' should be considered very broadly: leather clothes, baby clothes, underwear, everyday clothes, work clothes, sportswear, swimwear, as well as accessories such as scarves, bags, gloves and footwear (NVWA, 2016f).

Legal framework

When it comes to the mechanical properties, textiles must comply with the General Product Safety Directive, which has been laid down in Dutch law in the Commodities Act Decree of the same name. In this context, the EN 14682 standard (Safety of children's clothing. Cords and drawstrings on children's clothing - Specifications) is referenced in the annex to the Designation of General Safety Standards (Commodities Act) Regulation (*Warenwetregeling aanwijzing algemene veiligheidsnormen*). It is assumed that compliant products do not pose a hazard in terms of the hazards dealt with in the standard. The Toys (Commodities Act) Decree 2011 (*Warenwetbesluit Speelgoed 2011*) applies to toy disguise costumes for children aged up to 14.

Identification of relevant physical hazards

Accident data collected by VeiligheidNL (Krul et al., 2019) show that clothing, as a product group, is regularly involved in injuries (more than 1,600 A&E treatments out of a total of approximately 110,000). In addition, clothing accessories are also sometimes mentioned. The mechanisms of injury most frequently mentioned are falling, contact with object, physical strain and thermal exposure. Obstructed breathing is very rarely recorded as a mechanism of injury. This information provides insufficient guidance for identifying the hazards presented by clothing.

Searching the scientific literature with combinations of terms such as 'clothing', 'textile', 'risk', 'epidemiology', 'child' or 'injury' only resulted in a few relevant publications. These often concerned chemicals, clothing for protection against UV radiation or flammability (particularly in relation to burn injuries in developing countries). Combining this with specific search terms such as 'drawstrings', 'cords' or 'choking' also yielded almost no results. Sometimes, the research in this area focuses on trends in consumer product recalls (Niven et al., 2019). Sep & Thies (2007) have reviewed strangulation accidents, following an accident on a slide. The rate of incidence of this type of injury was 0.7 deaths/100,000 children per year, half of which were the result of an accident. Cords for window furnishings (such as curtains, blinds) inside the house often played a role in accidents involving toddlers.

Safety Gate

In addition, an overview has been made of the Safety Gate notifications from 2014 to 2018 relating to the physical safety of textiles. In Safety Gate, the product category of clothing, textiles and fashion items was selected.

The selected risk types were asphyxiation, burns, choking, cuts, damage to hearing, damage to sight, drowning, electric shock, entrapment, environment, fire, health risk/other, injuries, strangulation and other, or combinations thereof.

Table 17 displays the 10 most important risk types per year for textiles.

Table 17 Safety Gate notifications relating to the physical safety of textiles in the period from 2014 to 2018

	2014	2015	2016	2017	2018
Total number of notifications	417	261	175	196	177
Choking	28	51	51	55	61
Strangulation	138	84	49	44	32
Injuries, strangulation	82	34	21	17	6
Choking, Injuries		6	1	5	5
Injuries	166	85	47	68	
Burns	2		5	7	
Fire					2
Drowning, injuries, strangulation					1
Chemical, injuries, strangulation			1		
Chemical, other		1			
Burns, fire	1				

The Safety Gate notifications give an idea of the specific items focused on by European authorities and the associated hazards identified by them. In recent years, the clothing, textiles and fashion items product group has accounted for less than 10% of the total number of Safety Gate notifications. Given the frequency of notifications of strangulation and choking, cords have received the most attention and, over the years, products involving cords have been found to pose a serious risk. There are notably a large number of notifications in 2014, which can be attributed to the Cords and Drawstrings PROSAFE Joint Action (PROSAFE, 2015b). This one-off peak clearly shows that, with additional surveillance efforts, more products with potentially dangerous properties are found.

UV resistant clothing

In 2017, NVWA conducted a market survey on the UV protection provided by UV resistant swimwear for babies and young children (NVWA, 2017e). Of the 47 UV protection garments examined, 44 met the requirements. Two garments did not offer enough protection to be sold as UV protection clothing. One garment reported a higher UPF value than was measured. The risk with these products is that parents may misjudge the amount of protection offered, which can lead to overexposure to UV radiation. The market-wide survey shows that most UV protection swimwear provides sufficient sun protection, with values exceeding 50 UPF.

Exposure

Exposure to the physical hazards of textiles is possible via direct contact. People wear clothes almost all day long, often in different combinations. Contact with bedlinen occurs during the period of sleep. Contact with home textiles is less frequent. There is a daily exposure to textiles.

Risks

The most serious scenarios are a garment (scarf) or part of it (hoodie drawstring) getting caught around the neck or wound around an axle and a toddler getting entangled in a curtain cord. Furthermore, long-term damage to health is possible if clothing claiming to protect against UV radiation does not adequately block radiation.

Scenarios involving falls are certainly more frequent, but the role of textiles is not clear. Clothing is worn daily by everyone. The proportion of clothing containing specific hazards, such as cords, is not known. Most clothing with a claim of UV protection meets the requirements. The likelihood of fatal strangulation of children due to various types of accidents involving cords or drawstrings on clothing and curtain cords seems small but is not negligible (3 to 4 per million children in the Netherlands). The likelihood of being overexposed to UV radiation depends on many factors, and clothing has only a limited influence on this. Overall, the likelihood of exposure to defective textiles (cords) is assessed as rare.

Conclusion

Obstruction of breathing by garments or curtain cords can be fatal (severity category 4). The likelihood of fatal strangulation of children by defective textiles (cords) is assessed as rare. The combination of likelihood and severity results in low to medium risk for the consumer.

The long-term damage to health caused by inadequate UV protection is irreversible (severity sategory 3). The likelihood of being overexposed to UV radiation depends on many factors, and clothing has only a limited influence on this. Therefore, the likelihood is assessed as rare. The combination of likelihood and severity results in a low risk for the consumer.

4.3.15. Fire risk of textiles

Textiles can be a fire hazard. Textiles with certain properties mostly catch fire when they come into contact with open flame. Here, two injury scenarios are most likely, i.e. burns and internal burns and/or lung damage due to inhalation of combustion gases.

Legal framework

EN 1103 is a European test method for measuring the burning behaviour of textiles. The American ASTM D1230 standard is used worldwide to test and assess the fire safety of apparel textiles. The Toys (Commodities Act) Decree 2011[48] applies to the fire safety of toy disguise costumes for the age category up to 14 years. EN 71-2 describes the prescribed test method and more detailed requirements (see also Section 4.3.12). Within the Netherlands, agreements have been made regarding the enforcement of certain fire safety requirements, i.e. the Enforcement Agreements for Fire Safety of Clothing in accordance with the Commodities Act[49] and the Covenant on the Fire Safety of Nightwear[50].

Hazard identification

For textiles to burn, ignition from a heat source is necessary. Fire or flames are not necessary. The mere application of heat can ignite textiles (e.g. a hot iron on a cotton shirt). When textiles burn, toxic smoke is produced.

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[48] Decree of 21 January 2011 establishing the Toys (Commodities Act) Decree 2011. Bulletin of Acts and Decrees 2001, 57.

[49] Enforcement Agreements for Fire Safety of Clothing in accordance with the Commodities Act. Bulletin of Acts and Decrees 2006, 28.

[50] Covenant on Nightwear Fire Safety. Bulletin of Acts and Decrees 1997, 76.

Plant fibres such as cotton are easily flammable, and the flames can spread throughout the garment. Synthetic fibres such as nylon and polyester do not catch fire but melt on contact with fire. The molten drops cause severe burns.

Exposure

Loose-fitting clothing and loosely woven fabrics catch fire more quickly than tight-fitting clothing and tightly woven fabrics because oxygen can more easily reach the fire. Fabrics treated with flame retardant chemicals are difficult to ignite or burn slowly. When skin comes into contact with burning textiles, this results in burns. Inhalation of toxic fumes can lead to a reaction of the airways.

Risks

Between 2014 and 2018, Safety Gate received 10,062 notifications relating to a potentially high-risk consumer product. There were 1,079 (11%) notifications that involved fire and/or burns, in addition to possible other risk categories. From these Safety Gate notifications, a selection was made from notifications in the following categories: clothing, textiles and fashion items, furniture, decorative articles, hobby and sports equipment and protective equipment. Based on this, it can be seen that Safety Gate contains 18 notifications of textile products that could be a fire hazard because they are highly flammable. These include disguise costumes or other clothing and accessories such as wigs and masks (N=15), chairs (N=1) and pillows (N=2).

For thermal exposure as the mechanism of injury, the VeiligheidNL report mentions 'other clothing' 21 times, 'other household linen' 10 times and some types of garments less than 10 times (Krul et al., 2019).

In 2003, the VWA took 75 samples of fabric from rolls sold in fabric shops and market stalls to consumers to be used for making their own clothes. Sixty of the 75 samples were assessed for burning behaviour. A surface flash[51] occurred in two of the 60 samples, which means that these would not meet the standard established in the Draft Fire Safety in Clothing, Nightwear and Disguise Costumes (Commodities Act) Decree (*ontwerp-Warenwetbesluit Brandveiligheid kleding, nachtkleding en verkleedkleding*). Twenty-one of the 60 samples examined demonstrated some form of melting behaviour (VWA, 2003).

In 2003, the VWA took 108 samples of home textiles (including net curtains or other curtains and upholstery fabrics) from various home furnishing companies. Since no standards or criteria have been defined for home textiles, the results have been assessed based on criteria from the Covenant on the Fire Safety of Nightwear. Of the 108 samples tested, 107 meet the requirement regarding the flame spread time. One of the 108 samples tested does not meet the requirement for surface flash. Thirty-seven of the 108 samples tested show some form of melting behaviour. One of the six samples claiming to be fire resistant or fire retardant does not meet that claim (VWA, 2004b).

In 2008, VWA randomly sampled 79 items of children's nightwear on the Dutch market. These include pyjamas, nightshirts and morning coats, all intended to be worn by children. All the samples were tested to see whether they met the fire safety requirements as stated in the Covenant on the Fire Safety of Nightwear. Three (all pyjamas) of the 79 samples did not meet the requirements of the Covenant. In these cases, the requirement specifying that the flame should not burn through a 52 cm-long measuring wire within 17.0 seconds after ignition of the cloth was not met. Molten droplets did not ignite an underlying filter paper in any of the above cases (VWA, 2009c).

In 2008, VWA sampled 83 items of summer clothing (incl. blouses, shirts and dresses) on the Dutch market, of which 49 were for adults and 34 for children (VWA, 2009b). In 2009, VWA sampled 78 items of Christmas clothing (including blouses, skirts, shirts and dresses) on the Dutch market (VWA, 2009d). Using the ASTM D1230 test method, the garments were tested for

[51] Surface flash is a rapid burning of the surface of the fabric without the basic material catching fire. The phenomenon may occur if the fabric comes briefly into contact with a flame, especially for textile products with a roughened (hairy/fuzzy) surface.

compliance with fire safety requirements as agreed in the Fire Safety Enforcement Agreements in accordance with the Commodities Act. The study shows that both the sampled summer clothing and the sampled Christmas clothing comply with the minimum requirements with regard to burning behaviour (VWA, 2009d;2009b).

In 2010, BuRO assessed the risk of injury (burns, lung damage) due to festive articles, such as costume boas and wigs, as high (BuRO, 2010b). For reducing this risk, it was strongly advised to stay away from ignition sources when using these products. Furthermore, a limit value of 40 mm/s for the flame spread speed was advised. In the run-up to the 2010 FIFA World Cup, the NVWA carried out a study on the fire safety of costume boas and wigs for this event. BuRO has assessed the risk of these products (BuRO, 2010a;2011a) and concluded that a health risk could not be excluded. The same risk mitigation measures were proposed (warning to stay away from ignition source and a limit value of 40 mm/s for the flame spread speed). Most of the wigs that were tested complied with this limit value. For boas, it proved technically difficult to make the feathers consistently fire retardant. Furthermore, the use of flame retardants was not considered desirable, since these entailed a chemical health risk.

Textiles can be treated with flame retardants to prevent them from catching fire, prevent the spread of the flames and minimise the extent of damage caused by fire (Hofland & Dijkman, 2016). However, the flame retardants present in textiles may pose a chemical risk (see also the section on chemical risks). Hence, certain choices have to be made in the area of risk management.

Conclusion

Textiles that catch fire can cause serious burns and lead to inhalation of toxic combustion gases. Home textiles such as curtains or carpets can contribute greatly to the spread of a house fire. Severity can range from minor burns to death (1-4). Based on a worst-case scenario, the severity is classified as more than 10% disability or death. Textiles are widely used. All consumers come in contact with textiles. The above-mentioned studies on the fire safety of textiles by the NVWA have been carried out some years ago. It is uncertain whether the results are representative of the current situation. Within this group, the likelihood of health effects is assessed as small because a consumer generally comes into contact with a source of fire only occasionally. The overall likelihood of exposure to flame retardant textiles is assessed as rare. The combination of likelihood and severity results in a low risk for the consumer.

4.3.16. Physical risks of other products

Consumer products that do not fall under one of the subdomains (with specific legislation) are categorised by the NVWA as general consumer products. This is a very diverse segment. This includes, for example, jewellery, handheld tools and sports equipment.

Legal framework

Consumer products must comply with the General Product Safety Directive[52] 2001/95/EC. This Directive lays down general safety requirements but does not stipulate any specific requirements. Generally, a product must be safe and must not, under normal or reasonably foreseeable conditions of use, present any risk or only the minimum risks compatible with the product's use that are considered to be acceptable and consistent with a high level of protection for the safety and health of persons.

Identification of relevant physical hazards

VeiligheidNL's assessment (Krul et al., 2019) shows that these general consumer products score high in terms of the number of accidents. For example, bicycles (including racing and mountain bikes), balls, fixed installations/objects on playgrounds/playparks, raw materials and structural components, chairs and couches, beds, bicycle parts, walking or other aids, equipment for roller

[52] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. OJ L 11, 15.1.2002, p. 4-17

skating, inline skating, rollerblading or skateboarding and tables are the top-ten product groups for all mechanisms of injury combined: these are involved in 78,000 injuries out of a total of about 110,000 injuries. From this list, only playpark equipment is subject to specific regulations; if this product group is excluded, the number of accidents is almost 69,000.

Falling is by far the most common mechanism of injury for products in general: nearly 69,000 recorded falls out of a total of about 110,000 treatments at A&E departments). According to (Krul et al., 2019), one-third of all falls leading to A&E treatments involve a bicycle, 18% involve a bed, 10% involve a chair and 6% involve a couch.

Under 'contact with object as the mechanism of injury', balls were often mentioned (over 7,900 times), followed by bicycles and bicycle spokes (2,660 and 1,980 times). Products in this subdomain which were mentioned more than 50 times and which caused relatively serious injuries were trousers, racing bicycles, punching bags, cross-country motorcycles, mountain bicycles, wheelchairs, scooters (moped, light moped, motorcycle), motorised go-karts, child bike seats.

Physical strain as the mechanism of injury occurs relatively often (more than 100 times) involving products such as beds, chairs, balls and couches; the severity level is usually not very high. Specific products are mentioned relatively seldom under foreign body as the mechanism of injury; the most frequently mentioned 'product' is splinter/shard and another product that stands out are batteries (161 times, mostly with a low severity level).

An overview has been made of the Safety Gate notifications from 2014 to 2018 relating to the physical safety of products that are not specifically regulated. In Safety Gate, the following product categories were selected: chemical products, decorative articles, food-imitating products, furniture, gadgets, hand tools, hobby/sports equipment, jewellery, kitchen/cooking accessories, laser pointers, lighters, pressure equipment/vessels, stationery, and other.

The selected risk types were asphyxiation, burns, choking, cuts, damage to hearing, damage to sight, drowning, electric shock, entrapment, fire, health risk/other, injuries, strangulation and other, or combinations thereof.

The most important results of this assessment are presented in Table 18.

Table 18 Safety Gate notifications relating to the physical safety of other consumer products in the period from 2014 to 2018

Year	Total number of notifications in Safety Gate	Main product categories	Main risk types
2014	159	Other (39) Hobby/sports equipment (36)	Injuries + damage to sight + burns, fire + fire (106)
2015	154	Other (40) Lighters (27)	Injuries + fire + choking + environment (109)
2016	130	Hobby/sports equipment (41) Other (22)	Injuries + fire + environment + choking (80)
2017	83	Hobby/sports equipment (23) Other (13)	Injuries + environment + damage to sight + fire (61)
2018	102	Hobby/sports equipment (21) Laser pointers (16)	Fire + injuries + damage to sight + environment (70)

The share of this product group in the total number of Safety Gate notifications (see Table 18) is less than 10%. Hobby and sports equipment often emerges as an important product category; these appear to include self-balancing scooters as well as bicycles, climbing equipment and many other categories of products.

Exposure

The exposure is highly variable for these products. Jewellery may be worn for long periods of time, while handheld tools are only used occasionally by many people. It is therefore difficult to make a general statement about exposure. The accident records provide some kind of indication: balls, raw materials and structural components, bicycles, bicycle parts, chairs, and couches and tables are part of the top ten under contact with object as the mechanism of injury. This indicates that general injuries often occur as a result of collision with or being hit by the product. However, details of the role of the products in these injuries are not available for the entire group of products.

Risks

There are few concrete indications of risks attributable to general consumer products. This is partly because of the wide scope of this subdomain. In particular, it is often not clear which product-related hazards are important. Based on the Safety Gate notifications it appears that there are concerns about the risk of eye injuries in connection with laser pointers, electrical safety and fire risks in connection with self-balancing scooters and fires in connection with lighters; however, the numbers are more an indication of the attention focused on these products by certain Member States, rather than a risk.

In 2017, the NVWA inspected disposable plastic lighters available in shops, supermarkets and on the internet in the Netherlands. It specifically considered the flame height, extinction time, resistance to dropping and increased temperature and the filling rate (NVWA, 2017c). Almost a quarter of the lighters did not meet the requirements. A lighter can, in principle, cause a fire (e.g. if children play with it) and this can have fatal consequences (severity category 4); it is difficult to assess how much greater the risk of this becomes if the lighter does not comply with the requirements. The overall likelihood of the occurrence of a fire caused by a failed lighter is assessed as rare.

Conclusion

Due to the large variety in the types of products, no general conclusion can be drawn regarding the physical risks to consumers from defective products within the general product safety subdomain.

For lighters that do not meet the safety requirements, the risk is assessed as low.

5. Assessment of the chemical risks of consumer products

5.1. General

Chemical risks arise from substances that make up the product or are present as contaminants and may possibly migrate from the product. These substances may be toxic, irritating or sensitising in case of acute incidental ingestion or long-term exposure above a certain limit value.

As part of the hazard identification process, the intrinsic hazards of substances are specified: classification as carcinogenic (causing cancer) and/or mutagenic (causing heritable changes) and/or reprotoxic (harmful to reproduction) and/or sensitising (causing hypersensitivity and allergies) (where the aforementioned classifications are usually abbreviated to CMRS), acute toxicity or specific long-term toxicity.

The effects of a substance will only occur if a person is exposed to it by inhalation, ingestion or skin contact. The extent of the effect will then depend on the dose, duration and frequency of exposure. The oral route (ingestion) plays a much smaller role in the case of consumer products as compared to food, but the sucking on products by children can contribute significantly to exposure.

Animal testing continues to be necessary for demonstrating the safety of chemicals in consumer products. Since the requirements for dossiers are determined by international organisations such as the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA), the NVWA has no direct influence on this. However, a great deal of research is being carried out for the purpose of replacing, reducing and improving animal testing. Moreover, testing ingredients for cosmetic products on animals has been banned for some time now.

5.1.1. Contact dermatitis

Contact dermatitis is an acute inflammation of the skin caused by irritants or allergens. The main symptom is itching; changes in the skin range from erythema to blisters and sores, often located on or near the hands, although they may occur on any exposed skin surface.

Contact dermatitis can be subdivided into irritant contact dermatitis (ICD) and allergic contact dermatitis (ACD). ICD accounts for 80% of all cases of contact dermatitis and is often caused by cumulative exposure to weak irritants such as soap or water (Tan et al., 2014; Bains et al., 2019). In ICD, the innate immune system is activated because the damaged skin is exposed to external stimuli, leading to an immediate local skin inflammation (Bains et al., 2019). In contrast, ACD is caused by a delayed immune response. The first thing to occur is sensitisation, activating the adaptive immune system (sensitisation phase). In this way, the immune system is programmed to recognise an allergen immediately upon subsequent exposure. Subsequent exposure leads immediately to a rapid skin inflammation (elicitation phase) (Tan et al., 2014; Kostner et al., 2017).

5.2. Exposure to chemical substances

A consumer may be exposed to chemicals via three routes: skin absorption, inhalation and oral ingestion. The chemicals may come from a variety of sources (e.g. one or more consumer products and foods) and a consumer may be exposed via multiple routes of exposure. This is known as aggregate exposure (Lorenz et al., 2011; RIVM, 2012). For assessing the exposure to chemicals from specific products, the RIVM has developed the computer program ConsExpo, which is accessible online at https://www.consexpoweb.nl/. Input data such as frequency and duration of use are usually determined based on expert judgement; as far as BuRO is aware, there are no accessible sources of information on the use of all the various kinds of consumer products. At the level of the subdomains, only an overall indication of exposure can be provided.

5.2.1. Skin absorption

The skin consists of three layers: epidermis, dermis and subcutis. The epidermis is a barrier that prevents the loss of moisture and protects the body from absorbing substances from outside the body (exogenous substances). The properties of the uppermost layer of the epidermis (stratum corneum) and the properties of a chemical substance determine how and at what speed a

substance can penetrate the skin. The structure of the stratum corneum is comparable to a brick wall. The stones (keratinocytes) are held together by cement (fats) (Elias, 1983; van Smeden et al., 2014). Exogenous substances can diffuse through the skin via three routes: through the cells (transcellular), between the cells (intercellular) and via other channels (sweat glands, sebaceous glands and hair follicles). An exception to this is tattooing, where the epidermis is punctured to inject ink into the dermis. Healthy skin contains moisture that allows water-soluble and small molecules to easily penetrate the skin via the transcellular route. In contrast, fat-soluble molecules penetrate the skin via the intercellular route. This route is slower than the transcellular route because the space between the cells is limited. The thickness of the stratum corneum differs; it is thicker on the feet than in the armpit, so the degree of absorption of substances is also different. If the skin is damaged, there may be an increased absorption of exogenous substances (Biesterbos, 2016).

5.2.2. Inhalation

The respiratory tract can be divided into the upper airways (nasal cavity, paranasal sinus, oral cavity, throat and larynx above the vocal cords) and the lower airways (larynx below the vocal cords, trachea and lungs). The trachea branches into two main bronchi, which then branch into smaller bronchi with alveoli at their ends. Gas exchange with the blood takes place in the alveoli. The water solubility and reactivity of molecules determine whether exogenous substances are absorbed via the respiratory tract (Medinsky & Bond, 2001). Water-soluble molecules can diffuse into the nasal mucosa lining the airways, possibly preventing them from reaching the alveoli in the lungs (Johanson, 1991; Mörk & Johanson, 2006). Some molecules may react with components of the nasal mucosa, lowering the concentration in the respiratory tract and leaving only a small fraction of the substance available for absorption into the alveoli (Medinsky & Bond, 2001). Therefore, the gas exchange in the alveoli mainly occurs with substances with poor solubility in water and this hardly reacts with the nasal mucosa. The degree to which a substance is absorbed by the blood is determined by the blood-gas partition coefficient.

The amount and location of aerosol deposition in the respiratory tract is determined by factors such as particle size, concentration and water solubility of the aerosol substance, geometry of the respiratory tract and factors related to respiration (e.g. respiratory rate) (Klaassen, 2001; Rostami, 2009). Small aerosols penetrate deep into the respiratory tract where they can reach the alveoli and then get absorbed into the blood. Alveolar macrophages can remove aerosols before they are actually absorbed (Klaassen, 2001; Biesterbos, 2016).

5.2.3. Oral ingestion

After a substance is ingested via the mouth, it can be absorbed into the blood via the gastrointestinal tract. The exact location where a substance is absorbed depends on the properties of the substance, such as acidity or fat solubility. The fraction of the ingested substance that reaches the systemic circulation depends on the amount absorbed by the epithelial cells of the gastrointestinal tract and possible conversion in the liver (first-pass effect) (Biesterbos, 2016).

5.3. Description of the chemical hazards

This chapter describes the chemical hazards in detail: how can they cause damage to health, how severe can the damage be, which product properties determine the effects and severity, and which group of people is most sensitive to these hazards?

5.3.1. Allergenic fragrances

Dermal route

Exposure to fragrances can cause people to become sensitised. This means that repeated exposure to a certain dose of this substance may lead to the development of eczema (allergic contact dermatitis), often in the face, armpits or on the hands. Contact allergy can be severe and can potentially affect one’s capacity for work.

In 1999, the Scientific Committee on Cosmetic products and Non-Food Products intended for consumers (SCCNFP) identified a set of 26 fragrances, generally recognised as potential skin allergens (SCCNFP, 1999). In 2012, the Scientific Committee on Consumer Safety (SCCS) conducted a review of clinical, epidemiological and experimental studies to draw up lists of established allergenic fragrances, probable allergenic fragrances and possible fragrance allergens (SCCS, 2012a).

The following allergenic aromatic substances are most frequently reported in relation to allergies in consumers:

- Amylcinnamal
- Amyl cinnamyl alcohol
- Benzyl alcohol
- Benzyl salicylate
- Cinnamyl alcohol
- Cinnamal
- Citral
- Coumarin
- Eugenol
- Geraniol
- Hydroxycitronellal
- Hydroxymethylpentylcyclohexenecarboxaldehyde
- Isoeugenol

In addition, there is a list of substances that are less frequently reported and less well documented:

- Anisyl alcohol
- Benzyl benzoate
- Benzyl cinnamate
- Citronellol
- Farnesol
- Hexyl cinnamaldehyde
- Lilial
- d-Limonene
- Linalool
- Methyl heptine carbonate
- 3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one

Two more fragrances (natural mixtures) may be added to this list:

- Extracts of oakmoss
- Extracts of tree moss

Generally speaking, most consumers, including those sensitised to certain fragrances, can tolerate a maximum exposure of 0.8 µg/cm² (0.01% in cosmetic products). Therefore, the SCCS is of the opinion that a limit value of 0.01% in cosmetic products provides sufficient protection (SCCS, 2012a).

A Dutch cosmetovigilance study showed that fragrances score high on the list of allergenic substances to which Dutch consumers test positive (Salverda et al., 2013).

Inhalation route

For fragrances, inhalation exposure is also involved, for example, in the case of perfumes and air fresheners. The RIVM has carried out a study to find out whether inhalation of allergenic fragrances in air fresheners can cause sensitisation of the respiratory tract (ter Burg et al., 2014). Sensitisation by inhalation of allergenic fragrances was assessed as occurring very rarely. This was

confirmed by research by Basketter et al. (Basketter et al., 2019). However, perfumes or fragrances can act as a trigger for asthma[53].

Cosmetic products

Annex III of the Cosmetic Products Regulation[54] lists all the 26 allergenic fragrances mentioned above in the 'Dermal route' section. It is mandatory to mention the name of the substance in the list of ingredients if its concentration exceeds:

- 0.001% in products that do not rinse off (leave-on products)

- 0.01% in products that are rinsed off (rinse-off products)

Toys

The Toy Safety Directive[55] also contains requirements with regard to fragrances. No distinction is made between the route of exposure or type of toy. For toys, possible routes of exposure may be dermal, inhalation or oral. Annex II, Section II, Point 11 contains a list of 55 allergenic fragrances that are not allowed to be present in toys, and only traces of these fragrances shall be permitted provided that such presence is technically unavoidable under good manufacturing practice and if their concentration does not exceed 100 mg/kg. In addition, there is a list of 11 allergenic fragrance whose names must be declared if their concentration exceeds 100 mg/kg:

- 4-Methoxybenzyl alcohol
- Benzyl benzoate
- Benzyl cinnamate
- Citronellol
- Farnesol
- Hexyl cinnamaldehyde
- Lilial
- d-Limonene
- Linalool
- Methyl heptine carbonate
- 3-Methyl-4-(2,6,6-trimethyl-2-cyclohexeen-1-yl)-3-buteen-2-on

A number of allergenic fragrances may not be used in olfactory board games, cosmetic kits and olfactory toys intended for children under the age of three.

5.3.2. Asbestos

Asbestos is a silicate mineral. A total of six types of asbestos have been distinguished based on the REACH Regulation: chrysotile and the so-called amphiboles, i.e. amosite, crocidolite, anthophyllite, tremolite and actinolite. The various types of asbestos generally consist of fibres that are very difficult to break but which easily split in a longitudinal direction.

Asbestos can cause mesothelioma (pleural and peritoneal cancer), lung cancer, laryngeal cancer and ovarian cancer. In addition, a positive association has been observed with pharyngeal, stomach and colon cancer. The International Agency for Research on Cancer (IARC) further states that all forms of asbestos are proven human carcinogens (Group 1) (RIVM, 2018). Long, strong and thin asbestos fibres (length >5 µm and with a length to thickness ratio >5) cannot be properly removed from the lungs after inhalation, as a result of which, often decades later, they may give rise to chronic effects and tumours (BuRO, 2018b). No clear association between oral exposure to asbestos and increased cancer incidence has been demonstrated (RIVM, 2018). Skin contact with asbestos fibres does not lead to any health issues (BuRO, 2018b; RIVM, 2018).

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[53] https://www.longfonds.nl/astma/prikkels/geuren.

[54] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59-209..

[55] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (Text with EEA relevance). OJ L 170, 30.6.2009, p. 1–37.

Limit values for a Negligible Risk (NR) and a Maximum Acceptable Risk (MAR) are used for asbestos. The Health Council of the Netherlands has made certain recommendations for these limit values (Table 19) (Gezondheidsraad, 2010). The limit value for NR indicates that, with exposure to an asbestos concentration of 3 fibres per m^3 during one's lifetime, the probability of death due to mesothelioma is 1 in 10^6; the MAR level is higher than this by a factor of 100 (BuRO, 2018b; RIVM, 2018).

Cosmetic products must comply with the Cosmetic Products Regulation[56]. In Annex II, asbestos is listed under No 762. The substances listed in Annex II are prohibited substances.

Table 19 MAR and NR values recommended by the Health Council of the Netherlands and the previous (then current) values for asbestos, by type of asbestos (Gezondheidsraad, 2010).

	Proposed new MAR and NR values			**Current legal limit values**	
	Chrysotile in fibres per m^3	Mixed exposure to chrysotile and up to 20% amphibole in fibres per m3	100% amphibole in fibres per m3	Chrysotile in fibres per m^3	Amphibole in fibres per m3
MAR	2800	1300	300	100000	10000
NR	28	13	3	1000	100

5.3.3. Azo compounds and primary aromatic amines

Azo dyes belong to a group of organic dyes with a wide spectrum of colours that are used for colouring different materials (e.g. textiles, leather, paper and plastics). Azo dyes have one or more azo groups (-N=N- group). Under some conditions, reductive cleavage of an azo group can occur. This results in the release of primary aromatic amines that are used in the synthesis of the dye (Zeilmaker et al., 2000).

Free amines may be present in azo dyes. In the determination of aromatic amines in azo dyes, dithionite is added to release all the amines. The concentration of amines determined in this way is the maximum amount that can be released from an azo dye (FO, 2014).

Annex XVII of the REACH Regulation[57] contains a restriction for azo dyes (Entry 43). Textiles and leather, which come in prolonged contact with the skin or oral cavity, must not contain azo dyes that can release aromatic amines at concentrations of 30 mg/kg or higher (see Table 20).

Requirements for chemical substances in toys are laid down in EN 71-9. For toys and toy parts made of wood, paper, textiles or leather intended for children under the age of three or intended to be placed in the mouth or liable to come into intensive contact with the skin and for liquid, coloured toys, requirements have been set out regarding the presence of primary aromatic amines. Action limits have been set for nine primary aromatic amines. An action limit applies for substances that are not allowed to be present in toys because of their toxicological properties. Therefore, the limit of quantification of the method in EN 71-11 is the limit value (see Table 20).

A special standard has been published for finger paints: EN 71-7. This states that azo dyes must not be used in finger paints which, by reduction of one or more azo groups, could release certain specified aromatic amines. Such aromatic amines must not be detectable in finger paints (see Table 20). For a number of carcinogenic primary aromatic amines, it is stated that they must not be present at concentrations above 10 mg/kg, with a group limit of 20 mg/kg.

[56] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59-209..

[57] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. OJ L 396, 30.12.2006, p. 1-520

In the Netherlands, the chemical safety of tattooing colourants is regulated in the Commodities Act Decree on Tattooing Colourants [58]. With respect to aromatic amines, tattooing colourants must not contain any substances that could form the aromatic amines included on the list.

Table 20 Restrictions for aromatic amines

Substance	Textile and leather	Toys	Finger paints	Tattooing colourants
Biphenyl-4-ylamine	30 mg/kg[1]		N.D.[1]	Absent
Benzidine	30 mg/kg[1]	5 mg/kg	N.D.[1]	Absent
4-Chloro-o-toluidine	30 mg/kg[1]		N.D.[1]	Absent
2-Naphthylamine	30 mg/kg[1]	5 mg/kg	N.D.[1]	Absent
o-Aminoazotoluene	30 mg/kg[1]		10 mg/kg[2]	Absent
5-Nitro-o-toluidine	30 mg/kg[1]		10 mg/kg[2]	Absent
4-Chloroaniline	30 mg/kg[1]	5 mg/kg	10 mg/kg[2]	Absent
4-methoxy-m-phenylenediamine	30 mg/kg[1]		10 mg/kg[2]	Absent
4,4'-Methylenedianiline	30 mg/kg[1]		10 mg/kg[2]	Absent
3,3'-Dichlorobenzidine	30 mg/kg[1]	5 mg/kg	10 mg/kg[2]	Absent
3,3'-Dimethoxybenzidine	30 mg/kg[1]	5 mg/kg	10 mg/kg[2]	Absent
3,3'-Dimethylbenzidine	30 mg/kg[1]	5 mg/kg	10 mg/kg[2]	Absent
4,4'-Methylenedi-o-toluidine	30 mg/kg[1]		10 mg/kg[2]	Absent
6-Methoxy-m-toluidine p-cresidine	30 mg/kg[1]		10 mg/kg[2]	Absent
4,4'-Methylene-bis-(2-Chloroaniline)	30 mg/kg[1]		10 mg/kg[2]	Absent
4,4'-Oxydianiline	30 mg/kg[1]		10 mg/kg[2]	Absent
4,4'-Thiodianiline	30 mg/kg[1]		10 mg/kg[2]	Absent
o-Toluidine	30 mg/kg[1]	5 mg/kg	10 mg/kg[2]	Absent
4-Methyl-m-phenylenediamine	30 mg/kg[1]		10 mg/kg[2]	Absent
2,4,5-Trimethylaniline	30 mg/kg[1]		10 mg/kg[2]	Absent
o-Anisidine	30 mg/kg[1]	5 mg/kg	10 mg/kg[2]	Absent
4-Aminoazobenzene	30 mg/kg[1]		10 mg/kg[2]	Absent
A mixture of: disodium (6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)(1-(5-chloro-2-oxidophenylazo)-2-naphtholato)chromate(1-); trisodium bis(6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)chromate(1-)	30 mg/kg[1]			
Aniline		5 mg/kg	10 mg/kg[2]	
2,4-Xylidine			10 mg/kg[2]	

[58] Decree of 14 August 2003 on establishing rules concerning the safety of tattooing Commodities Act Decree on Tattooing Colourants. Bulletin of Acts and Decrees 2003, 342.

Substance	Textile and leather	Toys	Finger paints	Tattooing colourants
2,6-Xylidine			10 mg/kg[2]	
4-Amino-3-fluorophenol,			10 mg/kg[2]	
6-Amino-2-ethoxynaphthalene			10 mg/kg[2]	

1. Not detectable. Each primary aromatic amine is detectable from 5 mg/kg onwards. The presence of an azo dye is demonstrated if, after reduction, the concentration of primary aromatic amines is >30 mg/kg.
2. The sum of primary aromatic amines must not exceed 20 mg/kg.

In case of plastic food contact materials[59] primary aromatic amines must not migrate in a detectable quantity. The detection limit is 0.01 mg substance per kg food or food simulant. This limit value applies to the sum of released primary aromatic amines. According to the Commodities Act Regulation on Food Contact Materials [60], Appendix A, Chapter 0, Article 0.5.1(e), the following is stated in general terms for all food contact materials: materials or articles manufactured using aromatic isocyanates or colourants prepared by diazo coupling must not release primary aromatic amines in a detectable quantity into food or food simulant. The detection limit is 0.01 mg substance per kg food or food simulant.

The aromatic amines benzidine, 2-naphthylamine, o-toluidine and 4-aminobiphenyl are known to cause bladder cancer in humans. In laboratory animals, these and other aromatic amines cause a variety of tumours (including those of the bladder, ceruminous glands, haematopoietic system and liver) (FO, 2014).

A quantitative dose-response assessment based on human data is only available for benzidine. The outcome suggests that humans are much more sensitive to the action of benzidine than laboratory animals (Zeilmaker et al., 1999; Zeilmaker et al., 2000; FO, 2014). The RIVM has calculated a negligible risk level (NRL) of 0.3 ng benzidine per person per day (Zeilmaker et al., 1999; Zeilmaker et al., 2000). An NRL represents the level of exposure that causes one additional case of cancer per million persons over a lifetime. NRLs have also been derived for other aromatic amines. For this purpose, the potency of an aromatic amine relative to benzidine was scaled based on laboratory animal data. Some amines (2,4-toluenediamine and 4,4'-diaminodiphenylmethane) are as potent as benzidine. Hence, the NRL is the same as that of benzidine. Other amines (o-anisidine, 3,3'-dichlorobenzidine and o-toluidine) are less potent and in those cases the NRL is higher (3 ng/day) (Zeilmaker et al., 1999; Zeilmaker et al., 2000).

5.3.4. Boron compounds

Boron (B) is an essential element in various biological processes and is necessary for the growth of plants, animals and humans. Human exposure occurs via the environment, food and drinking water. In consumer products such as cosmetics, boron can be found in various chemical compositions. The most common boron compounds are boric acid and boron salts such as borax, sodium perborate and sodium tetraborate. These are used as an antimicrobial preservative, hydrogen peroxide releaser and pH buffer in contact lens solutions (FO, 2018).

Since boron salts can occur in hydrated and non-hydrated forms and different synonyms are used, while interpreting the literature there may be confusion regarding the identity of the boron compound being discussed. A complete list of boric acid and boron salts is provided in Appendix A of the 2016 Health Canada report (Health Canada, 2016; FO, 2018).

Inorganic boron compounds are converted into boric acid in the aqueous parts of mucous membranes. With the help of the read-across approach, toxicity studies of boric acid are therefore relevant and useful for classification of inorganic borates (FO, 2018). Several development and reproduction studies in animals exposed to boric acid - and therefore to boron - showed that boron may have adverse effects on fertility, reproduction, and development. For example, exposure to

[59] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L12, 15.1.2011, p. 1-89. 1-89

[60] Regulation of 14 March 2014 establishing the Packaging and Consumer Articles (Commodities Act) Regulation for packaging and consumer articles that come in contact with food.

boron can result in decreased sperm production, a smaller foetus and prenatal mortality. In addition, boron can lead to adverse effects on the central nervous system, cardiovascular system and immune system, apoptosis in the gastrointestinal system and eye irritation (FO, 2018).

Certain elements in toys are regulated in Annex II, Chapter II, Point 13 of the Toy Safety Directive[61]. For each material category, limits have been set for the migration of boron (see Table 21). This is based on an estimated daily intake per material category. In addition, 10% of the Tolerable Daily Intake (TDI) has been taken into account because of the potential exposure to boron via other sources (food, environment). A child's body weight of 7.5 kg has been assumed. Migration is measured in accordance with the designated standard EN 71-3.

Table 21 Migration limit for various toy materials (mg/kg toy)

Element	Dry, brittle, powder-like or pliable	Liquid or sticky	Scraped off
Boron	1200	300	15,000

Annex II of the Cosmetic Products Regulation[62] lists the following boron compounds: N,N-dimethylanilinium tetrakis(pentafluorophenyl)borate (1184); boric acid (1395); borates, tetraborates and octaborates (1396); sodium perborate (1397), perboric acid, monosodium salt trihydrate (1398); perboric acid, sodium salt (1399); dibutyltin hydrogen borate (1400); nickel bis(tetrafluorborate) (1401). Annex II of the Cosmetic Products Regulation concerns prohibited substances that, therefore, may not be used in cosmetic products.

The CLP Regulation[63] lists a number of boron compounds: boric acid, borax, sodium tetraborate, sodium octaborate and hydrated sodium octaborate. These borates are listed in Annex VI of the CLP Regulation with a harmonised classification as Reproductive Toxicant Category 1B (Repr. 1B, H360 FD). This classification applies from a specific concentration of ≥4.5% (sodium tetraborate), ≥5.5% (boric acid) and ≥8.5% (borax). This corresponds to 1% boron.

5.3.5. Dioxins and polychlorinated biphenyls (PCBs)

Dioxins, furans[64] and polychlorinated biphenyls (PCBs) are classified as Persistent Organic Pollutants (POPs). POPs are substances that are persistent in the environment, degrade slowly and can accumulate in the body[65]. Dioxins and PCBs are widely present in the environment, mainly as residues arising from past use. In the meantime, emission levels of these substances have been reduced by imposing legal requirements on the emission of dioxins from waste incineration plants and a prohibition on the use of PCBs.

In the case of PCBs, a distinction is made between 12 dioxin-like PCBs and non-dioxin-like PCBs. Dioxins and PCBs lead to acute as well as chronic toxic effects. The most significant effects are on the liver or liver functions, reproduction and development (EFSA CONTAM Panel, 2018b). Exposure

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[61] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (Text with EEA relevance). OJ L 170, 30.6.2009, p. 1–37.

[62] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 4.12.2018, p. 59–209.

[63] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1-1355

[64] Polychlorinated dibenzofurans are chemical waste products mainly produced during industrial incineration processes. Furans are substances that have broadly the same properties as dioxins.

[65] Persistent Organic Pollutants (POPs) are chemical substances that possess a particular combination of physical and chemical properties such that, once released into the environment, they:
remain intact for exceptionally long periods of time (many years);
become widely distributed throughout the environment as a result of natural processes involving soil, water and, most notably, air;
accumulate in the fatty tissue of living organisms including humans, and are found at higher concentrations at higher levels in the food chain; and
are toxic to both humans and wildlife.
Source: Stockholm Convention, What are POPs? http://chm.pops.int/TheConvention/ThePOPs/tabid/673/Default.aspx

to dioxins can cause cancer in humans. The non-dioxin-like PCBs do not have the specific toxicological effects of dioxins and are less hazardous. To calculate the total concentration of dioxins and dioxin-like PCBs, the quantities of the individual substances are converted into dioxin equivalents by using Toxic Equivalency Factors (TEF). The TDI is based on the total Toxic Equivalents (TEQ) expressed as pg TEQ/kg body weight per day. EFSA has derived a TDI of 0.25 pg TEQ/kg body weight per day. This corresponds to a Tolerable Weekly Intake (TWI) of 2 pg TEQ/kg body weight per day (EFSA CONTAM Panel, 2018b).

5.3.6. Phenols

Phenols are aromatic compounds in which one or more hydrogen atoms on the benzene ring have been replaced by OH groups. Important phenols are bisphenols and alkylphenols.

Bisphenols

Bisphenols refers to a group of aromatic compounds of two phenols. Well-known bisphenols are bisphenol A (BPA), bisphenol F (BPF) and bisphenol S (BPS). These bisphenols are widely used as starting materials for the production of plastics, including polycarbonate and polyethersulfone. After the polymerisation reaction, residues of starting substances may be present in the final product. They are also used as starting materials for coatings based on epoxy resins. In addition, they are used in thermal paper and in recycled paper and paperboard.

EFSA has assessed the health risks of BPA (EFSA CEF Panel, 2015). A temporary TDI (tTDI) of 4 µg/kg body weight/day has been established. Currently, this TDI is being re-evaluated. EFSA has not identified any TDI for BPS and BPF.

Food contact materials

Restrictions on food contact materials are included in the Commodities Act Regulation on Food Contact Materials [66]. Plastic food contact materials are legislated at the European level (Regulation (EC) No 10/2011[67]).

For BPA, a new restriction came into force in 2018 (Regulation (EU) No 2018/213[68]): a Specific Migration Limit (SML) of 0.05 mg/kg food. This new SML is based on an EFSA advisory report on BPA (EFSA CEF Panel, 2015). Due to the potential endocrine disrupting properties of BPA, Regulation (EU) No 321/2011[69] came into force in 2011 banning the use of polycarbonate baby bottles. For BPS, an SML of 0.05 mg/kg food applies for plastic materials. BPF is not included on the positive list and is therefore not allowed in plastic food contact materials.

Children's articles

Soother mouth shields may be made of polycarbonate or polyethersulfone. The chemical safety aspect is regulated by the designated standard EN 1400. For these materials, a migration limit of BPA of 0.01 mg/l applies. There is also a standard applicable to soother holders: EN 12586. This is a few years older and sets a migration limit for BPA of 0.1 mg/l for plastic parts.

Toys

In 2017, an amendment was made to the Toy Safety Directive (Directive (EU) No 2017/898[70]). This Directive sets a migration limit of 0.04 mg/l for BPA (see Table 22).

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66 Regulation of 14 March 2014 establishing the Packaging and Consumer Articles (Commodities Act) Regulation for packaging and consumer articles that come in contact with food.

67 Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L12, 15.1.2011, p. 1-89. 1-89

68 Commission Regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials. OJ L 41, 14.2.2018, p. 6–12.

69 Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011 amending Regulation (EU) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles. OJ L87, 02.04.2011, p. 1-89. 1-2

70 Commission Directive (EU) 2017/898 of 24 May 2017 amending, for the purpose of adopting specific limit values for chemicals used in toys, Appendix C to Annex II to Directive 2009/48/EC of the European

Table 22 Overview of migration limits for bisphenol A, F and S in various plastic consumer products

Category	Bisphenol A	Bisphenol F	Bisphenol S
Food contact materials	0.05 (mg/kg)	Not authorised	0.05 (mg/kg)
Soother mouth shield	0.01 (mg/l)	Not regulated	Not regulated
Soother holder	0.1 (mg/l)	Not regulated	Not regulated
Toys	0.04 (mg/l)	Not regulated	Not regulated

Cosmetic products

In the Cosmetic Products Regulation[71], BPA is listed in Annex II under No 1176; this means that the substance is prohibited in cosmetic products. BPA may only be present as a technically unavoidable contaminant. A maximum concentration of 50 ppb is considered acceptable. BPF and BPS are not mentioned in the Cosmetic Products Regulation. In general, a cosmetic product must be safe when it is used as intended.

Nonylphenol

Nonylphenol is part of the group of alkylphenols. Nonylphenols are primarily used as raw material for the production of nonylphenol polyethoxylates (NPEO). NPEOs are used in detergents, emulsifiers, antistats and solvents in consumer, agricultural and industrial products (Lu & Gan, 2014).

Nonylphenol is an endocrine disruptor (Danish EPA, 2000; Lu & Gan, 2014; Acir & Guenther, 2018; Li et al., 2019). It consists of several isomers, each of which has a different estrogenic potency. Therefore, it is important to identify the isomers to which humans are exposed and not to limit a chemical assessment to a quantification of total nonylphenol. Nonylphenol may also have effects on the nervous system and cognition (Acir & Guenther, 2018).

The Danish Environmental Protection Agency (EPA) has derived TDIs of 0.005 mg/kg body weight per day for nonylphenol and 0.013 mg/kg body weight per day for nonylphenol ethoxylate (Danish EPA, 2000). Li and colleagues derived a preliminary TDI of 0.025 mg/kg body weight per day for nonylphenol (Li et al., 2019).

According to Annex XVII of the REACH Regulation[72], Entry 46, nonylphenol (and nonylphenol ethoxylates) are subject to the following restriction for consumer products: these substances must not be present in concentrations exceeding 0.1% in cleaning agents, cosmetic products or other personal care products.

Annex II to the Cosmetic Products Regulation[71] lists nonylphenol and 4-nonylphenol (branched) under No 1168. This means that these substances are prohibited in cosmetic products.

5.3.7. Formaldehyde

Aldehyde (also called alkanal) is an organic chemical compound with a carbonyl group to which a hydrogen atom is bonded. The simplest aldehyde is formaldehyde, which is used as a disinfectant and preservative. It is also used as a starting material for certain resins (melamine resins). Formaldehyde is irritating to the nose and pharynx. In addition, formaldehyde causes allergic dermatitis and occupational asthma after contact. The IARC classifies formaldehyde as a human carcinogen (IARC, 2009).

Parliament and of the Council on the safety of toys, as regards bisphenol A. OJ L 138, 25.5.2017, p. 128–130.

[71] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 4.12.2018, p. 59–209.

[72] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. OJ L 396, 30.12.2006, p. 1-520

Dermal exposure

Annex V of the Cosmetic Products Regulation[73] contains a list of the permitted preservatives with accompanying restrictions. Formaldehyde and paraformaldehyde are not authorised for use as preservatives. Certain preservatives are also permitted, which fall into the category of formaldehyde donor. For all finished products containing preservatives that release formaldehyde, from a concentration of 0.05% onwards, the label must state 'Contains formaldehyde'. Formaldehyde used in nail hardening products must not be present in concentrations above 5%. The presence of formaldehyde must be declared on the label.

Annex C of the Toy Safety Directive[74] sets out specific chemical requirements for toys intended for children under 36 months or in other toys intended to be placed in the mouth. Requirements for formaldehyde are included for several toy matrices:

- 30 mg/kg (concentration limit) in textile toy material
- 30 mg/kg (concentration limit) in leather toys
- 30 mg/kg (concentration limit) in paper toys
- 10 mg/kg (concentration limit) in water-based toy material

There is a special standard for finger paints: EN 71-7. Annex B of this standard contains a list of preservatives and the restrictions applicable to them. Only the preservatives included in this list may be used. Formaldehyde or paraformaldehyde is not on this list, but some formaldehyde donors are included.

Table 23 displays an overview of the permitted formaldehyde donors for cosmetic products and finger paints and their accompanying restrictions.

Table 23 Restrictions on formaldehyde and formaldehyde donors in cosmetic products and finger paints

Substance	Cosmetic products	Finger paints
Formaldehyde	Not authorised	Not authorised
Paraformaldehyde	Not authorised	Not authorised
2-bromo-2-nitropropane-1,3-diol	0.1%	0.1%
5-bromo-5-nitro-1,3-dioxane	0.1%[1]	Not authorised
Benzylhemiformal	0.15%[1]	Not authorised
Diazolidinyl urea	0.5%	0.5%
DMDM hydantoin	0.6%	0.6%
Imidazolidinyl urea	0.6%	0.6%
Quaternium-15	Not authorised	0.2%
Sodium hydroxymethylglycinate	0.5%	0.5%

1. Only authorised in rinse-off products

For both cosmetic products and finger paints, the used preservatives must be declared on the label. However, for finger paints, formaldehyde is not declared on the label if a formaldehyde donor is used as a preservative, even though formaldehyde can be formed in the product.

The extent of the relationship between formaldehyde donors in cosmetic products and contact allergy to formaldehyde was studied via patch tests (De Groot et al., 2009; De Groot et al., 2010). It was found that these formaldehyde donors can generate sufficient free formaldehyde (>200 ppm) to cause contact dermatitis. Patients with an allergy to formaldehyde are therefore advised to avoid products containing these formaldehyde donors. According to Salverda et al. (2013),

[73] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59–209.

[74] Commission Directive (EU) 2019/1929 of 19 November 2019 amending Appendix C to Annex II to Directive 2009/48/EC. OJ L 298, 19.11.2019, p. 51–-54.

quaternium-15 and formaldehyde rank 11 and 12 among allergens that people have tested positive for. In Denmark, a 10-year study on the incidence of contact allergy to formaldehyde was performed using patch tests (Fasth et al., 2018). The prevalence of contact allergy to 1% formaldehyde was 1.5% and varied between 0.97% and 2.3%, with a decreasing trend over this 10-year period. Contact allergy to 2% formaldehyde was found in 2.4% of the population and no significant trend was observed. A positive reaction to quaternium-15 was observed most frequently among all formaldehyde donors. Cosmetic products were the most common source.

Formaldehyde may be added to textiles to make them wrinkle-resistant. According to the Commodities Act Decree on Formaldehyde in textiles [75], a product must carry the warning 'Wash before first use' if it contains more than 120 mg/kg formaldehyde. After the first wash, the level of formaldehyde in the product must not exceed 120 mg/kg.

Chemical substances and mixtures must comply with the CLP Regulation[76] on classification, labelling and packaging. Formaldehyde is classified as a skin allergen. From 0.2% formaldehyde or more, a mixture must be classified as a skin allergen, and a special warning sentence must be placed on the label. From 5% onwards, a mixture is irritating to the skin and eyes and can cause irritation of the respiratory tract. From 25% onwards, a mixture is classified as corrosive to the skin.

Currently, an application to classify formaldehyde as a biocidal product (PT02, PT03 and PT22) is pending. Formaldehyde and paraformaldehyde are not authorised as plant protection products.

Oral exposure

Formaldehyde may also be used as a raw material for food contact materials. A well-known example is melamine consumer products (formaldehyde-melamine resin). Plastic food contact materials must comply with Regulation (EU) No 10/2011[77]. For formaldehyde, an SML of 15 mg/kg food applies. An EFSA advisory report from 2006 uses a TDI of 150 µg/kg body weight. This is derived from the NOAEL of 260 mg/l published by WHO (WHO, 2005).

Toys may also contain formaldehyde and children may be exposed to this if they suck on their toys. According to the Toy Safety Directive[74], a migration limit of 1.5 mg/l is applicable for polymeric toy material.

Inhalation exposure

Some adhesives are formaldehyde based. For example, when applying adhesives to the floor, there may be exposure to formaldehyde through inhalation. Chipboard may also be bonded with a formaldehyde resin. According to the Commodities Act Decree on Chipboard [78], chipboard may not contain more than 10 mg of formaldehyde per 100 g of board material, with the exception of chipboard used in furniture.

Chipboard is also sometimes used in toys. According to the Toy Safety Directive[79], an emission limit of 0.1 ml/m^3 applies to toys made of resin bound wood.

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[75] Decree of 22 March 2001 establishing the Formaldehyde in Textiles (Commodities Act) Decree. Bulletin of Acts and Decrees 2001, 178.

[76] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1-1355

[77] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. Text with EEA relevance. OJ L 12, 15.1.2011, p. 1-89

[78] Decree of 17 April 2012 amending various decrees pursuant to the Commodities Act and a number of other decrees in connection with the introduction of some corrections and some other amendments. Bulletin of Acts and Decrees 2012, 193.

[79] Commission Directive (EU) 2019/1929 of 19 November 2019 amending Appendix C to Annex II to Directive 2009/48/EC. OJ L 298, 19.11.2019, p. 51–-54.

5.3.8. Chlorinated paraffins

Chlorinated paraffins are complex technical mixtures of polychlorinated alkanes that vary in terms of chain length and the degree of chlorination. Commercially available chlorinated paraffins can be divided into three groups: short-chain chlorinated paraffins (SCCP), medium-chain chlorinated paraffins (MCCP) and long-chain chlorinated paraffins (LCCP). SCCPs consist of 10-14 carbon atoms, MCCPs consist of 14-18 carbon atoms and LCCPs consist of 18 or more carbon atoms. Some technical mixtures of chlorinated paraffins contain a combination of compounds from the groups. Some new mixtures of chlorinated paraffins do not belong to any of the groups (SCHER, 2008; EFSA CONTAM Panel, 2019).

The acute oral toxicity of chlorinated paraffins is low (SCHER, 2008; EFSA CONTAM Panel, 2019). In its draft advisory report, EFSA identifies the liver, kidney and thyroid as the target organs for repeated exposure of laboratory animals to SCCP and MCCP mixtures. The liver is the target organ in laboratory animal exposure to LCCP mixtures (EFSA CONTAM Panel, 2019).

EFSA has derived a $BMDL_{10}$ of 2.3 mg/kg body weight per day for oral exposure to SCCP (C10-14, 58% chlorination) and a $BMDL_{10}$ of 36 mg/kg body weight per day for oral exposure to MCCP (C14-18, 52% chlorination). No reference point was derived for LCCP because the observed liver effects are considered secondary to exposure (EFSA CONTAM Panel, 2019).

SCCP (C_{10}-C_{13}) are classified as persistent. Therefore, products cannot be placed on the market if the concentration exceeds 1% (POP Regulation[80]).

5.3.9. Isothiazolinones

Isothiazolinones are substances used as preservatives against fungal and bacterial growth. Isothiazolinones are used in personal care products, detergents and cleaning products and water-based paints. The main substances are methylisothiazolinone (MI), chloromethylisothiazolinone (CMI), benzisothiazolinone (BIT) and octylisothiazolinone (OIT).

The SCCS concludes that the use of BIT in cosmetic products is not safe because of the skin-sensitising properties of BIT (SCCS, 2012c). In addition, the SCCS concludes that the use of MI in leave-on cosmetic products is not safe due to the induction of contact allergy. The use of MI in rinse-off cosmetic products is safe up to a concentration of 0.0015% (SCCS, 2015).

Annex V of the Cosmetic Products Regulation (Regulation (EC) No 2009/1223) lists all the authorised preservatives for cosmetic products and their restrictions (see Table 24). In 2014, the use of a mixture of CMI/MI in leave-on cosmetic products was prohibited in Europe[81] and its use in rinse-off cosmetic products was limited to a maximum of 0.0015% (Chowdhury, 2016). Since 2017, the same applies to MI, it is only authorised for use in rinse-off products[82].

For aqueous toy materials intended for children under the age of three or those intended to be put in the mouth by children, limit values have been laid down for isothiazolinones pursuant to Directive (EU) 2015/2116[83] and Directive (EU) 2015/2117[84], since these substances have been identified by SCCS as allergenic substances (SCCS, 2012c;2015). It has been decided that these

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[80] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (Text with EEA relevance). PE/61/2019/REV/1. OJ L 169, 25.6.2019, p. 45–77.

[81] Commission Regulation (EU) No 1003/2014 of 18 September 2014 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products. Text with EEA relevance. *OJ L 282, 26.9.2014, p. 1-4.*

[82] Commission Regulation (EU) No 2016/1198 of 22 July 2016 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products. OJ L 198, 23.7.2016, p. 10–12.

[83] Commission Directive (EU) 2015/2116 of 23 November 2015 amending, with a view to establishing specific limit values for chemicals used in toys, Appendix C to Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys as regards benzisothiazolinone (Text with EEA relevance) OJ L 306, 24.11.2015, p. 20-22.

[84] Commission Directive (EU) 2015/2117 of 23 November 2015 amending, for the purpose of adopting specific limit values for chemicals used in toys, Appendix C to Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards chloromethylisothiazolinone and methylisothiazolinone, both individually and in a ratio of 3:1 (Text with EEA relevance) *OJ L 306, 24.11.2015, p. 23--25.*

substances are not authorised for use in toys containing aqueous media, where the limit of quantification is retained as the limit value (see Table 24).

A special standard has been published for finger paints (EN 71-7). It is referenced under the Toy Safety Directive[85]. Annex B of this standard contains a list of the permitted preservatives with the accompanying restrictions. MI, CMI and BIT are not included on this list.

Table 24 Restrictions on isothiazolinones in cosmetic products and aqueous toy materials

Substance	Cosmetic products	Toys containing aqueous media[1]
Reaction mass of: 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazolin-3-one (3:1)	0.0015%[2]	1 (mg/kg)
5-Chloro-2-methylisothiazol-3(2H)-one	Not authorised	0.75 (mg/kg)
2-Methylisothiazol-3(2H)-one	0.0015%[2]	0.25 (mg/kg)
1,2-Benzisothiazol-3(2H)-one	Not authorised	5 (mg/kg)

1. With the exception of finger paints, for which these substances are not authorised
2. Only authorised in rinse-off products

Chemical mixtures, including paints, cleaning agents and adhesives, are subject to the CLP Regulation[86]. Detergents are also subject to the Detergents Regulation[87]. Table 25 indicates when a mixture containing isothiazolinones is classified under a particular hazard category:

H314: Causes severe burns and eye damage
H315: Causes skin irritation
H317: May cause an allergic skin reaction
H318: Causes serious eye damage
H319: Causes serious eye irritation

Table 25 CLP classification of chemical mixtures containing isothiazolinone

Substance	CLP classification
Reaction mass of: 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazolin-3-one (3:1)	Corrosive to eyes 1; H318: C≥0.6% Irritating to eyes 2; H319: 0.06%≤C<0.6% Corrosive to skin 1C: C≥0.6% Irritating to skin 2; H315: 0.06%≤C<0.6% Skin allergen 1A: C≥0.0015%
5-Chloro-2-methylisothiazol-3(2H)-one	Not classified
2-Methylisothiazol-3(2H)-one	Corrosive to eyes 1; H318: C≥5% Irritating to eyes 2; H319: 1%≤C<5% Corrosive to skin 1B; 314: C≥3% Irritating to skin 2; H315: 1%≤C<3% Skin allergen 1A; H317: C≥0.1%
1,2-Benzisothiazol-3(2H)-one	Corrosive to eyes 1; H318: C≥5% Irritating to eyes 2; H319: 1%≤C<5% Irritating to skin 2; H315: C≥10% Skin allergen 1; H317: C≥0.05%

85 Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (Text with EEA relevance) *OJ L 170, 30.6.2009, p. 1-37.*

86 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1-1355

87 Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (Text with EEA relevance) *OJ L 104, 8.4.2004, p. 1–35.*

Under some laws, it is mandatory to inform consumers about the presence of certain allergenic substances. For cosmetic products, finger paints and detergents, it is mandatory to declare the used preservatives on the label. For chemical mixtures, this depends on the concentration, i.e. if the mixture needs to be classified as a skin allergen. This is indicated per isothiazolinone in Table 25.

Isothiazolinones are also active substances for biocidal products or plant protection products. Table 26 indicates the extent to which they are authorised for use as active substances. Isothiazolinones are authorised as biocidal products for various product types. The necessary application has been submitted for CMI and BIT. Isothiazolinones are not authorised as a plant protection product.

Table 26 Authorisation of isothiazolinone as active substance

Substance	Biocidal products[1]	Plant protection product[2]
Reaction mass of: 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazolin-3-one (3:1)	PT02, PT04, PT06, PT11, PT12, PT13	Not authorised
5-Chloro-2-methylisothiazol-3(2H)-one	PT06[3]	Not authorised
2-Methylisothiazol-3(2H)-one	PT06[3], PT11, PT12, PT13	Not authorised
1,2-Benzisothiazol-3(2H)-one	PT02[3], PT06[3], PT09[3], PT10[3], PT11[3], PT12[3], PT13[3]	Not authorised

1. https://echa.europa.eu/nl/information-on-chemicals/biocidal-active-substances
2. https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN
3. The application for approval is currently pending.

Isothiazolinones may cause an allergic reaction on skin contact. Based on the local lymph node assay (LLNA), exposure to CMI leads to the highest risk of sensitisation, followed by MI, OIT and BIT. Due to the above limitations, the cosmetic and non-cosmetic industries have introduced derivatives such as dichloro-octylisothiazolinone (DCOIT), butyl-benzisothiazolinone (BBIT) and methyl-benzoisothiazolinone (MBIT) (Herman et al., 2019). Cases of allergic contact dermatitis have also been described for the new derivatives.

5.3.10. Laughing gas

Laughing gas (N_2O) is a colourless, non-irritating, sweet-smelling and sweet-tasting gas. From the end of the 18th century, it was used in medicine to anaesthetise patients for a short period of time. However, laughing gas is no longer used as commonly during operations since other means are available. During childbirth, laughing gas (a mixture of 50% laughing gas and 50% oxygen) is used by women as a self-administered painkiller. Laughing gas is also used as a propellant in the food industry (e.g. in whipped cream syringes) and as an intoxicant (Trimbos instituut, 2018).

Laughing gas displaces oxygen from the lungs which leads to oxygen deprivation in the body. The resulting symptoms include headache, dizziness, confusion, disorientation, agitation, decreased awareness, tightness in the chest, heart spasms, paresthesia (tingling), decreased motor skills, loss of balance, sweating, pale skin, blurred vision, pain in the mouth or throat, nausea, vomiting and diarrhoea (NVIC, 2019a).

Since laughing gas diffuses into the air-containing cavities faster than nitrogen diffuses out, there may be an increase in the pressure inside or the volume of the cavity. This effect depends on the extent of exposure to laughing gas and blood flow to the cavity and can lead to damage and possibly death (Brodsky & Cohen, 1986). Cardiovascular effects may occur if patients with heart disease are exposed to laughing gas. But even in healthy volunteers, one hour of exposure to 60% laughing gas with 40% oxygen leads to an increase in heart rate, stroke volume, cardiac output and blood pressure (Brodsky & Cohen, 1986).

Laughing gas causes the oxidation of vitamin B12, which then can no longer function as a coenzyme in the enzyme methionine synthase (Flippo & Holder, 1993; Maze & Fujinaga, 2000).

Vitamin B12 is necessary for the production of myelin. Myelin is a part of the nervous system and contributes to an efficient transmission of nerve impulses (West et al., 1990). Treatment with or the long-term use of laughing gas can lead to vitamin B12 deficiency (Trimbos instituut, 2018). Reduced vitamin B12 concentrations in the blood can cause nerves to malfunction (neuropathy). Treatment with vitamin B12 often helps in relieving symptoms (Vishnubhakat & Beresford, 1991).

Since July 2016, the trade in laughing gas for recreational use no longer falls under the Medicines Act (*Geneesmiddelenwet*)[88] but under the Commodities Act[89]. Examples of the recreational use of laughing gas are balloons containing laughing gas or laughing gas canisters. No specific product safety rules have been laid down for this. The Commodities Act states that a product must not present any special health or safety hazards in view of its intended use.

5.3.11. Metals and metal compounds

Aluminium

Aluminium is an element that occurs in high concentrations in the soil. Hence, aluminium is a natural component of food and drinking water. Aluminium is also used as a food additive. Aluminium can migrate from utensils, kitchen equipment and packaging to food (EFSA AFC Panel, 2008b). Aluminium is also present in many consumer products, such as cosmetic products. Aluminium is also used in medicines and dental implants (EFSA AFC Panel, 2008b).

Aluminium compounds have a low acute toxicity (Tietz et al., 2019). EFSA has concluded that genotoxicity is not relevant for oral human exposure (EFSA AFC Panel, 2008b). Aluminium has been linked to degenerative diseases (such as Alzheimer's disease) and to breast, lung and gallbladder cancer. However, there is no scientific consensus on this (FO, 2013; Tietz et al., 2019).

Aluminium particles may irritate the skin. No irreversible toxic effects after dermal exposure have been described in the literature (Tietz et al., 2019). Dermal absorption is assumed to be minimal, since aluminium salts dissolve in water and precipitate in sweat glands. Only a limited number of studies have been conducted on the dermal absorption of aluminium. However, these demonstrate that the absorption of aluminium via the skin does occur (FO, 2013). The BfR describes one study in humans that reports a penetration rate of 0.0014% (BfR, 2014b).

For oral exposure to aluminium, EFSA has derived a TWI of 1 mg/kg body weight per week (EFSA AFC Panel, 2008b).

Cadmium

Cadmium occurs naturally in the environment. Humans are exposed to cadmium via various routes. For non-smokers, food is the main source. Long-term exposure to cadmium may cause kidney damage (EFSA, 2012).

For oral exposure to cadmium, EFSA has derived a TWI of 2.5 µg/kg body weight per week (EFSA, 2012).

Chrome

Chromium occurs naturally in soil, rocks, animals and plants. Chromium may exist in different forms of oxidation. The hexavalent (chromium VI) and trivalent (chromium III) forms are the most biologically relevant.

Chromium absorption from food is relatively low and depends on the form of oxidation. In the stomach, chromium VI reduces to chromium III. Chromium VI can pass through cell membranes, while chromium III cannot. Between these two forms, chromium VI is the more toxic form (EFSA CONTAM Panel, 2014). For a risk assessment, it is therefore important to know the form of chromium that a person has been exposed to.

[88] Act of 8 February 2007 establishing a new Medicines Act. Bulletin of Acts and Decrees 2007, 93.
[89] Commodities Act. Bulletin of Acts and Decrees 1935, 793.

The IARC has classified chromium VI as a human carcinogen (Group 1) in relation to lung cancer and cancer of the nose and sinuses. This is based on results of occupational exposure studies (EFSA CONTAM Panel, 2014). Dermal exposure to chromium VI may lead to allergic contact dermatitis (SCHER, 2015).

For oral exposure to chromium, EFSA has derived a TDI of 300 µg/kg body weight per day. For oral exposure to chromium VI, EFSA has derived a $BMDL_{10}$ of 1 mg/kg body weight per day. In relation to this $BMDL_{10}$ value, the margin of exposure must not be less than 10,000, because it involves exposure to a potentially genotoxic and/or carcinogenic substance (EFSA CONTAM Panel, 2014). If the margin of exposure is less than 10,000, there is reason for concern for the health of the consumer.

For children, the Scientific Committee on Health and Environmental Risks (SCHER) has derived a virtual safe dose after oral intake of chromium VI at which an additional cancer risk of 1 in 10^6 is accepted, i.e. 0.0002 µg/kg body weight per day (SCHER, 2015).

Cobalt

Cobalt occurs naturally in the environment and is used as an alloy in steel that needs to be strong and durable. These include products such as tools, vehicle engines, magnets and orthopaedic and other medical items. Cobalt is also used in jewellery, ceramics, cement, plastics and leather (Fowler Jr., 2016).

Inhalation exposure to cobalt may lead to asthma. In addition, dermal exposure to cobalt may lead to contact dermatitis in individuals who are sensitised (Yoshihisa & Shimizu, 2012).

Mercury

Mercury may occur in various forms: in metallic form, as a cation (Hg^{2+}) and in organic form (methylmercury). The most common form of mercury found in food is methylmercury (especially in fish). Methylmercury is the most toxic form, and this can accumulate in predatory fish. Mercury is released into the environment through human activities such as coal combustion, waste incineration and mining (including gold mining), as well as through volcanic eruptions. Consumers may also be exposed to mercury when mercury thermometers break, through jewellery containing mercury or if amalgam fillings are used.

Prolonged exposure to methylmercury can lead to adverse effects on neurodevelopment and on the liver, kidneys, immune system and reproductive system (EFSA CONTAM Panel, 2012a).

It is important to distinguish between levels of total mercury and methylmercury, because the type of compound (and therefore the toxicity) may vary. Often only total concentration of mercury is measured, and this information is not sufficient for a risk assessment (Maulvault et al., 2015).

Lead

Lead occurs naturally in the environment. Lead occurs in organic and inorganic form. The main route of exposure is via food (EFSA CONTAM Panel, 2010).

Lead absorption via oral exposure depends on the characteristics of the host and the physical/chemical properties of the ingested lead. Absorption is lower in the presence of food. Lead accumulates in liver, kidneys and bone tissue. The half-life of inorganic lead in bone lies between 10 and 30 years. The absorption of lead through the skin is much lower than absorption through inhalation or oral ingestion (EFSA CONTAM Panel, 2010).

The developing brain is more sensitive to lead poisoning than the adult brain. In children, elevated blood lead concentrations are associated with reduced IQ scores. EFSA has identified neurotoxicity in children and cardiovascular and renal toxicity as the critical effects. The IARC has classified inorganic lead as a possible human carcinogen (Group 2A) (EFSA CONTAM Panel, 2010).

For oral lead exposure, EFSA has derived a $BMDL_{01}$ of 0.50 µg/kg body weight per day for neurotoxicity, 1.50 µg/kg body weight per for effects on systolic blood pressure and 0.63 µg/kg body weight per for effects on the prevalence of chronic kidney disease (EFSA CONTAM Panel, 2010).

Nickel

Humans are exposed to nickel via various routes. A consumer ingests nickel via drinking water and food, via contact with consumer products such as tools, kitchen articles and toys and via inhalation. Nickel is also present in the air. The main route is oral ingestion.

Occupational exposure by inhalation to high concentrations of nickel has led to an increase in the incidence of lung cancer among workers. Oral exposure does not lead to cancer. Dermal exposure to jewellery that emits nickel causes sensitisation. Piercing the earlobes is considered the main cause of sensitisation. When sensitised persons come into contact with nickel again, this may lead to a severe or less severe form of contact dermatitis (SCHER, 2012).

Organotin compounds

Organotin compounds belong to the group of fungicides. In the past, organotin compounds were widely used as fungicides in paints for ships and as disinfectants in industrial cooling water. Triorganotin compounds are the most important and most toxic within this group. The use of organotin compounds in fungicides is now prohibited. However, these substances are persistent and are still found in surface water.

EFSA has established a TDI of 0.25 µg/kg body weight per day for tributyl, dibutyl, triphenyl and di-n-octyltin. The critical endpoint is immunotoxicity (EFSA CONTAM Panel, 2004).

Legal requirements

Annex II of the Toy Safety Directive[90], Chapter II, Point 13, sets out requirements for the migration of heavy metals from three different material categories (see Table 27). This is based on the average daily intake: 8 mg for scratched off; 100 mg for dry, brittle, powder-like or pliable; 400 mg for liquid or sticky. In addition, 10% of the TDI (due to exposure from other sources) has been assumed and a body weight of 7.5 kg. There is a designated standard for determining the migration of elements from toys: EN 71-3.

Table 27 Overview of migration limits of heavy metals from toys (mg/kg toy)

Element	Dry, brittle, powder-like or pliable	Liquid or sticky	Scraped off
Aluminium	2250	560	28130
Antimony	45	11.3	560
Arsenic	3.8	0.9	47
Barium	1500	375	18750
Boron	1200	300	15000
Cadmium	1.3	0.3	17
Chromium (III)	37.5	9.4	460
Chromium (VI)	0.02	0.005	0.2
Cobalt	10.5	2.6	130
Copper	622.5	156	7700
Lead	2.0	0.5	23
Manganese	1200	300	15000
Mercury	7.5	1.9	94
Nickel	75	18.8	930

[90] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (Text with EEA relevance) *OJ L 170, 30.6.2009, p. 1-37.*

Element	Dry, brittle, powder-like or pliable	Liquid or sticky	Scraped off
Selenium	37.5	9.4	460
Strontium	4500	1125	56000
Tin	15000	3750	180000
Organic tin	0.9	0.2	12
Zinc	3750	938	46000

A number of elements are listed in Annex II of the Cosmetic Products Regulation[91]. This means that these substances are prohibited in cosmetic products.

- Antimony and its compounds (No 40)
- Arsenic and its compounds (No 43)
- Barium salts (46), with the exception of barium sulphide under the conditions laid down in Annex III and barium sulphate, lakes, salts and pigments prepared from colouring agents listed in Annex IV
- Cadmium and its compounds (No 68)
- Chromium, chromic acid and its salts (No 97)
- Zirconium and its compounds (191), with the exception of the substances listed under number 50 in Annex III and the zirconium lakes, pigments or salts of the colouring agents listed in Annex IV
- Mercury and its compounds (No 221) with the exception of those listed in Annex V (preservatives)
- Lead and its compounds (No 289)
- Strontium lactate (402); strontium nitrate (403); strontium polycarboxylate (404)

Annex XVII of the REACH Regulation[92] lays down restrictions for certain metals:

- Organic tin compounds may no longer be used as biocidal products in anti-fouling paints. Di- and tributyltin may no longer be present in consumer products in a concentration greater than the equivalent of 0.1% by weight of tin (Entry 20).
- Cadmium and its compounds may not be present in beads and metal components of jewellery in a concentration greater than 0.01% by weight (Entry 23).
- Nickel must not migrate from sticks inserted into pierced ears and other parts of the human body in excess of 0.2 µg/cm^2/week; this migration limit also applies to metal intended for direct and prolonged contact with the skin (Entry 27).
- Chromium (VI) compounds must not be present in leather articles that come in contact with the skin in a concentration greater than 3 mg/kg (Entry 47).
- Lead and its compounds must not be present in components of jewellery in a concentration greater than 0.05% by weight (Entry 63).

Limit values for the migration of heavy metals have also been laid down for various material categories of food contact materials. For plastic[93] and ceramic[94], these are laid down in European legislation. For other materials, these are laid down via national legislation[95]. Table 28 and Table 29 provide an overview of this.

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91 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59–209.

92 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. OJ L 396, 30.12.2006, p. 1-520

93 Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L12, 15.1.2011, p. 1-89.

94 Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs. OJ L 277, 20.10.1984, p. 12-16.

95 Regulation of 14 March 2014 establishing the Packaging and Consumer Articles (Commodities Act) Regulation for packaging and consumer articles that come in contact with food.

Table 28 Migration limits of heavy metals from food contact materials (mg/kg food)

Element	Plastic	Glass and glass ceramic	Metal	Enamel
Barium	1	1		1
Cobalt	0.05	0.05	0.05	0.05
Copper	5		5	
Iron	48			
Lithium	0.6	0.6	0.6	0.6
Manganese	0.6	0.6	0.6	
Zinc	25			
Antimony		0.04		
Arsenic		0.01	0.01	0.01
Boron		1		1
Cadmium		0.01	0.01	0.01
Cerium		1		
Chrome		0.1	0.1	0.1
Lead		0.1	0.1	0.1
Nickel		1	1	
Rubidium		1		1
Zirconium		2	22	
Mercury				0.005
Selenium				0.01
Strontium				1
Antimony			0.04	
Bismuth			1	
Vanadium			0.05	

Table 29 Migration limits for lead and cadmium from ceramic food contact materials

Element	Non-fillable objects and fillable objects with an internal depth not exceeding 25 mm measured between the lowest point and the horizontal plane passing through the upper edge	All other fillable objects	Cooking ware; packaging and storage vessels having a capacity of more than three litres
Lead	0.8 mg/dm^2	4.0 mg/l	1.5 mg/l
Cadmium	0.07 mg/dm^2	0.3 mg/l	0.1 mg/l

5.3.12. Microplastics

In general, microplastics are defined as small solid plastic particles (smaller than five millimetres) that are poorly soluble in water and very difficult to biodegrade. Microplastics may be added to products as ingredients, e.g. in personal care products or cleaning products. These microplastics

subsequently end up in the wastewater. Treatment plants can remove these microplastics from wastewater to a large extent[96], but some will still end up in surface water. The majority of microplastics are created through the abrasion of larger pieces of plastic, such as synthetic textiles and larger plastic waste (Eunomia, 2016). Microplastics differ in size, type of plastic and the additives present (e.g. flame retardants and plasticisers). Microplastics are widely found in the environment, but the risks to humans and the ecosystem are still largely unknown.

Several EU Member States have a prohibition on products or certain types of products containing microplastics, often the so-called microspheres in rinse-off cosmetic products.

The European Commission has asked ECHA to prepare an Annex XV restriction dossier on the use of intentionally added microplastics in consumer products or in products for professional use. In January 2019, ECHA published the restriction dossier (ECHA, 2019b). In this restriction dossier, microplastics are not permitted in a concentration exceeding 0.01% by weight in cosmetic products, detergents, medical devices, fertilisers and for agricultural and horticultural uses. In the restriction file, microplastics are understood to mean:

- Plastic particles of which 1% or more by weight all have dimensions between 1 nm and 5 mm
- Synthetic fibres between 3 nm and 15 mm in length, where the ratio of length to diameter is greater than 3

According to the schedule published by ECHA, this proposal will possibly be adopted by the European Commission in 2022.

In 2016, EFSA has published a note on microplastics and nanoplastics in food (EFSA, 2016). According to EFSA, more research is needed not only on the presence of microplastics and nanoplastics in food, but also the toxicokinetics and toxicity, as well as research on the breakdown of microplastics and the possible formation of nanoplastics in the human gastrointestinal tract.

5.3.13. Mineral oil

Mineral oil is a general name for mineral oil hydrocarbons (MOH), oil of mineral origin (petroleum). MOHs can also be artificially produced from coal, natural gas and biomass (EFSA CONTAM Panel, 2012b; Van de Ven B.M. et al., 2018; Buijtenhuijs & van de Ven, 2019). There are two types of mineral oil hydrocarbons, i.e. mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH). MOSH and MOAH are present in various types of food.

The acute toxicity of MOSH is low. MOSH are neither mutagenic nor carcinogenic. Animal studies conducted with rats have shown that MOSH with a carbon number between 16 and 40 could accumulate in tissues and cause microgranulomas in mesenteric lymph nodes and the liver, where they could lead to inflammation. Microgranulomas have also been observed in humans, but dose-effect data for this are missing (EFSA CONTAM Panel, 2012b).

The acute toxicity of MOAH is low. Within the group of substances referred to as MOAH, there are substances with mutagenic and carcinogenic properties. Mutagenicity of MOAH is primarily caused by aromatics with three to seven aromatic ring structures (including alkylated polycyclic aromatic hydrocarbons (PAHs) and non-alkylated PAHs) (EFSA CONTAM Panel, 2012b).

In 2012, EFSA applied the margin of exposure (MOE) approach to MOSH to derive a reference point (RP), which was the no-observed-adverse-effect-level (NOAEL) of 19 mg/kg body weight per day. EFSA has not derived any health-based guidance value for MOAH, since this group of compounds has been classified as genotoxic carcinogens and there is an absence of carcinogenicity studies conducted with MOAH compounds (EFSA CONTAM Panel, 2012b).

5.3.14. Nanomaterials

There are varying definitions of a nanomaterial. The Cosmetic Products Regulation[97] defines a nanomaterial as an insoluble or biopersistant and intentionally manufactured material with one or

[96] https://www.rivm.nl/microplastics/nieuwsbrief/nieuwsbrief-1-november-2017/waterzuivering-vermindert-microplastic-emissies

[97] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59–209.

more external dimensions, or an internal structure, on the scale from 1 to 100 nm. For cosmetic products, it is mandatory to mention the term 'nano' among the ingredients on the packaging if a nanomaterial is involved. Also, for each cosmetic product containing nanomaterials, the manufacturer must ensure a high level of protection of public health.

A recommendation from the European Commission made in 2011[98] defines a nanomaterial as a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is/are in the size range of 1 nm to 100 nm. In 2018, the European Commission updated the REACH Regulation regarding nanomaterials[99]. The definition provided in the Commission Recommendation applies to the REACH Regulation. Minimum standard information relating to nanoforms in the technical dossier and in the chemical safety report is necessary for ECHA to verify whether the potential risks have been adequately assessed (ECHA, 2017a).

Since 1 January 2020, there is a requirement to provide more information on nanomaterials placed on the market in the European Union. ECHA has prepared a new guideline to help companies deal with the changed regulations. In addition, the guideline on read-across between nanoforms and sets of nanoforms has been updated. The amendment of the REACH Regulation is expected to greatly increase the amount of information available on nanomaterials.

5.3.15. Nitrosamines and nitrosatable compounds

Nitrosamines or N-nitroso compounds are organic compounds with the general formula R_1-R_2-N-NO. Often these substances are not added to products as such but are formed by the reaction of a nitrosatable substance with a nitrosatable substance. Nitrosatable substances are often amines, amides and urea compounds. Nitrosating substances include nitrite and nitrate. Nitrosamines are potentially carcinogenic substances. N-nitrosodiethanolamine (NDELA, $R_1 = R_2 = C_2H_5OH$) and N-nitrosodimethylamine (NDMA, $R_1 = R_2 = CH_3$) are classified based on the CLP Regulation[100].
In rubber products, accelerators are added for the vulcanisation step. Often carbamates are used for this. As a by-product, nitrosamines and nitrosatable substances are produced during the vulcanisation step. Humans may be exposed to nitrosamines and nitrosatable substances through skin contact with rubber. Examples include toys, tool handles, sports equipment, rubber tiles. Oral exposure may also occur (soothers, toys put into the mouth). The concentration of nitrosamines and nitrosatable substances may change over time. For balloons, the migration of nitrosamines has been found to increase with time.

For toys, the migration requirements for nitrosamines and nitrosatable substances are laid down in the Toy Safety Directive[101]. For rubber toys, the release limit is 0.05 mg/kg for nitrosamines and 0.1 mg/kg for nitrosatable substances. For finger paints, a limit value of 0.02 mg/kg for NDELA is specified in EN 71-12.

For rubber soothers and teats, Directive 93/11/EEC[102] lays down a migration limit of 0.01 mg/kg rubber for nitrosamines and 0.1 mg/kg rubber for nitrosatable substances.

Nitrosamines may also be present in certain liquid products, including cosmetic products and finger paints. They are not added to the product, but are formed by the reaction of a nitrosatable substance and a nitrosatable substance. Examples of nitrosatable substances are:

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[98] Commission Recommendation of 18 October 2011 on the definition of nanomaterial. OJ L 275, 20.10.2011, p. 38–40.

[99] Commission Regulation (EU) 2018/1881 of 3 December 2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III,VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances. OJ L 308, 4.12.2018, p. 1–20.

[100] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1-1355

[101] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (Text with EEA relevance) *OJ L 170, 30.6.2009, p. 1-37.*

[102] Commission Directive 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers *OJ L 93, 17.4.1993, p. 37-38.*

- Alkanolamines (e.g. diethanolamine, diisopropanolamine)
- Amides (e.g. cocamide)
- Fatty acid alkanolamides (e.g. cocamide diethanolamine (cocamide DEA))
- Amines (secondary, tertiary and quaternary)
- Amine oxides (e.g. cocamidopropylamine oxide)

Nitrosating substances include nitrite or nitro compounds such as bronopol. The Cosmetic Products Regulation[103] lists the following in Annex II, under No 410: nitrosamines, e.g. dimethylnitrosoamine, nitrosodipropylamine, 2,2'-nitrosoiminobisethanol. Substances listed in Annex II to this Regulation may not be used in cosmetic products. Annex III of the Cosmetic Products Regulation contains restrictions relating to certain raw materials to prevent the formation of nitrosamines. For example, the following restriction is included for sodium nitrite (nitrosating agent): 'Not to be used with secondary and/or tertiary amines or other substances forming nitrosamines'.

For a number of nitrosatable substances, e.g. 2-(4-methyl-2-nitroanilino)ethanol, the following restriction is listed:
- Not to be used with nitrosating systems
- Maximum nitrosamine concentration: 50 µg/kg

For the preservatives (Annex V) bronopol and 5-bromo-5-nitro-1,3-dioxane, the following restriction is listed: 'Avoid formation of nitrosamines'.

For cosmetic products, dermal exposure is the main area of concern. The SCCS has published an advisory report in 2012 on nitrosamines and secondary amines in cosmetic products (SCCS, 2012b). The potencies of nitrosamines were ranked based on carcinogenicity studies in rats. The SCCS believes that the limit of 50 µg/kg provides sufficient protection, but stresses that this limit value of 50 µg/kg applies to the raw materials and not to the final product.

5.3.16. Solvents

Benzene

Benzene is an apolar solvent and is an aromatic compound. Short-term inhalation or oral exposure to high concentrations of benzene can lead to dizziness, accelerated heart rate, headache, unconsciousness, and even death. If benzene comes in contact with the skin, this can lead to redness and sores. Prolonged exposure to benzene has an effect on the immune system and possibly reprotoxic effects, and this can lead to cancer of blood-forming organs (ATSDR, 2007). The IARC has classified benzene as a human carcinogen (Group 1) (IARC, 2017a).

Chloroform

Chloroform (trichloromethane or methyltrichloride) is an organic solvent that is also used as an intoxicant. Chloroform has effects on the central nervous system, liver and kidneys after a single occasion of high oral or inhalation exposure. With prolonged exposure, it has effects on the liver and kidneys. Skin exposure can lead to ulcers (ATSDR, 1997). The IARC has classified chloroform as a possible human carcinogen (Group 2B) (IARC, 1999b).

Dichloromethane

Dichloromethane (methylene chloride) is an organic compound used as a solvent in paint strippers and degreasers. Effects on the nervous system (including dizziness) become apparent following the inhalation of large amounts of dichloromethane. Once such exposure ends, the effects may disappear. Direct skin contact with large amounts of dichloromethane cause redness and burning of the skin. The IARC has classified dichloromethane as a possible human carcinogen (Group 2A) (IARC, 2017b).

[103] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59–209.

Methyl tert-butyl ether

Methyl tert-butyl ether (MTBE) is an organic compound used as a solvent. After oral ingestion or inhalation of large amounts of MTBE, headaches, nausea, dizziness and irritation of the nose or airways may occur. If MBTE comes into direct contact with the skin, irritation of the skin may occur. Prolonged inhalation exposure could cause cancer (ATSDR, 1996). The IARC concluded that MBTE is not classifiable as to its carcinogenicity in humans (Group 3) (IARC, 1999b).

Toluene

Toluene or methylbenzene is used as a solvent and as a raw material in chemistry. Like benzene, toluene is an aromatic compound. Short-term exposure to toluene has effects on the nervous system (including headaches and dizziness). With repeated long-term exposure, effects on the nervous system may be permanent (including problems with cognition and loss of vision). In addition, long-term exposure to toluene may have effects on the liver and kidneys (ATSDR, 2015). The IARC has concluded that toluene is not classifiable as to its carcinogenicity in humans (Group 3) (IARC, 1999a).

Legal aspects

Chemical mixtures must be classified, labelled and packaged in accordance with the CLP Regulation[104]. Table 30 contains an overview of the classification into hazard categories based on this Regulation.

The REACH Regulation[105] contains certain restrictions for chemical substances (Annex XVII). For chloroform, toluene, and dichloromethane, the restrictions are listed under Entries 43, 48, and 59, respectively. Entries 28, 29 and 30 lay down restrictions for mixtures that are placed on the market as consumer products, which contain substances classified as carcinogens, mutagens and reproductive toxicants under Categories 1A, 1B and 2 and which are listed in Appendices 1 to 6. These mixtures may not be placed on the market in concentrations exceeding the limit value for classification as carcinogenic, mutagenic or reprotoxic.

Table 30 Classification and restrictions of solvents according to the CLP and REACH Regulations

Substance	CLP classification	REACH restriction
Benzene	Muta 1B; Carc 1A; Asp Tox 1; STOT RE 1	<0.1% by weight for consumer products[1]
Chloroform	Rep 2; Carc 2; STOT RE 1	≤0.1% by weight in consumer products[2]
Dichloromethane	Carc. 2	≤0.1% by weight in paint strippers[3]
Methyl tert-butyl ether	Skin irr. 2	
Toluene	Rep. 2; Asp. Tox 1; STOT RE 2, STOT SE 3	≤0.1% by weight in adhesives or spray paints for the consumer market[4]

1. Entry 28, Annex XVII REACH Regulation
2. Entry 43, Annex XVII REACH Regulation
3. Entry 59, Annex XVII REACH Regulation
4. Entry 48, Annex XVII REACH Regulation

[104] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1-1355

[105] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. OJ L 396, 30.12.2006, p. 1-520

Annex II of the Cosmetic Products Regulation[106] includes benzene (No 47), chloroform (No 366) and dichloromethane (No 1389). This means that these substances may not be used in cosmetic products. Annex III lists toluene, with the restriction that a maximum of 25% of this may be used in adult nail products.

For toys, limits are specified in EN 71-9 for solvents used in plastic toys. The following Table 31 displays these, both for migration and inhalation.

Table 31 Limits for solvents in plastic toys according to EN 71-9

Substance	Migration (mg/l)	Inhalation (mg/m^3)
Trichloroethylene	0.02	33
Dichloromethane	0.06	3000
2-Methoxyethyl acetate	A total limit of 0.5 applies to these five substances	
2-Ethoxyethanol		
2-Ethoxyethyl acetate		
Bis(2-methoxyethyl) ether		
2-Methoxypropyl acetate		
Methanol	5	
Nitrobenzene	0.02	33
Cyclohexanone	46	136
3,5,5-Trimethyl-2-cyclohexene-1-on	3	200
Toluene	2	260
Ethylbenzene	1	5000
Xylene	2	870
1,3,5-Triethylbenzene		2500
n-Hexane		1800

5.3.17. Parabens

The word 'parabens' refers to a group of alkyl esters of 4-hydroxybenzoic acid. Parabens are used as preservatives in products such as cosmetic products and finger paints in concentrations up to 0.8% (total). They prevent the growth of fungi and bacteria. The Cosmetic Products Regulation[107] sets requirements for individual parabens; in addition, a group limit for parabens has also been established (see Table 32). Finger paints are subject to similar requirements (EN 71--7). Propyl- and butylparaben must not be used in skin care products for application on babies' bottoms. The skin of babies' bottom is sometimes irritated or damaged, which may result in increased absorption due to the damaged skin. Isopropyl-, isobutyl-, phenyl-, benzyl- and pentylparaben are listed in Annex II to the Cosmetic Products Regulation (prohibited substances). These parabens are prohibited because of the lack of sufficient data for assessing whether they are safe for use.

Table 32 Overview of legal requirements for parabens in cosmetic products and finger paints

Paraben	Cosmetic products in general	Leave-on cosmetic products for the nappy area	Finger paints
Methylparaben	0.4%	0.4%	0.4%
Ethylparaben	0.4%	0.4%	0.4%
Sum of propyl- and butylparaben	0.14%	Not authorised	0.14%

[106] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59–209.

[107] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59–209.

Sum of methyl-, ethyl-, propyl- and butylparaben[1]	0.8%[1]	0.8%[2]	0.8%[1]
Isopropylparaben	Prohibited[3]	Prohibited[3]	Not authorised[4]
Isobutylparaben	Prohibited[3]	Prohibited[3]	Not authorised[4]
Phenylparaben	Prohibited[3]	Prohibited[3]	Not authorised[4]
Benzylparaben	Prohibited[3]	Prohibited[3]	Not authorised[4]
Pentylparaben	Prohibited[3]	Prohibited[3]	Not authorised[4]

1. The sum of methyl-, ethyl-, propyl- and butylparaben may not exceed 0.8%, while the sum of propyl- and butylparaben may not exceed 0.14%
2. Sum of only methyl- and ethylparaben, propyl- and butylparaben are not authorised
3. Prohibited substances according to Annex II of the Cosmetic Products Regulation (EC) No 1223/2009
4. Not listed in Annex B of EN 71-7 (list of permitted preservatives in finger paints)

In 2010 and 2013, the SCCS assessed the use of parabens in cosmetic products (SCCS, 2010a;2013b). The SCCS found that propyl- and butylparaben can be used safely up to a maximum concentration of 0.19%. For methyl- and ethylparaben, concentrations of up to 0.4% are considered safe. Parabens are potential endocrine disruptors. According to the SCCS, the estrogenic properties of parabens seem to increase with increased chain length. For cosmetic products, only the short-chain parabens are permitted as preservatives.

The RIVM has carried out a literature study on the toxicity of methyl-, ethyl-, propyl- and butylparaben (Brand et al., 2018; Hessel et al. 2019). The acute toxicity of these four parabens is low (LD_{50} values between 2000 and 8000 mg/kg body weight). Methyl-, ethyl- and propylparaben do not cause any skin or eye irritation. In the case of butylparaben, there is a slight skin irritation, but this substance is assessed as a non-sensitising substance. The literature does not provide sufficient data to classify methyl-, ethyl-, propyl- and butylparaben as endocrine disruptors.

A Dutch cosmetovigilance study showed that parabens did not appear on the list of allergenic substances that Dutch consumers have tested positive to (Salverda et al., 2013). Recent research from the United States confirms that, in terms of contact allergy, parabens pose little or no problems (Fransway et al., 2019).

5.3.18. Perfluorinated compounds

Per- and polyfluoroalkyl substances (PFAS) is a group name for fluorinated aliphatic hydrocarbons. There is no harmonised definition for PFAS as yet. In general, these are compounds with one or more -C_nF_{2n+1} units. The Organisation for Economic Co-operation and Development (OECD) uses the following definition for PFAS: compound having a perfluoroalkyl unit consisting of three or more carbon atoms (e.g. –C_nF_{2n}–, n≥3) or a perfluoroalkyl ether unit consisting of two or more carbon atoms (–$C_nF_{2n}OC_mF_{2m}$–, n and m≥1). More than one thousand PFAS are known (OECD, 2018). PFAS are used in a variety of consumer and industrial products such as protective coatings for clothing, paper, insecticides, paint and fire-fighting foams (Noorlander et al., 2011; EFSA CONTAM-Panel, 2012a). Since these substances are very stable, they are also very persistent and do not readily break down in the environment or through the action of organisms.

The most well-known PFAS are PFOS (perfluorooctane sulfonate) and PFOA (perfluorooctanoic acid). Due to their persistence, bioaccumulation and toxicity, most uses of PFOS and a few related compounds were prohibited in 2008 (Vandermeersch et al., 2015).

PFOS and PFOA are rapidly absorbed into the gastrointestinal tract and excreted unchanged via urine and faeces. The estimated half-lives of human excretion for PFOS and PFOA are approximately five years and two to four years, respectively (EFSA CONTAM Panel, 2018a). Human exposure to PFOS or PFOA is associated with effects on fat and carbohydrate metabolism and increased serum cholesterol concentrations. Epidemiological studies in humans demonstrated effects on the liver and overall development (Krafft & Riess, 2015). PFOS caused tumours in the rat liver and PFOA caused Leydig cell tumours in the rat. Both substances lead to neurotoxic developmental effects and effects on gene expression relevant for signal transmission in the brain

(EFSA CONTAM Panel, 2018a). PFOS and PFOA accumulate in the liver, where the bioaccumulation of PFOA is lower than that of PFOS (EFSA CONTAM Panel, 2018a).

GenX is the trademark name for a technology used to make coatings (fluoropolymers) and GenX chemicals are used as replacements for PFOA. In this technology, two fluorine-containing substances FRD-902 and FRD-903 are used and the fluorine compound E1 is formed. Some of the substances are emitted into the air and some are discharged into wastewater. Under physiological conditions (e.g. in water or blood) FRD-902 and FRD-903 are converted to the ion HFPO-DA (2,3,3,3-Tetrafluoro-2-(heptafluoropropoxy)propanoic acid). HFPO-DA is responsible for the observed toxicological effects of GenX. The harmful effects of GenX are comparable to those of PFOA: GenX substances are possibly carcinogenic to humans and have effects on the liver. However, GenX substances are less harmful to reproduction than PFOA. At the end of June 2019, HFPO-DA was designated as a Substance of Very High Concern (SVHC) by ECHA (ECHA, 2019a) and was therefore included on the REACH Candidate List. Substances on the Candidate List are likely to be eventually placed on the Authorisation List, which means that after a certain date the substance may no longer be placed on the market or used unless an authorisation has been granted for the specific use in question. In November 2018, the American Environmental Protection Agency (EPA) issued draft standards for GenX substances[108]. The proposed subchronic and chronic reference doses are 0.0002 and 0.00008 mg/kg body weight per day, respectively.

There is a shift from PFAS to the use of perfluorosulfonates and perfluorocarboxylic acids with shorter chains and perfluoroalkylethercarboxylic acids (including GenX). These substances have been demonstrated in Dutch surface water (Gebbink et al., 2017).

In 2016, the RIVM derived a TDI for PFOA of 12.5 ng/kg body weight per day (Zeilmaker et al., 2016). In 2018, EFSA derived a TWI of 6 ng/kg body weight per week for PFOS and 6 ng/kg body weight per week for PFOA (EFSA CONTAM Panel, 2018a). The RIVM has derived a provisional TDI of 21 ng/kg body weight per day for GenX (Janssen et al., 2017).

Food contact materials are regulated by material category. Only starting substances and additives included in the list of permitted substances may be used for the manufacture of the food contact materials, provided the restrictions are complied with. An overview of all the authorised PFAS for food contact materials can be found in a RIVM report (Bokkers et al., 2019). Some material categories are regulated at the European level and others at the national level. There is a specific regulation for plastic food contact materials, i.e. Regulation (EC) No 10/2011[109]. At the national level, material categories are regulated in Appendix A of the Commodities Act Regulation on Food Contact Materials [110]: Chapter II - Paper and paperboard, Chapter III - Rubber and rubber products and Chapter X - Coatings.

Due to their environmentally persistent properties, PFOS is restricted to a concentration of 0.1% by weight in articles (Regulation (EU) No 850/2004[111]). For coatings, a restriction of 1 µg/m^2 applies.

5.3.19. Polycyclic aromatic hydrocarbons

Polycyclic aromatic hydrocarbons (PAHs) consist of a large number of different compounds that contain a varying number of aromatic rings. The best-known PAH compound is benzo[a]pyrene. This substance has carcinogenic properties (genotoxic carcinogen), and a few other PAHs are also carcinogenic. The toxicity arises due to the formation of reactive epoxides. Not all PAHs are carcinogenic. PAHs occur in the environment and arise from combustion processes. Black colourants and carbon black used as a raw material may contain PAHs. In addition to consumer products, food is a relevant source of exposure to PAHs.

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[108] Source: EPA, https://www.epa.gov/sites/production/files/2018-11/documents/factsheet_pfbs-genx-toxicity_values_11.14.2018.pdf

[109] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L12, 15.1.2011, p. 1-89. 1-89

[110] Regulation of 14 March 2014 establishing the Packaging and Consumer Articles (Commodities Act) Regulation for packaging and consumer articles that come in contact with food.

[111] Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants. OJ L 158, 30.4.2004, p. 7-49

Since PAHs are almost always found as mixtures, the toxicity of the total dose must be assessed. Given that the composition of the mixtures differs, the degree of possible carcinogenicity also differs. The relative potency of a number of PAHs with respect to benzo[a]pyrene (BaP) is known. In the past, BaP was used as a reference substance to express the carcinogenic potential of a mixture (Bokkers B.G.H. et al., 2016). However, in 2008, EFSA concluded that BaP is not a good indicator of the occurrence of PAHs in food. EFSA introduced a combination of four or eight PAHs to be used as a reference (EFSA CONTAM Panel, 2008).

The EFSA CONTAM Panel derived an oral $BMDL_{10}$ of 0.070 mg/kg body weight per day for benzo[a]pyrene and 0.34 mg/kg body weight per day for PAH4 (EFSA CONTAM Panel, 2008).

Annex XVII of the REACH Regulation[112] contains the following restrictions for PAHs under Entry 50:

- Rubber or plastic components of consumer products that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity may not contain more than 1 mg/kg PAHs.
- Toys, including activity toys, and childcare articles that come into direct as well as prolonged or short-term repetitive contact with the skin or the oral cavity may not contain more than 0.5% by weight of PAHs.

The following PAHs fall under these restrictions:
- Benzo[a]pyrene
- Benzo[e]pyrene
- Benzo[a]anthracene
- Chrysene
- Benzo[b]fluoranthene
- Benzo[j]fluoranthene
- Benzo[k]fluoranthene

There is a special standard for finger paints: EN 71-7. This specifically includes a limit of 0.05 mg/kg for benzo[a]pyrene in black finger paint.

Annex II of the Cosmetic Products Regulation[113] includes a list of prohibited substances. The following PAHs are included in that list (No 612; 637 to 643):
- Benzo[a]pyrene
- Dibenzo[a,h]anthracene
- Benzo[a]anthracene
- Benzo[e]pyrene
- Benzo[j]fluoranthene
- Benzo[e]acenanthrene
- Benzo[k]fluoranthene
- Chrysene

The Commodities Act Decree on Tattooing colourants[114] refers to Appendix II of the Cosmetic Products Regulation. These substances are also prohibited in tattooing colourants.

5.3.20. Siloxanes

Siloxanes are chemical compounds with a chain of alternating silicon and oxygen atoms. The silicon atoms are carriers of one or two organic groups. Siloxanes are subdivided into two groups: linear (polydimethylsiloxane (PDMS)) and cyclic siloxanes. The main cyclic siloxanes are octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5). Linear and cyclic siloxanes are used in cosmetic products. If a mixture of cyclic siloxanes is used, this mixture is called 'cyclomethicone' (Danish EPA, 2005).

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[112] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. OJ L 396, 30.12.2006, p. 1-520

[113] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59-209

[114] Decree of 14 August 2003 on establishing rules concerning the safety of tattooing colourants (Tattooing Colourants (Commodities Act) Decree). Bulletin of Acts and Decrees 2003, 342.

The skin absorption of D4 and D5 is low because the substance evaporates quickly. D4 is a potential endocrine disruptor. Effects on reproduction have been observed (Franzen et al., 2017). Long-term inhalation exposure to D4 and D5 has effects on the lungs, liver and uterus (Dekant & Klaunig, 2016; Franzen et al., 2017). The SCCS considers D5 to be mildly irritating to the skin and eyes (SCCS, 2016c).

In 2010, the SCCS concluded that the use of cyclomethicone (D4, D5) does not pose a risk to consumers when used in cosmetic products (SCCS, 2010b). In 2016, SCCS concluded that the use of D5 in cosmetic products is safe, except in hair sprays that form aerosols and in sunscreen sprays (SCCS, 2016c).

In 2014, the Danish EPA assessed the risks of some siloxanes, including D4 and D5 (Greve et al., 2014). Both substances have low toxicity in case of inhalation. Effects of D4 on reproduction in rats are unlikely to be relevant to humans. An LOAEC of 430 mg/m^3 was derived for repeated inhalation exposure of rats to D4, based on inflammatory processes in the lung. Inhalation exposure of rats to high doses of D5 led to a significant increase in uterine tumours. An NOAEC of 440 mg/m^3 was found for repeated inhalation exposure of rats to D5, based on liver effects.

In 2018, D4, D5 and D6 were included in REACH's SVHC list (ECHA, 2018b). According to Regulation (EU) No 2019/831[115], cosmetic products may no longer contain D4 as of June 2019. Based on the REACH Regulation[116], placing rinse-off cosmetic products with a D4 or D5 concentration greater than 0.1% on the market has been prohibited since 31 January 2020. Subsequently, it has been proposed that the use of D4, D5 and D6 should be limited to a maximum concentration of 0.1% in consumer or professional cosmetic products that are not rinsed off the skin after application. It has also been proposed to limit the use of D6 to a maximum concentration of 0.1% in rinse-off cosmetic products.

5.3.21. UV filters

Natural sunlight consists mostly of ultraviolet A (UVA) and a small amount of ultraviolet B (UVB) rays. UVA rays consist of long waves that penetrate deep into the skin. UVB rays are more powerful than UVA rays but have a shorter wavelength, which means that they do not penetrate as deeply into the skin. Sunburn is mainly caused by UVB rays. UV filters are added to cosmetic products and textiles so that the product can protect the consumer against the sun. These are substances that are solely or mainly intended to protect the skin from certain types of UV radiation by absorbing, reflecting or scattering the UV radiation.

UV filters can be divided into two types: organic and inorganic UV filters. Organic UV filters are always used in combination with other organic UV filters or inorganic UV filters. Examples of organic UV filters are 4-aminobenzoic acid, benzophenone, octocrylene, camphor derivatives, octylmethoxycinnamate and octyltriazone. Examples of inorganic UV filters are zinc oxide (ZnO) and titanium dioxide (TiO_2) (Gilbert et al., 2013; Parwaiz et al., 2019). A single organic UV filter does not provide sufficient SPF (sun protection factor). Scientists pay special attention to both types of filters. It is known that some organic UV filters are unstable under the influence of UV light and disintegrate, whereby reactive oxygen species (ROS) and possibly toxic derivatives are formed. Organic UV filters may cause an allergic or a photoallergic skin reaction. In the case of inorganic UV filters, the use of nanoparticles is subject to debate. Zinc oxide and titanium dioxide nanoparticles are cytotoxic (Gilbert et al., 2013). Some UV filters (benzophenone, camphor derivatives, cinnamate derivatives) have potential endocrine disrupting properties (Wang et al., 2016).

[115] Commission Regulation (EU) 2019/831 of 22 May 2019 amending Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products. OJ L 137, 23.5.2019, p. 29–63.

[116] Commission Regulation (EU) 2018/35 of 10 January 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards octamethylcyclotetrasiloxane ('D4') and decamethylcyclopentasiloxane ('D5'). OJ L 6, 11.1.2018, p. 45–47.

Cosmetic products must comply with the Cosmetic Products Regulation[117]. For UV filters, only those listed in Annex VI of this Regulation may be used, provided that the listed restrictions are complied with. In addition, all ingredients, including UV filters, must be declared on the label. Table 33 displays the authorised UV filters and the applicable restrictions.

Table 33 Overview of approved UV filters for cosmetic products and conditions

UV filter (INCI name)	Maximum concentration	Other	Instructions for use/ warnings
Camphor Benzalkonium Methosulfate	6%		
Homosalate	10%		
Benzophenone-3	6%	Not more than 0.5% to protect the product formulation	Contains benzophenone-3
Phenylbenzimidazole Sulfonic Acid	8% (as acid)		
Terephthalylidene Dicamphor Sulfonic Acid	6% (as acid)		
Butyl Methoxydibenzoylmethane	5%		
Benzylidene Camphor Sulfonic Acid	6% (as acid)		
Octocrylene	10% (as acid)		
Polyacrylamidomethyl Benzylidene Camphor	6%		
Ethylhexyl Methoxycinnamate	10%		
PEG-25 PABA	10%		
Isoamyl p-Methoxycinnamate	10%		
Ethylhexyl Triazone	5%		
Drometrizole Trisiloxane	15%		
Diethylhexyl Butamido Triazone	10%		
4-Methylbenzylidene Camphor	5%		
Ethylhexyl Salicylate	4%		
Ethylhexyl Dimethyl PABA	8%		
Benzophenone-4, Benzophenone-5	5% (as acid)		
Methylene Bis-Benzotriazolyl Tetramethylbutylphenol	10%		
Methylene Bis-Benzotriazolyl Tetramethylbutylphenol (nano)	10%	Do not use in applications that may result in lung exposure for the end	

[117] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59–209.

UV filter (INCI name)	Maximum concentration	Other	Instructions for use/ warnings
		user through inhalation Nanoform requirements[1]	
Disodium Phenyl Dibenzimidazole Tetrasulfonate	10% (as acid)		
Bis-Ethylhexyphenol Methoxyphenyl Triazine	10%		
Polysilicone-15	10%		
Titanium Dioxide	25%		
Titanium Dioxide (nano)	25%		
Diethylamino Hydroxy Benzoyl Hexyl Benzoate	10%		
Tris-Biphenyl Triazine (nano)	10%	Do not use in sprays Nanoform requirements[1]	
Zinc Oxide	25%	Do not use in applications that may result in lung exposure for the end user through inhalation	
Zinc Oxide (nano)	25%	Do not use in applications that may result in lung exposure for the end user through inhalation Nanoform requirements[1]	
Phenylene Bis-Diphenyl Triazine	5%	Do not use in applications that may result in lung exposure for the end user through inhalation	

[1.] Nanoform requirements relate to the purity, particle size, size distribution, shape of the particles, solubility in water, presence or absence of a coating.

5.3.22. Flame retardants

Flame retardants are a group of substances that are used in a variety of household products and upholstery to prevent the material from igniting or to retard a fire.

Brominated flame retardants

Brominated flame retardants fall under the category of Persistent Organic Pollutants (POPs). POPs are substances that are persistent in the environment, degrade at a slow rate and can accumulate in the body. Major groups of brominated flame retardants include polybrominated diphenyl ethers

(PBDEs), polybrominated biphenyls (PBBs), hexabromocyclododecans (HBCD), hexabromobenzene (HBB), TBBPA and other phenols such as tribromophenol (TBP), decabromodiphenyl ethane (DBDPE) and 1,2-bis(2,4,6-tribromophenoxy)ethane (BTBPE) (EFSA CONTAM-Panel, 2012b; Vandermeersch et al., 2015). Polybrominated diphenyl ethers (PBDEs) and hexabromocyclodecans (HBCDDs) are the two main groups. These compounds vaporise from various applications into the ambient air and thus end up in food. The use of HBCDDs has been severely restricted in Europe and worldwide, but the substance will continue to be released from existing materials in the coming decades. The eight major PBDE congeners are BDE 28, 47, 99, 100, 153, 154, 183 and 209 (EFSA CONTAM-Panel, 2011).

Brominated flame retardants are toxic, and the most harmful effects are with respect to neurological development.

Phosphate flame retardants

Phosphate flame retardants can be used to replace brominated flame retardants, since the use of brominated flame retardants is restricted or prohibited. Phosphate flame retardants are divided into three groups: inorganic, organic and halogen containing phosphates. Halogenated phosphates include tris(chloropropyl) phosphate (TCPP), tris(2-chloroethyl) phosphate (TCEP), and tris(1,3-dichloro-2-propyl) phosphate (TDCPP) (van der Veen & de Boer, 2012).

Chlorinated phosphates are potentially carcinogenic (TCPP, TCEP and TDCPP). TCPP accumulates in the liver and kidneys. TCEP has effects on blood clotting and reproduction. TDCPP is potentially neurotoxic (van der Veen & de Boer, 2012).

Legislation

Requirements for flame retardants in toys are set out in EN 71-9. Accessible textile materials used in toys for children aged under three are subject to the so-called action limit. An action limit implies that a certain substance must not be present in toys based on its toxicological properties. Hence, the limit of quantification of the method in EN 71-11 is the limit value.

Tri-o-cresyl phosphate: 50 mg/kg

Tris(2-chloroethyl) phosphate: 50 mg/kg

Annex XVII of the REACH Regulation[118] imposes restrictions on certain flame retardants:

- Diphenylether, octabromo derivative must not be present in mixtures and articles in a concentration greater than 0.1% by weight (Entry 45).
- Tris (2,3 dibromopropyl) phosphate may not be used in textile articles intended to come into contact with the skin (Entry 4).

5.3.23. Volatile organic compounds

Volatile organic compounds (VOCs) is the collective name for a group of hydrocarbons that evaporate easily. There is no single univocal definition of volatile organic compounds. VOCs are used in petrol, paints, detergents and cosmetic products (RIVM, 2019b).

If large amounts of VOCs are inhaled, dizziness, headache, fatigue and irritation of the throat, nose and eyes may occur. Skin contact with products containing high levels of VOCs can lead to eczema. VOCs may be harmful to the unborn child (RIVM, 2019b).

The toxicity of certain specific VOCs is discussed elsewhere (see benzene, methylene chloride, formaldehyde and methyl tert-butyl ether under the 'Solvents' section).

[118] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. OJ L 396, 30.12.2006, p. 1-520

5.3.24. Plasticisers

Plasticisers are added to plastics (especially in certain PVC applications, commonly referred to as soft PVC) to make the material flexible and soft. The concentrations can be as high as 50% and sometimes even higher. For a long time, phthalates in particular were used as plasticisers: di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), butyl benzyl phthalate (DBP), diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), diisooctyl phthalate (DNOP). A precautionary prohibition on these six phthalates was published in 2005 (Directive 2005/84/EC[119]). This has led to the use of alternative plasticisers, such as citrates, adipates, terephthalates (including di-2-ethylhexyl terephthalate (DEHTP), diisononyl 1,2-cyclohexanedicarboxylic acid (DINCH) and 1-isopropyl-2,2-dimethyltrimethylene diisobutyrate (TXIB)). A risk assessment by BuRO shows that these alternative plasticisers can be safely used in toys up to certain limits (BuRO, 2010c). These limits must therefore be set out in the form of a migration limit.

Both dermal and oral exposure may occur to plasticisers in plastic products. Dermal exposure could involve skin contact with plasticised plastics, such as toys, children's articles, textiles, sex toys, or even garden hoses. Oral exposure could occur when children suck their toys as well as via hand-to-mouth contact after play. Plasticisers can migrate into food via food contact materials.

A list of permitted plastic additives has been drawn up for food contact materials. Only approved additives may be used. Most of the authorised additives are subject to a restriction in connection with migration into food.
Under the CLP Regulation[120], DEHP, DBP, DIBP and BBP belong to Reproductive Toxicant Category 1B (H360FD: May damage fertility. May damage the unborn child). The remaining plasticisers (DINP, DIDP, DNOP, DEHTP, DINCH and TXIB) are not classified under this Regulation.

Toxicity data for four phthalates (DEHP, DBP, BBP and DIBP) can be found in the restriction dossier and the corresponding advisory report from the Committee for Risk Assessment (RAC) (RAC, 2012). Here, the focus is on oral exposure, since the extent of dermal absorption is assessed as very low. The available toxicity data show that these four phthalates have low acute toxicity and do not cause skin or eye irritation or skin sensitisation. Long-term effects on repeated exposure show effects on the liver and kidneys. The main toxicological endpoint is reprotoxicity. The following DNELs (Derived No-Effect Level) have been derived:
- DEHP: 0.035 mg/kg body weight/day
- DBP: 0.0067 mg/kg body weight/day
- BBP: 0.5 mg/kg body weight/day
- DIBP: 0.42 mg/kg body weight/day

Annex XVII of the REACH Regulation[121] lays down the following restrictions for phthalates in toys and childcare articles:
- The sum of DEHP, BBP, DBP and DIDP concentrations in plasticised plastic may not exceed 0.1% by weight (Entry 51). The requirement for DIBP enters into effect on 7 July 2020.
- The sum of DINP, DIDP and DNOP concentrations in plasticised plastic may not exceed 0.1% by weight, if the toy or childcare article can be placed in the mouth (Entry 52).

The Cosmetic Products Regulation[122] lists DBP (No 675), DEHP (No 677), BBP (No 1152) and DIBP (No 1492) and dihexyl phthalate (No 1559). Substances listed in Annex II may not be used in cosmetic products.

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[119] Directive 2005/84/EC of the European Parliament and of the Council of 14 December 2005 amending for the 22nd time Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates in toys and childcare articles) *OJ L 344, 27.12.2005, p. 40–43. 40–43.*

[120] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1-1355

[121] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. OJ L 396, 30.12.2006, p. 1-520

[122] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59–209.

A number of plasticisers have been evaluated by EFSA and have also been authorised as additives for food contact materials. These plasticisers are not classified as reprotoxic by ECHA.

- For DINP, a TDI of 0.15 mg/kg body weight per day has been set by EFSA (EFSA AFC Panel, 2005).
- For DIDP, a TDI of 0.15 mg/kg body weight per day has been set by EFSA (EFSA AFC Panel, 2005).
- For DEHTP, TDI of 1 mg/kg body weight per day has been set by EFSA (EFSA AFC Panel, 2008a).
- For DEHTP, TDI of 1 mg/kg body weight per day has been set by EFSA (EFSA AFC Panel, 2006).
- For TXIB, an SML of 3 mg/kg food has been derived by EFSA (normally corresponding to a TDI of 0.05 mg/kg body weight per day) (EFSA AFC Panel, 2006).

5.3.25. Acids and 2-phenoxyethanol

In cosmetic products, 2-phenoxyethanol and certain acids are used as preservatives. Preservatives are regulated in Annex V of the Cosmetic Products Regulation[123]. The following restrictions apply to these acids and 2-phenoxyethanol:

- 2-Phenoxyethanol: 1%
- Sorbic acid (and salts): 0.6% (as acid)
- Benzoic acid (and salts): 2.5% (acid) in rinse-off, 1.7% in oral products, in 0.5% in leave-on cosmetic products

Citric acid and lactic acid may be used without restriction as, for instance, pH regulators.

The SCCS has published an advisory report on 2-phenoxyethanol as a preservative in cosmetic products (SCCS, 2016a). According to the SCCS, 2-phenolxyethanol can be safely used as a preservative in cosmetic products up to a concentration of 1%. This substance has been assessed as non-sensitising to skin. In the United States, 2-phenoxyethanol is assessed as a non-irritant and non-sensitising substance (Poudrier, 1990). It was concluded that 2-phenoxyethanol can be safely used in cosmetic products in concentrations up to 1%.

For the four acids, there is no SCCS advisory report assessing their safety as ingredients in cosmetic products. Although cosmetic products do not fall under the scope of the CLP Regulation[124], the hazard classification of these substances according to this CLP Regulation has been taken into consideration as a reference. A harmonised classification exists for some substances. For other substances, the inventory of notified classifications by companies was examined. These four acids are often classified as Eye Irritant Category 1 or 2 and/or Skin Irritant Category 2. None of these four substances is classified as sensitising via the skin (skin allergens).

According to the general limit values, the following applies to the classification of a product or product mixture. Skin and Eye Irritant Category 2 means that, from a concentration of 10% or more, a product must be classified as an eye or skin irritant. For Eye Corrosive Category 1, the classification limit value is 1% for eye irritant products and 3% or more for eye corrosive products. Acute Toxicity Oral Category 4 implies that, from a concentration of 25% or more, a mixture must be classified as 'Harmful if swallowed'. STOT RE1 means toxic to specific target organs through repeated exposure, Category 1. From 1% onwards, a mixture must be classified as STOT Category 2, and from 10% onwards, as STOT Category 1. If the limit value of the Cosmetic Products Regulation is lower than the classification limit value according to the CLP Regulation, it means that a cosmetic product is not considered to be a skin or eye irritant, harmful if swallowed or toxic if inhaled.

Sorbic acid does not have a harmonised classification under the CLP Regulation. In the inventory of notified classifications of sorbic acid, most companies indicated that this substance falls under

[123] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59–209.

[124] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1-1355

Eye and Skin Irritant Category 2. The limit value for classification as an eye and skin irritant is higher than the limit value for cosmetic products.

Benzoic acid is classified under the CLP Regulation (harmonised classification) as Skin Irritant Category 2 and Eye Corrosive Category 1. This substance is harmful to the lungs if inhaled (STOT RE1: toxic to specific target organs through repeated exposure, Category 1). The limit value for classification as an eye irritant is higher than the limit value for cosmetic products. This means that products containing 1% or more of benzoic acid should not be used in the area around the eyes. Above 1%, the cosmetic product must be classified as 'May cause damage to lungs if inhaled' (STOT RE2). The extent to which inhalation is relevant for a cosmetic product depends on the use of this product.

Citric acid does not have a harmonised classification under the CLP Regulation. The CLP notifications of most companies classify this substance as Skin Irritant Category 2.

Lactic acid does not have a harmonised classification under the CLP Regulation. The CLP notifications of most companies classify this substance as Skin Irritant Category 2 and Eye Corrosive Category 1. From 1% onwards, the product is an eye irritant according to the CLP classification criteria.

A Dutch cosmetovigilance study showed that acids and 2-phenoxyethanol did not appear on the list of allergenic substances that Dutch consumers have tested positive to (Salverda et al., 2013). This is in keeping with the fact that these substances have not been classified or notified in accordance with the CLP Regulation as sensitising to skin.

5.4. Chemical risks per subdomain

This chapter describes, for each subdomain and as far as relevant, the specific chemical hazards that consumers may be exposed to, the route or mechanism by which such exposure may occur and the indications of actual exposure. Based on this, conclusions have been drawn about the risks.

Chemical risks have not been considered for amusement devices, portable climbing equipment, electrotechnical products, gas appliances, machinery (for private purposes), personal protective equipment and playground equipment.

5.4.1. Chemical risks of child use and care articles

Child use and care articles are products designed for children aged up to four years to help them sleep, to feed or carry them or products for them to suck on. Examples include soothers, teats, drink bottles, children's high chairs, cots, baby bouncers, as well as baby mattresses and stair gates. These items are made from a variety of materials, including plastic, wood and metal. Given the vulnerability of this group, the safety of child use and care articles is of high priority.

Legal framework

There are no specific regulations for child use and care articles. These articles have to comply with the General Product Safety Directive 2001/95/EC[125]. This Directive sets out general safety requirements but does not contain any specific chemical requirements. The general requirement is that these products should not present any particular hazards to children's safety or health under the intended and foreseeable conditions of use. More than 30 European standards have been published to ensure the safety of child use and care articles, 13 of which are referenced under the General Product Safety Directive. The main standards for chemical safety are: EN 1400 (soothers), EN 14350--2 (drinking equipment), EN 12868 (nitrosamines and nitrosatable substances) and EN 12586 (soother holders). A CEN Technical Report (TR 13387--2) has been published setting out requirements for various chemical substances or substance groups. In addition, the REACH Regulation[126] (Annex XVII) sets out requirements for the maximum concentration of phthalates in children's articles.

A number of child use and care articles are intended for food contact, and must therefore comply with the legislation for food contact materials, such as baby bottles and the matching teat. Plastic food contact materials must comply with Regulation (EU) No 10/2011[127]. Until a few years ago, baby bottles were often made of polycarbonate, for which bisphenol-A is a raw material. Due to the suspected endocrine-disrupting properties of bisphenol-A, a regulation prohibiting polycarbonate baby bottles came into effect in 2011 (Regulation (EC) No 321/2011[128]). Soothers and teats are made of natural rubber (latex) or silicone rubber. Directive 93/11/EC[129] sets requirements for the release of nitrosamines and nitrosatable substances from soothers and teats There is no specific EU legislation for food contact materials made of silicone and rubber. In the Netherlands, national legislation for rubber food contact materials is included in the Commodities Act Regulation on Foodpackaging and Food-utensils, Part A, Chapter III: Rubber Products.

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[125] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. OJ L 11, 15.1.2002, p. 4–17.

[126] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. OJ L 396, 30.12.2006, p. 1-520

[127] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L12, 15.1.2011, p. 1-89. 1-89

[128] Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011 amending Regulation (EU) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles. OJ L87, 02.04.2011, p. 1-89. 1-2

[129] Directive 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N substances from elastomer or rubber teats and soothers. OJ L 93, 17.4.1993, p. 37–38.

Identification of relevant chemical substances

Between 2014 and 2018, the European notification system Safety Gate (Rapid alert system for dangerous non-food products) received 10,062 notifications relating to potentially high-risk consumer products. There were 2,562 (25%) notifications relating to the chemical substances category, in addition to other possible risk categories. During this period, only 24 Safety Gate notifications were published regarding the chemical safety of child use and care articles. By way of comparison: for toys, there were 1,094 notifications about chemical safety. This involved 16 notifications of excessive concentrations of phthalates. In particular, DEHP, and sometimes DINP, were mentioned. These substances were found in wristbands, toilet seat reducers, non-slip prints on baby sleeping bags, plastic bibs and plastic covers for pushchairs. There were also three Safety Gate notifications for excessive concentrations of flame retardants (TCEP, TCDP) in children's textile articles. These concerned a mattress, a pram and a car seat. There was also one Safety Gate notification for excessive release of chromium(VI) from baby shoes and one notification for excessive concentrations of lead, barium and chromium in a stair gate.

No Safety Gate notifications were found about the chemical safety of child use and care articles such as baby bottles, soothers, teats, soother holders and eating and drinking equipment. Babies and young children are likely to put these categories of products in their mouth. Hence, the chemical safety aspect is very important. Based on the relevant literature and studies conducted by the NVWA, the possible chemical substances contained in these product categories have been identified.

Exposure

Exposure to substances from child use and care articles can occur via different routes: oral, dermal and inhalation. Oral exposure can occur via food, but also through sucking or ingestion of material (e.g. scraped paint). In addition, there is dermal contact with these articles as well as possible oral exposure through hand-to-mouth contact. Finally, substances from child use and care articles may evaporate and therefore be inhaled by a child. For child use and care articles, the oral route will be the main route of exposure.

Risks

Baby bottles

For babies, there may be a relatively high intake of food that has been in contact with baby bottles. In 2011, the prohibition on polycarbonate baby bottles came into effect. Since then, baby bottles are being made from other materials, such as polyethersulfone, polypropylene, silicone and copolyester (Tritan®). Research by the Belgian government has shown that substances migrate from these alternative materials in low quantities, below the specific migration limit of these substances (Onghena et al., 2014; Onghena et al., 2016). The identified substances include: alkanes, phthalates, antioxidants (Irgafos 168, degradation products of Irganox 1010 and Irganox 1076). There was no detectable migration of bisphenol-A, bisphenol-F and bisphenol-S. However, some of these substances were not authorised within Europe in accordance with the Plastics Regulation (Regulation (EU) No 10/2011). Studies on the influence of use in relation to migration, based on five successive migration tests, showed that the migration of these substances decreases over time to a negligible level.

A specific standard has also been published for baby bottles, i.e. EN 14350:2. EN 14350:2 The current standard dates back to 2004, well before the prohibition on polycarbonate baby bottles was published. A new draft standard was prepared in 2018. This contains additional requirements for the release of heavy metals, both from the bottle and from the decoration on the outer surface of the bottle. For this, the same limits and test methods are used as for toys.

Soothers and teats

The teats available on the Dutch market are almost all made of silicone rubber and, to a lesser extent, latex rubber. Nitrosamines and nitrosatable substances may be present in latex rubber. These are suspected carcinogenic substances. These substances are not added to the material as such but are formed during the vulcanisation process from the added carbamates (accelerators).

Silicone teats do not normally contain nitrosamines or nitrosatable compounds, since no accelerators such as carbamates are used. Specific standards with chemical safety requirements have been developed for soothers as well as teats. EN 1400 applies to soothers and EN 14350-2 to teats that are part of drinking equipment. The chemical requirements for silicone soothers and teats in both the standards relate to the migration of heavy metals, concentration of formaldehyde, colour fastness and concentration of volatile substances. The test for the concentration of volatile substances appears to be more of a general quality requirement than something related to chemical safety. There is also a specific standard for determining the release of nitrosamines and nitrosatable substances: EN 12868.

A study by the NVWA found that soothers and teats made of silicone were available on the Dutch market (Bouma et al., 2003). Traces of nitrosamines were found in some silicone products, but this was well below the established limit. In one of the two rubber products examined, the migration of a nitrosatable substance was above the limit. The other rubber product contained MBT (mercaptobenzothiazole). Silicone soothers and teats also contain siloxanes. The migration of siloxanes has not been established. The standards (EN 1400 and EN 14350-2) lay down requirements for siloxanes, where this is considered as an indicator of the quality of the silicone material.

Mouth shields for soothers

Soothers are fitted with a so-called mouth shield. This prevents the soother from being swallowed by a baby or small child. For this reason, requirements have been specified regarding the size of the mouth shield and the ventilation holes. Chemical safety is also very important, as children may have soothers in their mouths for long periods of time.

In 2009, the NVWA carried out a market study on the safety of soothers and soother holders (VWA, 2010a). Most mouth shields for soothers were made of polycarbonate. Some were made of polypropylene. There was no detectable migration of bisphenol-A from the polycarbonate mouth shields. The polypropylene mouth shields were screened for the presence of other substances. Phthalates (DEHP, DNOP, DBP) were found in a number of mouth shields, but all were below the legal limit of 0.1% by weight. In 2009, the German BfR conducted a study on the release of bisphenol-A from soothers. In Germany too, no demonstrable release of bisphenol-A has been found (BfR, 2009).

In 2017, a study on the safety of soothers and soother holders was conducted as part of a PROSAFE Joint Action project (PROSAFE, 2018c). Eleven Member States (including the Netherlands) and Iceland participated in this project. The focus was on carrying out physical and mechanical studies. A total of 12 soothers were chemically tested for the migration of 2-mercaptobenzothiazole (MBT), antioxidants, formaldehyde and bisphenol-A. In addition, the colour fastness and the concentration of volatile substances were studied. The tests were carried out based on the requirements for these substances as stated in EN 1400. All the tested soothers met the requirements.

Soother holders

Soother holders are made of various materials, such as textile, metal, plastic and wood. The biggest safety concern for soother holders relates to physical and mechanical safety. In particular, the maximum length (in connection with the possibility of strangulation) and integrity (in connection with the possibility of choking on small parts) is of great importance. In addition, a child may also put a soother holder into his or her mouth. This is why EN 12586 lays down requirements for chemical safety. This standard includes requirements relating to heavy metals, nickel release, formaldehyde, plasticisers, colouring agents, primary aromatic amines, monomers and wood preservatives. Some soother holders serve a dual function because of the addition of a toy element (e.g. a soft toy). In that case, the product must also meet the requirements for toys.

The 2009 study on the safety of mouth shields for soothers (VWA, 2010a) also examined soother holders. The plastic parts were screened for the presence of substances. Some plasticisers were found, but these were below the legal limit of 0.1% by weight.

In the PROSAFE study, 12 soother holders were also examined for chemical safety in accordance with EN 12586 (PROSAFE, 2018c). Tests were carried out for the release of heavy metals, nickel,

formaldehyde, dyes (primary aromatic amines), monomers and the concentration of phthalates and wood preservatives. All 12 soother holders tested complied with EN 12586 with respect to the chemicals included in the tests.

Children's cutlery, feeding utensils and drinking equipment

A special standard has been published for children's cutlery and feeding utensils: EN 14372. This standard is mainly focused on physical and mechanical safety. Another standard - EN 14350 - contains requirements for drinking equipment intended for babies and small children. Children's cutlery, feeding utensils and drinking equipment must comply with legislation on food contact materials in terms of chemical safety. Additional requirements are set forth in these standards relating to the concentration of phthalates, migration of heavy metals and colour fastness.

In 2005, the NVWA carried out a study on the chemical safety of children's cutlery, feeding utensils and drinking equipment (VWA, 2005a). Special attention was paid to cutlery and the spouts of drinking cups/non-spill mugs, since these come into contact with the mouth. These products are often made of soft materials, to prevent possible injury. The most commonly encountered material types were polyethylene, polypropylene and silicone. During this study, DEHP, antioxidants, photoinitiators, UV absorbers, lubricants, solvents, fatty acids, hydrocarbons and mono- and oligomers were found. However, in all cases the migration remained below the legal limit.

Children's high chairs

There is a special standard for high children's high chairs: EN 14988. Mainly physical and mechanical requirements are defined for children's high chairs. With respect to chemicals, the only requirements set are those relating to the migration of heavy metals (in accordance with EN71-3). However, it is possible that a child may suck the edge of a children's high chair or that food might come into contact with the chair tray. An NVWA study from 2015 examined the release of heavy metals (NVWA, 2015e). This showed that all the children's high chairs examined complied with the requirements for heavy metals as defined in the standard applied.

Baby mattresses and mattress covers

Babies and small children spend a lot of their time sleeping and therefore have intensive contact with their mattresses. A specific standard has been published for mattresses for cots and cribs: EN 16890. With respect to chemical safety, requirements have only been laid down for the migration of heavy metals, in accordance with EN71-3. Annex XVII of the REACH Regulation[130] sets out requirements for primary aromatic amines and phthalates. The POP Regulation[131] lays down requirements for certain brominated flame retardants. There was one Safety Gate notification regarding excessive concentrations of the flame retardant tris(1,3-dichloro-2-propyl) phosphate (TDCPP). This was present in a concentration of 89,700 mg/kg and the rate of migration was 500 mg/m^2. An American study of baby mattresses and mattress covers found that 17 of the 20 products tested contained at least one plasticiser in a range of concentrations from 1 to 35% (Boor et al., 2015). DEHP, DINP, diisononyl 1,2-cyclohexanedicarboxylic acid (DINCH) and bis(2-ethylhexyl) isophthalate (iso-DEHP) were frequently found. Flame retardants, including pentabromodiphenyl ether (pentaBDE) and triphenyl phosphate (TPP) and unreacted isocyanates (NCO) were also identified in baby mattresses made of polyurethane foam. However, the question is to what extent such products from the US market are actually available on the European market.

[130] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. OJ L 396, 30.12.2006, p. 1-520

[131] Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants. OJ L 158, 30.4.2004, p. 7-49

Conclusion

Nitrosamines and nitrosatable substances in soothers and teats

Nitrosamines and nitrosatable substances are potentially carcinogenic substances or the precursors thereof (Severity Category 4). Babies and small children have a high exposure to teats and soothers. Nitrosamines and nitrosatable substances occur almost exclusively in latex rubber. Almost all the soothers and teats available on the Dutch market are made of silicone rubber. An NVWA study has shown that almost all soothers and teats comply with the legal limits, which are based on health-based guidance values. However, this study is rather dated. The likelihood of exposure to nitrosamines and nitrosatable substances from soothers and teats is assessed as rare. The health risk from exposure to nitrosamines and nitrosatable substances from teats and soothers is assessed as low to medium.

Bisphenols in baby bottles and mouth shields for soothers

Bisphenols are potential endocrine disruptors (Severity Category 4). The intake of food from baby bottles can be very high for babies. Soother use is also high for some babies and toddlers. Studies conducted by the NVWA or other Member States have shown that almost all child use and care articles comply with the legal limits, which are based on health-based guidance values. For some chemicals, such as bisphenol-A, the product standards are outdated compared to the legal restrictions. Complying with the product standard does not always provide sufficient guarantee of safety. There are little or no data on the release of bisphenols other than bisphenol-A from baby bottles and soothers. Therefore, the likelihood of exposure to bisphenols from child use and care articles is assessed as rare. The health risk from exposure to bisphenols is assessed as low to medium.

Soother holders

Soother holders are made of different materials. The following substances may be present: heavy metals (Severity Category 3-4), nickel (Severity Category 3), primary aromatic amines (PAAs) (Severity Category 4), formaldehyde (Severity Category 3), phthalates (Severity Category 4) and wood preservatives (Severity Category 4). Soother holders are used mainly by young children (0--3 years). Children may have dermal and oral contact with soother holders. Studies show that soother holders meet the requirements of the standard. The likelihood is therefore assessed as rare. The risk is subsequently assessed as low to medium, depending on the severity.

Children's cutlery, feeding utensils and drinking equipment

Various additives are present in the plastic materials used for these articles, such as DEHP (Severity Category 4), antioxidants, photoinitiators, UV absorbers, lubricants (Severity Category 2). These are all authorised substances. These additives can potentially migrate into the food. However, NVWA research has shown that the migration of these substances remained below the legal limit. The likelihood is therefore assessed as rare. The health risk is subsequently assessed as low to medium.

Children's high chairs

Heavy metals are harmful substances and some are possibly neurotoxic (Category 3--4). Babies and small children sit regularly in high chairs. They may chew or gnaw on the top of the high chair and ingest scratched-off paint in the process. NVWA research shows that the scraped-off paint meets the requirements for toys. These requirements are based on health-based guidance values. The likelihood of exposure to heavy metals from children's high chairs is assessed as rare. The health risk is subsequently assessed as low.

Flame retardants, plasticisers and isocyanates in baby mattresses and mattress covers

Flame retardants are potentially neurotoxic substances (Severity Category 4). Plasticisers are potentially reprotoxic substances (Severity Category 4). In general, isocyanates are sensitising substances (Severity Category 3). Babies and small children sleep a lot and therefore have intensive contact with their mattress and mattress cover. American research demonstrates the presence of flame retardants, plasticisers and unreacted isocyanates. There are no data available for mattresses in the Dutch market. The likelihood of exposure to these substances from

mattresses is assessed as rare. The health risk from substances in baby mattresses and mattress covers is therefore assessed as low to medium.

5.4.2. Chemical risks of biocidal products and plant protection products

According to the definition provided in the Biocidal Products Regulation (Regulation (EC) No 528/2012[132]), biocidal products are substances or mixtures of one or more active substances intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on, any harmful organism by any means other than mere physical or mechanical action. The term 'harmful organism' means any organism that has an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, on animals or the environment. These are usually microorganisms such as bacteria, viruses and fungi, but may also include, for example, insects and rodents.

Active substances in biocidal products can be harmful to humans, animals and the environment. Examples include disinfectants, articles treated with biocidal products[133] such as textiles (so-called treated articles), wood preservatives and fungicides in water-based paints. Biocidal products have a very wide range of applications, both for the professional and personal purposes. They are divided into 22 product types[134]. Four main groups can be distinguished:

1. Disinfectants: these are intended to kill bacteria, fungi and other microorganisms. They may include soaps or liquids to disinfect the skin, as well as products for disinfecting hospital floors, stables, feeding troughs, swimming water and drinking water and for fighting algae.
2. Preservatives: these inhibit the growth of bacteria, fungi and other microorganisms and ensure that perishable products can be stored and used for longer periods of time. Examples of non-food applications include windshield wiper fluid, water-based paints, cleaning agents, woodworm control agents, textiles and fungicides in the construction industry.
3. Pesticides: these are used to control or repel annoying or harmful pests. Examples include ant repellents and rodenticides, cat deterrents, mosquito repellents and insecticides to kill insects such as wasps. Pesticides that are specifically intended to protect plants are called plant protection products. These include pesticides against weeds, snails, aphids and fungi. Plant protection products are not covered by the product types of the Biocidal Products Regulation, but are regulated separately (see below).
4. Other biocidal products include antifouling agents: these are products designed to prevent the growth and deposition of organisms on hulls of ships or other structures used in the water.

Plant protection products

Plant protection products should be distinguished from biocidal products. These products are intended to ensure the normal development of plants and are regulated by the Plant Protection Products Regulation (Regulation (EU) No 1107/2009[135]). These products are used, for example, to control fungi, insects and weeds. Slug pellets and herbicides are examples of plant protection products that fall under the consumer products category.

Legal framework

The Biocidal Products Regulation (Regulation (EC) No 528/2012) is in effect since 1 September 2013. In the Netherlands, this Regulation, together with the Plant Protection Products Regulation, has been implemented in the Plant Protection Products and Biocides Act (*Wet gewasbeschermingsmiddelen en biociden, Wgb*). Active substances in biocidal products imported into or manufactured in the EU must be reported to ECHA. After studying and assessing the efficacy and safety for humans, animals and the environment, the products are authorised by placing them on a list of permitted substances. Subsequently, entrepreneurs who wish to market

[132] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. OJ L 167, 27.6.2012, p. 1–123.
[133] https://www.ctgb.nl/biociden/aanvraag-indienen/afwijkende-producten/treated-articles
[134] https://www.ctgb.nl/biociden/aanvraag-indienen/afwijkende-producten/productsoorten
[135] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the making available on the market and use of plant protection products. OJ L 309, 24.11.2009, p. 1–50.

the plant protection product or biocidal product in the Netherlands must submit an application for product authorisation.

In the Netherlands, the Dutch Board for the Authorisation of Plant Protection Products and Biocides (*College voor de toelating van gewasbeschermingsmiddelen en biociden, Ctgb*) assesses whether plant protection products and biocidal products are safe for people, animals and the environment. Only authorised substances may be marketed on the Dutch market. These can be recognised by the number starting with 'N' displayed on the label.

Identification of relevant chemical substances

Between 2014 and 2018, Safety Gate received 10,062 notifications relating to a potentially high-risk consumer product. Of these notifications, 2,562 (25%) related to the chemical substances category, in addition to other possible risk categories. The Safety Gate system was searched for notifications regarding the chemical safety of biocidal products. The search was carried out with the term 'chemical product', followed by 'product' for each year. Additional search terms included 'biocide', 'biocidal' and '528/2012'. There was only one notification regarding an unauthorised biocidal product, i.e. anti-mosquito patches for children. Subsequently, the search was conducted using the terms 'chemical product' and 'plant protection' and '1107/2009'. This did not produce any results.

The RIVM report (Woutersen et al., 2019b) shows that the ISA database contains 92 substances that occur in products entered in the database as biocidal products, plant protection products or veterinary medicines and that are sold in DIY shops. The RIVM website[136] was consulted to identify the functional substance group and chemical substance group to which the substance belonged. If this information could not be found there, this search was continued on the internet. Next, the ECHA database[137] and the EU Pesticides Database[138] were consulted to check whether the substance has been authorised as an active substance in accordance with the Biocidal Products Regulation or the Plant Protection Products Regulation.

In addition, the results of an NVWA study on biocidal products were also examined. The annual reports of the NVIC were also consulted for information requests on biocidal products.

Exposure

Exposure to biocidal products depends on the way in which the active substance is applied. This may be in the form of a liquid or a spray. This results in dermal or inhalation exposure. In the case of treated articles, the active substance may also be integrated into the product, such as in the case of anti-bacterial textiles. Wearing this type of textile therefore involves prolonged skin contact with an active substance.

NVIC data

Every year, the NVIC receives tens of thousands of information requests relating to incidents of human or animal poisoning. By recording these information requests, it is possible to identify trends in the frequency of poisonings with specific substances. Figure 3 summarises the number of reported exposures (%) to pesticides and disinfectants from 2014 to 2018 (NVIC, 2015;2016;2017;2018;2019b).

[136] https://rvszoeksysteem.rivm.nl/
[137] https://echa.europa.eu/information-on-chemicals/biocidal-active-substances
[138] https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN

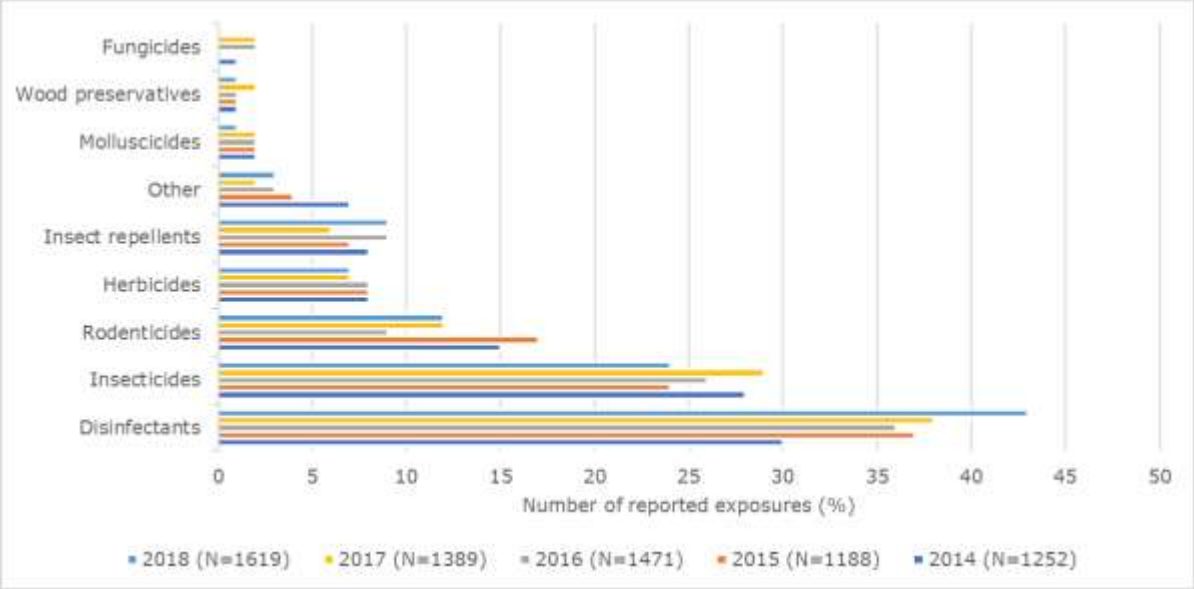

Figure 3 Overview of the number of reported exposures (%) to pesticides and disinfectants across the various product groups in the pesticide and disinfectant category from 2014 to 2018

Most exposures to pesticides and disinfectants occurred among children aged 0-4 years and adults aged 18-65 years. Most of the reports concerned potential intoxications with disinfectants. Surface disinfectants were the agent/product with the highest number of reports.

Water disinfectants

The number of exposures to water disinfectants increased from 84 in 2014, to 120 in 2015, to 143 in 2018 (NVIC, 2016;2019b). In particular, there has been an increase in the number of reports of incidents involving chlorine tablets used to disinfect small swimming pools. Chlorine tablets are available on the market to maintain the water quality of private pools in the garden. These tablets contain chloroisocyanuric acid or chloroisocyanurates. The most common manner of exposure is via the inhalation of chlorine gas when opening the package. Chlorine gas may be generated if the tablets are not stored in a completely dry place.

Rodenticides

In 2015, the NVIC reported that particularly young children were being exposed to molluscicides, rodenticides, insect repellents and insecticides. These are often products that are used in and around the home, in places that are easily accessible to children (e.g. slug pellets in the garden or mosquito repellents in the bedroom) (NVIC, 2016). In 2018, there was an increase in the number of consultations for exposure to alpha-chloralose-based rodenticides. The increase was due to the expiry of re-registration of anticoagulant-based rodenticides intended for private purposes. The mechanism of action of alphachloralose is different from that of anticoagulants: instead of interfering with the clotting mechanism of blood, alpha-chloralose results in a decreased level of consciousness and a drop in body temperature (NVIC, 2019b).

Imidacloprid & non-cyanopyrethroids

The number of reported exposures to imidacloprid almost halved in 2017 compared to previous years (29 in 2017, 45 in 2016 and 56 in 2015). Besides being used as a plant protection product, imidacloprid is also used as an anti-flea agent for pets. It is possible that negative publicity about this substance has influenced consumers and reduced the sales of products containing imidacloprid. In this context, it is notable that the number of exposures to non-cyanopyrethroids has actually increased (from 96 in 2016 to 129 in 2017). Perhaps these are being used as a substitute for imidacloprid (NVIC, 2018).

Cyanopyrethroids

The number of cases of exposure to cyanopyrethroids has significantly increased: from 45 in 2017 to 78 in 2018 (NVIC, 2019b). This group of insecticides is used for controlling the box tree moth and other insects.

Risks

The safety of these products for humans, animals and the environment is assessed in advance by the Ctgb. Health risks may occur if the product is not used properly, such as if it is not diluted according to the instructions. For unauthorised biocidal products, there is often no information about either the efficacy or safety. These products may pose a risk.

ISA database

The products listed in the ISA database have been used for the assessment (Woutersen M, 2019). For this, the RIVM has prioritised 274 potentially hazardous substances. The ISA database lists 92 substances that are present in biocidal products, plant protection products or veterinary medicines. These 92 substances come from different substance groups:

- Solvents
- Preservatives
- Active substances for biocidal products
- Active substances for plant protection products

Solvents

Solvents can be divided into various chemical groups:

- Benzenes and alkylbenzenes
- Glycol ethers
- Alchohols
- Ketones
- Petroleum derivatives
- Amides
- Phenols
- Hydrocarbons
- Halogenated hydrocarbons

Preservatives

The ISA database lists five substances as preservatives. Some substances can be classified as preservatives as well as biocidal active substances. The difference lies in the concentration levels. Of the five substances, two are not authorised under the Biocidal Products Regulation. These are:

- 4-Chloro-2-methylphenol
- Benzalkonium chloride

Active substances for biocidal products

The biocidal products category lists 36 different active substances. Most of these substances (29) are authorised by ECHA. It has not been checked whether a Dutch authorisation also exists, because the actual products concerned and their applications are not known. Six of these substances are not authorised under the Biocidal Products Regulation. These are:

- Naphthalene
- Foxim
- Benzalkonium chloride
- Resorcinol
- Triadimenol
- Trichlorfon

Therefore, based on the ISA database, unauthorised biocidal products are available in the DIY segment. However, the actual products involved, the claims made by them or the application for which the product is used are not known since this is an anonymised database. It is therefore

impossible to estimate the level of exposure or carry out a risk assessment based on that. It has not been further examined whether the substances authorised in Europe are also authorised in the Netherlands.

Active substances for plant protection products

A total of 27 different active substances are present in the list of products falling under the category of plant protection products. A number of these substances (15) are authorised as plant protection products. It is impossible to check whether or not these are also authorised in the Netherlands, because the actual products concerned and their applications are not known. There are also a number of substances in the list that are not authorised as plant protection products. The following 12 substances were present among the plant protection products, even though these products are not authorised according to the EU database:

- Amitraz
- Amitrole
- Allethrin
- Chlorothalonil
- Chlorpropham
- Difethialon
- Dimethoate
- Permethrin
- Propiconazole
- Thiram
- Triadimefon
- Triadimenol

Based on the ISA database, unauthorised plant protection products are available in the DIY segment. However, the actual products involved, the claims made by them or the application for which the product is intended are not known since this is an anonymised database. It is therefore impossible to estimate the level of exposure or carry out a risk assessment.

Veterinary medicinal products

Veterinary medicinal products are also present within the DIY segment. The database listed 10 substances that fall under this product category. This included both solvents and active substances. Veterinary medicinal products fall under a different legislation and are beyond the scope of the consumer products domain, and hence they are not discussed further here.

NVWA study on biocidal products: hand disinfection

In 2018, the NVWA carried out a market study on hand disinfectants (NVWA, 2019b). Of the 47 hand disinfectants examined, 60% were not authorised by the Ctgb; their efficacy and safety had not been tested. Of the 22 authorised disinfectants, two-thirds lacked the mandatory information. In particular, the hazard information was missing, followed by the instructions for use and the user manual. In three cases, the composition did not correspond to the authorisation, resulting in a different effect than when the Ctgb tested the product. In 70% of the cases, the product was not allowed to be sold as a disinfectant in shops or on websites. Online shops sometimes offer hand disinfectants that are not authorised in the Netherlands, but are authorised in other European countries. Active substances used in hand disinfectants are: ethanol, 1-propanol, 2-propanol, chlorhexidine digluconate, sodium hypochlorite, hydrogen peroxide, didecyldimethyl ammonium chloride (DDAC), benzalkonium chloride, 2-phenylphenol, triclosan, and limonene.

The NVWA market survey of hand disinfectants confirms the impression that emerged from the ISA database, namely that unauthorised biocidal products (and plant protection products) are available on the Dutch market. Unauthorised products may pose a health risk. These products have not been tested for safety and efficacy. In addition, products that contain active substances used as biocidal products or plant protection products, but are not placed on the market as such may pose a risk to consumers due to improper use, and through that, exposure to these substances.

Conclusion

Active substances for biocidal products and plant protection products generally have harmful effects on both humans and the environment. The severity of the health effect is assessed as long-term and irreversible (Severity Category 3). The ISA database shows that the DIY segment within the Dutch market may offer biocidal products and plant protection products containing unauthorised substances. The impression that unauthorised biocidal products are present on the consumer market is confirmed by the NVWA study. The information requests from the NVIC show that there is accidental exposure of children to biocidal products. Most of the reports related to potential intoxications with disinfectants, particularly chlorine tablets. Biocidal products and plant protection products are not products that are used frequently. Consumers are expected to be aware of the fact that hazardous substances are present and to therefore use the product in accordance with the instructions for use, with or without the use of personal protective equipment. If used in accordance with the instructions, the risk is assessed as low. If used incorrectly, the risk may be considerably higher. The likelihood of exposure to unauthorised active substances is assessed as occasional. Unauthorised biocidal products and plant protection products may pose a risk if consumers are exposed to active substances in an unsafe manner. This risk is assessed as medium to high.

5.4.3. Chemical risks of chemical substances in consumer products

All consumer or other products contain chemical substances. Chemical substances can be offered as single substances, as part of chemical mixtures of one or more active chemical substances, and in the form of objects. Important product groups are paints and lacquers, adhesives and sealants, detergents and cleaning products, construction chemicals and automotive products. In addition, there are chemical substances in certain objects (not specifically chemical products, but objects that are given a special shape, surface or pattern during production that determines the function of the object to a greater extent than the chemical composition). In most cases, chemical substances are not intended to be released from these objects (NVWA, 2016g).

Legal framework

The REACH Regulation[139] regulates the registration obligation and safety assessment of substances produced within or imported from outside the EU. REACH stands for Registration, Evaluation, Authorisation and restriction of CHemicals. Chemical substances are registered by ECHA. Based on the REACH Regulation, chemical substances can be placed on three different lists:

1. List of candidate substances for authorisation
2. List of substances subject to authorisation (Annex XIV, REACH)
3. List of substances and their restrictive measures (Annex, XVII, REACH)

Authorisation means that European approval has been granted for the use of a substance. Unauthorised substances may not be used.

The CLP Regulation[140] (classification, labelling and packaging) is based on the Globally Harmonised System (GHS) of the United Nations. The Regulation lays down detailed criteria for labelling elements: pictograms and standard warning sentences for hazards, prevention, response, storage and disposal for each hazard class and category. Corrosive chemicals are indicated by a hazard symbol for corrosive substances displayed on the packaging; for such chemicals, contact with the skin must be avoided by wearing suitable gloves. Similarly, the packaging of flammable gases and vapours, liquids, aerosols and solids display a hazard symbol for flammable substances.

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[139] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. OJ L 396, 30.12.2006, p. 1-520

[140] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1-1355

Some substances or mixtures must be provided with a Child Resistant Fastening (CRF). A Tactile Warning of Danger (TWD) enable blind and visually impaired people to determine whether a product contains a hazardous substance or mixture. Table 34 and Table 35 give an overview of the hazard class or category for which a Child Resistant Fastening or Tactile Warning of Danger is required.

Table 34. Hazard classifications that give rise to the CLP provisions for Child Resistant Fastenings and/or Tactile Warnings of Danger

Hazard class, category	Child Resistant Fastening	Tactile Warning of Danger
Acute toxicity 1--3	X	X
Acute toxicity 4		X
STOT-SE 1	X	X
STOT-SE 2		X
STOT-RE 1	X	X
STOT-RE 2		
Skin Corrosion 1, Subcategories 1A, 1B and 1C	X	X
Respiratory Sensitisation (Category 1, Subcategories: 1A and 1B)		X
Aspiration Hazard 1 ***It should be noted that a CRF and TWD are not required if the substance or mixture is supplied as an aerosol or in a container fitted with a fixed spray and if the substance or mixture is not classified for any other hazard that gives rise to the need for a CRF or TWD***	X	X
Mutagenicity in Germ Cells 2		X
Carcinogenicity 2		X
Reproductive Toxicity 2		X
Flammable Gases 1 and 2		X
Flammable Liquids 1 and 2		X
Flammable Solids 1 and 2		X

Table 35. Substances that immediately give rise to the need for CLP provisions for Child Resistant Fastenings and/or Tactile Warnings of Danger if they are present in the indicated or in a higher concentration in other substances or mixtures

Name of the substance	Concentration limit	Child Resistant Fastening	Tactile Warning of Danger
Methanol	3%	X	X*
Dichloromethane	1%	X	X**

* It should be noted that methanol mixtures above a certain concentration also require a Tactile Warning of Danger, since these mixtures must then be classified under Flammable Liquid Category 2, STOT-SE Category 1 or 2.

** In addition, mixtures containing dichloromethane in concentrations greater than 1% would be classified as Carcinogenic Category 2, and these would therefore require a Tactile Warning of Danger.

Under the CLP Regulation[141], companies in the Netherlands that make hazardous products available on the market are obliged to notify the NVIC of the composition of these products and the relevant safety information. Hazardous products display hazard symbols on the label. The NVIC uses this product-specific information to assess the severity of exposure and inform professional care providers about the health effects and treatment options for incidents of poisoning involving these hazardous products.

Detergents must not only comply with the obligations under REACH and the CLP Regulation but also with the Detergents Regulation (EC) No 648/2004[142]. This Regulation requires that detergents should contain only surfactants that are fully biodegradable. It is also mandatory to provide information on the label (for consumer products) about the ingredients and the presence of possible allergenic substances (preservatives and allergenic fragrances).

Identification of relevant substances

Between 2014 and 2018, Safety Gate received 10,062 individual notifications relating to potentially high-risk consumer products. Of these notifications, 2,562 (25%) related to the chemical substances category, in addition to other possible risk categories. For chemical substances in consumer products, there were 134 notifications of deviations. For this, the notifications in the following categories were searched specifically with the keyword 'REACH': chemical products, construction products, decorative articles, electrical appliances and equipment, gadgets, hand tools, hobby/sports equipment, kitchen/cooking accessories, motor vehicles, other and stationery. Most of the notifications concerned halogenated hydrocarbons (21%), asbestos fibres (20%) and heavy metals (19%).

In the ISA database, products are classified based on different categories. For chemical substances in consumer products, the following categories were examined in greater detail: battery pack or battery, construction product, maintenance product, detergents, animal care, gases in pressurised cylinder, windscreen wiper fluid, technical fluid, paint products and objects. The categorised products contain 239 unique chemical substances. These chemical substances can be categorised into chemical substance groups, such as petroleum derivatives, benzenes, acrylates, alcohols, boron compounds, phthalates, halogenated hydrocarbons, glycol ethers, isocyanates, isothiazolinones, metals, nonylphenols and organic acids.

Exposure

Exposure to chemical substances from consumer products can occur via different routes: oral, dermal and inhalation. Chemical burns occur when the skin comes into contact with aggressive chemicals, especially strong acids (including hydrochloric acid, sulphuric acid, nitric acid and hydrogen fluoride) or strong bases (including sodium hydroxide, calcium hydroxide, barium hydroxide, and potassium hydroxide). Chemicals that are swallowed or inhaled can also damage the oesophagus or lungs or other organs (Mekkes, 2017). Fire risks due to chemical substances in consumer products are discussed separately under the assessment of the physical risks of consumer products.

Risks

NVIC

The NVIC receives tens of thousands of questions each year about cases of poisoning of humans and animals. By recording these information requests, it is possible to identify trends in the frequency of poisonings with specific substances. Figure 4 summarises the number of reported

[141] Regulation (EC) No 1272/2008 of the European Parliament and of the council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1-1355

[142] Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents. OJ L 104, 8.4.2004, p. 1–35.

exposures (%) to household and DIY products across various product groups from 2014 to 2018 (NVIC, 2015;2016;2017;2018).

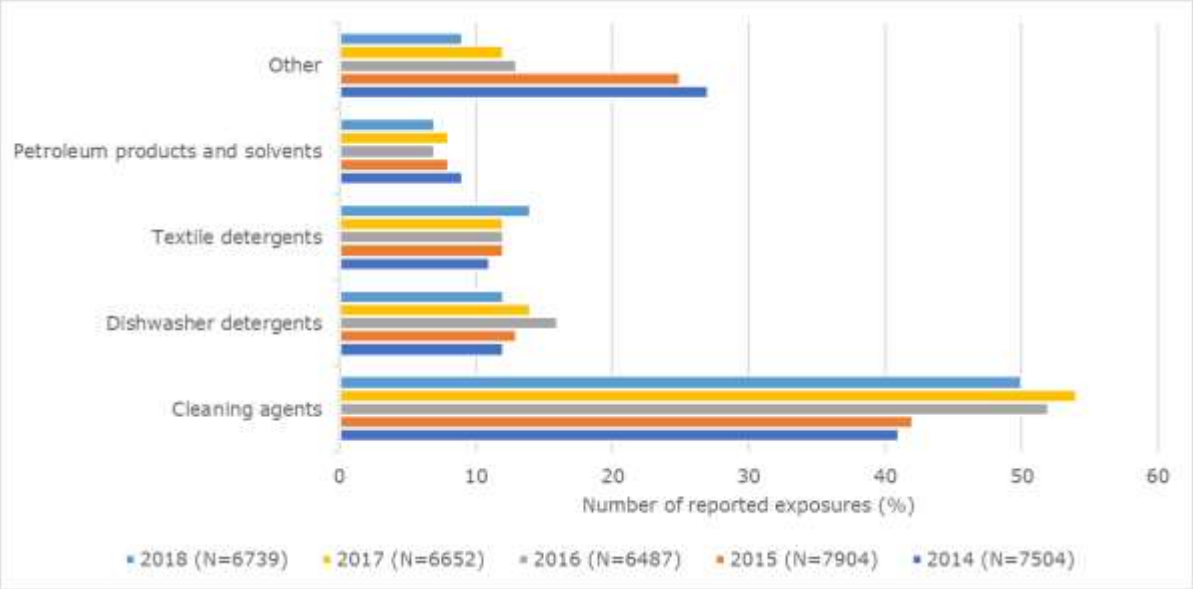

Figure 4 An overview of the number of reported exposures (%) to household and DIY products across the different product groups in the household and DIY products category from 2014 to 2018

The breakdown by different product groups was more extensive in the NVIC annual overviews of 2014 and 2015 than in the later annual overviews. For the sake of clarity, only the reported exposures to product groups that recur in all the annual overviews have been displayed. The product groups that do not appear in all the annual overviews have been added to the group called 'Other'. This also explains why the size of this group was relatively large in 2014 and 2015. Most exposures to household products occurred in children aged 0 to 4 years (NVIC, 2015;2016;2017;2018;2019b).

Chlorine-containing products

In 2014 and 2015, there were a greater number of reports relating to chlorine-containing products than in previous years (NVIC, 2015;2016). A large proportion of the reports involved persons aged 13 and above. Some of these involved people who were using chlorine-containing products incorrectly, which resulted in them being exposed to chlorine fumes (NVIC, 2015). The chlorine-containing products category contains the highest number of reports for the period from 2014 to 2018.

Liquid textile detergents

In 2014, there were a greater number of reports relating to liquid textile detergents than in 2012 and 2013. The NVIC attributes a high exposure of children to liquid textile detergents to the growing popularity of liquid caps (Wijnands-Kleukers et al., 2014; NVIC, 2015). In 2015, NVIC received 279 reports of exposure to liquid caps, most of which involved oral exposure (NVIC, 2016). The number of exposures of children up to 12 years of age to textile detergents in capsules increased from 222 in 2016 and 223 in 2017 to 296 in 2018 (NVIC, 2019b). The NVIC had not expected this increase, given the various preventative measures (including a national safety campaign).

Hand dishwashing liquids

In 2014, there were a greater number of cases of exposure to hand dishwashing liquids among children up to 12 years of age than in 2013. This is probably due to the use of hand dishwashing liquids to make bubble mixtures (NVIC, 2015).

Fragrance oil

In 2014, there were a greater number of reports about fragrance oil than in 2013. This is a type of oil that can spread a pleasant fragrance through scented sticks or when heated with a special

burner. Most reports involved young children who had drunk the oil. There were also reports of children getting fragrance oil in their eyes. Fragrance oils usually contain volatile oils and sometimes glycols (NVIC, 2015).

Descalers

An important finding in 2015 concerned the ingestion of descalers because people had forgotten that a water kettle or coffee maker had been treated with a descaler. Descalers usually contain an acid (citric acid or sulfamic acid) (NVIC, 2015).

Dishwasher products

In 2015, there were a greater number of reports involving dishwasher products than in 2013 and 2014. These reports often related to children under the age of 13 who had ingested a whole or part of a dishwasher tablet. A dishwasher tablet contains irritant compounds that, when ingested, can lead to problems in the mucous membranes in the mouth, throat and gastrointestinal tract and cause vomiting (NVIC, 2015).

Unblockers

In 2015, there were a greater number of reports about persons aged 13 and above relating to unblockers than in 2013 and 2014. Most case of exposure were via skin contact, although ingestion, inhalation and eye contact have also been reported. Unblockers often contain sodium hydroxide or sulphuric acid. Both of these compounds are highly corrosive and cause tissue damage in case of exposure (NVIC, 2015).

DIY products

In 2018, the Danish EPA studied the potential health risks arising from the use of 38 products that can be used in DIY projects. The Danish EPA studied three scenarios involving the renovation of wood floors, cement floors and bathrooms. Both water-based and solvent-based products were considered. Without proper precautions (ventilation and use of personal protective equipment), all the products examined pose a risk to health, except for two water-based paints (Danish EPA, 2018a). The Danish EPA's study is limited to three scenarios, but the report also identifies other scenarios that could potentially pose risks, if proper precautions are not taken. These include: renovation projects involving exposure to hazardous substances that were previously authorised (e.g. PCB-containing paints and sealants, paints containing asbestos, lead and mercury), renovation projects involving exposure to mineral dusts (e.g. cement grinding), use of spray paints and adhesives, use of hardwood indoors and outdoor use of organic solvent-based wood preservatives and paints (Danish EPA, 2018a).

In the United States, several NGOs have urged the US EPA to take immediate action to warn consumers about 1-bromopropane (1-BP) (NGO's, 2019). 1-BP is a solvent present in adhesives. The US EPA concludes in its draft risk assessment that 1-BP may pose a risk to consumers under certain use scenarios, such as use in adhesives or cleaning products (US EPA, 2019). In 2012, ECHA placed 1-BP on the candidate list for authorisation as a substance of very high concern (ECHA, 2012). From 4 July 2020, 1-BP may only be used if an authorisation has been requested and obtained for such use.

Household and cleaning products

The HERA (Human and Environmental Risk Assessment) project was initiated in 1999 by AISE (international Association for Soaps, Detergents and Maintenance Products) and Cefic (European Chemical Industry Council). As part of this initiative, risk assessments have been carried out for various ingredients in household cleaning products, which have revealed no or negligible risk for the consumer[143].

In 2010, the Danish EPA studied the risks of oven cleaners and ceramic hob cleaners. Products containing the solvents n-methyl-2-pyrrolidone, petroleum distillates, turpentine and dipropylene glycol monomethyl ether were assessed for potential health risks during use. The Danish EPA concluded that use of such cleaners does not pose a risk. An exception to this is the use of products containing turpentine in a poorly ventilated area (Danish EPA, 2010a). Nevertheless, the Danish EPA recommended the use of 'regular' cleaning products when cleaning ovens and hobs,

[143] See https://www.heraproject.com/RiskAssessment.cfm for more details.

because such products are cheaper and the special products generally contain more aggressive ingredients. It also recommended minimising the number of different cleaning products in private households, limiting the use of cleaning products in general, and taking proper precautions during use (gloves and ventilation) (Danish EPA, 2010a).

In 2010, the Danish EPA studied the risks posed by car interior maintenance products. Products were selected from the following categories: cleaning products (including fabric, vinyl and glass cleaners), care products (e.g. for leather upholstery), air fresheners and anti-fog products. The Danish EPA concluded that inhalation exposure to chemicals from maintenance products posed no health risk when the car is used for a short (fifteen minutes) or long (five hours) drive immediately after the application (about once a week) of the products. Regarding skin exposure, the Danish EPA concluded that the use of maintenance products posed no risk as long as the user washed his or her hands after use or used the product occasionally (every 14 days). The conclusion remained unchanged even when both inhalation and dermal exposures were considered together (Danish EPA, 2010b). Nonetheless, when using car interior maintenance products, the Danish EPA recommended the following: ensuring adequate ventilation when using the products, using the smallest possible amounts, avoiding inhaling the sprays and washing hands after use or wearing gloves (Danish EPA, 2010b).

In 2004, the Danish EPA studied the risks posed by car exterior maintenance products (cleaning products and waxes). It concluded that, in general, most products could be used without any problems. The use of some products could possibly cause dry skin or dizziness if proper precautions (gloves and ventilation) were not taken. In addition, a number of products contain substances that can cause an allergic reaction. The Danish EPA stressed the importance of taking proper precautions when using these maintenance products (Danish EPA, 2004).

Cleaning products and air fresheners contain fragrances. Depending on the type of product, the percentage of the fragrance can vary between 1 and 50%. Basketter and colleagues concluded that little clinical evidence was available for the development of contact allergy from the use of household cleaning products and air fresheners. Despite dermatologists' assumptions that these products may induce allergic contact dermatitis, there is no clinical evidence of this either (Basketter et al., 2015). The use of individual products did not cause any problems, but the use of multiple products (products from the same segment as well as from other categories such as cosmetic products) can potentially cause the fragrance concentration to become so high that this leads to allergic contact dermatitis (Basketter et al., 2015).

Exposure to isothiazolinones (preservative) via household detergents (e.g. detergent, fabric softener) and paints can cause contact allergy. The use of isothiazolinones in cosmetic products is regulated, but its use in other consumer products is not yet regulated (Aerts et al., 2017). Research conducted in Switzerland indicates that household detergents form a more significant source of exposure to isothiazolinones than cosmetic products (Garcia-Hidalgo et al., 2018).

Laughing gas

In 2016, the Front Office Food and Product Safety operated by the RIVM and the RIKILT Institute of Food Safety (*RIVM/RIKILT Front Office Voedsel- en Productveiligheid, FO*) performed a risk assessment to determine whether there are potential health risks associated with the use of laughing gas (nitrous oxide). The FO concluded that no health effects are expected in case of average recreational use of laughing gas, with fewer than 10 balloons filled with laughing gas per event, monthly or less. When used in much larger quantities and/or with much greater frequency (e.g. a few dozen balloons each week), neurological and haematological effects may occur due to vitamin B12 deficiency. The use of laughing gas may have consequences for the unborn child. Furthermore, the FO concluded that no other specific long-term health effects are known besides those observed in case of intensive but brief, more long-term or regular exposure (FO, 2016).

In 2019, at the request of the Ministry of Health, Welfare and Sport, the Assessment and Monitoring Coordination Centre for new drugs (*Coördinatiepunt Assessment en Monitoring nieuwe drugs, CAM*) carried out a risk assessment of laughing gas. This request stemmed from an increasing number of reports of chronic use of laughing gas and an increase in the number of health-related incidents. Laughing gas is mainly used by adolescents and young adults. In 2018, 6.9% of the general population aged 18 and above had used laughing gas at some point and 2.7%

had done so in the past year. Among 20-24 year-olds, the use-during-the-past-year component was five times higher (14.6%). In recent years, use of laughing gas has become more widespread in both cities and towns and has become mainstream. The product is used in a variety of socio-demographic groups, ranging from young people who have never used alcohol or drugs to partygoers with extensive experience of various intoxicants. In 2016, the use-during-the-past-year component among partygoers aged 15-35 was 37%, the highest use after cannabis and Ecstacy. There is no age limit applicable for using laughing gas as in the case of alcohol, and therefore this might be used as an alternative for alcohol by under-18s.

The CAM concluded that acute health effects are limited when used in a controlled manner as medication. Incidental neurotoxicity may occur after single use. There is no limit below which the recreational use of laughing gas would be termed safe. In many cases, chronic use appears to cause moderate or severe health damage, as a result of vitamin B12 deficiency. Vegetarians, the elderly and people suffering from irritable bowel syndrome are at increased risk of vitamin B12 deficiency. Subsequently, the CAM assessed the risks to user health and public health as low to high and noted an increase in the use of laughing gas (CAM, 2019).

Conclusions

The chemical substances domain within consumer products covers a large number of different products containing a large number of different chemicals. Information on the possible risks to consumer health is only available for DIY products and household and cleaning products.

In general, the use of DIY products and household and cleaning products does not pose a risk to consumers as long as appropriate precautions (ventilation, gloves or face masks) are observed. A remaining area of concern is the exposure of children aged up to 12 to textile detergents. The number of reports received by the NVIC is increasing despite various preventive measures.

Household and cleaning products contain fragrances and isothiazolinones (preservative) that can cause contact dermatitis. In the case of fragrances, exposure to multiple products from the same or different segments (e.g. cosmetic products) may pose a risk, because each individual source contributes to the overall exposure. While the use of isothiazolinones in cosmetic products is regulated, their use in household detergents is not. Therefore, the latter also forms an important source of exposure. The fact that a particular substance is regulated for a particular product is not sufficient to limit exposure if this substance is also used in another product.

DIY products and household and cleaning products are used by many consumers. The likelihood of a health effect due to exposure to the fragrances and preservatives contained in these products is assessed as rare, if precautions are taken. The damage to health resulting from the use of DIY products and household and cleaning products is assessed as long-term effects that are possibly irreversible. The combined assessment of likelihood and severity results in a low risk for the consumer. It is likely that consumers do not always take appropriate precautions when working with DIY products and household cleaners. Here, it is a behavioural aspect of the consumer that may increase the likelihood of a health effect, but such an effect is not attributable to the product.

Laughing gas is mainly used by adolescents and young adults. Within this group, the likelihood of health effects is assessed as occasional. The damage to health resulting from the use of laughing gas is assessed as usually reversible with medical treatment. Although in some cases there may also be long-term effects that are possibly irreversible. The combined assessment of likelihood and severity results in a medium to high risk for the consumer. In some situations, e.g. in traffic situations, the use of laughing gas may also be a risk to third parties.

5.4.4. Chemical risks of cosmetic products

Cosmetics are personal care products: products to take care of our body, keep it clean, protect it, keep it in good condition, make it more beautiful or make it smell good. So this includes not just makeup, but also products such as shampoo, hair dyes, toothpaste, deodorant, cream, shaving cream, soap, perfume and sunscreen. Almost everyone in the Netherlands uses cosmetic products: men and women, young and old. Cosmetic products can be divided into several categories: bath and shower products, makeup products, deodorant and antiperspirants, perfumes, hair care products, skin care products, oral care products, shaving products, soaps, sun care products, and

other products (e.g. baby wipes with lotion, foot care products such as foot scrubs, sprays and foot baths, talcum powder, and intimate hygiene products). Some cosmetic products are specifically designed for babies and children (NVWA, 2016f).

Cosmetic products are composed of different ingredients. These ingredients determine the desired characteristics of the product, such as odour, colour, acidity, spreadability, shelf life and effect. The Dutch Cosmetics Association (*Nederlandse Cosmetica Vereniging, NCV*) defines the following ingredient groups: fluoride, fragrances, colourants, preservatives, fruit acids, UV filters and surfactants (https://www.ncv-cosmetica.nl/).

Legal framework

The European Cosmetic Products Regulation[144] outlines the legal regulations that cosmetic products must comply with. These products cannot contain any of the substances listed in Annex II of the Regulation. Annex III lists the substances that may be used in cosmetic products if they fulfil certain conditions. In addition, cosmetic products may only contain the colourants, preservatives or UV filters listed in Annexes IV, V or VI. A substance classified as Carcinogenic, Mutagenic or Reprotoxic (CMR) Category 2 under the CLP Regulation[145] may, in some cases, be used in cosmetic products. However, for this the SCCS must have assessed the use of these substances in cosmetic products as safe.

Based on the composition of or a claim made by a product, cosmetic products may be classified as a medical device or medicine. If so, the Cosmetic Products Regulation is no longer applicable, and this product becomes subject to the Medical Devices Act (*Wet op de medische hulpmiddelen*) or the Medicines Act. Medical devices must have a CE mark. A marketing authorisation is required to market medicines. If a product cannot be classified as a cosmetic product, medical device or medicine, it is classified as a commodity and falls under the Commodities Act.

Identification of relevant substances

The Consumer Exposure Skin Effects and Surveillance (CESES) project was initiated by the RIVM in 2009 at the request of the NVWA and the Ministry of Health, Welfare and Sport (Ministerie van VWS). The aim of the project is to monitor unwanted and allergic reactions after the use of cosmetic products. Since 2015, consumer complaints are being reported to the NVWA. At present, the CESES database only contains reports from a number of dermatologists. Ninety reports were received during the period from October 2015 to October 2017. Most of the allergic reactions were caused by isothiazolinones (preservatives) and fragrances (Woutersen, 2018). There were also three reports of allergic reactions to acrylates and methacrylates in nail care products. This represents an increase compared to previous years (Woutersen, 2018).

A report by Woutersen et al. (Woutersen et al., 2019b) shows that the ISA database contains 10 substances that occur in products classified as cosmetic products sold at DIY shops. These mainly include solvents, fragrances and a preservative.

Between 2014 and 2018, Safety Gate received 10,062 individual notifications relating to potentially high-risk consumer products. Of these notifications, 2,562 (25%) related to the chemical substances category, in addition to other possible risk categories. For cosmetic products, 299 deviations were reported. About one-third of the notifications concern substances added to cosmetic products as preservatives. In addition, one-third of the notifications concern substances added as skin-whiteners. The remaining notifications relate to fragrances and colourants, softening agents, heavy metals and pharmacologically active substances. The latter category includes substances that are also used in medicines.

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[144] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59–209.

[145] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1-1355

The Danish Consumer Council has found several possible endocrine disruptors and allergens in body lotion. These include parabens, butylated hydroxytoluene (BHT), cyclopentasiloxane, hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC), DMDM-hydantoin and diazolidinylurea (AWChemAdvise, 2018).

The Danish EPA has found several perfluorinated compounds (PFAS) in cosmetic products. PFAS are added to foundations, moisturisers, eye shadows and shaving creams to lower the surface tension of the skin, so that the product can penetrate the skin better (Danish EPA, 2018b).

Exposure

Exposure to substances from cosmetic products can occur via different routes: oral, dermal and inhalation. Most cosmetic products are applied to the skin. Some products remain on the skin and are absorbed into it (leave-on products), while others are washed off (rinse-off products). Oral exposure occurs in case of products used inside the mouth (e.g. toothpaste or mouthwash) or applied to the lips (e.g. lipstick or lip balm). Inhalation occurs when vapours or aerosols are released during the use of a product (e.g. deodorant, hairspray or powder).

A survey among Dutch consumers (N=516) shows that the use of personal care products varies widely. Usage depends on gender, age, level of education and skin type. The frequency of use and the quantity of a product used each time also varies (Biesterbos et al., 2013).

Risks

The NVIC receives tens of thousands of questions each year about cases of poisoning of humans and animals. By recording these information requests, it is possible to identify trends in the frequency of poisonings with specific substances.

Figure 5 shows the number of reported exposures (%) to cosmetic products from 2014 to 2018. The category 'Other' includes products such as contact lens fluid (medical device) and depilatory cream (NVIC, 2015;2016;2017;2018).

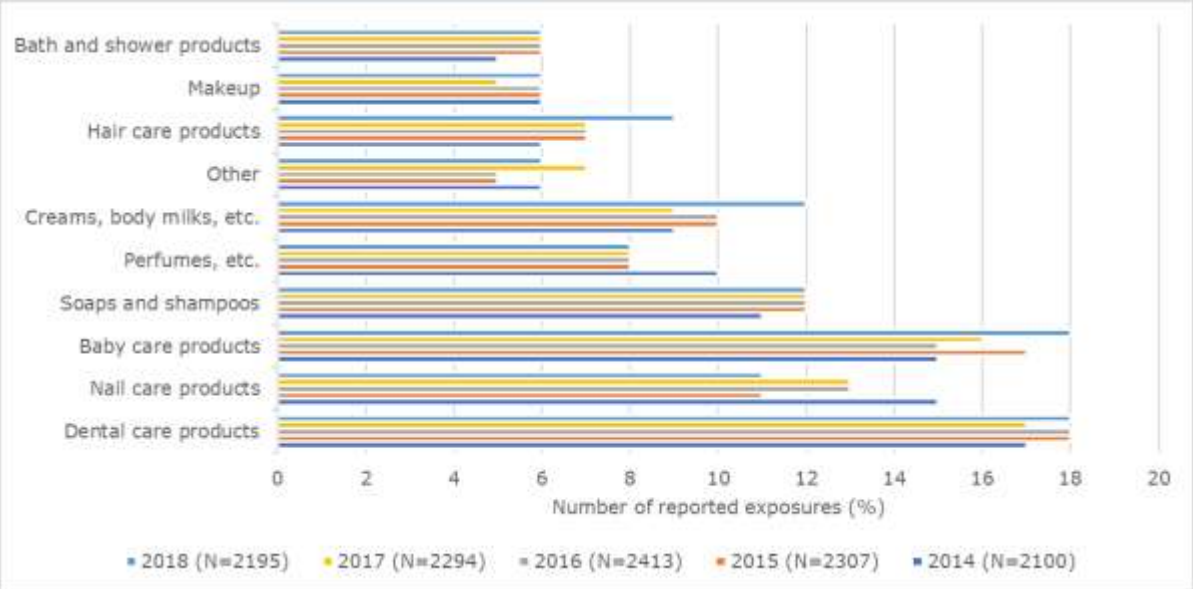

Figure 5 An overview of the number of reported exposures (%) to cosmetic products across different product groups in the cosmetic products category from 2014 to 2018 as reported to the NVIC

The majority of the exposures to cosmetic products involved young children aged up to four, mainly via oral exposure. The number of reports about toothpaste increased in 2015 compared to previous years (NVIC, 2015;2016). The reason for this increase is unclear. The most toxic ingredient in toothpaste is fluoride. In the period 2016-2018, toothpaste is the product with the highest number of reports (NVIC, 2017;2018;2019b). The number of exposures to nail polish remover decreased in 2015 (NVIC, 2016).

Acrylates

Acrylate monomers, including ethyl methacrylate (EMA) and hydroxyl methacrylate, are used in the application of gel or acrylic nails. The German BfR concluded that nail products containing high concentrations of acrylate monomers may cause contact dermatitis or irritation of the skin, mucous membranes and eyes. When used professionally in a nail salon, the risks can be minimised by avoiding skin contact and good ventilation. It is advised that products with high concentrations of methyl methacrylate should not be used (BfR, 2011).

Asbestos

Cosmetic products containing talc may be contaminated with asbestos fibres. In 2018, the NVWA was informed about talc-containing cosmetic products in which the Human Environment and Transport Inspectorate (IL&T) had found asbestos. Subseqently, BuRO issued an advisory report (BuRO, 2018b) and concluded that exposure to these products containing talc, in which asbestos was found, would be minimal provided that the exposure was for a limited amount of time. A screening of 296 products and the risk assessment show that asbestos is only rarely detectable in a product, and even then, the risk of inhalation exposure is very low. Therefore, it does not seem appropriate to prioritise intensive monitoring of asbestos via laboratory tests (BuRO, 2018b; NVWA, 2018).

Preservatives

In 2015, the Danish EPA studied the risks related to the use of preservatives in cosmetic products. It concluded that more attention needs to be focused on the sources of formaldehyde, because these sources are potentially sensitising and formaldehyde is classified as carcinogenic and mutagenic (Danish EPA, 2015b). Assuming a worst-case scenario where all sources of formaldehyde are present in cosmetic products used on a single day by both children and adults, the Danish EPA concluded that while DMDM hydantoin did not pose a risk, imidazolidinyl urea did (Danish EPA, 2015b).

A number of preservatives have been prohibited from cosmetic products in recent years, e.g. MI. The maximum permitted concentration of some preservatives has also been reduced. Almost no new authorised preservatives have been added. The range of preservatives to which a consumer is exposed is becoming smaller. As a result, there is an increase in the frequency of exposure to a particular preservative, which increases the likelihood of sensitisation to this preservative.

Phenylenediamine

Hair dyes may contain the allergenic substance p-phenylenediamine. Consumers can carry out an allergy test by applying the hair dye to their skin before actually dyeing their hair. The BfR has warned consumers that the concentration of p-phenylenediamine in the hair dye used in an allergy test is sufficient to sensitise someone (BfR, 2014d).

Pharmacologically active substances

Sometimes cosmetic products may contain pharmacologically active substances that are constituents of medicinal products, such as bimatoprost. Bimatoprost is a prostaglandin analogue that is prescribed in the Netherlands for the treatment of glaucoma. One of the side effects of bimatoprost is that it promotes the growth of eyelashes (Zorginstituut Nederland, 2019b). In 2018, the NVWA fined a chain of shops for selling an eyelash growth product containing bimatoprost. The product in question has been withdrawn from the market. The use of pharmacologically active substances that are constituents of medicinal products poses risks when used without medical supervision. Ignorance on the part of consumers could lead to interactions, in case cosmetic products and regular medicines are used at the same time.

In 2018, the NVWA examined hormone creams[146] sold via the internet. The creams are intended to reduce menopause symptoms in women and usually contain progesterone, dehydroepiandrosterone (DHEA), estriol or pregnenolone. The NVWA has asked the FO whether

[146] Currently, BuRO concludes that hormone creams do not fall under the scope of the Cosmetic Products Regulation. However, the exact status (medicine, medical device, cosmetic product or commodity) of these products remains unclear.

there are possible risks to public health when using these products without medical supervision. The FO concluded that the use of creams containing DHEA or estriol may pose a risk to menopausal women. An increased risk of cancer is expected in patients and ex-patients of breast cancer and/or hormone-sensitive cancer. With respect to the use of creams containing pregnenolone or progesterone, the FO concluded that risks to health cannot be excluded due to a lack of information and the existing contradictory information (FO, 2019).

As with medicines, the use of cosmetic or other products may cause side effects. From May 2015 to March 2019, the Netherlands Pharmacovigilance Centre Lareb received 77 reports about rubefacients[147]. These rubefacients can be purchased without a prescription at the pharmacy or via internet. The pharmacologically active substances methyl nicotinate and glycolsalicylate are responsible for local vasodilation, which makes the skin feel warm. The reports referred to allergic reaction, skin reaction and abdominal complaints. Lareb noticed that abdominal complaints arose even though the product was not applied to the abdomen. In 2017, the consumer information leaflet was updated (Lareb, 2019).

Fragrances

Fragrances may cause contact allergy. The prevention of contact allergy consists of two components, i.e. primary and secondary prevention. Primary prevention consists of preventing consumers from coming into contact with fragrances that could cause contact allergy by prohibiting the use of these fragrances in cosmetic products. Under secondary prevention, following a diagnosis, a consumer can try to avoid certain fragrances based on proper product information (Uter, 2017). Since, in case of primary prevention, a fragrance is specifically regulated for cosmetic products, consumers may still be exposed to that substance through other consumer products.

Isothiazolinones

The SCCS has issued advisory reports on the safety of use of methylchloroisothiazolinone (Mahony et al.) and methylisothiazolinone (MI) in cosmetic products (SCCS, 2009;2013a;2015). Based on these advisory reports, it was specified that the mixture methylchloroisothiazolinone/methylisothiazolinone (MCI/MI) could only be used at a low concentration (0.0015%) in rinse-off products from 2016[148]. This restriction has also been applied to methylisothiazolinone (MI) since 2017[149]. In 2016, the NVWA examined 152 eye creams for the presence and concentration of the MCI/MI mixture and MI. No MCI/MI was found in any of the eye creams. MI was found in six products, but at the time of the study (late 2016), these six products were in compliance with the legal requirements (NVWA, 2017h).

Metals

Aluminium salts in antiperspirants block the opening of sweat glands. The BfR studied the estimated absorption of aluminium through use of antiperspirants. It concluded that daily use of an antiperspirant containing aluminium on intact skin exceeded the TWI (1 mg/kg body weight) derived by EFSA. If the skin is damaged, e.g. by shaving, the exposure is higher and the TWI is exceeded even further (BfR, 2014b). Aluminium particles may irritate the skin. No irreversible toxic effects after dermal exposure have been described in the literature.

Recently, the BfR studied the total intake of aluminium salts by consumers via food, cosmetic products, food contact materials and medicines (BfR, 2019a; Tietz et al., 2019). In adults, cosmetic products (antiperspirants and teeth-whitening toothpaste) contribute largely to the total exposure. The total exposure exceeds the TWI. The BfR recommends reducing the use of cosmetic products containing aluminium (BfR, 2019a; Tietz et al., 2019).

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[147] Since rubefacients are not intended for skin care, these products are not covered by the Cosmetic Products Regulation but by the Commodities Act.

[148] Commission Regulation (EU) No 1003/2014 of 18 September 2014 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products. OJ, L 282 (26.9.2014), p. 1–4. 1–4.

[149] Commission Regulation (EU) No 2016/1198 of 22 July 2016 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products. OJ, L 198 (23.7.2016), p. 1–4. 10–12.

The SCCS has concluded that the use of aluminium compounds in cosmetic products is safe in the following amounts: 6.25% in deodorant (no spray) or antiperspirant (no spray), 10.60% in deodorant or antiperspirant (both in spray form), 2.65% in toothpaste and 0.77% in lipstick. According to the SCCS, aluminium exposure in the body through daily use of cosmetic products does not significantly contribute to the body burden. Exposure via food is the main contributor. The SCCS has not taken this contribution into consideration in its assessment (SCCS, 2020).

Microplastics

Polyethylene microplastics are added to exfoliators, shower gels and toothpastes to facilitate the cleaning effect. The size of the polyethylene particles is between 0.1 and 1 millimetre. The BfR studied whether skin absorption or oral ingestion of these particles might pose a health risk. Due to the size of the particles, there is not expected to be any absorption through healthy skin or through the gastrointestinal system. The BfR concluded that cosmetic products containing polyethylene microplastics did not pose a health risk (BfR, 2014c).

Mineral oils

According to the Cosmetic Products Regulation, mineral oils are allowed in cosmetic products if the complete refining history is known and if the raw material is not carcinogenic or the distillate has been tested with a specific method (IP346). The BfR studied the health risk from dermal exposure to mineral oils (MOSH and MOAH) in cosmetic products. It concluded that no health risk was expected because cosmetic products contained a low concentration of MOAH and MOSH is barely absorbed through the skin (BfR, 2018). It also concluded that no health risk was expected due to oral ingestion from the use of, for example, lip balm. But in this case, the product must meet the requirement of Cosmetics Europe, i.e. only those mineral oils may be added for which EFSA has established an ADI (BfR, 2018).

Parabens

In April 2016, the NVWA sampled 76 baby lotions and baby creams. These included 37 products for use in the nappy area and 39 care products for the entire body. Only leave-on products were sampled. The NVWA laboratory examined the baby lotions and creams for the presence and concentrations of the following parabens: methyl-, ethyl-, propyl- and butylparaben and salts thereof (parabens that may be used) and isopropyl, isobutyl, phenyl, benzyl and pentylparaben (parabens that may not be used). One of the 76 products studied contained parabens, including propylparaben. Propylparaben was present in low concentrations (0.014% m/m). Since this was a product intended for use in the nappy area, the use of this substance is not authorised. The sale of this product is prohibited. The product may pose health risks (NVWA, 2016i).

PFAS

Based on chemical assessment of cosmetic products, the Danish EPA performed a risk assessment for perfluorooctanoic acid (PFOA), perfluorbutanoic acid (PFBA), perfluoropentanoic acid (PFPeA), perfluorohexanoic acid (PFHxA) and perfluorheptanoic acid (PFHpA) in body lotion, foundation and concealer. It concluded that the measured concentrations of PFCA (perfluorocarboxylic acid; PFOA also belongs to this group) in the cosmetic products did not pose a health risk. If PFAS are used simultaneously in different products, a risk cannot be completely eliminated. The Danish EPA states that the latter scenario is not considered realistic (Danish EPA, 2018b).

UV filters

In early 2014, the NVWA sampled 176 sunscreen products. In these 176 products, butylmethoxyldibenzoylmethane (84%) and octocrylene (74%) are the most commonly used UV filters, usually in combination with one another. Titanium dioxide (TiO_2) is used to a lesser extent (41% of the products tested). If TiO_2 is applied, it is mainly in the nano form (58%). The UV filters (octocrylene and octyl methoxycinnamate) were found in four products, but these had not been declared on the label. The maximum permitted concentration of a UV filter was exceeded in three products. One product contained 11.8% octocrylene instead of 10% (limit), one product contained 5.8% octyl salicylate instead of 5% (limit), and one product contained 5.8% butyl methoxyldibenzoylmethane instead of 5% (limit) (NVWA, 2015c).

UV filters are not only used in sunscreen products, but also in other cosmetic products. This means that a consumer can be exposed to the same substances via different products. This can lead to sensitisation and subsequently the development of contact dermatitis or other long-term effects (Manová et al., 2014; Uter et al., 2014; Manová et al., 2015).

The use of TiO_2 and zinc oxide (ZnO) in nano form as UV filters is considered risk-free because these nanoparticles do not penetrate the skin and therefore do not reach the systemic circulation. There may be a risk from inhalation of these particles. Therefore, the use of sunscreen sprays and other cosmetic products in spray form is not recommended (Dréno et al., 2019; Schneider & Lim, 2019). Since the use of sunscreen products with TiO_2 and ZnO nanoparticles leave a white cast on the skin when applied, alternatives are being sought for these, such as cerium oxide (CeO_2) in nano form (Parwaiz et al., 2019).

In 2014, the Danish EPA identified 291 cosmetic products with UV filters in 11 shops in Denmark (Danish EPA, 2015c). The most common substances used were avobenzone, benzyl salicylate, exhylhexyl salicylate, octocyrlene and ethylhexyltriazone. The Danish EPA concluded that benzophenone-3, octocrylene, 2-ethylhexyl-4-(dimethylamino)benzoate, and isoamyl p-methoxycinnamate may pose a risk when the maximum permitted amount of these substances is added to sunscreen products (use of 18 grams per day). Where there is aggregate exposure via other cosmetic products, benzophenone, octocrylene, 2-ethylhexyl-4-(dimethylamino)benzoate and isoamyl p-methoxycinnamate pose a potential risk. The available data are not adequate for performing a risk assessment. Therefore, more research is needed to draw firmer conclusions (Danish EPA, 2015c).

Basically, a chemical added as a UV filter to a sunscreen product is supposed to be safe. A substance may only be added as an ingredient to a cosmetic product if it has been authorised for use. Nevertheless, one could argue that a risk-benefit assessment is still needed. Without UV filters, a product is not effective and may potentially cause skin cancer in the long term. A product with UV filters may cause a skin reaction or other unwanted effects, but it offers protection against the adverse effects of UV radiation (Lodén et al., 2011; Bora et al., 2018).

Vitamins

The main route of exposure to vitamin A is via food. In cosmetic products, vitamin A is added to reduce wrinkles. Combined exposure via food and the skin may be high enough to exceed the tolerable upper intake level. Therefore, the BfR recommends restricting the concentration of vitamin A in cosmetic products intended for the hands and face and not using vitamin A in lip products and products intended for application to the whole body (BfR, 2014a).

Conclusions

Between 2014 and 2018, the number of information requests received by the NVIC for cosmetic products remained stable, where these requests were mainly associated with oral exposure of children up to the age of four.

High concentrations of acrylate monomers may cause contact dermatitis or irritation of the skin, mucous membranes and eyes. It is not known whether products with a high concentration of acrylate monomers are available on the Dutch market. Gel or acrylic nails are applied for a certain group of consumers. The likelihood of health effects due to exposure to acrylate monomers is assessed as rare. The severity of health damage is assessed as long-term effects that are possibly irreversible. The combined assessment of likelihood and severity results in a low to medium risk for the consumer.

The likelihood of health effects due to exposure to asbestos from talc-containing cosmetic products is assessed as rare. Asbestos is rarely detectable, and these products are only used by a specific group. Some forms of asbestos may cause cancer, but it is not sufficiently known to what extent these forms are relevant in terms of exposure via consumer products in the Netherlands. The combined assessment of likelihood and severity results in low risk for the consumer.

Various preservatives (including formaldehyde sources, phenylenediamine and isothiazolinones) and fragrances can sensitise a consumer, and subsequently cause contact allergy. Almost every consumer uses cosmetic products. Cosmetic products almost always contain preservatives and

fragrances. It is not known whether the cosmetic products available on the Dutch market contain preservatives and fragrances in concentrations high enough to cause sensitisation or contact allergy. The likelihood of a health effect due to exposure to fragrances or preservatives in cosmetic products is assessed as rare. The severity of health damage is assessed as long-term effects that are possibly irreversible. The combined assessment of likelihood and severity results in a low risk for the consumer.

The Cosmetic Products Regulation focuses on specific products and prohibits or limits the presence of certain harmful ingredients, such as fragrances or preservatives. However, the use of these ingredients is not limited to cosmetic products alone. Other consumer products may also contain these ingredients, and therefore a consumer may continue to be exposed to these substances through the use of such products and perhaps develop contact dermatitis.

Some cosmetic products may contain pharmacologically active substances that are constituents of medicinal products. Use of these products poses risks when used without medical supervision. Ignorance on the part of consumers could lead to interactions if cosmetic products are used in combination with regular medicines. Hormone creams are sold on the internet to reduce menopause symptoms in women. There are potential risks associated with the use of these creams when used without medical supervision. The likelihood of a health effect due to exposure to cosmetic products containing pharmacologically active substances is assessed as rare. Cosmetics containing pharmacologically active substances are often restricted to specific products, which means that a limited group of consumers come into contact with them. The severity of health damage is assessed as long-term effects that are possibly irreversible. The combined assessment of likelihood and severity results in a low risk for the consumer.

The BfR recommends limiting the concentration of vitamin A in cosmetic products intended for the hands and face. Combined exposure to vitamin A via food and the skin may be high enough to exceed the acceptable upper intake limit. Whether this is also the case for the Dutch consumer is not known. The likelihood of health effects due to exposure to vitamin A via cosmetic products is assessed as rare. The severity of health effects is assessed as long-term effects that are possibly irreversible. The combined assessment of likelihood and severity results in a low risk for the consumer.

In adults, the total exposure to aluminium salts is largely determined by the use of aluminium-containing cosmetic products (antiperspirants and teeth-whitening toothpaste). The BfR recommends reducing the use of cosmetic products containing aluminium so that the total exposure does not exceed the TWI. The likelihood of a health effect due to exposure to cosmetics products containing aluminium salts is assessed as rare. This is a specific product that not every consumer will use. In addition, it is not known whether all antiperspirant products or 'teeth-whitening' toothpastes contain aluminium salts. The severity of health damage is assessed as long-term effects that are possibly irreversible. The combined assessment of likelihood and severity results in a low risk for the consumer.

The BfR concluded that cosmetic products containing polyethylene microplastics did not pose a health risk, because the particles are not absorbed via healthy skin or the gastrointestinal system. After all, there is no internal exposure. The likelihood of a health effect due to exposure to microplastics is assessed as rare. The severity of the health damage cannot be estimated because more research is needed on the toxicology of microplastics. In an absolutely worst-case scenario, if the severity is assumed to be more than 10% disability or death, the combined assessment of likelihood and severity results in a low to medium risk for the consumer.

The BfR concluded that MOAH is present in low concentrations in cosmetic products. MOSH is barely absorbed by the skin. The likelihood of health effects due to exposure to mineral oils from cosmetic products for the skin or lip balm is assessed as rare. The severity of health damage is assessed as more than 10% disability or death based on the effects of MOAH. The combined assessment of likelihood and severity results in a low to medium risk for the consumer.

Hardly any parabens have been found in baby lotions and creams. These products are intended for a specific, vulnerable group of consumers. The likelihood of health effects due to exposure to parabens via baby lotions and creams is assessed as rare. The severity of health effects is assessed as long-term effects that are possibly irreversible due to possible endocrine-disrupting

properties. The combined assessment of likelihood and severity results in a low risk for the consumer.

The Danish EPA has found PFAS compounds in several cosmetic products. The extent to which this study is representative of the Dutch market is unknown. Potentially, many consumers may be exposed, since almost everyone uses cosmetic products. The likelihood of health effects due to exposure to PFAS compounds in cosmetic products is assessed as rare. The severity of health effects is assessed as long-term effects that are possibly irreversible due to an increase in cholesterol levels. The combined assessment of likelihood and severity results in a low risk for the consumer.

Organic UV filters can cause sensitisation in consumers and subsequently lead to contact dermatitis. The likelihood of health effects due to exposure to organic UV filters is assessed as rare. Many consumers use products with UV filters. Sunscreen products contain permitted concentrations of UV filters. The severity of health effects is assessed as long-term effects that are possibly irreversible. The combined assessment of likelihood and severity results in a low risk for the consumer.

Inorganic UV filters often consist of nanoparticles that do not penetrate the skin and therefore do not involve any internal exposure. If inhaled, these particles can lead to internal exposure. It is not known to what extent nanoparticles are present in sunscreen sprays on the Dutch market. The likelihood of health effects due to exposure to inorganic UV filters is assessed as rare. The severity of health effects is assessed as long-term effects that are possibly irreversible. The combined assessment of likelihood and severity results in a low risk for the consumer.

5.4.5. Chemical risks of food contact materials

Food contact materials (FCM) comprise packaging and packaging materials. These are products that are used for non-commercial purposes during the preparation and consumption of food and drink, as well as materials that are intended to come into contact with food during the commercial preparation or production of food.

All kinds of materials are used in food packaging. Well-known examples are plastic, paper and paperboard, rubber, metal, glass and ceramics, textiles, wood and cork, or combinations of these. Packaging may contain or include substances that extend the shelf life of food. This kind of packaging is called active packaging. In addition, packaging can be provided with labels or materials that indicate the temperature, i.e. so-called intelligent packaging. Temporary packaging may also be used within the food production and transport domain, such as jute bags for cocoa beans or storage barrels.

In addition, there are consumer products, also referred to as food-utensils, which are used for food preparation or consumption. Examples include plates, pans, cutlery, cutting boards, storage boxes, kettles, food processors and cooking pots. Machinery used for food production on an industrial scale also contains materials that come into contact with food. Examples of this are conveyor belts and mixing machines.

Fixed water pipes, both public and residential, do not fall under the category of food contact materials. However, products fitted ‘after the tap’, including those with a fixed water pipe, do fall under this category.

The production of food contact materials involves the use of a wide range of chemical substances: raw materials (which may be recycled materials), monomers, oligomers, catalysts, printing inks, etc. New substances are often created during the production process, both intended (polymers) and unintended; the latter group is referred to in legislation as NIAS (non-intentionally added substances). Everyone comes into contact with food contact materials on a daily basis and may therefore be exposed to the substances contained in them. The extent to which this occurs depends on the release or migration of these substances from the food contact material to the food.

Legal framework

The general EU legislation consists of a framework regulation for marketing (Regulation (EC) No 1935/2004[150]) and a regulation for good manufacturing practice (Regulation (EC) No 2023/2006[151]).

The general requirements in Regulation (EC) No 1935/2004 are the following:

1) Materials and articles, including active and intelligent materials and articles, must be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities that could:
   a) endanger human health; or
   b) bring about an unacceptable change in the composition of the food; or
   c) bring about a deterioration in the organoleptic characteristics thereof.
2) The labelling, advertising and presentation of a material or article must not mislead the consumers.

Regulation (EC) 1935/2004 identifies 17 groups of food contact materials. Specific measures have been developed for some of these groups: plastics (Regulation EU No 10/2011[152]), active and intelligent materials (Regulation (EC) No 450/2009[153]), recycled plastics (Regulation (EC) No 282/2008[154]), epoxy derivatives (Regulation (EC) No 1895/2005)[155], ceramic materials (Directive 84/500/EEC[156]) and regenerated cellulose films (Directive 2007/42/EC[157]).

Finally, regulations have been laid down for certain specific substances: bisphenol-A, epoxy compounds, nitrosamines in rubber teats, polyamide and melamine articles from China and Hong Kong. An overview of all the applicable legislation can be found on the EU website[158].

In 2019, the European Commission published a recommendation (EU 2019/794[159]) for a coordinated control plan in order to establish the prevalence of certain substances migrating from materials and articles intended to come into contact with food. The substances to be studied (in certain types of food contact materials) include: primary aromatic amines; formaldehyde and melamine; phenol; bisphenols, including BPA and BPS; phthalates and non-phthalate plasticisers; fluorinated compounds; metals; and overall migration.

For several types of materials, there is no specific European harmonised legislation. In such cases, Member States may establish national regulations. The Commodities Act Decree on Food Contact Materials (*Warenwetbesluit verpakkingen en gebruiksartikelen*)[160] implements the general EU

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[150] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

[151] Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food. OJ L 384, 29.12.2006, p. 75–78.

[152] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L12, 15.1.2011, p. 1-89. 1-89

[153] Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food. OJ L 135, 30.5.2009, p. 3–11.

[154] Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006. OJ L 86, 28.3.2008, p. 9–18.

[155] Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food (Text with EEA relevance) OJ L 302, 19.11.2005, p. 28–32.

[156] Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs. OJ L 277, 20.10.1984, p. 12–16.

[157] Commission Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs. OJ L 172, 30.6.2007, p. 71–82.

[158] https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/legislation_en

[159] Commission Recommendation (EU) 2019/794 of 15 May 2019 on a coordinated control plan with a view to establishing the prevalence of certain substances migrating from materials and articles intended to come into contact with food. OJ L 129, 17.5.2019, p. 37–42.

[160] Decree of 30 May 2005 establishing the Commodities Act Decree on Food Contact Materials in relation to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJEU L 338).

legislation. The Dutch Commodities Act Regulation on Food Contact Materials [161] contains national requirements for paper and paperboard, rubber products and wood. The Netherlands also has a specific authorisation procedure for substances. For substances in materials other than plastics, producers may submit an application dossier to the Dutch government. The application may be based on the 'Note for Guidance For the Preparation of an Application for the Safety Assessment of a Substance to be used in Plastic Food Contact Materials' (EFSA, 2008).

Due to the lack of harmonised EU requirements, the principle of mutual recognition applies: if a Dutch importer can demonstrate that the food contact material meets the legal requirements of the country of origin and offers an equivalent level of safety for the Netherlands, the importer can legally market this product in the Netherlands.

Identification of relevant substances

RASFF

From 2014 to 2018, RASFF recorded 722 notifications relating to food contact materials. The Netherlands was involved in 94 of these notifications; 12 notifications were made by the Netherlands. Of these, 263 cases were classified as serious. Table 36 displays the reported substances. Formaldehyde and melamine were often found in melamine or bamboo articles. Some food contact materials demonstrate multiple deviations; commonly occurring combinations are the release of formaldehyde and melamine or the release of cadmium and lead. The large number of notifications about (heavy) metals is striking.

Some RASFF notifications on food contact materials relate to physical hazards in particular, usually because pieces of an article may break off or because it has a sharp edge.

Table 36 Notifications relating to substances in the RASFF in the period 2014 to 2018 for the Food Contact Materials product group

Substance	Group	Total	Number of serious risks
Primary aromatic amines	NIAS	99	98
Lead	Metals	56	52
Cadmium	Metals	52	50
Formaldehyde	Monomers	120	34
Melamine	Monomers	48	32
Cobalt	Metals	16	8
Aluminium	Metals	14	9
Nickel	Metals	71	8
Phthalates: DBP, DEHP, DIDP, DMP, DINP, DPHP	Plasticisers	21	7
Arsenic	Metals	4	3
Chrome	Metals	115	3
Iron	Metals	4	3
Manganese	Metals	79	3
Antimony	Metals	2	2
Lithium	Metals	4	2
Bisphenol A	Monomers	2	1
Butyl benzoate		1	1
P-tert-butylbenzoic acid (PTBBA)	Polymerisation additive	1	1

[161] Regulation of 14 March 2014 establishing the Packaging and Consumer Articles (Commodities Act) Regulation for packaging and consumer articles that come into contact with food.

Substance	Group	Total	Number of serious risks
Zinc	Metals	1	1
N-nitrosatable compounds	NIAS	1	1
Overall migration		88	
Volatile organic compounds		13	
Epoxidised soybean oil (ESBO)	Plasticisers	9	
Bis(2-ethylhexyl) terephthalate (DOTP)	Plasticisers	8	
Benzophenone	Photoinitiator	5	
Dehydroacetic acid E265		3	
3-Monochloro-1,2-propanediol (3-MCPD)	Product from chemical reaction	2	
Mineral oil, MOAH	NIAS	2	
Mineral oil, MOAH	NIAS	2	
1,2,3,4-Tetramethylbenzene		1	
2,4-Diethyl-9H-thioxanthen-9-one	Colouring agent	1	
2-Cyclohexylidene-cyclohexanone		1	
2-Ethyl-1,3-dimethylbenzene		1	
2-Methylnaphthalene		1	
3,5,5-Trimethyl-2-cyclohexeen-1-on		1	
4-Phenylbenzophenone	Photoinitiator	1	
Acrylonitrile	Monomer	1	
Cyclo-di-BADGE	Product from chemical reaction	1	
Cyclohexanone	Solvent	1	
Cyclohexanol	Solvent	1	
Naphthalene		1	
Silicone elastomer		1	
p-Toluene sulfonamide		1	

NIAS: non-intentionally added substance

Other substances

Groh et al. (2019) recently published a list of substances known to occur in plastic packaging. They entered these in a database of Chemicals associated with Plastic Packaging (CPPdb). This database contains 906 substances that are **likely** to occur and 3377 substances that **may** occur. The authors also studied the hazard classification of the group of 906 substances; there are 63 substances with the highest classification for human health and 68 for the environment. In addition, seven substances are classified as persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB) and fifteen as endocrine-disrupting chemicals (EDC). These substances are used in plastics as monomers, intermediates, solvents, surfactants, plasticisers, stabilisers, biocidal products, flame retardants, accelerators and colouring agents. The authors advise that the most hazardous substances should be studied in detail as possible candidates for substitution.

Geueke (2018) has published an overview of the so-called non-intentionally added substances (NIAS). These include contaminants in the starting materials, by-products of a polymerisation process and degradation products. Migration testing is often unable to identify all NIAS. This is a problem for coatings, which are produced in situ on a substrate.

The Danish Veterinary and Food Administration of the Ministry of Environment and Food has published a fact sheet on fluorinated substances in paper and paperboard (Danish Veterinary and

Food Administration, 2018). Under the instructions of the Nordic Council of Ministers, a number of studies have been carried out with regard to the presence of perfluorinated compounds in products, including food contact materials (Borg & Ivarsson, 2017; Trier et al., 2018). Via the REACH Regulation, the use of perfluorinated compounds with chains of eight or more carbon atoms is becoming increasingly restricted. Alternatives include shorter perfluoroalkyl acids, which would be less bioaccumulative. However, Brendel et al. (2018) have argued that these alternatives may also be problematic because they are highly mobile and therefore spread quickly in the environment.

In a study conducted by the University of Prague, 101 contaminants were found in paper food contact materials used in the Czech Republic (Vápenka et al., 2016). The most common types of substances found were phthalates, anthraquinone, aromatic hydrocarbons and photoinitiators. However, this study concerned complete extraction and not migration.

The presence of mineral oils (MOH) in food, e.g. in chocolate, has been reported in several publications. Packaging is often cited as a possible source, although contamination shortly after harvest or during processing is also possible. EFSA issued an advisory report in 2012 (EFSA CONTAM Panel, 2012b) where it concluded that the dietary intake of mineral oils was of potential concern. The European Commission issued a recommendation[162] in 2017 calling on Member States to monitor the presence of MOH in food and food contact materials.

The increasing use of recycled materials in the production of food contact materials may lead to more problems. For example, Puype et al. (2015) detected brominated flame retardants (BFR) in black food contact materials, presumably from waste electrical and electronic equipment (WEEE). Mixing of WEEE into recycled plastic material is not permitted.

Nanoparticles are used in various ways in food contact materials to improve the packaging (e.g. flexibility and temperature/humidity stability) or the antimicrobial activity, or used as sensors (Ćwiek-Ludwicka & Ludwicki, 2017).

Exposure

Exposure to substances from food contact materials will normally occur after these substances have migrated into food. To estimate the daily intake (worst case), an EU risk assessment of, for example, plastic food contact materials, assumes that a person eats 1 kg food per day that has been in contact with 6 dm^2 of the food contact material.

Risks

There are several factors that limit the ability to make a proper risk assessment of chemical substances in food contact materials, i.e. the lack of information regarding the identity of a substance (NIAS, impurities and products from chemical reactions), lack of toxicological data to characterise the hazards, and absence of exposure data. Often the risk assessment focuses on starting substances and additives, whereas these substances may change during the production of food contact materials. Hence, it is possible that the wrong substances are being assessed. (Muncke et al., 2017).

Food Standards Australia New Zealand (FSANZ) has recently published a summary of the information available on the migration of substances from packaging to food (FSANZ, 2017). It was concluded that the exposure due to this kind of migration is generally below the Threshold of Toxicological Concern (TTC) for non-genotoxic substances. Research is being carried out to characterise the risks of migration of substances from recycled paperboard. The weakness of this approach is that the TTC approach is not applicable to all substances.

Substances pose a risk to health only if they are able to migrate from food contact materials and be transferred to the food. The Specific Migration Limit (SML) is the maximum amount of a chemical that may migrate from a food contact material to food. It is a safety limit based on toxicological data. The SML for specific food contact materials is legally laid down for each material

[162] Commission Recommendation (EU) 2017/84 of 16 January 2017 on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food.

category. In addition, there is an overall migration limit of 60 mg/kg food for most material categories. This overall migration limit has been set because, in principle, food packaging must be inert and release as few substances as possible into the food.

Formaldehyde and primary aromatic amines

Based on Regulation (EU) No 284/2011[163], the NVWA has verified whether imported melamine and polyamide kitchenware from China and Hong Kong complies with the legal requirements for the migration of formaldehyde and primary aromatic amines. Between 2011 and 2013, 217 samples of melamine kitchenware were assessed for formaldehyde migration. Exceedance of the standard was observed in 20 samples. During the same period, 55 samples of polyamide kitchenware were assessed for the migration of primary aromatic amines. Two samples did not meet the standard and a third sample was rejected because loose particles were observed during the migration test (NVWA, 2014e). In 2014, NVWA sampled five articles (including plates and mugs from Thailand). No deviations were found (NVWA, 2015d).

The BfR has conducted further studies on the presence and migration of oligomers in polyamide kitchenware (BfR, 2019d). It was seen that cyclic oligomers can migrate into food in significant amounts. At high doses, these cyclic oligomers were found to have a health effect on the liver and thyroid. Based on toxicity data, a limit value of 5 mg/kg food was established. Studies showed that 10 of the 33 polyamide kitchen utensils examined had a higher release rate than 5 mg/kg food. The BfR therefore recommends using polyamide kitchenware for as short a time as possible at higher temperatures (above 70°C).

Metals

In the RASFF, metals such as lead and cadmium are usually mentioned in reference to articles made of glass or ceramic material. According to EFSA, it is not possible to establish a threshold value for lead below which no effect can be expected (EFSA CONTAM Panel, 2010). Cadmium has adverse effects on kidneys if ingested over a prolonged period, and the average dietary exposure for adults in Europe is close to or slightly exceeds the TWI of 2.5 µg/kg body weight (EFSA CONTAM Panel, 2009). The contribution of cadmium from food contact materials to the total exposure is unknown.

In 2013, the NVWA studied the release of lead and cadmium from tagines. A representative sample was taken of the tagines available on the Dutch market (n=30). Only one of the 30 tagines did not meet the then applicable migration limit (1.5 mg/l) for lead. The migration limit for cadmium applicable at that time (0.1 mg/l) was not exceeded. The report also discusses a renewal of migration limits and test conditions for heavy metals from food contact materials. In that case, the market study would need to be repeated (NVWA, 2014a). The current migration limits for lead and cadmium from ceramics are 4,0 mg/l and 0,3 mg/l, respectively.

Migration requirements for heavy metals vary by material category. For plastics, glass and glass-ceramics, metals and enamel, the difference lies mainly in the heavy metals for which a migration limit has been set. The migration limits are the same for each metal. The requirements for ceramic materials are different. Three different types of articles have been distinguished, each with their own limit for lead and cadmium. The food simulant used is also different (4% acetic acid instead of 3%). The migration limits for lead and cadmium are, respectively, a factor of 15 and 10 higher than for the other material categories (glass and glass-ceramics, metals and enamels).

There is no migration limit for aluminium in the Commodities Act Regulation on Food Contact Materials [164]. Aluminium and its alloys are used as food contact materials. Examples of this include pans, coffee pots, baking trays and aluminium foil. For catering purposes, aluminium trays are frequently used for serving both hot and cold food. Aluminium materials are known to have a significantly high rate of release when in contact with acidic, alkaline or salty foods. The highest

[163] Commission Regulation (EU) No 284/2011 of 22 March 2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China. *OJ L 77, 23.3.2011, p. 25–29.*

[164] Regulation of 14 March 2014 establishing the Packaging and Consumer Articles (Commodities Act) Regulation for packaging and consumer articles that come in contact with food.

exposure to aluminium occurs via food. Migration from food contact materials may contribute significantly to the overall exposure to aluminium (Tietz et al., 2019). The BfR recommends that acidic and salty foods in particular should not be prepared or stored in uncoated aluminium articles or aluminium foil (BfR, 2019c).

Mineral oils

From 2014 to 2018, there were two notifications in the RASFF for mineral oil present in or migrating from a food contact material. This concerned, respectively, paper muffin liners and paperboard boxes containing a certain type of pastry.

Based on the Europe-wide surveillance, van Heyst et al. (2018) have reported the initial results for Belgium. MOSH was found in 142 of the 198 assessed foods, at concentrations up to 84.82 mg/kg. The concentration of the MOAH fraction was below the LOQ (limit of quantification) in 175 food items; the remaining 23 samples had concentrations between 0.6 and 2.24 mg/kg. These results were compared to the so-called action thresholds derived by the Scientific Committee of the Belgian Federal Agency for the Safety of the Food Chain (FAVV-AFSCA). The threshold for MOSH was exceeded in only one food item; the threshold (detection limit) was clearly exceeded in the 23 food items in which MOAH was measured. The authors recommended that these cases be further studied to determine the source of the contamination.

van de Ven et al. (2018) have published a review of the toxicological knowledge on mineral oil and estimated the exposure via food. They concluded that no health effects are to be expected at current dietary exposure levels to MOSH. There must be more focus on MOAH, whereby it is especially important to identify the source; not all MOAH are carcinogenic, but it is difficult to make a distinction in the assessment, and it is therefore important to identify the source. The total concentration of MOAH does not provide information on whether the intake of MOAH is harmful.

On behalf of the Netherlands Institute for Sustainable Packaging (KIDV), Thoden van Velzen et al. (2018) prepared a report on the migration of mineral oils from food packaging made from recycled paper and paperboard. This report concludes that the calculated average exposure to MOSH does not pose a risk and particularly that the exposure to MOAH from less purified mineral oils should be minimised as much as possible.

Monomers

A great deal has been published on bisphenol-A in particular. EFSA lowered the TDI in 2015, resulting in a lower SML[165] of 0.05 mg/kg food (EFSA CEF Panel, 2015; Vilarinho et al., 2019). In previous years, the SML was higher (3.0 mg/kg food in 1990 and 0.6 mg/kg food in 2004). For many years now, the migration rate of bisphenol-A from various food contact materials has generally been below the applicable migration limit (Vilarinho et al., 2019).

PFAS

Perfluorinated compounds were not reported via the RASFF during the period from 2014 to 2018. However, increasing attention is being paid to these compounds due to their level of persistence, as a result of which they are being found everywhere in the environment. The SCHEER scientific committee set up by the EU has recently identified perfluorinated compounds as an emerging risk (SCHEER, 2018). The EFSA Panel on Contaminants in the Food Chain has issued an advisory report on two specific compounds: PFOS and PFOA (EFSA CONTAM Panel, 2018a).

In 2018, at BuRO's request, the RIVM reviewed the available information on per- and polyfluoroalkyl compounds (PFAS) (Bokkers et al., 2018). There are indications that significant amounts of perfluoroalkyl carboxylic acids and fluorotelomers can migrate from paper and paperboard into food simulants. For materials other than paper and paperboard, there is limited information. Migration of PFAS from fluoropolymers used as non-stick or other coatings is negligible, but for rubber or silicone articles it is not clear how strongly the PFAS are bound in the matrix. There is a lack of information on the migration of, and therefore the exposure to, PFAS.

[165] Commission Regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food, and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials.

Moreover, toxicity data are only available for a subset of the many types of PFAS; relative potency factors have been proposed for a number of related substances (Zeilmaker et al., 2018).

Plasticisers

Between 2010 and 2011, the migration of plasticisers from gaskets of lids of glass jars was assessed (N=308). The jars came from 22 European countries. In 24% of the gaskets from the jars, unauthorised plasticisers or plasticisers above the migration limit were found (McCombie et al., 2011). In 2013, a follow-up study assessed 48 lids of glass jars. In 29% of these jars, the migration limit of various plasticisers was exceeded (McCombie et al., 2013).

The EFSA CEF Panel has reviewed the 2005 risk assessment on the use of phthalates (DBP, BBP, DEHP, DINP and DIDP) in food contact materials. DINP contributes the most to consumer exposure (P95 intake: 0.4 – 7.0 µg/kg body weight per day). The Panel did not have enough information to comment on the contribution of phthalates from food contact materials to the total consumer intake (EFSA CEF Panel, 2019).

Nanomaterials

Whether nanoparticles can migrate from plastic polymers is unclear. The studies conducted on this do not give a consistent picture (Ćwiek-Ludwicka & Ludwicki, 2017).

SUP (Single-Use Plastics) Directive

In 2019, the so-called SUP Directive[166] was published. This Directive encourages both reuse and recycling. Both options entail risks due to the possible introduction of undesirable substances. In addition, single-use plastics are going to be prohibited in future, which will possibly lead to a shift to other materials. This Directive will enter into effect in July 2021. The recycling principle has been applied to paper and paperboard for several decades. Waste paper is permitted for use as a raw material without any requirements being imposed. Since 2008, the recycling of plastic has been permitted. However, the recycling process for plastics must meet strict requirements and be authorised[167].

Biological materials

A growing trend is the use of biological materials for food contact. This could include plastics made from vegetable raw materials. The best-known example of this is polylactic acid (PLA). If these raw materials are included on the list of permitted materials, and the end product also meets the legal requirements, these materials may then be safely used as food contact materials. Another category of biological materials is manufactured by adding plant fibres to, for example, plastics. A well-known example of this is the addition of bamboo fibres to melamine-formaldehyde resins. Bamboo is not authorised for use as an additive for plastic food contact materials. The BfR has carried out a study in this area (BfR, 2019b). Bamboo consumer articles are increasingly exceeding the migration limits of both formaldehyde (15 mg/kg) and melamine (2.5 mg/kg). Of the bamboo articles sampled, 44% exceeded the formaldehyde limit and 35% exceeded the melamine limit. The BfR does not recommend the use of consumer articles made of bamboo fibres for hot drinks.

Conclusion

A wide range of chemical substances are found in food contact materials. Whether these substances actually migrate into food depends on the combination of substance and food contact material. There is no or limited exposure to formaldehyde and primary aromatic amines from imported melamine, polyamide kitchenware and heavy metals from tagines, and mineral oils from paperboard boxes. There are no legal requirements for aluminium, but the literature shows that it may entail a health risk. Plasticisers from the lids of glass jars are known to migrate. More

[166] Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019 on the reduction of the impact of certain plastic products on the environment. OJ L 155, 12.6.2019, p. 1-19

[167] Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006. OJ L 86, 28.3.2008, p. 9–18.

research is needed on the migration of PFAS and nanoparticles from food contact materials. Therefore, no statement is made about a possible risk.

In the absence of migration, the likelihood of health effects due to exposure to chemical substances from food contact materials is assessed as rare. Depending on the type of chemical substance, the severity of health effects due to exposure to such substances from food contact materials is assessed as long-term effects that are possibly irreversible, or more than 10% disability or death. The combination of likelihood and severity results in a low risk of health effects.

The likelihood of health effects due to plasticisers from food contact materials is assessed as occasional, because there is evidence that these substances effectively migrate and are transferred to the food. The severity of health effects is assessed as more than 10% disability or death. The combination of likelihood and severity results in a medium to high risk, although this assessment involves large uncertainties. Aggregate exposure via other products may increase the risks for consumers.

Biological materials such as bamboo consumer articles, may pose a risk due to increased release of formaldehyde and melamine, in levels higher than the migration limit. These two substances are assessed at Severity Category 3. Exceeding this limit results in exposure above the health-based guidance value. A small (but perhaps growing) proportion of consumers are using such bamboo consumer articles. The likelihood of occurrence is therefore assessed as occasional. The risk is assessed as medium to high.

The SUP Directive intends to bring about changes with respect to food contact materials: it will do this, on the one hand, by encouraging reuse and recycling, and on the other hand, by prohibiting single-use plastics. Reuse and recycling involve risks because of the possible introduction of chemical substances as contaminants. The prohibition on single-use plastic may lead to substitution by other materials. But this must be done with care so as to avoid cases of regrettable substitution. Since this Directive will come into force in July 2021, these substitute materials are not yet known.

5.4.6. Chemical risks of toys

Toys may be made of various materials such as plastic, wood, textile, rubber or paint. This may involve different chemical substance groups per material category. For example, wood may contain preservatives and plastic may contain plasticisers. Another categorisation of toys is by age. It is generally accepted that children up to the age of three put toys into their mouths and suck on them, and it is therefore important to take the oral route into consideration as part of the risk assessment.

Legal framework

The safety of toys is regulated by the Toy Safety Directive 2009/48/EC[168]. In general, toys should not present a health hazard. In addition, Part III of Annex II contains specific requirements for chemical safety, such as the restriction on the use of carcinogenic, mutagenic and reprotoxic substances, requirements relating to allergenic fragrances, and migration limits for certain elements, nitrosamines and nitrosatable substances. Requirements for chemical substances are set forth in detail in various standards (EN 71 series). Some standards are focused on substances or groups of substances (certain elements, nitrosamines), while others are product-oriented (e.g. for finger paints).

Annex XVII of the REACH Regulation (Regulation (EC) No 1907/2006[169]) regulates a number of matters relating to the chemical safety of toys. A maximum concentration of 0.1% by weight is set for a number of phthalates in plastic. A maximum concentration is also defined for a number of polycyclic aromatic hydrocarbons (PAHs) in plastic and rubber.

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[168] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys. OJ L 170, 30.6.2009, p. 1–37.

[169] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. OJ L 396, 30.12.2006, p. 1-520

Plastics may contain short-chain chlorinated paraffins (SCCP). These substances are classified as persistent and therefore may not be placed on the market if the concentration exceeds 1% (Regulation (EC) No 519/2012[170]).

Identification of relevant substances in toys

Between 2014 and 2018, Safety Gate received 10,062 notifications relating to a potentially high-risk consumer product. Of these notifications, 2,562 (25%) related to the chemical substances category, in addition to other possible risk categories. In total, 1,094 Safety Gate notifications have been published relating to the chemical safety of toys. Of these, 957 notifications (almost 90%) concerned excessive plasticiser concentrations (in particular, diethylhexyl phthalate (DEHP), dibutyl phthalate (DBP) and diisononyl phthalate (DINP)). This Safety Gate overview shows that market surveillance authorities mainly check for substances that are regulated by law and/or for which there is a standard, such as phthalates, certain elements, nitrosamines and nitrosatable substances. It is also worth noting that Member States carry out studies on the latest toy crazes. Any deviating samples are reported in the Safety Gate system. Examples of such toy crazes are squishies and toy-slime.

In addition to this Safety Gate overview, studies by the NVWA and literature were used as sources of information on the presence of chemicals in toys. Study reports published by the Danish government (Danish Environmental Protection Agency) and NVIC reports were also consulted.

Exposure

Exposure to substances from toys can occur via different routes: oral, dermal and inhalation. Oral exposure can occur through the sucking on toys, as well as through ingestion of toy materials (e.g. finger paints or scratched-off paint). In addition, there is dermal contact with toys during play, as well as possible oral exposure subsequently through hand-to-mouth contact. Finally, substances from toys can evaporate, which a child can then inhale. Examples are puzzle mats on which a child can crawl or a play tent in which a child sits.

NVIC

The NVIC was consulted by phone in 2014 and 2015 regarding 944 and 1,053 reports of exposure to, respectively, toys and leisure products. In 2016, the NVIC was consulted by phone regarding 2,382 cases involving a total of 2,392 reports of exposures to leisure and DIY products. In 2017 and 2018, these numbers remained about the same. Most exposures to leisure and DIY products occurred in children aged 0 to 4 years. Exposure to painting supplies was most frequently reported (NVIC, 2017;2018). In 2018, the products with the most number of exposures were glow-in-the-dark sticks and batteries (NVIC, 2019b).

Glow-in-the-dark sticks

In 2014, exposures to glow-in-the-dark sticks or their contents were frequently reported especially during the months of January, November and December (NVIC, 2015). The number of exposures to these glow-in-the-dark sticks has been increasing for several years now. In 2018, the number of exposures (N=273) decreased compared to 2016 (N=396) and 2017 (N=343) (NVIC, 2019b). The largest group of patients is children up to 12 years of age (NVIC, 2016;2017;2018;2019b).

Growing crystals

In 2014, the NVIC received several requests for information after incidents where children had drunk from the liquid used for growing crystals. A crystal growing kit contains ready-to-use liquid or powder that must be dissolved in water. A porous stone is placed in the liquid on which crystals grow. The liquids in question are saturated salt solutions and usually contain ammonium phosphate and/or calcium sulphate (NVIC, 2015).

[170] Commission Regulation (EU) No 519/2012 of 19 June 2012 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annex I, OJ L159, 20.6.2012, p. 1--4.

Indoor play sand

The number of reports of exposure to indoor play sand has increased from three in 2014 to 11 in 2015. This is a relatively new product on the Dutch market and contains hardly any toxic ingredients. Since sand is not absorbed by the body, no particular complaints are to be expected when consuming this product (NVIC, 2016).

Toy-slime

The number of reports about toy-slime increased tenfold in 2018 (N=50) compared to 2017 (N=5). Most exposures involved children up to the age of 12 (NVIC, 2019b).

Risks

The risks for each material group contained in toys are described below. Studies have been carried out to identify the substances relevant to each material category. Based on market data on the occurrence of substances in certain toy materials (NVWA studies) and the hazard characterisation of the substances present, an attempt is made to describe the health risk.

Toys containing aqueous media

Toys containing aqueous media may include finger paints, other types of paints for children, toy-slime, as well as craft glues. This is a special category because of the potential for higher accidental ingestion and dermal exposure. Different groups of substances may be present in this type of toy.

Preservatives

Preservatives are added to toys containing aqueous media to prevent microbiological spoilage. This is particularly necessary for toys containing aqueous media that repeatedly come into contact with children's hands. Preservatives are often sensitising substances. Strict requirements have been laid down for finger paints. EN 71-7 contains a list of permitted preservatives, with restrictions per preservative. Finger paints are intended for children under the age of three and are intended for skin contact. Finger paints are subject to a declaration requirement for preservatives. There are also other categories of toys containing aqueous media, such as bubble mixtures and toy-slimes. For toys containing aqueous media intended for children under the age of three, limit values are set for isothiazolinones (MI, CMI) and formaldehyde, but there is no declaration obligation. These isothiazolinones must not be present because they are classified as contact allergens in cosmetic products. The limit value is set at the limit of quantification of the analytical method. Most toys containing aqueous media, such as toy-slime and putty, are intended for children above the age of three.

From 2014 to 2018, three Safety Gate notifications were published about preservatives in finger paints. These were formaldehyde, chloromethylisothiazolinone (CMI), methylisothiazolinone (MI) and benzisothiazolinone (BIT). In 2015, the NVWA performed a study on the chemical safety of finger paints (NVWA, 2015a). In four of the 29 finger paints examined, the concentration of one of the preservatives, BIT, CMI or MI, was too high. In 2016, the Danish Environmental Protection Agency (Danish EPA) conducted a study on preservatives in toys (Danish EPA, 2016b). The risk of allergic reactions when using toys containing parabens, 2-phenoxyethanol and bronopol was assessed as low.

Formaldehyde is considered to be a strong allergen. Persons who are allergic to formaldehyde may experience allergic reactions at low concentrations (60 ppm). Above this level of formaldehyde, there is a possible health risk. Isothiazolinones were not included in EPA's assessment. However, this group of preservatives is considered to be highly allergenic. This is why strict limits have been set. In 2018, an addition to EN 71-7 was published, whereby isothiazolinones, formaldehyde and paraformaldehyde are no longer included on the list of permitted preservatives for finger paints. A number of formaldehyde donors are still permitted for use as preservatives in finger paints. As of May 2021, a formaldehyde restriction of 10 mg/kg applies to other toys containing aqueous media.

Nitrosamines in finger paints

Nitrosamines may be formed in finger paints, depending on the raw materials used. Nitrosamines are potentially carcinogenic substances. Therefore, a requirement has been set in EN 71-12 regarding nitrosamine concentrations. There have been two Safety Gate notifications published since 2014 for excessive levels of N-nitrosodiethanolamine (NDELA). In NVWA's 2015 study, one sample exceeded the limit for NDELA (NVWA, 2015a). This was one of two Safety Gate notifications. For NDELA in cosmetic products, the SCCS has established that a level of 50 µg NDELA/kg cosmetic products provides a sufficient safety margin (SCCS, 2012d). For finger paints, this has been further reduced to 20 µg/kg in EN 71-12, because of the specific target group of finger paints (children). Dermal exposure has been identified as the main route of exposure. Finger paints containing NDELA above the limit value of 20 µg NDELA/kg finger paint are considered to present a serious risk to the health of the user.

Certain elements

For liquid toy materials, the requirements for certain elements are more stringent than for powder-like or scraped-off toy material, because the estimated intake is higher. These requirements are described in the Toy Safety Directive and in the harmonised standard EN 71-3 and are explained in a specific document (Europese Commissie, 2016). The migration requirements for the various certain elements present in toys are based on a child weighing 7.5 kg and an average daily intake of 400 mg. Furthermore, 10% of the TDI has been used, since there is also a certain level of exposure from other sources (food, drinking water, environment). All samples of finger paint examined by NVWA met these requirements (NVWA, 2015a).

Boric acid (borax) is often added to toy-slime, putty and modelling clay to cross-link the polymer chains. Children like to make the toy-slime themselves, and borax-containing liquids such as lens solution, are often used for this. After the limit value for boron in toys containing aqueous media was reduced to 300 mg/kg in 2013, several Safety Gate notifications were published about this. A total of 27 Safety Gate notifications were published with respect to boron compounds. At the request of the NVWA, the RIVM performed a risk assessment for boron in toy-slime (RIVM, 2019a). This shows that the limit value of 300 mg/kg offers sufficient protection. In case of high values, such as those reported in the Safety Gate notifications, there may be a health risk.

Plastic toys

Plasticisers

PVC toys are generally plasticised. Examples of such toys include dolls, bath toys and inflatable toys. A number of phthalates (plasticisers) are strictly regulated, since they are classified as reprotoxic. For DEHP, DBP and BBP, there is a restriction of 0.1% by weight, and for DINP, DNOP and DIDP, there is a restriction for toys that can be placed in the mouth. The Safety Gate overview from 2014 to 2018 shows that the majority of Safety Gate notifications for the chemical safety of toys involve plasticisers (1,033 out of 1,231 Safety Gate notifications). DEHP is found most frequently, followed by DBP and DINP.

The NVWA has carried out various studies on plasticised toys. In 2010, 205 different soft plastic toys and five different soft plastic child care articles were sampled, ranging from bath toys and space hoppers to teething rings and bibs (NVWA, 2011b). The rate of infringement was 19%. In particular, DEHP and DINP were found in excessively high concentrations. Di-2-ethylhexyl terephthalate (DEHTP), diisononyl 1,2-cyclohexanedicarboxylic acid (DINCH) and 1-isopropyl-2,2-dimethyltrimethylene diisobutyrate (TXIB) were found as alternative plasticisers. A risk assessment showed that these three alternative plasticisers did not pose a risk in the individual products examined (BuRO, 2010d). It was recommended that a migration limit be set for these alternative plasticisers. The most recent study is one involving dolls (NVWA, 2017b). Four of the 65 baby dolls did not meet the requirements for plasticisers. DEHP concentrations ranging from 10% to more than 30% were found. DINP and DIDP were also found, but the concentrations were lower than the legal requirement. However, whether or not this entails a health risk can only be determined once migration has also been identified (RIVM, 2016; BuRO, 2018a).

Polycyclic aromatic hydrocarbons (PAHs)

PAHs can be found in plastic toys. Since these are potentially carcinogenic substances, a restriction of 0.5 mg/kg was established in Annex XVII of the REACH Regulation in 2015. There were two Safety Gate notifications published in 2019 regarding excessive PAH concentrations in plastic toys. These concerned plastic spiders (total PAHs: 1,160 mg/kg) and plastic accessories on a teddy bear (benzo[a]anthracene: 0.95 mg/kg).

Solvents and monomers

Plastic toys may also contain solvents and monomers (starting materials). Examples of such toys include squishies. There have been 23 Safety Gate notifications published indicating that squishies contain the following substances:

- N,N-Dimethylformamide
- Cyclohexanone
- Bis(2-(dimethylamino)ethyl) ether)
- Triethylenediamine

Enforcement was based on a health risk through inhalation exposure. Denmark and Sweden have withdrawn the squishies from the market on this basis. The NVWA has also assessed squishies and found the same substances, as well as styrene, toluene and allergenic fragrances (citronellol, linalol and limonene)[171]. The concentration of these substances was in line with the requirements of the Toy Safety Directive, therefore these squishies were not withdrawn from the market in the Netherlands. In the meantime, this toy craze is over.

Bisphenol-A (BPA)

In 2017, a restriction of 0.04 mg/l for BPA was added to the Toy Safety Directive (Regulation (EU) No 217/898). This restriction is based on the temporary TDI (tTDI) set by EFSA in 2015 of 4 µg/kg body weight per day (EFSA CEF Panel, 2015). BPA is classified as a reprotoxic substance under the CLP Regulation (Regulation (EC) No 1272/2008[172]). BPA may be present as a residual monomer in plastic toys. In 2017, one Safety Gate notification was published regarding an excessive release of BPA from a plastic doll (0.178 mg/l). A study from Israel shows that there may be migration of BPA from toys (and children's articles) (Negev et al., 2018). This was found particularly in child use and care articles, but also in a few toys. An American study in a day-care centre showed that wipes wetted with isopropylalchol released BPA and phthalates (Andaluri et al., 2018). This concerned plastic toys for babies and small children. The estimated exposure to BPA from these toys was 2-243 ng/kg body weight. This is lower than the tTDI of 4 µg/kg body weight.

Isophorone and phenol

Bath and swimming toys, such as bath books and inflatable swimming toys often have prints on them. The printing inks used may contain residual solvents, including isophorone and phenol. Isophorone has a typical smell. In a number of consumer complaints, the off-smell can be traced back to these substances. EN 71-9 contains migration limits for both substances: 3 mg/l for isophorone; 15 mg/l for phenol. In 2004, the NVWA carried out a study in which it sampled 60 toys (VWA, 2004a). Migration was determined by dynamic agitation. There was no detectable migration of phenol. Isophorone migration occurred in half of the samples; however, this remained well below the defined migration limit.

Monomers

Five monomers have been identified by the EU Expert Group on the chemical safety of toys as being carcinogenic and present in toys. These are vinyl chloride, 1,3-butadiene, acrylonitrile, acrylamide and styrene. These five monomers can be found in acrylonitrile-butadiene-styrene copolymer, polyvinyl chloride and polystyrene. In a study performed by the Danish authorities, 30 samples of toys were assessed for vinyl chloride, butadiene, acrylonitrile and styrene (Danish EPA,

[171] https://www.nvwa.nl/nieuws-en-media/nieuws/2018/07/20/squishies-squeezies-voldoen-aan-onderzochte-chemische-eisen

[172] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures. OJ L 353, 31.12.2008, p. 1–1355.

2019). Acrylonitrile, butadiene and styrene were found in a number of samples. Subsequently, a migration test was performed with the positive samples. However, there was no detectable migration of these substances.

Certain elements

Bits of paint or small bits may get scraped off from plastic toys and these may contain certain elements. Therefore, requirements have also been established for certain elements in toys. Sometimes an excessive release of lead is found. Exceedances for cadmium, barium, aluminium, cobalt or arsenic are much less frequent. For the limits, see the hazard characterisation of certain elements. The limits are based on an average daily intake of 8 mg, a body weight of 7.5 kg and an intake amounting to 10% of the TDI (due to background exposure from other sources such as food and the environment).

Short-chain chlorinated paraffins (SCCPs)

Plastic toys may be contaminated with short-chain chlorinated paraffins (SCCPs). The acute oral toxicity of SCCPs is low. With repeated exposure, the liver, kidneys and thyroid may be affected. For environmental reasons (persistence), these substances may not be placed on the market if the concentration exceeds 1%. Six Safety Gate notifications have been published about plastic toys containing SCCPs. These included various types of toys such as stickers, dolls and bath toys. Only concentration data are available; there are no data on release due to sucking or dermal contact.

Rubber (latex) toys

This is a small category of toys. Examples are rubber ducks for the bath, squeaky toys and balloons or rubber parts of toys (handles, car tyres).

Nitrosamines and nitrosatable substances

Nitrosamines and nitrosatable substances may be present in rubber. Nitrosamines are potentially carcinogenic substances. Nitrosatable substances are the precursors and can react to form nitrosamines. Requirements for these substances are stipulated in the Toy Safety Directive and EN 71-12. From 2014 to 2018, 25 Safety Gate notifications were published regarding excessive release of nitrosamines and/or nitrosatable substances. The countries that actively monitor this are France, Germany and the Netherlands. In 2018, the NVWA carried out a study on balloons (NVWA, 2019a). In 16 of the 28 balloons tested, the level of nitrosamines and nitrosatable substances released was higher than the legal limit. According to the Scientific Committee on Consumer Safety (SCCS), the exceedance of the release limit for nitrosamines by a factor of two poses a serious health risk to children (SCCS, 2012d). Eleven of the 28 balloons tested exceeded the limit by a factor of two or more, and therefore these balloons pose a serious health risk.

PAHs

Rubber may contain PAHs, originating from the filler carbon black. Since these are potentially carcinogenic substances, a restriction of 0.5 mg/kg was laid down in Annex XVII of the REACH Regulation in 2015. Since 2016, five Safety Gate notifications of excessive levels of PAHs, particularly in rubber tyres from toy cars, have been published. The total PAH concentrations ranged from 7 to 350 mg/kg. In the case of one toy car, 55 mg/kg benzo[a]pyrene was reported. The dermal absorption of PAHs is limited (Bokkers et al., 2016).

Textile toys

Textile toys include soft-filled toys as well as toy disguise costumes, clothes for dolls and play tents. Textile toys may contain a number of hazardous substances. Azo dyes are colouring agents that may cleave into primary aromatic amines (PAAs). These PAAs are potentially carcinogenic. Textiles may also contain formaldehyde or may be treated with flame retardants, such as tris(1,3-dichloro-2-propyl) phosphate (TDCP) and tris(2-chloro-1-methylethyl) phosphate (TCPP). Three Safety Gate notifications have been published regarding this; these concern two bath books made of textile and one toy disguise costume set.

Metal toys

Metal toys sometimes contain certain elements. From 2014 to 2018, five Safety Gate notifications were published regarding the excessive release of cadmium and chromium (III). This related to kitchen sets and jewellery sets. Such toys also involve an excessive release of nickel. A requirement has been laid down for the release of nickel, because of rising awareness of this issue. During this period, 16 Safety Gate notifications were also published regarding excessive nickel release from metal parts of toys, such as key rings, handcuffs, jewellery sets and metal construction sets.

Wooden toys

Formaldehyde

Formaldehyde is irritating to the nose and pharynx. From 2014 to 2018, four Safety Gate notifications were published regarding excessive formaldehyde levels. The requirement applicable to wooden toys is that wooden toys or parts thereof must not release more than 80 mg/kg formaldehyde. The Safety Gate notifications mainly relate to puzzles for young children. In 2010, the NVWA carried out a study on the presence of formaldehyde in wooden puzzles. Formaldehyde was present in 22 of the 61 wooden toy samples tested. The highest value measured was 10 mg/kg, which is well below the limit value of 80 mg/kg.

Wood preservatives

EN 71-9 also contains a requirement relating to the release of various wood preservatives. In 2004, the NVWA carried out a study on such wood preservatives (VWA, 2004a). In this study, 75 wooden toys were sampled and examined. Pentachlorophenol was detected in one sample at a concentration of 12 mg/kg. This is many times higher than the limit of 0.4 mg/kg. Pentachlorophenol is a possible carcinogen and toxic when inhaled according to Annex VI of the CLP Regulation[173]. 2,4-dichlorophenol, 2,4,6-trichlorophenol, 2,4,5-trichlorophenol, 2,3,4,6-tetrachlorophenol, lindane, cyflutrin, cypermethrin and permethrin were not detected.

Certain elements

Wooden toys are often painted. Certain elements may be present in the paint. In 2016, the NVWA performed a study on certain elements in painted wooden toys (NVWA, 2017a). A total of 55 samples of wooden toys were tested; these were brightly coloured building toys (blocks, stacking towers) intended for children aged up to two. All 55 toy products (231 paint samples) met the requirements for metals (EN 71-3).

Scented sensory toys

Scented sensory toys are available on the market, though this is a relatively small segment. Examples are scented pencils, cosmetic kits, olfactory board games and squishies. Requirements for allergenic fragrances are laid down in Annex II, Part III, Point 11 of the Toy Safety Directive. For 55 fragrances, the concentrations may not exceed 100 mg/kg. For 11 of these fragrances, the name must be listed on the label at concentrations exceeding 100 mg/kg. In 2016 and in 2018, a Safety Gate notification was published about a scented felt tip pen with excessive levels of allergenic fragrances (benzyl alcohol, benzyl benzoate, geraniol, linalool). Two publications in the literature were found in which allergenic fragrances were determined in scented sensory toys (Masuck et al., 2010; Masuck et al., 2011). Fragrances that could cause contact allergy in the skin may also become bioavailable to children via the inhalation route. Exposure to allergenic fragrances via the inhalation route was assessed as between 2 and 200 ng/kg body weight/day.

Conclusion

Preservatives

A number of preservatives are classified as skin sensitisers (isothiazolinones, formaldehyde) (Severity Category 3). Toys containing aqueous media generally contain preservatives to prevent

[173] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures. OJ L 353, 31.12.2008, p. 1–1355.

microbial spoilage due to the frequency of contact and hand contact involved. Sometimes a combination of preservatives is used. There is often skin contact, prolonged or otherwise, with this type of toy (finger paints, toy-slime). NVWA studies and Safety Gate notifications show that the limit values for preservatives are exceeded. These limit values are often set at the limit of quantification. Isothiazolinones and formaldehyde score high on the list of contact allergies. Only in the case of finger paints is it mandatory to declare the preservative used on the label, so that consumers are warned. Preservatives are also present in other consumer products, including cosmetic products, detergents and cleaning products. Children must be protected so that they do not develop a contact allergy to preservatives. The likelihood of exposure to preservatives by playing with toys containing aqueous media is assessed as occasional. The health risk of developing contact allergy through exposure to preservatives in toys containing aqueous media is assessed as medium.

Nitrosamines and nitrosatable substances

Nitrosamines are potentially carcinogenic substances. Nitrosatable substances are precursors, from which nitrosamines can be formed (Severity Category 4). In finger paints and toy-slime, nitrosamines may be formed from certain secondary amines. Occasionally, concentrations higher than the limit value of 20 µg/kg have been found in finger paints. NDELA is known to have good dermal absorption potential. In rubber, nitrosamines can be formed from carbamates (accelerators). NVWA studies have shown that half of the balloons examined had an excessively high release of nitrosamines and/or nitrosatable substances. According to the SCCS, there is a serious health risk if the release of nitrosamines exceeds the limit value by a factor of two. In practice, such exceedances have occurred. The risk due to exposure to nitrosamines and nitrosatable substances from toys is assessed as high to severe.

Plasticisers

A number of plasticisers (DEHP, DBP, DIDP) are classified as reprotoxic (Severity Category 4). PVC toys often contain added plasticisers. DEHP and DINP are frequently found at concentrations above 0.1% by weight limit and sometimes up to 30% by weight. This is evident from both NVWA studies and Safety Gate notifications. There is no correlation between the migration rate and the concentration. The maximum measured migration rate of DEHP was 5 µg/cm^2/hr. It is assumed that a child plays with toys for an average of two hours a day and there is both dermal and oral exposure to plasticisers. Background exposure via other sources (household dust, other products, personal care products, food) must also be taken into account. A toy is normally assigned 10% of the health-based guidance value. The likelihood that the release of plasticisers from toys will exceed 10% of the health-based guidance value is assessed as occasional. The risk to health from exposure to plasticisers from toys has been assessed as medium to high, but aggregate exposure from other products may increase the risk.

Certain elements

For 17 metals and metal compounds, requirements are established based on health-based guidance values and estimated worst-case intake (Severity Category 3). For some metals the limit has been lowered by a factor of two because of toxicity. This includes arsenic, cadmium, chromium VI, lead, mercury and organic tin (Severity Category 4).

Children tend to suck on their toys and may ingest substances in this manner. There may also be oral exposure through hand-to-mouth contact. It has been assumed that the oral route is the most significant, because the dermal absorption of metals is very low. The worst-case daily intake has been determined per material category. Scratched off: 8 mg. Dry, brittle, powder-like or pliable toy material: 100 mg. Liquid or sticky toy material 400 mg. The limit values are calculated assuming 10% of the health-based guidance value and a body weight of 7.5 kg. NVWA studies on finger paints and painted toys show that these limit values are not exceeded. Safety Gate notifications show that infringements are often reported for boron in toy-slime (27 notifications in 2014--2018). Safety gate notifications have been published about the exceedance of limit values for other metals, including aluminium, cadmium, lead, chromium VI in toy products such as pencils, felt tip pens, crayons, grease pencils, metal toys, cosmetic kits and modelling clay. Tests based on EN 71--3 are one of the most frequently carried out chemical assessments.

For finger paints and painted wooden toys, the health risk from exposure to certain elements is assessed as low. For other toys, the health risk may be higher (low to medium).

Nickel

Dermal exposure to nickel may cause sensitisation (Severity Category 3). Nickel may also be present in other consumer products, including jewellery, spectacles, buttons and zippers. Children have a high level of dermal contact with their toys. It is undesirable for children to develop an allergy to nickel at a young age. Over a period of five years, 16 Safety Gate notifications were published for exceedances of the limit value for nickel release. These included toys such as key rings, handcuffs, jewellery boxes and metal construction sets. The likelihood of sensitisation by exposure to nickel is assessed as rare. The health risk of a consumer becoming sensitised to nickel by wearing jewellery is assessed as low.

Allergenic fragrances

A number of fragrances (26) are classified as skin allergens (Severity Category 3). This concerns a relatively small toy segment. There are no data on the presence of allergenic fragrances in scented sensory toys. However, the literature shows that scented sensory toys may lead to exposure to allergenic fragrances via inhalation and that these substances may become bioavailable. There is also cumulative exposure to allergenic fragrances, because these substances are also used in other products: cosmetic products, detergents and cleaning products and air fresheners. The likelihood of exposure to allergenic fragrances from toys is assessed as occasional. The health risk of sensitisation to allergenic fragrances by exposure to toys is assessed as medium to high.

PAHs

PAHs are potentially carcinogenic substances (Severity Category 4). In rubber toy material, PAHs may be present as fillers. A number of Safety Gate notifications have been published where the limit value of 0.5 mg/kg rubber was exceeded. This concerned, in particular, rubber tyres of toy cars, although dermal exposure to rubber tyres from toy cars will be limited. Oral exposure is possible via hand-to-mouth contact. The dermal absorption potential of PAHs is low. The likelihood of exposure to PAHs from toys is assessed as rare. The health risk from exposure to PAHs from toys is assessed as low to medium.

Bisphenols

Bisphenols are potential endocrine disruptors (Severity Category 4). Bisphenols (BPA, BPS, BPF) may be used as monomers in plastic toy material. Residues from starting materials may be present in the final product. Studies from the United States and Israel have shown that release of BPA can occur. The estimated exposure to BPA from toys remained below the health-based guidance value. One Safety Gate notification has been published about excessive release of BPA. Due to the negative attention focused on BPA, it is possible that this will be substituted by BPF, BPS or other bisphenols. The likelihood of exposure to BPA and other bisphenols from toys is assessed as rare. However, there are no data for toys on the Dutch market. The health risk from exposure to bisphenols from toys is therefore assessed as low to medium.

Formaldehyde

When inhaled, formaldehyde is irritating to the nose and pharynx (Severity Category 2). In resin-bonded wooden toys (chipboard), formaldehyde may be present in the glue/binding agent used. While playing with wooden toys, a child may inhale this formaldehyde. Formaldehyde was present in one-third of the samples examined by the NVWA. The highest concentration was far below the legal limit value. The likelihood of exposure to formaldehyde from wooden puzzles is assessed as rare. The risk is therefore assessed as low.

Wood preservatives

Pentachlorophenol is possibly carcinogenic and toxic by inhalation (Severity Category 4). Children tend to put their toys in their mouths. By chewing and gnawing their toys, children may ingest the substances contained in the toys. A study conducted by the NVWA has shown that pentachlorophenol was found in only one of the 75 samples of wooden toys tested, but this was present in a high concentration (12 mg/kg). Other wood preservatives were not detectable. The

study is rather dated (2004). The likelihood of exposure to pentachlorophenol is assessed as rare. The risk is therefore assessed as low to medium.

SCCPs

The acute oral toxicity of SCCPs is low. With repeated exposure, the liver, kidneys and thyroid may be affected. The restriction is imposed because these paraffins are biopersistent (Severity Category 3). There is a restriction on the concentration of SCCPs. No data are available about the exposure to these substances. Six Safety Gate notifications of excessive concentrations of SCCPs have been published over a five-year period. The likelihood of exposure to SCCPs from toys is assessed as rare. The risk is therefore assessed as low.

Solvents

Several solvents and other volatile substances have been detected in toys, such as isoferon, phenol, toluene, styrene (Severity Category 2--3). Exposure to these substances is mainly via inhalation. Some of these substances have a low odour detection threshold (isoferon, cyclohexanone) that alerts consumers through their 'chemical smell'. These substances are present in toys in cases where the evaporation process was incomplete, and for example, in toys packed in plastic after production. Over the course of time, these substances will evaporate. For a number of solvents, there are legal limit values based on migration. In practice, the level of migration remains below this limit. However, these limit values are quite old and may no longer be up to date. According to the Toy Safety Directive, the concentration of substances may not exceed the classification limit referred to in the CLP Regulation[174]. For solvents, this means that, in practice, 1% or more may be present. For toys, it is desirable to set lower limit values for these substances to avoid unnecessarily exposing children to solvents. This can be prevented by using good manufacturing practices. The likelihood of exposure is assessed as rare. This results in a low risk.

5.4.7. Chemical risks of playground equipment

Playground equipment consist of structures or elements used for the purpose of recreation and amusement. Examples include air cushions, water and other types of slides, climbing equipment, swings, seesaws, sand boxes, trampolines and combinations of these elements in a single piece of equipment. Playground equipment intended for private purposes are regarded as toys.

Since there is a fall hazard involved, requirements are also established for the surfacing. Rubber tiles are used for this type of surfacing. Recycled car tyres are sometimes incorporated in these rubber tiles, which introduces certain substances in the tiles.

Legal framework

Annex XVII of the REACH Regulation (Regulation (EC) No 1907/2006[175], Entry 50) sets a restriction of 1 mg/kg for the maximum concentration of polycyclic aromatic hydrocarbons (PAHs) in rubber or plastics. This restriction concerns rubber articles or rubber parts of articles that, under normal or reasonably foreseeable conditions of use, come into direct, prolonged or repeated short-term contact with the human skin and/or the oral cavity. According to ECHA's interpretation, rubber tiles for playgrounds fall within the scope of this restriction (ECHA, 2018a).

SCCPs (C_{10}-C_{13}) are classified as persistent substances. Therefore, products may not be placed on the market if the SCCP concentration exceeds 1% (Regulation (EC) No 519/2012[176]).

[174] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures. OJ L 353, 31.12.2008, p. 1–1355.

[175] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. OJ L 396, 30.12.2006, p. 1-520

[176] Commission Regulation (EU) No 519/2012 of 19 June 2012 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annex I, OJ L159, 20.6.2012, p. 1--4.

Identification of relevant chemical substances

So far, the NVWA has only studied the PAH concentration in rubber tiles, in accordance with the restriction specified in Entry 50 of the REACH Regulation. Between 2014 and 2018, Safety Gate received 10,062 notifications relating to a potentially high-risk consumer product. Of these notifications, 2,562 (25%) related to the chemical substances category, in addition to other possible risk categories. No notifications were found in the Safety Gate system about rubber tiles. In addition, the relevant literature was searched for references to chemical substances in rubber tiles.

Exposure

Dermal exposure occurs when children's hands, arms and legs come into contact with rubber surfaces. Subsequently, oral exposure may occur via hand-to-mouth contact. When it gets really hot in the summer, there may also be inhalation exposure, especially to volatile PAHs.

Risks

PAHs

In 2014, the NVWA conducted a study on PAHs in rubber tiles (NVWA, 2014b). This study was initiated following an odour-related complaint from a consumer. The rubber tile was found to contain 1400 mg/kg PAHs. In addition, 21 rubber tiles and other surfacing for playgrounds were sampled and examined for PAH concentrations. The concentrations found were much lower, ranging from undetectable to a maximum of 112 mg/kg. At the time of the study, the REACH restriction of 1 mg/kg was not yet in effect.

In 2013, the RIVM carried out a risk assessment (RIVM, 2013). Based on this, BuRO has written an advisory report (BuRO, 2014). Assuming reasonably foreseeable behaviour, BuRO assumes that the health risk is negligible up to a PAH concentration of approximately 50 mg/kg. Above approximately 1,000 mg/kg, the maximum permissible risk of 1 in 10,000 may be exceeded during prolonged periods of play.

In 2016, the RIVM carried out an assessment of whether the current product standard for PAHs in rubber tiles adequately protects users from developing cancer (Bokkers et al., 2016). In the absence of reliable data, such as the extent to which children come into contact with the PAHs in the tiles, only an indication could be given. In a worst-case scenario, the negligible risk level was slightly exceeded.

SCCPs

Chlorinated paraffins (SCCPs) are used in car tyres. Due to the use of recycled car tyres in rubber tiles, these substances are also found in the tiles. A study by Fuel et al. (Brandsma et al., 2019) shows that rubber tiles contain 16-74 µg/g. A small proportion of this is C_{10}-C_{13} chlorinated paraffin (ranging from 2-7 µg/g to a maximum of 25 µg/g). The concentration of chlorinated paraffins remains well below the maximum standard of 1% by weight (1 x 10^7 µg/g).

Other substances

Llompart et al. have studied rubber tiles for the presence of chemicals (Llompart et al., 2013). In addition to PAHs, they demonstrated a wide range of hazardous substances, including phthalates, antioxidants (e.g. BHT, phenols), benzothiazole and derivatives.

Conclusion

PAHs in rubber tiles

PAHs are potentially carcinogenic substances (Severity Category 4). The use of recycled car tyres as a raw material makes it probable that PAHs will be present in the rubber tiles. Rubber tiles are subject to a legal restriction of 1 mg/kg for PAHs. This restriction provides a sufficient level of protection for children at play. However, producers of rubber tiles find it difficult to achieve the limit value of 1 mg/kg in practice. There is a serious health risk involved from a concentration of 1,000 mg/kg onwards. Most rubber tiles will stay under this level. Based on the BuRO risk

assessment, the health risk due to exposure to PAHs from rubber tiles is assessed as low to medium.

SCCPs in rubber tiles

The acute oral toxicity of SCCPs is low. With repeated exposure, the liver, kidneys and thyroid may be affected. The restriction is imposed because these paraffins are biopersistent (Severity Category 3). The presence of SCCPs in rubber tiles is likely, because of the use of recycled car tyres as raw material. For SCCPs, the requirement is based on the effects on the environment. A literature study shows that the concentration is low and the health risk from exposure to SCCPs from rubber tiles is therefore assessed as low.

Other substances

For other substances, there is insufficient insight into the presence and level of exposure. As a result, the risk cannot be assessed.

5.4.8. Chemical risks of tattooing and piercing

Tattoos are permanent markings on the skin made using ink and a needle. Tattooing involves the puncturing of the epidermis and injection of ink into the dermis. The cells in the dermis then encapsulate the ink. Applying permanent makeup is also a form of tattooing, but here the ink is only applied to the epidermis and will fade after a few years. Permanent makeup (PMU) is mainly used for correcting minor physical imperfections or for decorating the body (NVWA, 2016f).

Tattoo inks usually consist of one or more pigments, a solvent (a mixture of water and alcohol as a disinfectant), and a thickening agent to obtain a proper mixture. Given the wide variety in the different colours of inks, the inks contain many different chemicals. Aftercare ointments are applied to a wound after the application of a tattoo. They have a protective effect. In addition, generally available disinfectants are also used (NVWA, 2016f).

There are several ways to remove a tattoo, such as chemical destruction[177], cryotherapy[178], dermabrasion[179], salabrasion[180] or thermal destruction[181]. When these methods are used, the skin takes a long time to heal. Afterwards, a patient may experience pain and suffer from skin discolouration and scarring. Also, the tattoo may not be completely removed (ink retention). Since better methods (lasers) are available, it is advised to stop using these methods (Kirby et al., 2013).

The laser is currently the best-known tool for removing unwanted tattoos. In this process the pigment is heated very briefly (millionth of a second) causing the relatively large balls of pigment in the ink to disintegrate. After that, the immune system clears away the pigment particles broken up into small pieces. By choosing an optimal wavelength for the laser, the normal skin pigmentation remains intact. Laser treatments are not entirely without risks, since in some cases the toxic degradation products of colouring inks (amines in the case of azo dyes) are known to be released. If the heated pigment heats the skin up too much, there may be scarring (Karsai et al., 2010; NVWA, 2016f).

It is estimated that, on average, 12% of Europeans are tattooed, with a higher prevalence among young adults. Most tattoo inks in Europe are imported from the US, while PMU inks are produced in the EU (Piccinini et al., 2016).

In case of piercings, the skin is punctured with a needle. A small bar, ring or other piercing jewellery is inserted into the hole. Sometimes the piercing penetrates not just skin but also cartilage. Piercings can be done in many places on the body, e.g. through the tongue, eyebrow or navel (NVWA, 2016f).

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[177] Piercing or making an incision in the skin to apply tannic acid and/or silver nitrate to the tattoo; applying a phenolic solution or trichloroacetic acid (TCA).
[178] Applying liquid nitrogen to the tattoo.
[179] Shaving the skin using a rapidly rotating brush with steel wire or a rapidly rotating disc with diamond grit.
[180] Abrading the skin using NaCl and an abrasive brush.
[181] Use of thermal or electrocautery or infrared coagulation.

Legal framework

The Commodities Act Decree on Tattooing colourants[182] imposes requirements to ensure the chemical safety of tattoo inks. For example, tattooing colourants may not contain the following: substances that can form aromatic amines (Annex I of the Commodities Act Decree on Tattooing colourants); substances listed in Annex II of the Commodities Act Decree; substances listed in Annex II of the Cosmetic Products Regulation[183]; substances listed in Conditions Column G of Annex IV of the Cosmetic Products Regulation; substances classified as carcinogenic, mutagenic or reprotoxic according to the CLP Regulation[184]; and preservatives.

The General Chemical Product Safety (Commodities Act) Decree (*Warenwetbesluit algemene chemische productveiligheid*)[185] imposes requirements with regard to the concentration of nickel and nickel compounds in piercings. Nickel may not be used in bars that are inserted into holes in the ears and other parts of the human body, unless the rate of nickel release from such bars is no greater than 0.2 µg/cm^2/week.

Identification of relevant substances

In 2012, the Danish EPA sampled 65 tattoo inks available in the Danish market. Heavy metals, PAHs and primary aromatic amines were found in these tattoo inks. Phthalocyanine was found in blue, green and violet inks. Phthalocyanine has not been evaluated by the IARC. The most critical effect of exposure to phthalocyanine compounds is a decrease in the red blood cell count (Danish EPA, 2012).

Between 2014 and 2018, Safety Gate received 10,062 individual notifications relating to potentially high-risk consumer products. Of these notifications, 2,562 (25%) related to the chemical substances category, in addition to other possible risk categories. For tattoo inks and permanent makeup, there were 121 notifications for deviations relating to chemical substances. Most of the notifications concerned heavy metals (38%), aromatic amines (33%) and PAHs (28%).

In 2014 and 2015, for piercings, there were four Safety Gate notifications for deviations relating to chemical substances. Three notifications concerned nickel, and one concerned lead. Between 2016 and 2018, there were no Safety Gate notifications for deviations relating to chemical substances for piercings.

Exposure

Exposure to substances from tattoo inks or other related products takes place via direct contact with the skin. The skin consists of three layers: epidermis, dermis and subcutis. In a tattoo, exogenous pigment is introduced into the dermis. A tattoo basically remains for life, so the consumer is exposed to the chemical substances that are inserted into the skin as well as to their degradation products for a long period of time. The amount of chemical substances a consumer is exposed to depends on the size of the tattoo. One person may have a small tattoo, while another may have his or her entire body covered with tattoos.

When piercings are applied, the skin is punctured, which causes temporary damage to the skin. Chemicals can pass through damaged skin more easily than through intact skin. As far as exposure to chemical substances from piercings is concerned, the period from application until the skin has recovered is the most critical period.

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[182] Decree of 14 August 2003 on establishing rules concerning the safety of tattooing colourants (Tattooing Colourants (Commodities Act) Decree). Bulletin of Acts and Decrees 2003, 342.

[183] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59–209.

[184] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1-1355

[185] Decree of 4 February 1994 limiting the marketing and use of certain hazardous substances or preparations (General Chemical Product Safety (Commodities Act) Decree). Bulletin of Acts and Decrees 1994, 105.

Risks

Since the legislation governing tattooing and PMU products differs from one Member State to another, certain products may be allowed to be sold and used in one Member State but not in another. This makes it difficult to ensure the proper protection of consumer health (Piccinini et al., 2016). Based on the REACH Regulation, studies are conducted on the dermal toxicity of substances, but intradermal exposure is not included in these studies. Therefore, producers of raw materials for tattoo inks are unable to justify the safe use of these inks. In addition, REACH focuses only on raw materials; ready-to-use inks or impurities are not taken into consideration (Laux et al., 2016).

Many people with tattoos experience short-term, recurring or long-term problems due to skin reactions. The cause of these skin reactions has not been investigated, except for a few cases. The number of people who have suffered an allergic reaction as a result of a tattoo is unknown. Tattoo inks contain known allergens (metals, dyes and preservatives). It is possible that chemicals that do not normally penetrate the skin may nevertheless cause an allergic reaction when injected directly into the dermis (Danish EPA, 2017). The Danish EPA has recommended that substances classified as allergens under the CLP Regulation should not be allowed in tattoo inks, that all ingredients of the ink should be declared regardless of whether they are hazardous or not, and that studies should be initiated to better understand, diagnose and prevent adverse reactions (Danish EPA, 2017). Partly based on this recommendation, Denmark, Italy and Norway have submitted a restriction dossier for substances in tattoo inks and PMU (ECHA, 2017b).

A henna tattoo is a temporary tattoo where henna powder, mixed with water or oil, is applied to the skin. Henna colours the skin. The longer the substance stays on, the darker the colour. A synthetic dye (paraphenylenediamine, PPD) may be added to speed up the drying process and create a darker shade (‘black henna’). PPD is a contact allergen and has been found in mixtures for henna tattoos in concentrations greater than the permitted amount in hair dye (6% in the finished product). When these mixtures are applied, sensitisation or an allergic reaction may occur (Calogiuri et al., 2010).

Tattoo inks

Having a tattoo is popular and many people get tattoos. At the same time, the number of tattoos being removed is also increasing. The long-term effects of chemicals in tattoo inks are still unknown, but are potentially a major concern given the large group of exposed consumers. To gain further insight into this area, there is a need for epidemiological studies and studies on how the chemicals from tattoo inks behave in the body (Laux et al., 2016; Piccinini et al., 2016; CD-P-SC, 2017; Danish EPA, 2017). A complete risk assessment of the ingredients of tattoo inks is desirable but not yet possible. Data on phototoxicity, absorption, distribution, metabolism, excretion and health-based guidance values (DNEL) are lacking (Laux et al., 2016; Piccinini et al., 2016). Testing systems to derive health-based guidance values are also unavailable (CD-P-SC, 2017). The Danish EPA could not conduct any risk assessment for chemicals in tattoo inks in 2012 because it was not possible to estimate exposure quantitatively (i.e. the systemic dose) (Danish EPA, 2012).

In 2013, BuRO concluded that the levels of PAHs sometimes found in tattoo ink are of concern (BuRO, 2013). In the period 2015-2016, the NVWA sampled 52 different black tattoo and permanent makeup inks. The NVWA laboratory examined the inks for the presence of PAHs and heavy metals. In total, 17 inks exceeded the limits for PAHs. Of these, three contained the carcinogenic substance benzo[a]pyrene. In 16 of the assessed inks, the sum of 10 PAHs was exceeded. In total, 10 samples demonstrated exceedances of several heavy metals or combinations thereof (arsenic, cadmium, cobalt, lead and zinc). Compared to results from 2014, the NVWA concluded that there was only a limited improvement in the safety of the inks (NVWA, 2017f). In 2015, BuRO issued an advisory report on the risks of azo dyes in tattoo ink (BuRO, 2015). Brightly coloured tattoos in red, orange, yellow and green may be applied with ink containing aromatic amines. When inks containing aromatic amines are used, this results in a non-negligible additional cancer risk (BuRO, 2015).

Under the influence of light, aromatic dyes in tattoos can disintegrate. This causes the colour of a tattoo to fade. Some disintegration products have carcinogenic properties. PAHs and other ink

components can absorb UV radiation, which can create reactive oxygen components (Laux et al., 2016).

Researchers at the BfR examined the lymph nodes of four deceased people with tattoos for the presence of dyes and other chemical compounds derived from tattoo inks. The researchers demonstrated that tattooing colourants can enter the lymph nodes via the skin. Nickel, chromium, aluminum, copper, cadmium, manganese, zinc and titanium were also found in the lymph nodes. It was mostly nanoparticles that ended up in the lymph nodes. Larger particles remained behind in the skin (Schreiver et al., 2017).

Until now, it has been assumed that tattoo inks contaminated with heavy metals can cause an allergic reaction. Researchers at the BfR have discovered that micro and nano-metal particles from tattooing needles may also end up in the skin and lymph nodes and thus cause an allergic reaction. This is an allergic reaction to nickel and chromium (Schreiver et al., 2019).

Cremation ash

Some people want a tattoo in memory of a deceased person applied with the cremation ashes from the deceased. The FO conducted an exploratory risk assessment to determine whether it is safe to use cremation ash in tattoo ink. It was an exploratory assessment due to the lack of sufficient data. The FO concluded that there was no risk of systemic toxicity for metals, dioxins, furans and dioxin-like PCBs. It was unable to make any statement for PAHs and other possible contaminants that are present. No information was available about possible local adverse reactions in the treated skin area or about sensitisation due to the presence of cremation ashes in tattoos (FO, 2015). BuRO was unable to comment on whether tattoos with cremation ashes complied with the legal requirements as laid down in the Tattoos and Piercings (Commodities Act) Decree and the Commodities Act Decree on Tattooing colourants. Given the composition of cremation ash, it may contain harmful substances such as PAHs, which are potentially carcinogenic. Therefore, BuRO advised the NVWA to apply the precautionary principle by pointing out to tattooists that tattoos with cremation ashes must meet the legal requirements for safety and health (BuRO, 2016).

Tattoo removal products

For tattoo removal, surgery and laser treatments are currently the gold standard. Surgery is the preferred solution for small tattoos in areas with sagging skin, but this leaves scars. A laser treatment takes a long time and is painful, with no guarantee that the tattoo will be completely gone. Both methods are expensive and not all consumers can or want to pay for them. That is why consumers are looking for alternatives. Various methods are offered on the internet. The risk of using tattoo removal cream or ointment is that they may lead to the development of contact eczema or cause chemical burns and scars. Since these creams or ointments contain substances that reduce the pigment in the skin, it seems as if the tattoo is fading. There is no cream or ointment on the market that actually removes tattoos (Kluger, 2015). On the internet, the use of TCA (trichloroacetic acid) is still being promoted, despite the fact that this method is no longer used professionally because it leads to scarring. The use of TCA may result in chemical burns that require subsequent medical treatment (Kluger, 2015). On the internet, several products (e.g. e-raze® and Tatt2Away®) are available that all work according to the same principle. Small holes are made in the skin at the site of the tattoo and a chemical substance[186] is then applied repeatedly over a number of days. A crust forms that, when removed, also removes the pigment from the tattoo. The risks of this method are that it may lead to the development of necrosis, secondary infections and scarring, and risks may also arise due to inexpert use by non-medical professionals (Kluger, 2015). In addition, tattooists and other non-medical professionals are interested in the topic because the market is growing, laser equipment from Asia is becoming affordable, and because there is a weakness in the EU regulations regarding the use of lasers for cosmetic procedures by non-medical professionals (Kluger, 2015). This last point has been addressed in the Netherlands by the Quality Framework for Cosmetic Care (*Kwaliteitskader Cosmetische Zorg*) (Zorginstituut Nederland, 2019a). The Quality Framework for Cosmetic Care is

[186] E-raze® contains zinc oxide, magnesium oxide, calcium oxide, isopropanol, triethanolamine and benzoic acid.

intended for all healthcare providers and healthcare institutions that carry out cosmetic or aesthetic medical treatments. It describes the national agreements on how cosmetic care must be organised. The Framework forms a basis for the external supervision by the Health and Youth Care Inspectorate (IGJ). In order to perform cosmetic procedures, the relevant training must be completed, experience must be gained, and this experience must be demonstrably maintained (Zorginstituut Nederland, 2019a).

Piercing

It is assumed that ear piercings are the main source of nickel sensitisation (Johansen & Werfel, 2019; Markel et al., 2019). The restriction of nickel under REACH has substantially reduced the prevalence of nickel allergy in Europe (Ahlström et al., 2017). But this has not yet eliminated the nickel allergy problem (Johansen & Werfel, 2019). In the Netherlands, consumer products (jewellery, metal on clothing, watches and sewing equipment) that do not comply with the nickel restriction have been found. Only one piercing was tested and this was in compliance with the nickel restriction (Biesterbos et al., 2011). Contact with these products may cause nickel allergy in sensitised consumers.

Conclusions

There may be substances in tattoo ink that can be harmful to health. Tattoo inks contain known allergens (metals, dyes and preservatives) and azo dyes. Even substances that normally do not cause an allergic reaction when applied to the skin, may nevertheless cause an allergic reaction when applied. The particular route of exposure in case of tattoos (intradermal) has not been taken into consideration in the safety assessment of chemicals under REACH. Brightly coloured tattoos in red, orange, yellow and green may be applied with ink containing aromatic amines. The use of inks containing aromatic amines poses a non-negligible additional cancer risk.

The long-term effects of chemicals in tattoo inks are still unknown, but are potentially a major concern given the large group of exposed consumers. A full risk assessment of the ingredients of tattoo inks is desirable but not yet possible due to a lack of data.

The synthetic colourant paraphenylenediamine is a contact allergen. When this substance is added to henna powder, application to the skin may result in sensitisation or an allergic reaction.

The safety of tattoos with cremation ashes has been assessed in an exploratory manner. The presence of PAHs and other unknown contaminants may be a cause for concern. Further studies are required in this area.

Various methods are offered on the internet for the removal of tattoos. Apart from being ineffective, the use of chemical agents is not without risk (chemical burns, necrosis, secondary infections and scarring). When using a laser, toxic degradation products may be released from the tattoo inks.

Having a tattoo is becoming increasingly popular, especially among young adults. Therefore, the target group is quite large. Inks contain aromatic amines, PAHs and allergens. The amount of aromatic amines, PAHs and allergens to which a consumer is exposed depends on the size of the tattoo. The likelihood of health effects is assessed as occasional. The damage to health resulting from the application of a tattoo is assessed as long-term effects that are possibly irreversible. The combined assessment of likelihood and severity results in a medium to high risk for the consumer, although there are large uncertainties in this assessment.

Some of the consumers who get a tattoo later regret having done this and they then try to get the tattoo removed with a laser treatment. It is not clear how many consumers this involves. When using a laser, toxic degradation products of colour inks are released. The amount depends on the size of the tattoo being removed. The likelihood of health effects is assessed as rare. The damage to health resulting from the removal of a tattoo using a laser is assessed as long-term effects that are possibly irreversible. The combined assessment of likelihood and severity results in a low risk for the consumer.

The number of consumers who try to remove a tattoo using chemical products is not known. The use of chemical products may cause contact eczema, chemical burns and scarring. The likelihood

of health effects is assessed as rare. The damage to health resulting from the removal of a tattoo using chemical products is assessed as long-term effects that are possibly irreversible. The combined assessment of likelihood and severity results in a low risk for the consumer.

5.4.9. Chemical risks of textiles

The word 'textile' literally means 'that which is woven'. A piece of textile consists of long or short threads that have been woven, knitted, knotted, braided or felted. It may be used as a raw material on the roll from which an end product is made, such as clothing. Textiles include a range of end products such as clothing, linen, bed linen, home textiles, furnishing fabrics, carpets and rugs. It also includes haberdashery, yarns and knitting yarns. The term 'clothing' should be considered very broadly: leather clothes, baby clothes, underwear, everyday clothes, work clothes, sportswear, swimwear, as well as accessories such as scarves, bags, gloves and footwear (NVWA, 2016f).

Chemical substances are added to improve the properties of textiles. They can help make textiles more fire resistant as well as stronger, more durable, moisture resistant, shinier or dirt repellent (NVWA, 2016f). Some clothing is treated with chemical substances to give it, for example, an anti-bacterial function. This is then considered as a treated article and falls under the Biocidal Products Regulation. Swimwear for babies and small children are sometimes treated with substances to make them UV resistant.

Legal framework

Requirements have been laid down for the chemical properties of textiles and leather. There are several articles of law in Dutch legislation and European regulations that are applicable to clothing and textiles. The Commodities Act Decree on Formaldehyde in textiles [187] sets out requirements for formaldehyde concentrations that are allowed to be present in textiles before and after washing. The REACH Regulation[188] establishes requirements for chemical substances in consumer products. Important requirements for textiles and leather are laid down in Annex XVII (restricted substances), Annex XIV (requirements for SVHCs) and the candidate list of substances in articles that are subject to authorisation. According to Annex XVII, from 1 November 2020 onwards, textiles may no longer be placed on the market if they contain certain levels of carcinogenic, mutagenic or reprotoxic (CMR) substances. The concentration of formaldehyde is lower than the level currently described in the Commodities Act Decree. For metal clothing accessories and haberdashery, such as press-studs, fasteners, rivets and metal logo tags, there are requirements relating to the release of nickel (Annex XVII, REACH Regulation). Annex XVII also contains a restriction for chromium VI in leather (3 mg/kg) and azo dyes in textiles (30 mg/kg). Regulation 2019/1021[189] prohibits the use of certain persistent organic pollutants such as polybrominated diphenyl ethers used as flame retardants, perfluorooctane sulfonates (PFOS) and short-chain chlorinated paraffins (SCCPs) in textiles and leather.

Identification of relevant substances

Between 2014 and 2018, Safety Gate received 10,062 individual notifications relating to potentially high-risk consumer products. Of these notifications, 2,562 (25%) related to the chemical substances category, in addition to other possible risk categories. For textiles, there were notifications regarding 363 deviations relating to chemical substances. The substance involved in one notification is not known. The largest proportion of notifications (77%) related to heavy metals, mainly chromium VI. Other notifications concerned aldehydes, aromatic amines, azo dyes, biocidal products, phenols, phthalates, halogenated hydrocarbons and PAHs.

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[187] Decree of 22 March 2001 establishing the Formaldehyde in Textiles (Commodities Act) Decree. Bulletin of Acts and Decrees 2001, 178.

[188] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. OJ L 396, 30.12.2006, p. 1-520

[189] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (Text with EEA relevance). PE/61/2019/REV/1 OJ L 169, 25.6.2019, p. 45-77. 45-77

In 2014, the RIVM compiled a ranking of the substances registered for use in textiles in the European legislation REACH. The RIVM identified 788 substances, 32 of which were assigned the highest priority. Most of the high priority substances were colouring agents and flame retardants (Nijkamp et al., 2014). In the report, the RIVM prepared an overview of the then recent reports describing chemical substances in textiles. Substances and substance groups mentioned in this context are: nanoparticles, persistent organic pollutants, chlorinated aliphatic industrial chemicals, nonylphenol ethoxylates, phthalates, formaldehyde, isocyanates, biocidal products (aldicarb, parathion), azo dyes that release aromatic amines and heavy metals (Nijkamp et al., 2014).

Clothing may be treated with biocidal products. In 2018, a new Dutch standard became available for clothing treated with permethrin (NEN 8333:2018). This treatment is intended to keep ticks away (Kennisnetwerk Biociden, 2018).

The Changing Markets Foundation has published a study report on the presence of chemical substances in carpets available on the European market (Changing Markets Foundation, 2018). The assessments were carried out by Vrije Universiteit Amsterdam, the Ecology Center in the United States and the University of Notre Dame in France. A total of fifteen carpets were examined. The carpets were found to contain the following substances: phthalates, flame retardants, nonylphenol, perfluorinated compounds, biocidal products, bisphenols and isocyanates (Changing Markets Foundation, 2018).

Exposure

Exposure to substances in textiles occurs via direct skin contact or via inhalation if the substances evaporate. If the skin is damaged in any way, chemical substances can enter the body more easily, so exposure is greater than with intact skin. Oral exposure only occurs when textiles are placed in the mouth, e.g. by sucking or chewing (babies and children). Conducting a risk assessment is complicated by the limited availability of exposure data (Nijkamp et al., 2014).

Risks

Most chemical substances used in the manufacture of textile products are washed out after production. However, residues of these substances may remain in the final product, and the consumer may be exposed to these residues during use. Although regulated substances are controlled within the EU, controlling the presence of non-regulated chemical substances in textiles, and particularly in clothing, remains a challenge. This is due to the continuous relocation of textile production to countries with less stringent environmental and working conditions requirements, the complex world of raw materials and the large number of producers involved in the various production steps (Rovira & Domingo, 2019). Changing fashion trends mean that different dyes and other chemicals are increasingly being used in the production process of clothing (Fransson & Molander, 2013; Luongo et al., 2014).

Flame retardants and trace elements may be present in textiles in such high concentrations that the possibility of dermal exposure cannot be ignored. The exact contribution of dermal exposure needs to be studied further (Abdallah et al., 2015; Abdallah & Harrad, 2018; Rovira & Domingo, 2019). Azo dyes and aromatic amines from textile dyes may cause contact allergy. Due to their carcinogenic properties, 22 aromatic amines are prohibited in clothing in the EU. Research shows that azo dyes also contain aromatic amines. This is a cause for concern (Bruschweiler & Merlot, 2017). Perfluorinated compounds (PFOS and PFOA) are present in textiles and migrate into washing water. This results in direct and indirect (via the environment) exposure of consumers (Supreeyasunthorn et al., 2016). Information on dermal exposure to metallic nanoparticles (mainly silver) from textiles is limited (Rovira & Domingo, 2019).

In 2012, the BfR made an overview of potential problems relating to clothing. It concluded that chemical substances in clothing can cause contact allergy. Besides this local effect, systemic toxic effects are not expected. Aromatic amines prohibited in the EU may still be present in imported textiles (BfR, 2012).

In 2014, KEMI (Swedish Chemicals Agency) collected available and relevant information on the health risks of potentially hazardous substances in textile products (KEMI, 2014). KEMI concluded that information on chemical substances in this domain was not properly communicated, making it

unclear which chemical substances are present in textile products. The presence of potentially hazardous substances in textile products, including azo dyes, required further research. In 2014, the Danish EPA studied the use of biocidal products to protect clothing from pests during transportation and the potential risks to consumers due to such use. The study focused on clothing imported from countries outside the EU (Danish EPA, 2014). The Danish EPA concluded that the use of biocidal products could not be verified based on the product information. Subsequently, 34 items of clothing worn directly on the skin were assessed for the presence of biocidal products. Formaldehyde (3-23 mg/kg) was found in seven of these items and permethrin (367-407 mg/kg) was found in two items. The Danish EPA concluded that formaldehyde and permethrin at the concentrations found in clothing do not pose a health risk to children or adults (Danish EPA, 2014).

Antibacterial fibres and various antibacterial chemicals available in the international market are synthetic in origin and not environmentally friendly. The textile industry is looking for more environmentally friendly alternatives. The focus is on natural antibacterial products. This may include plant extracts, essential oils or natural pigments (Tawiah et al., 2016; Raichurkar et al., 2017). 'Natural' does not automatically mean without risk; this needs to be studied further where appropriate.

ANSES identified chemical substances in clothing and footwear that may be sensitising or irritating to the skin (ANSES, 2018). This concerned the following substances and substance groups: 1,4-phenylenediamine, benzyl benzoate, chromium VI, dyes, nonylphenol and nonylphenol ethoxylate, parabens, butylated hydroxytoluene, 2-phenoxyethanol, cadmium, nickel, 2-mercaptobenzothiazole, biocidal products, aniline, formaldehyde and para-tert-butylphenol and dromethrizole. Subsequently, ANSES made a general recommendation for a study on the association between contact allergy and exposure to benzyl benzoate, parabens, and dromitrizole. ANSES stressed that consumers should always wash clothes before wearing them. It recommended that the French and other authorities should limit and systematically monitor the presence of 1,4-phenylenediamine in clothing and footwear, limit the presence of 2-phenoxyethanol, cadmium, 2-mercaptobenzothiazole and aniline, lower the legal limit for chromium VI and establish a legal limit for nickel (ANSES, 2018). Following the French report, France and Sweden jointly submitted a proposal for restrictions to ECHA to better protect consumers from the risks of skin allergies (ANSES, 2019b; KEMI, 2019)[190].

Leather products

Between 2000 and 2006, the concentration of chromium VI was determined in 850 leather products in Germany. Chromium VI was detected in half of these products, and the concentration was higher than 10 mg per kg leather in one-sixth of the products. The BfR concluded that the levels of chromium VI found could potentially cause allergic reactions (BfR, 2007).

Jeans

In 2018, the NVWA sampled 104 pairs of jeans. Only unwashed and unbleached jeans with a dark or bright colour (black, dark blue, red, green or yellow) were included in the study. These colours contain the highest concentration of azo dyes. The NVWA laboratory tested the jeans for the presence and concentration of aromatic amines that can be formed from azo dyes, as well as for the presence and concentration of formaldehyde. One or more aromatic amines were found in seven pairs of jeans. These included the aromatic amines benzidine, 4-methylene-m-phenylenediamine, 4-chloroaniline, o-anisidine and 3,3'-dimethoxybenzidine at concentrations of 0.2 to 4 mg/kg. These concentrations are lower than the legal requirement of 30 mg/kg. Formaldehyde was found in four pairs of jeans at a concentration of 8 to 31 mg/kg. These concentrations are lower than the legal requirement of 120 mg/kg (NVWA, 2019c).

Sports and work gloves

In 2017, NVWA sampled 28 sport gloves and 24 work gloves. Based on ISO 17075, the NVWA examined the leather in the gloves for chromium VI concentrations. With respect to chromium VI concentrations, the gloves need to fulfil the requirement specified under No 47 in Annex XVII of

[190] More details can be found on the ECHA website https://echa.europa.eu/nl/registry-of-restriction-intentions/-/dislist/details/0b0236e182446136.

the REACH Regulation (Regulation (EC) No 1907/2006). The concentration of chromium VI must be less than 3 mg/kg. Four of the 28 sports gloves (14%) and one of 24 work gloves (4%) examined contained excessive concentrations of chromium VI (NVWA, 2017d).

Carpet

In 2016, the Danish EPA examined nursery carpets for the presence of volatile organic compounds (VOC), phthalates and perfluorinated compounds (PFAS). Chemical assessment of 21 carpets showed that there was an evaporation of VOCs[191] and diethyl phthalates in varying concentrations from all the carpets after one day. The concentration of VOCs that evaporated from the carpets decreased with the passage of time. PFOA was found in five carpets. Based on a risk assessment, the Danish EPA concluded that there was no cause for concern if these carpets were used in the nursery (Danish EPA, 2016a).

Conclusions

Most chemical substances used in the manufacture of textile products are washed out after production. However, residues of these substances may remain in the final product, and the consumer may be exposed to these residues during use. Information on chemical substances in this domain is not properly communicated, making it unclear which chemical substances are present in textile products.

Flame retardants and trace elements may be present in textiles in such high concentrations that the possibility of dermal exposure cannot be ignored. The exact contribution of dermal exposure needs to be studied further. PFAS and aromatic amines are also present in textiles. Information on skin exposure to (silver) nanoparticles from textiles is limited. The likelihood of exposure to flame retardants, PFAS and aromatic amines in textiles is assessed as rare. The severity of health effects due to exposure to flame retardants and PFAS is assessed as long-term effects that are possibly irreversible and as causing more than 10% disability or death (aromatic amines). For flame retardants and PFAS, the combination of likelihood and severity results in a low risk for the consumer. For aromatic amines, the combination of likelihood and severity results in a low to medium risk for the consumer.

Textiles may contain a large number of substances (such as azo dyes/aromatic amines, alkylphenols, perfluorinated compounds and the specific substances chromium VI, 2-phenoxyethanol, cadmium, 2-mercaptobenzothiazole and nickel) that can potentially sensitise or irritate the skin, causing local effects. Every consumer comes into contact with textiles in some way or the other. Textiles sometimes contain high concentrations of allergenic substances. The likelihood of health effects is assessed as rare. The damage to health resulting from exposure to textiles containing allergenic substances is assessed as long-term effects that are possibly irreversible. The combined assessment of likelihood and effect results in a low risk for the consumer.

5.4.10. Chemical risks of other products

Consumer products that do not fall under one of the subdomains (with specific legislation) are categorised by the NVWA as general consumer products. This is a very diverse segment. These include scented candles, jewellery, tools and sporting goods. The risks associated with child use and care articles have been described separately in this document and are not included in this category.

Legal framework

Consumer products must comply with the General Product Safety Directive 2001/95/EC[192]. This Directive sets out general safety requirements but does not contain any specific chemical requirements. The general requirement is that a product must be safe and that, under normal or reasonably foreseeable conditions of use, it must not present any risk or present only the

[191] Including naphthalene, phenol, styrene, toluene, dimethylformamide, dichloromethane and benzene.
[192] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. OJ L 11, 15.1.2002, p. 4–17.

minimum risks that are compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons.

For certain chemical substances in products, restrictions have been imposed in Annex XVII of the REACH Regulation (EC) No 1907/2006[193]. Cadmium and its compounds must not be present in beads and metal components of jewellery in a concentration greater than 0.01% by weight (Entry 23). Nickel must not migrate from any post assemblies that are inserted into holes in the ears and other parts of the human body at a rate higher than 0.2 µg/cm^2/week. This migration limit also applies to metal intended for direct and prolonged contact with the skin (Entry 27). Lead and its compounds must not be present in components of jewellery in a concentration greater than 0.05% by weight (Entry 63). Rubber or plastic components of consumer products that come into direct, prolonged or short-term repetitive contact with the human skin or the oral cavity may not contain more than 1 mg/kg PAHs (Entry 50).

SCCPs (C_{10}-C_{13}) are classified as persistent substances. Therefore, products may not be placed on the market if the SCCP concentration exceeds 1% (POP Regulation (EC) No 519/2012[194]).

Identification of relevant chemical substances

Between 2014 and 2018, Safety Gate received 10,062 notifications relating to a potentially high-risk consumer product. Of these notifications, 2,562 (25%) related to the chemical substances category, in addition to other possible risk categories. In total, there were 319 Safety Gate notifications about the chemical safety of all the consumer products not covered by one of the other subdomains. In addition, information was derived from NVWA studies, scientific literature and ANSES.

Exposure

There are a wide variety of products in this category. The exposure will be different for each product. For most products, dermal and inhalation exposure will be the main routes of exposure.

Risks

Rubber consumer products

From 2014 to 2018, 11 Safety Gate notifications were published regarding excessive levels of PAHs in consumer products in this subdomain. These notifications concerned tool handles and sports equipment. The detected concentrations of PAHs exceeded 1500 mg/kg. There are no exposure data. The dermal absorption of PAHs is limited (Bokkers et al., 2016). In addition to PAHs, SCCPs were also found in these types of products up to a concentration of 2% by weight.

Jewellery

For jewellery, specific restrictions are set in Annex XVII of the REACH Regulation for a number of heavy metals: lead, cadmium and nickel. Nickel is a skin allergen. Long-term exposure to cadmium may cause kidney damage. Inorganic lead is a possible carcinogen. In addition, lead is classified as neurotoxic. Most of the Safety Gate notifications (248 out of 319) related to exceedances of the cadmium concentration in jewellery. Concentrations of up to 95% by weight have been reported. Exceedances of the restriction for lead and an excess release of nickel were also reported.

In the period 2016-2017, the NVWA conducted a study on the presence of lead, cadmium and nickel in jewellery (NVWA, 2017i). In this study, 21% (24 of 113) of the necklaces and earrings examined did not meet the assessed safety requirements. Moreover, 15% of the jewellery

[193] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. OJ L 396, 30.12.2006, p. 1-520

[194] Commission Regulation (EU) No 519/2012 of 19 June 2012 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annex I, OJ L159, 20.6.2012, p. 1--4.

contained too much cadmium, 8% contained too much lead, and 5% of the earrings released too much nickel.

Sex toys/erotic articles

This segment consists of different types of products. Some are intended for internal contact, such as vibrators, dildos, anal plugs. These products come into contact with the mucous membranes. There is also a category of inflatable toys (e.g. a doll) or products such as an artificial vagina. In 2002, the Ministry of Housing, Spatial Planning and the Environment Inspectorate carried out a study on cadmium concentrations in erotic articles. Approximately 37% of the products examined were found to contain cadmium at concentrations exceeding 100 mg/kg (maximum permitted concentration). Due to the possible health risk, the VWA studied the release of cadmium, which was between 0 and 439 µg of cadmium per article. Subsequently, the RIVM carried out a risk assessment (Baars AJ & Van Leeuwen FXR, 2002). Internal use of erotic articles may lead to exposure to cadmium, but this does not lead to any adverse health effects.

Since the products are often made of soft material, plasticisers may be present. A number of plasticisers are classified as reprotoxic. In 2009, the VWA carried out a study on various consumer products in the erotic sector, including vibrators and dildos (VWA, 2009a). A total of 71 different erotic articles, including vibrators, dildos, balls, butterflies and artificial vaginas, were examined. The articles were intended for both men and women and for both vaginal and anal use. These products are mostly made in China. The majority were made of plasticised PVC. The most frequently detected plasticisers were DEHP and DINP. The release of plasticisers was also found in certain products. Based on these results, a risk assessment has been performed (Janssen PJCM & Bremmer HJ, 29 September 2010; BuRO, 2011b). In case of intensive use, professional or otherwise, a health risk may arise due to exposure to phthalates.

Hygiene products

There have been media reports about the presence of hazardous substances in a number of hygiene products (diapers, sanitary towels, tampons). When chlorine gas is used for bleaching cotton, this may lead to the formation of dioxins. Dioxins are carcinogenic substances. Scialli's research shows that, since 2001, chlorine is generally no longer being used for bleaching cotton (Scialli, 2001). Dioxins may still be present as a widespread environmental contaminant, but a link with a condition such as endometriosis has not been demonstrated and exposure from food is many orders of magnitude higher.

A report on substances in nappies was recently published by ANSES (ANSES, 2019a). The substances detected in diapers include volatile organic compounds, PAHs, dioxins, furans, formaldehyde, pesticides and fragrances. There are no epidemiological data to demonstrate a link between health effects and the wearing of diapers. However, several chemical substances have been found in the layers of the diaper. ANSES does not rule out the possibility of a health risk associated with the wearing of disposable diapers.

Conclusion

Rubber consumer products

PAHs are potentially carcinogenic substances (Severity Category 4). The acute oral toxicity of SCCPs is low. With repeated exposure, the liver, kidneys and thyroid may be affected (Severity Category 3). A restriction has been laid down because these paraffins are biopersistent.

Safety Gate notifications indicate that there are rubber consumer products on the European market containing excessive levels of PAHs and SCCPs. These include, for example, tool handles and sports equipment. High levels of PAHs (up to 1500 mg/kg) have been reported. In case of tool handles and sports equipment, there is dermal contact, which may be intensive. There is a restriction on the concentration of both substance groups. There are no known data on the release of these substances. Dermal absorption of these substances is limited. For SCCPs, the requirement is based on the effects on the environment. A concentration of up to 2% has been reported. There are no exposure data. The likelihood of exposure to PAHs or SCCPs through dermal contact with rubber handles or sports equipment is assessed as rare.

The health risk from exposure to PAHs from rubber consumer products is assessed as low to medium. The health risk from exposure to SCCPs from rubber consumer products is assessed as low.

Nickel in jewellery

Dermal exposure to nickel may cause sensitisation (Severity Category 3). Nickel is not only present in jewellery, but can also be found in spectacles, zippers, buttons, watches, etc. When someone is sensitised to nickel, a reaction may occur even at a low dose.

The majority of consumers wear jewellery with some regularity, involving frequent and prolonged skin contact. Consumers sometimes wear multiple pieces of jewellery at the same time. A study conducted by the NVWA showed that 5% of the tested earrings had excessively high nickel release. Safety Gate notifications also show that there are regular cases of exceedance in Europe. The likelihood of sensitisation occurring due to cumulative exposure to nickel is assessed as rare. The health risk of a consumer becoming sensitised to nickel by wearing jewellery is assessed as low to medium.

Lead and cadmium in jewellery

Long-term exposure to cadmium may cause kidney damage (Severity Category 3). Inorganic lead is a possible carcinogen. In addition, lead is classified as neurotoxic (Severity Category 4).

The majority of consumers wear jewellery with some regularity, involving frequent and prolonged skin contact. Consumers sometimes wear multiple pieces of jewellery at the same time. A study by the NVWA shows that 15% of the earrings examined had excessive cadmium concentrations and 8% had excessive lead concentrations. Safety Gate contains notifications about the exceedance of cadmium concentrations in particular. High concentrations have been found: for cadmium, up to 50%, and for lead, up to 14%. The concentrations cannot be directly linked to exposure. There are no data on migration to the skin. The absorption of lead and cadmium through the skin is low. The likelihood of consumers being exposed to lead and cadmium by wearing jewellery is assessed as occasional.

The overall health risk of exposure to lead and cadmium from wearing jewellery is assessed as high to severe for lead and medium to high for cadmium.

Plasticisers in sex toys and erotic articles

Some of the plasticisers (DEHP, DIDP) are classified as reprotoxic (Severity Category 4). Long-term exposure to cadmium may cause kidney damage (Severity Category 3).

The percentage of the population using sex toys is not known. The frequency and duration of use vary; for private purposes, one hour twice a week is assumed. Intensive professional use is assumed to be two hours a day for five days a week. Given the good blood circulation in the vaginal and anal tissues, it is assumed that the cadmium and DEHP released during use are immediately and completely absorbed into the bloodstream.

The 2002 study showed that about 37% of the vibrators examined contained more than 100 mg/kg cadmium. The release of cadmium was between 0 and 439 µg cadmium per article. The exposure to cadmium remains below the health-based guidance value.

The NVWA study in 2009 showed that the majority of sex toys were made of plasticised PVC. The most frequently detected plasticisers were DEHP and DINP. DEHP concentrations vary from 9 to 77% by weight. The highest measured migration rate of DEHP was 23.9 µg/10 cm^2/min. The contact area with tissue (vaginal or anal) is estimated to be 125 cm^2. For private use, the exposure to DEHP remains below the health-based guidance value. In case of intensive professional use, a health risk may arise due to exposure to DEHP.

The health risk in case of intensive use (worst case) is assessed as low to medium, while the health risk when used for private purposes is assessed as low. However, it should be noted that the measurement data are outdated and that the consumer market for these products is dynamic. As a result, it is not possible to make an adequate assessment of the risks of products currently available on the market.

Dioxins in hygiene products

Dioxins are carcinogenic substances (Severity Category 4).

Babies and small children use a lot of disposable diapers. Women use monthly hygiene products (sanitary towels, panty liners, tampons). In case of diapers, there is frequent and prolonged contact. For feminine hygiene products, the contact is less frequent. No data were found on potential exposure to dioxins from hygiene products. Since chlorine is hardly ever used as a bleaching agent, there is rarely any formation of dioxins. The likelihood of exposure is therefore assessed as rare.

The health risk from exposure to dioxins from hygiene products is assessed as low to medium.

6. Assessment of the microbiological risks of consumer products

6.1. General

Microbiological risks arise due to the presence of pathogens in a consumer product. These may include bacteria, parasites, viruses, yeasts and fungi. Each of these pathogens have different reservoirs and they also differ in terms of the conditions under which, and the period of time for which, they can survive or remain infectious (US FDA, 2012).

The effects of microbiological risks can range from mild (diarrhoea, itching) to severe (necrosis, sepsis, death). In order to identify the hazards, it is important to understand the microbiological hazards associated with consumer products and the route of transmission through which the use of these consumer products can lead to infections. The characterisation of microbiological hazards looks at how potential microbial hazards can get into consumer products, whether they can survive in them and whether growth or accumulation occurs. In addition, a statement is made regarding the maximum severity of the risk. The exposure assessment provides insight into how often and to what extent pathogens occur in consumer products and lead to cases of disease in humans. Subsequently, the risk assessment examined whether the pathogen is likely to occur in products in the Netherlands, whether it causes a relevant burden of disease in the Netherlands, and whether consumer products contribute to this in any way. Since the microbiological hazards and risks arising from consumer products are still unexplored territory, all the subdomains have been assessed for this microbiological component and not just those found relevant in advance.

6.2. Transmission of microorganisms

The extent to which exposure to microorganisms can lead to a risk of infection depends on virulence, host-related factors and environmental factors. The microorganism may be a bacterium, virus or parasite that is capable of causing an infection. The host may be susceptible to infection to a greater or lesser extent after exposure, depending on age, sex, susceptibility and behaviour. Environmental factors are extrinsic factors that influence the microorganism and the possibility of exposure, such as geography, climate and population density.

Transmission occurs when a microorganism leaves the reservoir (or host), is spread via a route of transmission and enters the body of a susceptible host through a '*porte d'entrée*', where it can become pathogenic and cause infection. A reservoir may be living organisms (plants or animals) as well as non-living material such as soil or water. Transmission may occur as a result of direct contact, e.g. touching or via droplets on the mucous membranes of the nose, eyes or mouth. Indirect transmission may occur via objects such as toys, clothing, hospital equipment or clothes or water. In some cases, the microorganism may multiply on the object before transmission occurs. Airborne transmission may also occur when microorganisms enter the body through aerosols or dust, usually via the respiratory tract.

Exposure to pathogens does not necessarily mean a risk of infection. This depends on where the pathogen ends up. Many bacteria belong to the commensal microbiota of humans, such as those that reside on the skin or in the gut, where these bacteria are in balance with each other. But when an intestinal or skin bacterium enters the body via a '*porte d'entrée*' elsewhere, e.g. via a bladder catheter in the bladder or via skin cream in a wound, it can grow into numbers that lead to infection. The susceptibility and resistance of the host also plays a role.

The route of transmission and pathogenic potential differs per pathogen and therefore the hazard identification describes the virulence per microbiological hazard.

6.3. Descriptions of microbiological hazards

In this chapter, the microbiological hazards are identified and described in detail as far as possible: how can they cause damage to health, how severe can the damage be, what is the route of transmission taken by the pathogen and which group of people is most sensitive to these hazards?

6.3.1. Data sources for hazard identification

Safety Gate

Part of the information on microbial risks in consumer products was obtained from the notifications in the European information system Safety Gate: Rapid alert system for dangerous non-food products (Table 37).

Table 37 Microorganisms detected in consumer products reported in Safety Gate from 2014 to 2018

	2014*	2015*	2016*	2017*	2018*
Indicator organisms					
Aerobic mesophilic colony-forming unit count**	31	12	29	18	10
	12	*6*	24	18	9
Specified bacteria	3	1	3	3	3
Specified fungi	2	0	2	1	1
Specified yeasts					
Coliform bacteria	1	0	0	0	0
Error in sterilisation process	1	0	0	0	0
Opportunistic or other pathogens					1
Pseudomonas spp. **	7	4	8	5	3
Specified *P. aeruginosa*	7	4	*4*	4	3
Specified *P. putida*	0	0	0	1	0
Staphylococcus aureus	1	0	1	0	0
Burkholderia cepacian	1	1	0	0	0
Stenotrophomanas maltophilia	0	0	0	1	0
Enterobacter cloacae	1	0	0	3	0
Enterobacter gergoviae	0	0	2	1	0
Enterobacteriaceae	0	0	2	3	0
Total	43*	17*	42*	31*	14*

* Including notifications involving more than one microorganism or group of microorganisms: 9 notifications in 2014; 5 in 2015; 11 in 2016; 10 in 2017; 6 in 2018.
** Part not specified.

RASFF

With respect to consumer products, notifications about food contact materials are made in the RASFF. These relate to measurements in the products before they actually come into contact with the food, i.e. about the hazards inherent in the product. In the substantiation, the notifications from the period 2014-2018 for the food contact materials product category, in which microbiological hazards were involved, have been assessed. Of the 722 notifications from 2014 to 2018, one case referred to a microbial hazard, i.e. aerobic mesophilic microbiota. Although this is not a microorganism that is pathogenic to humans, the aerobic mesophilic colony-forming unit count is used as a hygiene indicator and indicator of pathogens that can survive along this route.

RIVM report

Based on the RIVM report (De Jonge, 2019), the following pathogens may be present in consumer products that fall within the scope of this domain description: the bacteria *Actinobacteria, Bacillus spp., Burkholderia cepacia, Candida albicans, Candida parapsilosis, Enterobacter gergoviae,*

Enterobacteriaceae, Escherichia coli, Klebsiella oxytoca, Legionella spp., Mycobacterium chelonae, Pseudomonas aeruginosa spp., Salmonella spp., Serratia marcescens and *Staphylococcus aureus*; the parasite *Toxocara*; the fungi *Basidiomycota, Ascomycota, Histoplasma capsulatum*; and the yeast *Candida krusei*. Viruses are also mentioned but not further specified.

Recent developments during the pandemic

At the time of the publication of this risk assessment, there is an ongoing pandemic involving a new coronavirus for humans named SARS-CoV-2. Although the virus emerged after the date followed for inclusion of literature references, it was decided to describe the pandemic situation caused by a virus. Since little was initially known about this virus, published scientific data are still scarce at this stage and the reliability of these data is currently difficult to assess, the websites of WHO (www.who.int), BfR (www.bfr.bund.de) and RIVM (www.rivm.nl) have been used as sources of information about the pandemic of the 'coronavirus disease 2019' or COVID-19.

6.3.2. Description of pathogens

Identification of microbial hazards causing human disease

The microorganisms mentioned below are part of the long list of microorganisms that can occur in consumer products, based on the three data sources mentioned above (RAPEX, RASFF, RIVM report). The microorganisms on this list can be classified with regard to their pathogenic potential (Table 38).

- Frequently associated with disease or notifiable under the contingency plans or guidelines of the LCI, RIVM: *Bacillus spp.*, *Escherichia coli*, *Salmonella spp. Staphylococcus aureus*, *Legionella spp.*, BRMO (specifically *Klebsiella oxytoca*, *Pseudomonas aeruginosa*, and *Stenotrophomanas maltophilia*) *Toxocara,* and viruses, specifically including SARS-CoV-2
- Occasionally (as an opportunistic infection) associated with disease in the Dutch population: *Ascomycota*, *Burkholderia cepacia*, *Candida albicans*, *Candida parapsilosisi*, *C. krusei*, *Enterobacter cloacae*, *Enterobacter gergoviae*, *Histoplasma capsulatum*, *Serratia marcescens*, *Mycobacterium chelonae*, and *Pseudomonas putida*
- Microbial organisms that are virtually never associated with disease in humans (based on data from the RIVM website, Bad Bug Book, Google Scholar) are: *Basidiomycota*, *Actinobacteria* and indicator organisms (aerobic mesophilic colony-forming unit count for bacteria, fungi and yeasts, coliform bacteria)

Pathogenic microorganisms

Bacillus spp.

Taxonomy

The genus *Bacillus* includes a large number of spore-forming, Gram-positive, rod-shaped and motile bacteria. *Bacillus spp*. belongs to a group of related bacilli, also known as *B. cereus sensu lato*. The *Bacillus cereus* group sensu lato includes eight species: *B. cereus sensu stricto, B. anthracis, B. thuringiensis, B. weihenstephanensis, B. mycoides, B. pseudomycoides, B. cytotoxicus,* and *B. toyonensis*. Of these species, the anthrax bacterium *B. anthracis* is known as a pathogen because it is used as a weapon in bioterrorist attacks. Of all the *Bacillus* species that can cause disease in humans, *B. cereus* is the one that causes the most relevant burden of disease, including in the Netherlands. *B. thuringiensis*, which is almost indistinguishable from *B. cereus sensu stricto*, is used as a biological plant protection product because it produces certain enzymes that kill plant parasites.

Growing conditions

The members of the *B. cereus* group occur everywhere in the environment and can therefore be isolated from the soil. The spores of *B. cereus* survive the pasteurisation process and can continue to grow, for example, in lotions. Although this microbe usually cannot grow at temperatures below 10°C, cold-tolerant strains are known to be able to grow even at 4 to 6°C . These cold-tolerant strains grow less well at 37°C and do not produce cereulide, the toxin that causes nausea and

vomiting. Anaerobic growth is possible, but if oxygen is available, higher growth rates are achieved. Salt tolerance is significant, up to 7.5%. The cold-tolerant strains are more acid-sensitive than the heat-loving ones. At pH 3.5, heat-loving strains die quickly and cold-tolerant strains even more rapidly.

The spores of *B. cereus* can survive heating, dehydration and other conditions that kill the bacteria themselves. Spores are formed as a survival strategy when conditions are unfavourable. The spores themselves cannot multiply in this case, but change into a normal cell when the conditions are favourable again. Some spores can survive dry heating above 120°C . The ability to form spores means that *B. cereus* is often found in products that have undergone a heating step that kills off all other bacteria. The growth of *B. cereus* is often significant in products containing high levels of starch or other hydrocarbons.

Spores of *B. anthracis* are highly resistant to heat (boiling for 10 minutes), cold, pH and chemicals. Germination takes place after infection. In soil, the bacteria will sporulate (RIVM, 2002).

Virulence

For all members of the *Bacillus genus*, virulence is determined by the specific toxins. *Bacillus cereus* produces two different types of toxins that cause symptoms after ingestion. Cereulide induces violent vomiting within hours of ingestion, sometimes accompanied by diarrhoea. This toxin is formed in starchy products. Cereulide is extremely stable. The enterotoxin of *B. cereus* causes short-term diarrhoea and abdominal cramps and is formed only at relatively high concentrations of the cells, starting from 10^5 to 10^6 cells per ml.

Bacillus anthracis spores can germinate in lymphatic vessels after contact with damaged skin, ingestion or inhalation and can subsequently enter the bloodstream. In case of cutaneous anthrax, the production of toxins begins after germination and these toxins can cause local tissue necrosis and oedema. In the later, systemic phase, life-threatening internal bleeding can occur. After inhalation, mild respiratory symptoms develop, which progress to severe shortness of breath with high fever or bloody sputum. Without treatment, the likelihood of death is more than 80% (RIVM, 2002). After ingestion via food, abdominal anthrax may develop, with symptoms such as nausea, vomiting, fever, abdominal pain and bloody diarrhoea. Oropharyngeal anthrax may also develop, with fever, lymph node swelling and sepsis. Even with treatment, there is a 50% likelihood of death for this form of infection.

Burden of disease

In 2018, the estimated number of cases of disease caused by *B. cereus* in the Netherlands was more than 50,000, with about 10% attributed to the environment and 90% to food, travel or contact with people or animals. Hospitalisation is rare and the cause of death is not attributed to *B. cereus*. The number of disability-adjusted life years (DALYs) due to *B. cereus* was estimated at 32 (Pijnacker, 2019) in 2018. Cases of anthrax in humans are rare in the Netherlands; the last known case dates from 1994 (RIVM, 2002).

Legal framework

No microbiological criteria have been laid down in legislation with regard to the presence of *Bacillus spp.* in consumer products. Anthrax (caused by *Bacillus anthracis*) is a Category C notifiable disease: mandatory measures cannot be imposed, but notification and personal data are required to enable the implementation of voluntary/advised measures for the patient or others in the community (Table 39).

Pathogenic *Escherichia coli*

Taxonomy

Escherichia coli belongs to the family *Enterobacteriaceae*. Not all *E. coli* variants are pathogenic to humans, since only a small proportion belongs to the group of pathogenic *E. coli*. This group consists of several diarrhoea-causing *E. coli* variants, the best known of which is the shiga toxin-producing *E. coli* (STEC). This was previously also referred to as vero(cyto)toxin-producing *E. coli* (VTEC) (RIVM, 2010).

Growing conditions

E. coli is a bacterium that occurs in the intestines of many warm-blooded animals and therefore also occurs in faeces/manure. Although growth mainly occurs in that environment, *E. coli* can survive outside that environment as well. Thereafter, it can continue to grow after being absorbed into the gut, and in case of pathogenic variants, cause disease. Many (though not all) *E. coli* variants are particularly acid resistant and therefore can survive gastric passage better than most microbes. STEC is a facultative anaerobe that does not form spores and that cannot or cannot easily grow at low temperatures. The ability to survive outside the intestine for long periods of time and maintain infectivity is an additional risk factor in the case of *E. coli*.

Virulence

Infections may be symptom-free, accompanied by mild abdominal pain, diarrhoea with or without abdominal pain or even bloody diarrhoea, and severe kidney problems (haemolytic uraemic syndrome, HUS). The latter condition can be fatal, even for people who were healthy up to that time. The risk of pathogenic *E. coli* is further increased by the fact that the minimum infective dose is particularly low. For some strains, it is even believed that a single viable cell can cause infection.

Burden of disease

In 2018, the estimated number of cases of disease caused by pathogenic *E. coli* in the Netherlands was more than 2,000, with about 17% attributed to the environment and 83% to food, travel or contact with people or animals. Although the number of infections caused by *E. coli* is low compared to other infections of microorganisms, the burden of disease caused by pathogenic *E. coli* is relatively high due to the potentially serious course of the infection. This is reflected in the relatively large number of DALYs despite the limited number of sick people: 150 DALYs in 2018 (Pijnacker, 2019). The course of an infection with pathogenic *E. coli* depends on the virulence of the specific strain and the susceptibility of the patient.

Legal framework

Contamination of consumer products with *E. coli* is reported in Safety Gate. The microbiological requirement in EC-type approval protocol No. 2 (test protocol for toys containing aqueous media) (NB-TOYS, 2016) and ISO 17516 (cosmetic products) states that *E. coli* must not be present. STEC/EHEC infections (causative agents shiga-toxin-producing *Escherichia coli* (STEC)/enterohemorrhagic *Escherichia coli* (EHEC)) are Category B2 notifiable diseases, hence legal measures and a prohibition on practising a profession may be imposed (Table 39).

Legionella spp.

Taxonomy

Legionella belongs to the family *Legionellaceae*, which is divided into about 50 species. The species *L. pneumophila* is divided into 15 serogroups. The other species together are also called non-*pneumophila* (RIVM, 2008). This includes *Legionella longbeachea*.

Growing conditions

Legionella spp. is generally found in watery environments and moist soils. *L. pneumophila* can multiply in various unicellular organisms in nature. *Legionella spp*. can also reproduce in an artificial environment, such as a water supply system; it can do this most successfully in the presence of a biofilm and in sediment, where single-cell organisms are also present. *Legionella spp*. is resistant to very low pH, has an optimal temperature of 37°C (human body temperature), can grow at temperatures between 20°C and 50°C, also survives at lower temperatures (0-20°C) and dies at temperatures above 50°C (RIVM, 2008). *Legionella spp*. can travel through the air via aerosols or dust. If these aerosols or dust are inhaled, *Legionella spp.* can grow further in the lungs and cause infection.

Burden of disease

Annually 200 to 300 legionella pneumonia cases are reported in the Netherlands, but the actual number of infections is estimated to be 800 per year (RIVM, 2008).

Virulence

Legionella spp. causes pneumonia. Admissions to the intensive care unit occur quite regularly. It can take up to months or years to recover (RIVM, 2008). Most cases of disease (80%) are caused by *L. pneumophila* serotype 1, about 10% by serotypes 2--15, and about 10% by *Legionella* non-*pneumophila*.

Legal framework

No microbiological criteria have been laid down in legislation with regard to the presence of *Legionella* in consumer products. Legionellosis is a Category C notifiable disease: mandatory measures cannot be imposed, but notification and personal data are required to enable the implementation of voluntary/advised measures for the patient or others in the community (Table 39).

Salmonella spp.

Taxonomy

Salmonella belongs to the family *Enterobacteriaceae*. The genus *Salmonella* consists of two species: *Salmonella* enterica and *Salmonella bongori*. The species is divided into subspecies (subsp.) and serovars. There are over 2,600 known serovars. Most *Salmonellae* that cause disease in humans and warm-blooded animals belong to the *Salmonella enterica* subsp. Enterica group. Within this group, the names are often shortened to only the serovar, e.g. *Salmonella* Enteritidis instead of *Salmonella enterica* subsp. *enterica* Enteritidis (Brenner et al., 2000; Agbaje et al., 2011; Issenhuth-Jeanjean et al., 2014).

Growing conditions

The species of the genus *Salmonella* have many physiological properties in common. *Salmonella* grows best in the intestines of warm-blooded animals, but it can also quite easily flourish in reptiles in warm environments, on eggs and in abiotic environments with sufficient nutrients. *Salmonella spp.* are particularly robust and can grow under widely varying conditions and survive for long periods under very unfavourable conditions. In general, *Salmonella* is found in almost all environments, animal intestines and soil, as well as in surface water and animal feed. The temperatures at which growth is possible range from 5 to 55°C, although this is not true for all serotypes, but the temperature range is wider than that of most other bacterial species. As a result, *Salmonella* bacteria sometimes survive heat treatments that effectively kill off other species. In particular, cells grown at fairly high temperatures can often survive even higher temperatures and certain serotypes, e.g. *S. Senftenberg,* are particularly heat resistant. This adaptive capacity increases the risk of *Salmonella,* because heat-based control measures are not always as effective as expected. In most cases, freezing hardly reduces the numbers of viable cells in the case of *Salmonella*.

Salmonella is a facultative anaerobic bacterium that does not form spores (RIVM, 2006). The bacteria can ferment in the absence of oxygen or use electron acceptors other than oxygen. The pH range of optimal growth is neutral, but growth is possible at pH 4.5 to 9.5. After growth at low pH for some time, adaptation take places, which then makes growth and survival at even lower pH possible. As a result, *Salmonella* sometimes survives fermentations that effectively kill off other species. Acid tolerance also induces growth and survival under other unfavorable conditions such as high salinity. At temperatures between 10 and 30°C, salt tolerance increases with temperature.

Burden of disease

In 2017, the estimated number of cases of disease caused by *Salmonella* in the Netherlands was more than 27,000, with about 13% attributed to the environment and 87% to food, travel or contact with people or animals. The number of DALYs in 2018 was estimated at 1100 (Pijnacker, 2019).

Virulence

The degree to which *Salmonella* species and serotypes are pathogenic varies greatly depending on the extent to which the bacteria can adhere to and invade epithelial cells of the intestinal wall. Some *Salmonella* bacteria are not pathogenic at all, and others are only pathogenic for susceptible

hosts. The most virulent *S. typhi* variants should be distinguished from other subspecies and serotypes. The *S. typhi* variants are the only ones able to invade and survive in macrophages, thus leading to a chronic infection. The incubation period is up to one month. The symptoms of the disease consist of severe diarrhoea with accompanying abdominal pain, fever, headache and a general feeling of exhaustion. Fatalities have been known to occur. The other species, as far as they are pathogenic, have a much shorter incubation period of up to three days. Since, in this case, the infection is limited to the intestines, diarrhoea and abdominal pain are the main symptoms.

The minimum infective dose for a *Salmonella* infection varies greatly. Cases have been reported where the reconstructed number of viable cells was less than 10 and others where only ingestion of more than a million cells would cause disease. Survival of the gastric passage largely determines the extent of the infective dose. Usually *Salmonella* is killed by the stomach acid. If, for any reason, the stomach is less acidic than normal, e.g. when using antacids, there is a greater likelihood of an infection of the intestines at the same dose. If *Salmonella* becomes resistant to acid through exposure to low pH, the likelihood of intestinal infection increases.

Legal framework

The microbiological requirement in EC-type approval protocol No. 2 (test protocol for toys containing aqueous media) states that *Salmonella* spp. must not be present. Typhoid fever (caused by *Salmonella typhi*) and paratyphoid fever (caused by *Salmonella paratyphi*) are Category B2 notifiable diseases, hence legal measures and a prohibition on practising a profession may be imposed (Table 39).

Staphylococcus aureus

Taxonomy

The genus *Staphylococcus* consists of 36 different species. The Staphylococcus relevant to the human disease burden are the coagulase-positive species, the most well-known of which is *Staphylococcus aureus*. *Staphylococcus aureus* are Gram-positive spherical bacteria. They form clusters of cells that look like bunches of grapes under the microscope. The multi-resistant variant, methicillin-resistant *S. aureus*, known by the abbreviation MRSA, is a well-known problem in hospitals and can almost be considered a separate entity.

Growing conditions

S. aureus is part of the normal microbiota of the skin and mucous membranes of mammals and birds. The wide distribution of *S. aureus* is partly due to its ability to survive and grow under different conditions. The bacterium is facultatively anaerobic and resistant to dehydration. It is isolated from air, surface waters, sewage and dust. Salt tolerance capacity is extremely high due to the ability to adjust its internal water activity to the external situation. *S. aureus* does not form spores. *S. aureus* produces enterotoxins during the exponential growth phase. Toxin formation occurs only at high cell concentrations (>105 cfu/g). These toxins are very heat stable.

Burden of disease

The symptoms of an *S. aureus* infection are mild (gastroenteritis). With proper treatment, the likelihood of mortality is low (van Kreijl et al., 2004; Bouwknegt et al., 2015). When *S. aureus* enters the bloodstream, toxic shock may occur, with a likelihood of death. This may theoretically happen if *S. aureus* enters the bloodstream through a lesion in the intestines, although this rarely happens in practice. The estimated number of cases of food poisoning due to the *S. aureus* toxin is high, but since the consequences are limited, the patient rarely needs to go to the doctor and therefore an estimate is not very reliable. With this caveat in mind, the estimated number of cases in the Netherlands in 2018 was nearly 300,000, with about 3% attributed to the environment and 97% to food, travel or contact with people or animals. The number of DALYs in 2018 was estimated at 220 (Pijnacker, 2019).

Virulence

The main symptom of *S. aureus* poisoning is vomiting. This may occur as early as 30 minutes after ingestion of the contaminated product. Other symptoms include nausea, abdominal cramps,

diarrhoea and headaches. *S. aureus* cells do not interact with the intestinal wall; the disease symptoms are caused solely by the toxins.

Legal framework

Contamination of consumer products with *S. aureus* is reported in Safety Gate. The microbiological requirement in EC-type approval protocol No. 2 (test protocol for toys containing aqueous media) and ISO 17516 (cosmetic products) states that *S. aureus* must not be present.

Toxocara

Taxonomy

Toxocara (a roundworm) is a parasite with several life stages, one of which is infectious to humans. The infectious stage is when the eggs are produced (with larvae inside them). The roundworms produce thousands of eggs every day that end up in the environment via faeces from animals such as dogs, foxes and cats (Overgaauw, 2018).

Growing conditions

After ingestion, the larvae are released under the influence of gastric juice; they can migrate from the intestine via bloodstream, lymph or abdominal cavity to the liver and lungs. When coughed up, they can re-enter the intestine and grow into adult worms.

Burden of disease

In the presence of large numbers of larvae, non-specific flu-like symptoms may develop: this is called visceral larva migrans (VLM) (Overgaauw). In the lungs, the larvae can cause asthma and inflammation of the respiratory tract (Pinelli & Aranzamendi, 2012; Overgaauw). In some cases, serious complications can occur such as myocarditis, life-threatening pneumonia and nephritis. In recent decades, about 10% of the Dutch population has been exposed to *Toxocara*, mainly through contact with animals and soil (Mughini-Gras et al., 2016). A larva in the eye that dies can cause choroidal granuloma (Overgaauw). In the nervous system, an infection can cause neurotoxocariasis, which can lead to epileptic seizures.

Virulence

Generally, large numbers of larvae are needed to cause an infection.

Legal framework

No microbiological criteria have been laid down in legislation with regard to the presence of *Toxocara* in consumer products. Toxocara is not a notifiable disease.

Viruses

Viruses are very small microorganisms. The structure of viruses is diverse and may consist of double-stranded or single-stranded DNA or RNA with or without an envelope (external structure). Viruses need a host cell to multiply. In addition, viruses are generally host-specific. This means that viruses that are pathogenic to humans do not multiply in consumer products and that contaminated consumer products do not spoil due to contamination with viruses.

Viruses that are pathogenic for humans and that can be transmitted via the faecal-oral route are often simple in structure and therefore less sensitive to environmental factors. This makes them resistant to processing steps, such as freezing or drying. Therefore, early introduction of viruses in the domain, e.g. due to inadequate hygiene, may pose a risk despite the subsequent processing steps within the domain. Spread of viruses may occur early in the domain through contamination with human or animal faecal material or later in the domain through hand contact in case of insufficient personal hygiene. The viruses that can cause disease in humans and that are transmissible via consumer products are basically all those that can be spread via the faecal-oral route, of which norovirus is the most successful in terms of pathogenicity. If a consumer product or parts thereof are ingested orally, viruses may also be ingested via this route, which can then multiply and cause disease.

Respiratory viruses are generally more complex in structure than other viruses that are transmissible by the faecal-oral route. As a result, respiratory viruses are more sensitive to

environmental factors, such as disinfectants or heating, which may cause them to lose their structure and efficacy. SARS-CoV-2 is a respiratory virus. Due to the specific, worldwide problem with this pandemic virus, the characteristics of this virus have been elaborated in more detail.

SARS-CoV-2

Taxonomy

SARS-CoV-2 is a virus new to humans that emerged in December 2019. It belongs to the family *Coronaviridae*. CoV are positive single-stranded RNA viruses with an envelope.

Growing conditions

SARS-CoV-2 requires a host cell to multiply. This means that the virus does not multiply in or on consumer products, although it can survive on such products. The likelihood of this route of exposure leading to infection is low, because the virus is not very stable in the environment (www.bfr.bund.de). In the human body, the virus seems to multiply mainly in the lower and upper respiratory tract, but studies for this are still ongoing. The main route of spread is from person to person, via droplets from coughing or sneezing.

Virulence

SARS-CoV-2 causes illnesses ranging from very mild (cold) to very serious (double pneumonia, death). Although not enough is known about this, host-related factors, such as obesity and underlying illnesses, seem to influence the severity of the course of infection.

Burden of disease

Although it is still too early for gathering reliable data on the burden of disease, it is clear that the social burden due to COVID-19 is very high. In the Netherlands, more than 20,000 confirmed infections were recorded in the period from 27 February 2020 to 9 April 2020, of which almost 8,000 involved hospitalisation. What is specific to this virus is that about 20% of the patients who are admitted to hospital end up in the intensive care unit, with an average stay of several weeks. This made it necessary to double the capacity of intensive care units throughout the Netherlands. A total of 2,396 confirmed cases died (www.rivm.nl). At present (9 April 2020), it is unclear what percentage of the population became infected and experienced a mild form of the infection.

Attempts have been made to limit the spread of the virus as far as possible through a package of measures. Measures taken include ‘social distancing’, which means keeping a physical distance of one-and-a-half metres from one another, working from home on a large scale, staying at home as much as possible and certainly in the case of mild or serious symptoms, and the closure of cafes, restaurants, gyms, etc. In this way, even though the background prevalence of the virus is high at the time of the pandemic, the possibility for spread via consumer products can be limited if the measures are followed.

Legal framework

No microbiological criteria have been laid down in legislation with regard to the presence of viruses in consumer products.

HRMO

HRMO stands for ‘highly resistant microorganisms’. Some of the pathogens mentioned in the RIVM report on the microbiological hazards of consumer products are also described in the HRMO guideline (Preventie, 2019). These bacteria can develop resistance to certain antimicrobial agents and be difficult to treat when they cause an infection.

Klebsiella oxytoca is routinely found in humans in nasal, oral or intestinal tracts and can cause infections in immunocompromised persons. These usually involve wound infections or blood infections caused by contaminated invasive medical devices (Preventie, 2019).

Pseudomonas aeruginosa is an opportunistic bacterium routinely found in humans in the throat, nasal mucosa, skin or faeces. In the environment, the bacterium can also be found in soil and water and on plants. The bacteria can survive as long as there is a moist environment (Preventie, 2019). It can cause pneumonia in immunocompromised persons or bloodstream infections if the

natural barrier is interrupted, such as during mechanical ventilation, use of a urinary catheter or in case of burns (VWS, 2011). The bacteria may be resistant to carbapenem, an antibiotic that is considered to be last resort treatment to which bacteria are often still sensitive. Outbreaks with resistant variants mainly occur in hospitals. Contamination of consumer products *Pseudomonas aeruginosa* is reported in Safety Gate. *Pseudomonas aeruginosa* can form toxins (PHAC).

Stenotrophomanas maltophilia belongs to the group of highly resistant microorganisms, and as an opportunistic bacterium, it is associated with respiratory-associated infections (Preventie, 2019). These bacteria are found in human sputum as well as in soil, water and plants and can survive as long as the environment remains moist (Huang et al., 2008).

Legal framework

Contamination of consumer products with *Pseudomonas aeruginosa* and *Stenotrophomanas maltophilia* is reported in Safety Gate. The microbiological requirement in EC-type approval protocol No. 2 (test protocol for toys containing aqueous media) and ISO 17516 (cosmetic products) states that *Pseudomonas aeruginosa* must not be present. For the remaining HRMO, no microbiological criteria have been laid down in the consumer products legislation. Carbapenemase-producing *Enterobacteriaceae* (in *Klebsiella* species, *E. coli*, *Enterobacter* species) are notifiable (Table 39).

Opportunistic microorganisms

Burkholderia cepacia is an opportunistic bacterium that can cause pneumonia in immunocompromised individuals, e.g. those with cystic fibrosis.

Enterobacter is a genus of bacteria in the family *Enterobacteriaceae*. A number of species within this genus are often seen to be the cause of hospital-acquired infections. One of these is the species *Enterobacter gergoviae* which occurs in the environment and which can cause skin and eye infections in vulnerable people but is rarely seen as a pathogen in healthy people. This bacterium survives in various cosmetic products. *Enterobacter cloacae* is an opportunistic bacterium found in the environment (soil, water) and is present in the human gut. In its resistant form, the bacterium is regularly seen in hospital outbreaks, as an infection of the soft tissues, respiratory or urinary tract and in cases of sepsis or endocartidis (Davin-Regli & Pages, 2015).

Serratia marcescens also belongs to the family *Enterobacteriaceae* and is part of the commensal intestinal biota of humans. Infections with this bacterium generally occur in hospitals, e.g. as a wound infection or urinary tract infection, and particularly in immunocompromised persons.

Mycobacterium chelonae is one of the non-tuberculous mycobacterial species. It is an opportunistic pathogen that can cause respiratory infection or wound infection after surgery, especially in immunocompromised persons.

Pseudomonas putida is considered to be a spoilage organism in meat products (Mohareb et al., 2015) as well as an opportunistic bacterium that can cause hospital-related infections such as urinary tract infection, pneumonia, bloodstream infection or wound infections, often due to infection via invasive devices (Yang et al., 1996).

Yeasts, together with fungi, form a separate group of microorganisms. *Candida albicans* is a yeast that occurs as a commensal in humans in areas such as the mouth and intestine. If the immune system is weakened or if certain antibiotics are used, the yeasts can start to form threads that lead to a fungal infection. *Candida parapsilosisi* is a yeast that occurs as a commensal in humans on the hands. In immunocompromised persons, it can cause wound or tissue infections and sometimes sepsis. *Candida krusei* is a yeast-like fungus that can cause infections of mucous membranes in case of reduced resistance (Samaranayake & Samaranayake, 1994).

Ascomycota, also known as the sac fungi, forms a phylum (with over 50,000 species) within the world of fungi. The fungus is associated with disease in humans, e.g. certain species can cause hallucinations, skin infections and swimmer's eczema. *Histoplasma capsulatum* is a fungus found in bat excreta and soil. In case of reduced resistance, this fungus can cause respiratory or bloodstream infections (Gómez et al., 2018).

Legal framework

Contamination of consumer products with *Burkholderia cepacia, Enterobacteriaceae, Enterobacter gergoviae, Enterobacter cloacae, Pseudomonas putida* and *Candida albicans* is reported in Safety Gate. The microbiological requirement in EC-type approval protocol No. 2 (test protocol for toys containing aqueous media) and ISO 17516 (cosmetic products) states that *Candida albicans* must not be present. The microbiological requirement in EC-type approval protocol No. 2 (test protocol for toys containing aqueous media) states that the *Enterobacteriaceae* may be present at levels ≤1 × 10^2 cfu per gram of ml. No microbiological criteria have been laid down in legislation with regard to the presence of other opportunistic pathogens in consumer products.

Other non-pathogenic microorganisms

This section describes microbial organisms that may occur in consumer products, but which have only rarely been associated with human disease.

Basidiomycota, also known as the club fungi, belongs to the world of fungi.

Actinobacteria are symbiotic bacteria with a number of fungal characteristics, often found in soil or water.

Indicator organisms are not considered pathogenic in themselves but indicate a hygiene-related or other condition of the product, where there is a likelihood of pathogens being present. These involve pathogens that, under the same conditions as the indicator organisms, can enter and survive in the product. For example, non-pathogenic *E. coli* is an indicator of faecal contamination, where faecal pathogens may have entered the product via the same route as *E. coli*. In consumer products, the following indicators are often used to provide insight into the microbial safety of a product: coliform bacteria and aerobic mesophilic colony-forming unit count for bacteria, fungi and yeasts. Yeasts can be an indicator of product spoilage. In general, yeasts are not pathogenic, although they may produce mycotoxins.

Legal framework

The microbiological requirement in EC-type approval protocol No. 2 (test protocol for toys containing aqueous media) states that the total aerobic colony-forming unit count should be ≤1 ×10^3 cfu per gram or ml and that yeasts and moulds should be ≤1 ×10^2 cfu per gram or ml. The microbiological requirement in ISO 17516 (cosmetic products) states that the total aerobic colony-forming unit count should be ≤1 ×102 cfu per gram or ml in the case of products intended for children under the age of three or for use in the eye area or mucous membranes. For other cosmetic products, the microbiological requirement for the aerobic colony-forming unit count is somewhat less stringent at ≤1 ×103 cfu per gram or ml. No microbiological criteria have been laid down in legislation with regard to the presence of other non-pathogenic microorganisms in consumer products.

Table 38 Overview of microorganisms found in consumer products

Microorganism	Pathogen	Disease caused by
Actinobacteriaa	No	N/A
Ascomycota	Opportunistic	Ingestion, invasive
Basidiomycota	No	N/A
HRMO	Yes	Invasive, ingestion, inhalation
K. oxytoca	Yes	Invasive
P. aeruginosa	Yes	Inhalation, invasive
S. maltophilia	Yes	Inhalation
B. cereus	Yes	Ingestion of cells/spores[195]
B. anthrax	Yes	Inhalation, invasive, ingestion
B. cepacia	Opportunistic	Inhalation
C. albicans	Opportunistic	Ingestion, mucous membranes
C. krusei	Opportunistic	Mucous membranes
C. parapsilosisi	Opportunistic	Invasive
***E. coli* (STEC)**	Yes	Ingestion of cells

[195]Diarrhoea-type symptoms

Microorganism	Pathogen	Disease caused by
E. cloacae	Opportunistic	Ingestion, invasive
E. gergoviae	Opportunistic	?
H. capsulatum	Opportunistic	Inhalation
Indicator organisms	No	N/A
M. chelonae	Opportunistic	Inhalation, invasive
P. putida	Opportunistic	Invasive
***Salmonella* spp.**	Yes	Ingestion of cells
S. aureus	Yes	Ingestion of toxins
S. marcescens	Opportunistic	Invasive
Toxocara	Yes	Ingestion of larvae/in eye
Viruses[196]	Yes	Ingestion, inhalation

Table 39 Overview of infectious diseases subject to mandatory notification under the Public Health Act (*Wet publieke gezondheid, Wpg*) for which transmission via consumer products is theoretically possible

Obligation to report infectious diseases	Pathogen	Category[1]
Typhoid fever	*Salmonella typhi*	B2
Hepatitis A	Hepatitis A virus	B2
Paratyphoid	*Salmonella paratyphi*	B2
STEC/EHEC infection	Shiga-toxin producing *Escherichia coli* (STEC)/enterohemorrhagic *Escherichia coli* (EHEC)	B2
Anthrax	*Bacillus anthracis*	C
Carbapenemase-producing *Enterobacteriaceae*	*Klebsiella* species, *E. coli*, *Enterobacter* species	
MRSA infection	*Staphylococcus aureus*	C

[1] Categories A, B1, B2 and C are specified in greater detail in Section 22 of the Public Health Act.

[196] Human pathogenic species of viruses cannot multiply outside their living host. Therefore, the main factor is survival or preservation of infective capacity.

6.4. Microbiological risks per subdomain

For each subdomain, this chapter describes the product properties that determine the effects and severity of the hazards presented by the product. Furthermore, for each subdomain, the specific microbiological hazards that consumers may be exposed to, the route or mechanism by which such exposure may occur, and the indications of actual exposure are also described. Subsequently, the findings of the hazard characterisation performed in Step 2 and exposure estimation in Step 3 are combined, and conclusions are drawn about the risks.

6.4.1. Microbiological risks of amusement devices

An amusement device is a structural device, either temporary or permanently installed, designed to propel people for the purpose of amusement or recreation, powered by a non-human energy source. Examples include roundabouts and roller coasters (NVWA, 2016f).

Legal framework

The safety of amusement devices is regulated in the Commodities Act Decree on Amusement Devices and Playground Equipment[197]. Amusement devices must be designed and manufactured in such a way that, when used under reasonably foreseeable conditions, they do not endanger the safety or health of persons. No further microbiological requirements have been specified in this Decree.

Identification of relevant microbiological pathogens

From 2014 to 2018, there were 119 notifications in Safety Gate concerning microbiological contamination of consumer products in Europe. None of these notifications concerned products falling within the amusement devices subdomain. In the RIVM report, no scientific literature concerning the microbiological contamination of amusement devices was found (De Jonge, 2019). An additional literature search [((fairground ride) or funfair) micro*] did not yield any relevant studies. The NVWA does not monitor the microbiological safety of amusement devices. Inspections are not focused on microbiological safety (NVWA website: inspections of amusement devices).

Exposure

In case of amusement devices, exposure to pathogenic microorganisms may occur due to environmental contamination, e.g. via surfaces that are often touched by insufficiently washed hands or via contact with infected material such as vomit or faeces of animals or humans. Infections may occur when people touch contaminated surfaces with their hands and then touch their mouths or food with the same hands. This mainly involves pathogens that can cause gastroenteritis and which can spread easily from person to person, such as norovirus or *E. coli.* On the one hand, amusement devices are used by many different people and nausea, with possible vomiting, can be expected in rotating rides. On the other hand, these consumers will not be using amusement devices on a daily basis and will generally be healthy during use, which means that the exposure to pathogens will be limited and will cause disease in fewer cases. Based on a survey of restaurants, a background prevalence of 5% can be expected for norovirus (Boxman et al., 2011). No data are available on the frequency of use of amusement devices. If amusement devices are specifically intended for high-risk groups, such as at gatherings of elderly people, small children, pregnant women or immunocompromised persons, exposure to HRMOs or opportunistic pathogenic microorganisms is possible, provided they have a chance to survive in the environment.

[197] Decree of 3 September 1996 establishing a general order in council for the implementation of the Dangerous Equipment Act (Safety of Amusement Devices and Playground Equipment Decree (*Besluit veiligheid attractie- en speeltoestellen*)). Bulletin of Acts and Decrees 1996, 474, last amended by Bulletin of Acts and Decrees 2016-189

High-risk products

No cases of disease were reported in the national surveillance of notifiable diseases where the source was traceable to an amusement device. No disease burden estimates have been attributed to amusement devices. The RIVM report does not describe any outbreaks or infections via this route. An additional literature search [(fairground ride) (infection or outbreak)] did not yield any relevant studies. However, literature is available on a higher risk of environmental contamination in crowded places (Gautret & Steffen, 2016).

Conclusion

Pathogenic microorganisms may occur on amusement devices, since such devices are used by many different, although generally healthy, people. The frequency of occurrence is unknown. Also, the frequency of use of amusement devices is not known, but usually such devices are not used daily. If these pathogens can survive in the environment for a long time and cause human-to-human infections, they can lead to disease via amusement devices. In this case, the hazard is not inherent in the product, but the way it is used (hygiene) plays a primary role. The extent to which infections effectively occur via this route is not known. Since the expected users of amusement devices are healthy individuals, opportunistic pathogens will not cause disease and the main risk will be for gastroenteritis due to infection with norovirus or *E. coli*. Based on a study carried out in crowded places (restaurants), the prevalence of norovirus is assumed to be 5%, which means the likelihood of infection due to amusement devices is assessed as low. The severity is assessed as low (rapidly reversible without medical treatment in the case of a healthy population; usually reversible with medical treatment in the case of a vulnerable population). For amusement devices, the risk posed by human pathogenic microorganisms is therefore assessed as low.

6.4.2. Microbiological risks of child use and care articles

Child use and care articles are products intended for children up to the age of four, to help them sleep, to feed or carry them or products for them to suck on. Examples include soothers, teats, drink bottles, children's high chairs, cots, baby bouncers, as well as baby mattresses and stair gates. These are made from a variety of materials, including plastic, wood and metal. Given the vulnerability of this group, safety is of high priority.

Legal framework

There are no specific regulations for child use and care articles. These articles have to comply with the General Product Safety Directive 2001/95/EC[198]. This Directive does not contain specific microbiological or other requirements. In general, these products must not present particular hazards to children's safety or health under the intended and foreseeable conditions of use. A number of child use and care articles, such as baby bottles and their teats, are intended for food contact and must therefore comply with this legislation. For soothers, teats and baby bottles, the mandatory instructions for use, based on a harmonised standard (EN 1400, EN 14350), state that these articles must be boiled (10 minutes) before they are used for the first time and after each occasion of use.

Identification of relevant microbiological pathogens

From 2014 to 2018, there were 119 notifications in Safety Gate concerning microbiological contamination of consumer products in Europe. None of these notifications concerned products in the child use and care articles subdomain, such as baby bottles, soother, teats or eating and drinking equipment. In the RIVM report, no scientific articles on the microbiological contamination of child use and care articles were found (De Jonge, 2019). An additional literature search [soother micro*] yielded a few relevant studies on soothers (Brook & Gober, 1997; Comina et al., 2006), where the main focus was on proper hygiene to prevent the formation of a biofilm in which microorganisms can grow. The NVWA does not monitor the microbiological safety of child use and

[198] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. OJ L 11, 15.1.2002, p. 4-17

care articles. In 2014, following a complaint, inspections were carried out by the NVWA to check the safety of soothers, but these did not focus on microbiological safety (NVWA, 2015b). In 2009, following a complaint, a study was conducted on the microbiological contamination of baby bottles. The silicone pressure valve was visibly contaminated and tests showed contamination with bacteria (3.1^{e}7/ml) and yeasts (1.5^{e}4/ml). The mandatory instructions for use, which are required to state that a bottle must be cleaned and boiled before it is used for the first time, were missing and a written warning was issued for this (personal communication, A. Akkerman, NVWA).

Exposure

Products such as baby bottles, soothers and tableware are used on a daily basis by about 3% of the Dutch population under the age of three (source: Statline CBS). These categories of products are intended or likely to be put into the mouth by babies and young children. As a result, pathogens that can cause disease after oral ingestion and can survive in the environment for a certain period of time *(E. coli*, *Salmonella spp.*, norovirus) may lead to infections via this route.

Baby mattresses are intended to be used for prolonged periods of time, which may result in direct or indirect skin contact with, and the inhalation of, the microorganisms (yeasts, moulds) present in the mattresses. Skin contact may lead to infection via wounds and inhalation may lead to respiratory infection. Given the vulnerability of the target population, microbiological safety is important.

High-risk products

No cases of disease were reported in the national surveillance of notifiable diseases where the source was traceable to child use and care articles. No disease burden estimates have been attributed to child use and care articles. The overview of scientific literature (De Jonge, 2019) does not describe any outbreaks or infections via this route. An additional literature search [soother micro* (infection or outbreak)] did not yield any relevant studies.

Conclusion

Pathogenic microorganisms may occur on child use and care articles, but in most cases the current practices (mandatory instructions for use) are sufficient to minimise the risk. The extent to which pathogens occur or the extent to which the instructions for use are correctly followed is not known. If pathogens survive the production process and can subsequently survive for a long time in the environment, they may lead to disease via child use and care articles. The hazard may be inherent in the product, but the use of the product (boiling for less than 10 minutes) can increase the risk of infection. It is not known to what extent infections actually occur via this route. These products are used daily by approximately 5% of the Dutch population. Given the vulnerability of this target population, the microbiological safety of this product group is very important. For child use and care articles, the risk posed by human pathogenic microorganisms in the Netherlands is currently assessed as low to medium, based on likelihood (low if used correctly and frequent use by a large group) and severity (usually reversible with medical treatment in a vulnerable target population).

6.4.3. Microbiological risks of biocidal products and plant protection products

Biocidal products are substances or mixtures containing one or more active substances that are used to destroy, deter, render harmless or prevent the action of harmful organisms. The term ‘harmful organism’ means any organism that has an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, on animals or the environment. These are usually microorganisms such as bacteria, viruses and fungi, but may also include, for example, insects and rodents (NVWA, 2016f).

Active substances in biocidal products can be harmful to humans, animals and the environment. Moreover, they are not always recognisable as biocidal products, even though people can come into contact with them. Examples include disinfectants, articles treated with biocidal products[199] such as textiles (so-called treated articles), wood preservatives and fungicides in water-based

[199] https://www.ctgb.nl/biociden/aanvraag-indienen/afwijkende-producten/treated-articles

paints. Biocidal products have a very wide range of applications, both for the professional and private purposes. Biocidal products are divided into 22 product groups[200].

Plant protection products should be distinguished from biocidal products. These products are intended to ensure the normal development of plants and are regulated by the Plant Protection Products Regulation (Regulation (EU) No 1107/2009. These products are used, for example, to control fungi, insects and weeds. Slug pellets and herbicides are examples of plant protection products that fall under the consumer products category.

Legal framework

The Biocidal Products Regulation (Regulation (EC) No 528/2012) has been in effect since 1 September 2013[201]. In the Netherlands, this Regulation, together with the Plant Protection Products Regulation, has been implemented via the Plant Protection Products and Biocides Act[202]. Active substances in biocidal products imported and manufactured in the EU must be notified to ECHA. After studying and assessing the efficacy and safety for humans, animals and the environment, the products are authorised by placing them on a list of permitted substances. Subsequently, entrepreneurs who wish to market the plant protection product or biocidal product in the Netherlands must submit an application for product authorisation.

In the Netherlands, the Board for the Authorisation of Plant Protection Products and Biocides assesses whether plant protection products and biocidal products are safe for people, animals and the environment. Only authorised substances may be marketed on the Dutch market. These can be recognised by the number starting with 'N' displayed on the label.

Identification of relevant microbiological pathogens

From 2014 to 2018, there were 119 notifications in Safety Gate concerning microbiological contamination of consumer products in Europe. None of these notifications concerned products falling within the biocidal products and plant protection products subdomain. In the RIVM report, no scientific literature on the microbiological contamination of biocidal products and plant protection products was found (De Jonge, 2019). However, articles concerning biodegradable detergents and cleaning products were found, i.e. about microbial-based cleaning products (MBCPs) in which microorganisms *(Bacillus*) are used as active ingredients (Tayabali & Ashby, 2018). Another type of product used are biopesticides to which bacteria are added, including species that may also contain pathogenic strains *(Bacillus, Pseudomonas, Burkholderia*). It is possible that these pathogenic strains cannot be distinguished from non-pathogenic strains, and as a result, these pathogenic strains also end up in the products (Cook et al., 1996; Heydari & Pessarakli, 2010; Sundh et al., 2011; Ferreira et al., 2019). In the period 2012--2014, NVWA carried out inspections of biocidal products and plant protection products, but the inspections were not focused on microbiological safety (NVWA, 2015g). One aspect of microbiological safety that may play a role in biocidal products and plant protection products is that pathogens may develop resistance to these products. These effects are evaluated by the Ctgb when authorising a product (https://english.ctgb.nl/biocidal-products/assessment-framework/evaluation-manual). If the development of resistance plays a role, a warning sentence is included.

Exposure

Biocidal products and plant protection products are used for killing harmful organisms, including microorganisms. Therefore, it is unlikely that these products are contaminated with microorganisms or that their use poses a risk of contamination with microorganisms. However, it is possible that the use of these products will lead to the selection of microorganisms based on their resistance to the product. These resistant microorganisms can subsequently end up in the

[200] https://www.ctgb.nl/biociden/aanvraag-indienen/afwijkende-producten/productsoorten

[201] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. OJ L 167, 27.6.2012, p. 1-123

[202] Act of 17 February 2007 containing rules for the authorisation, placing on the market and use of plant protection products and biocidal products. Bulletin of Acts and Decrees 2007, 386, last amended by Bulletin of Acts and Decrees 2019-385

environment and/or cause disease. In addition, there are MBCPs that are not considered contaminated in themselves, but which contain microorganisms, such as *Bacillus,* as an active ingredient. These microorganisms may be inhaled during use of the product (Berg et al., 2018). It is not known to what extent biocidal products are used as consumer products, but it is assumed that this is not on a daily basis and that they are used only by a small proportion of the adult population who are generally expected to be healthy.

Another use of biocidal products is as a disinfectant for surfaces and materials in the food industry, but this is less relevant for consumer products. The risk of such use with respect to food is assessed within other domains.

High-risk products

No cases of disease were reported in the national surveillance of notifiable diseases where the source was traceable to the microbiological contamination of biocidal products and plant protection products. No disease burden estimates have been attributed to the microbiological contamination of biocidal products or plant protection products. The overview of scientific literature (De Jonge, 2019) does not describe any outbreaks or infections via this route. However, the RIVM overview describes a risk assessment of *Bacillus* via MBCPs for carpet cleaning, where the risk of inhalation of *Bacillus* via MBCPs for carpet cleaning is assessed as low due to the low likelihood of inhalation and minimal adverse effects (Berg et al., 2018). An additional literature search focused on infection [biocidal and (infection or outbreak)] mainly yielded studies on the prevention of infectious diseases. An additional search focused on the development of resistance leading to disease [biocidal and (infection or outbreak) and resistance] yielded articles involving products that fall under a different subdomain (cosmetic products) and no articles on the use of biocidal products as consumer products.

Conclusion

Biocidal products and plant protection products do not in themselves pose a microbial risk to consumers. The risk arises from their use, as a result of which the selection of resistant pathogens may occur. Biocidal products are used in consumer products (falling under a different subdomain) and resistance to these biocidal products is known to occur. It is unknown to what extent these products could lead to disease in consumers. However, the selection of resistant pathogens is an undesirable situation from a public health perspective. The development of resistance to biocidal products and plant protection products is evaluated by the Ctgb when authorising a product. The risk of the development of resistance in human pathogenic microorganisms via biocidal products and plant protection products in the Netherlands is currently assessed as low, based on likelihood (rarely occurring, because not used daily and used only by a small proportion of the population) and severity (at a personal level, easily reversible without medical treatment; at the public health level, potentially long-term, irreversible effects). The risk is inherent in the product.

6.4.4. Microbiological risks of chemical substances in consumer products

All products, for consumers or otherwise, contain and are made up of chemical substances. Chemical substances can be offered as single substances, as part of chemical mixtures of one or more active chemical substances, and in the form of objects. Important product groups are paints and lacquers, adhesives and sealants, detergents and cleaning products, construction chemicals and automotive products. In addition, there are chemical substances in 'objects' (not specifically chemical products, but objects that are given a special shape, surface or pattern during production that determines the function of the object to a greater extent than does the chemical composition). This often involves combinations of articles and mixtures, which are regarded as articles for legal purposes.

Legal framework

There are several legal regulations applicable to chemical substances in consumer products. These regulations do not include any microbiological criteria.

Identification of relevant microbiological pathogens

From 2014 to 2018, there were 119 notifications in Safety Gate concerning microbiological contamination of consumer products in Europe. Three of these notifications concerned products falling within the chemical substances in consumer products subdomain. In 2014, a notification was published of a *Burkholderia cepacia* contamination in the cleaning fluid used for cleaning screens and keyboards that came from Taiwan. The product has been withdrawn from the market in 10 European countries because it can cause infection in people with cystic fibrosis or a weakened immune system. The Netherlands was not involved in this. In 2016, there were two reports of an anomalous aerobic microbiological colony-forming unit count, one in liquid used for bubble machines and one in liquid for fogging machines, where both originated in China and had been intercepted at the border of Italy. Risk of infection arises due to inhalation or contact with eyes. In the RIVM report, one scientific article concerning the microbiological contamination of chemical substances in consumer products was found (De Jonge, 2019). This refers to the detection of fungi *(Aspergillus niger, A. flavus* and *Penicillium citrinum*) and bacteria *(Bacillus brevis, B. polymyxa, B. laterosporus, Lactobacillus gasseri, L. brevis, Escherichia coli* and *Proteus mirabilis*) in paint from Nigeria (Obidi et al., 2009). The microbiological safety of chemical substances in consumer products is not monitored. No inspection results were found (NVWA website: chemical substances in consumer products, inspection results) that focused on microbiological safety. However, one case is known in which an index case with an infectious wound infected other people via the foam used at a foam party (oral information, K. Bouma).

Exposure

Exposure to microorganisms via chemical substances in consumer products may occur via various routes. Inhalation is possible, e.g. when contact is made with products used for bubble machines and fog machines or when using cleaning fluids for cleaning the monitor and keyboard. In such cases, respiratory pathogens, in particular, can lead to infections (Table 38). In case of oral exposure, pathogens (often also food-related) that can cause disease after ingestion will lead to infections (Table 38). Contact via the skin or skin wounds, eyes or mucous membranes also offers a '*porte d'entrée*' for microorganisms to enter the body, where they can cause an infection. This mainly concerns invasive pathogens (Table 38). It is not known how frequently consumers use products containing chemical substances. It is assumed that exposure to, e.g. bubble machines and fog machines, is limited (a few times a year) and that the use of cleaning fluids for monitors and keyboards is more frequent (a few times a month).

High-risk products

No cases of disease were reported in the national surveillance of notifiable diseases where the source was traceable to the microbiological contamination of chemical substances in consumer products. No disease burden estimates have been attributed to the microbiological contamination of chemical substances in consumer products. The overview of scientific literature (De Jonge, 2019) does not describe any outbreaks or infections via this route. It is not known to what extent the bacterium *Burkholderia cepacia* (reported in cleaning fluid for screens via Safety Gate) causes disease via chemical substances in consumer products. It is primarily considered to be an opportunistic pathogen.

Conclusion

Pathogenic microorganisms may occur in chemical substances in consumer products, where the known cases involve opportunistic pathogens. The extent of this occurrence is unknown. The frequency of use is not known, but it can be assumed that these products are not used daily. If the target population of the product is a potentially vulnerable population, the microbiological safety of this product group is of specific importance. In case of products used at festivals, such as fog and bubble machines, it can be expected that a part of the population is vulnerable. It is not known to what extent infections actually occur via this route. For chemical substances in consumer products, the risk posed by human pathogenic microorganisms in the Netherlands is currently assessed as low, based on likelihood (rare due to unknown, but probably, low frequency of use) and severity

(in the general population, easily reversible without medical treatment, and in vulnerable groups, usually reversible with medical treatment). The risk is inherent in the product.

6.4.5. Microbiological risks of cosmetic products

Cosmetics are personal care products, i.e. products used to take care of our body, to keep it clean, to make it more beautiful or to make it smell good. So this includes not just makeup, but also products such as shampoo, hair dyes, toothpaste, deodorant, cream, shaving cream, soap, perfume and sunscreen. Almost everyone in the Netherlands uses cosmetic products: men and women, young and old. Cosmetic products can be divided into several categories: bath and shower products, makeup products, deodorant and antiperspirants, perfumes, hair care products, skin care products, oral care products, shaving products, soaps, sun care products, and other products (wet wipes (e.g. baby wipes with lotion), foot care products (e.g. foot scrubs, sprays and foot baths), talcum powder, and intimate hygiene products). Some cosmetic products are specifically designed for babies and children (NVWA, 2016f).

Cosmetic products are composed of different ingredients. These ingredients determine the desired characteristics of the product, such as odour, colour, acidity, spreadability, shelf life and effect. The Dutch Cosmetics Association defines the following ingredient groups: fluoride, fragrances, colourants, preservatives, fruit acids, UV filters and surfactants (https://www.ncv-cosmetica.nl/).

Legal framework

The safety of cosmetic products is regulated in the Commodities Act Decree on Cosmetic products and the European Cosmetic Products Regulation (Regulation (EC) No 1223/2009)[203]. The Cosmetic Products Regulation stipulates that cosmetic products must be safe for human health when used under normal or reasonably foreseeable conditions of use. The guideline with respect to Annex I of this Regulation sets out requirements for the microbiological quality of cosmetic products. This refers to an SCCS guideline (SCCS, 2016b), which in turn refers to ISO 17516 for the microbiological requirements applicable to the final product (Table 40). Cosmetic products do not need to be sterile. There are general requirements for the total aerobic colony-forming unit count and specific requirements for a number of pathogenic microorganisms.

Table 40 Microbiological requirements for cosmetic products according to ISO 17516

Microorganism	**Products intended for children under the age of three or for the eye area or mucous membranes**	**Other products**
Total aerobic colony-forming unit count	≤1 × 10^2 cfu per g of ml	≤1 × 10^3 cfu per g of ml
Escherichia coli	Absent	Absent
Pseudomonas aeruginosa	Absent	Absent
Staphylococcus aureus	Absent	Absent
Candida albicans	Absent	Absent

According to Article 19 of the Cosmetic Products Regulation (EC) No. 1223/2009, the label must indicate the date of minimum durability. This means the date by which the cosmetic product should preferably be used, provided that it is stored properly. If the date of minimum durability is longer than 30 months, the consumer must be informed of the period of time for which the cosmetic product may be used after opening without harm to the consumer. The period-after-opening is indicated by the symbol displayed below, followed by the actual period (in months and/or years).

[203] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59-209

Identification of relevant microbiological pathogens (transmission route)

Cosmetic products generally contain water and organic materials, making them vulnerable to microbial contamination (Lundov & Zachariae, 2008; Halla et al., 2018). Contamination may occur during production, when using the product or when naturally contaminated raw materials (such as clay) are used. Preservatives are added to most products to resist the growth of microbial contamination during use. If the number of available preservatives is limited and perhaps will become more so in future, this may lead to the selection of resistant pathogens.

Of the 119 notifications in Safety Gate in Europe from 2014 to 2018, 50 involved the microbiological contamination of cosmetic products (Table 41).

Table 41 Safety Gate notifications about microbiological contamination of cosmetic products in the period from 2014 to 2018

Product group	Number of notifications	Deviation	Origin	Notifying country	Related to NL
Undiluted use on skin, including face					
Face cream	1	Total aerobic colony-forming unit count (1)	UK (1)	Czech Republic (1)	No (1)
Face mask	3	*Pseudomonas aeruginosa* (1) Total aerobic colony-forming unit count (4) Fungus (1)	Austria (1) UK (1) France (2)	Germany (1) UK (1) France (2)	Yes (1) No (3)
Facial water	1	Total aerobic colony-forming unit count (1)	India (1)	Czech Republic (1)	No (1)
Facial makeup	1	Fungus (1)	China (1)	Ireland (1)	No (1)
Body lotion	1	Total aerobic colony-forming unit count (1)	Czech Republic (1)	Czech Republic (1)	No (1)
Hand/foot/skin cream	5	Total aerobic colony-forming unit count (3) *Pseudomonas aeruginosa* (3) *Staphylococcus aureus* (1) *Enterobacter gergoviae* (1)	Russia (1) UK (1) France (1) Switzerland (1) Spain (1)	Estonia (1) UK (1) Germany (2) Spain (1)	No (5)
Shaving lotion	1	*Pseudomonas aeruginosa* (1) Total aerobic colony-forming unit count (1)	India (1)	Germany (1)	No (1)
Deodorant	1	*Burkholderia spp.* (1)	UK (1)	Denmark (1)	No (1)
Talcum powder/Holi powder	3	Total aerobic colony-forming unit count (3)	India (3)	Ireland (1) Germany (2)	No (1)
Direct use around or in the eyes					

Product group	Number of notifications	Deviation	Origin	Notifying country	Related to NL
Eyeshadow	1	Total aerobic colony-forming unit count (1)	China (1)	Bulgaria (1)	No (1)
Makeup remover	2	*Enterobacter gergoviae* (1) Total aerobic colony-forming unit count (1)	UK (1) Estonia (1)	UK (1) Estonia (1)	No (2)
Use on skin and hair incl. diluted with water, possibly forming aerosols					
Hair dye	8	Total aerobic colony-forming unit count (9) *Enterobacter cloacae* (1) Yeast (1) Fungus (1)	India (2) Czech Republic (3) Germany (1) Russia (2) France (1)	Slovakia (5) Finland (1) Lithuania (2) Ireland (1)	No (9)
Hair shampoo/conditioner	3	*Pseudomonas aeruginosa* (2) Total aerobic colony-forming unit count (3) Fungus (1)	Germany (2) India (1) Italy (1)	Germany (1) Austria (1) Czech Republic (1) Italy (1)	No (4)
Baby shampoo	1	*Pseudomonas aeruginosa* (1) Total aerobic colony-forming unit count (1)	Bulgaria (1)	Bulgaria (1)	No (1)
Bath/shower gel	8	Total aerobic colony-forming unit count (8) *Enterobacteriaceae* (1) *Pseudomonas spp.* (4)	Greece (5) Czech Republic (1) The Netherlands (1) UK (1)	Greece(4) Czech Republic (2) The Netherlands (1) Croatia (1)	Yes (1) No (7)
Liquid hand or other soap	2	*Enterobacter gergoviae* (1) Total aerobic colony-forming unit count (1)	Germany (1) UK (1)	Germany (1) Ireland (1)	No (2)
Direct use in mouth with possibility of swallowing, inhalation and contact with wounds					
Mouthwash	1	*Pseudomonas aeruginosa* (1) Total aerobic colony-forming unit count (1)	Bulgaria (1)	Germany (1)	No (1)
Toothpaste	4	Total aerobic colony-forming unit count (4) Yeast (1) Fungus (1)	India (4)	Latvia (1) Portugal (1) France (1) Slovakia (1)	No (4)

The period 2005-2017 described in a scientific article, which is included in the RIVM overview (De Jonge, 2019). This is a report regarding the selection of *Pluralibacter gergoviae* due to the use of biocidal products in cosmetic products against which this bacterium is resistant (Vincze et al., 2019) (Valkova et al., 2002).

The scientific literature overview prepared by the RIVM includes 46 articles describing the microbial contamination of products (De Jonge, 2019). Of this, 18 articles contained prevalence data or positive findings in used or unused products within the cosmetic products sub-domain (Table 42).

Table 42 Microbiological hazards in cosmetic products reported in scientific literature (De Jonge, 2019)

Product group	N	Microorganism and prevalence (/[concentration]/% positive findings from n tests)	Origin	Reference
Undiluted use on skin, including face				
Face mask	.	Total aerobic colony-forming unit count [c] 358000000	India	(Kulkarni et al., 2011)
Moisturising cream	12	Total aerobic colony-forming units 38.6% Yeast 17%; mould 67% *Pseudomonas aeruginosa* 44% *Staphylococcus aureus* 33% *Enterobacter* 1005	Iran	(Badyeh et al., 2015)
Cream (unused/used)	2x24	*Bacillus spp*. 38% (unused); 54% (used) *S. aureus* 25% (unused); 38% (used) *E. coli* 0% (unused); 8% (used)	Iran	(Behravan et al., 2005)
Skin care clay	-	Review of treatment process with possibility of presence of pathogens	Spain	(López-Galindo et al., 2007)
Skincare	49	Total aerobic colony-forming unit count >10^3: 16% *E. coli* 16% *Pseudomonas spp.* 14% *Staphylococcus spp.* 18% *Bacillus spp*. 12% Oil-in-water (compared to water-in-oil) products most frequently contaminated	Nigeria	(Okeke & Lamikanra, 2001)
Cream (various types)	23		Italy	(Campana et al., 2006)
Cellulite cream (ingredients)	32	100% negative (tested for total aerobic colony-forming unit count, yeast, fungus, coliform, *S. aureus, P. aeruginosa*	Finland	(Sainio et al., 2000)
Direct use around or in the eyes				
Eye makeup (2 brands)	5	Total aerobic colony-forming unit count positive for 1 brand Fungus positive in both brands Gram-positive cocci	Malaysia	(Effa Shahrina et al., 2018)
Decorative contact lenses	285	98 (34%) microbially contaminated, notably *Bacillus* and *Pseudomonas* species	USA	(Land et al., 2018)
Use on skin and hair incl. diluted with water, possibly forming aerosols				
Hair & skin care	57	Total aerobic colony-forming units 38.6% *Bacillus spp*. positive *Pseudomonas spp*. positive *Staphylococcus spp.* positive	Jordan	(Abu Shaqra & Al-Groom, 2012)

Product group	N	Microorganism and prevalence (/[concentration]/% positive findings from n tests)	Origin	Reference
Shower gel/bath foam/liquid soap	47	11% positive for *Staphylococcus spp.*or *Pseudomonas putida*	Italy	(Campana et al., 2006)
Direct use in mouth with possibility of swallowing, inhalation and contact with wounds				
Mouthwash	.	*Burkholderia cepacia* outbreak, 5 batches positive	Germany	(Martin et al., 2012)
Toothpaste	21		Italy	(Campana et al., 2006)
Raw materials				
Calcium carbonate powder	Pooled	Total aerobic colony-forming unit count (low) Bacilli positive Actinobacteria positive	Switzerland	(Di Maiuta & Schwarzentruber, 2011)
Overview of articles				
FDA eye makeup survey	93	60% negative; 32%<100 cfu/ml(g); 8%>100 cfu/ml(g); including Bacillus spp, *Staphylococcus spp*.	USA	(Periz et al., 2018)
Cosmetic products from markets	93	*S. aureus* 6.5% [<10] *Burkholderia cepacia* 4% [79000] *P. aeruginosa* 1% [3500] *Candida krusei* 1% [550000]	Turkey	(Birteksoz Tan et al., 2013)
Fraud with toothpaste	63	60% positive for bacterial species (including *Pseudomonas spp.*, *Enterobacter gergoviae, Klebsiella oxytoca, Bacillus spp., Burkholderia cepacia)*	Turkey	(Brzezinski & Craft, 2012)
Risk assessment Bacillus spp. Via eye makeup	-	*Bacillus spp*. positive (but route does not lead to disease)	UK	(Pitt et al., 2015)
Safety Gate recalls 2005-2008	173	24 products were contaminated, most frequently with *Pseudomonas aeruginosa*	EU, Asia	(Lundov & Zachariae, 2008)
Monitoring of cosmetic products, Bulgaria 1995-2002	680 local 236 import	145/680 (21%) positive; 15/236 (6%) positive 39% *Enterobacteriaceae* Standard for bacterial growth, yeast and fungus, *P. aeruginosa* and *S. aureus* exceeded	Bulgaria and imports	(Gatseva et al., 2004)
Sensitivity of microbes in cosmetic products to contaminants	8	*Pseudomonas aeruginosa, E. coli* and *S. aureus* resistant to various antibiotics	Jordan	(Abu Shaqra et al., 2014)

Based on the above-mentioned study in Iran (Behravan et al., 2005), it can be concluded that *Bacillus* spp. and *S. aureus* are found more frequently in opened creams used by healthy individuals than in unopened packages. It is not mentioned whether the date of minimum durability had been indicated or exceeded. It can be concluded that *E. coli* was not found in unopened packages, but in opened and used packages. The discovery of this bacterium is therefore attributed to use, unhygienic or otherwise.

Monitoring of cosmetic products takes place on the basis of Regulation (EC) No 1223/2009. According to Article 8 of this Regulation, cosmetic products must be produced according to Good Manufacturing Practice (GMP). During GMP inspections of cosmetic product manufacturers, the NVWA makes use of the ISO 22716 standard. The NVWA also monitors samples of cosmetic products based on the microbiological requirements specified in ISO-17516, although the focus is on chemical safety. Inspections (NVWA website: inspections, cosmetic products subdomain) focus on different products within the cosmetic products subdomain. In the period 2009-2010, dossiers were checked for the completeness of product information (NVWA, 2011a). No microbiological deviations were found (Art. 6.b). 6.b: In 2007, 355 cosmetic products intended for babies and children under the age of three and 400 cosmetic products for children over the age of three were examined. Of the products for babies and children under the age of three, 5% were found to have a colony-forming unit count of >10 cfu/g; and of the products for children over the age of three, this was 8%. In addition, the products were assessed, partly via a challenge test and partly via the dossiers, to see whether these products were sufficiently preserved and resistant to microbiological contamination with *Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Candida albicans* and *Aspergillus niger*. The challenge test score was moderate or poor for 27% of the products (NVWA, 2007).

Exposure

Consumer products within the cosmetic products subdomain are used daily by almost the entire Dutch population. The way in which a product is used determines whether the pathogens can actually end up at the particular place in the human body where they can cause disease.

Most cosmetic products are applied to the skin. Some products remain on the skin and are absorbed into it (leave-on products), while others are washed off (rinse-off products). Invasive opportunistic or other pathogens will be able to enter the body mainly via this route, for example, through small wounds in the skin, and cause infection.

Oral exposure occurs in case of products used inside the mouth (e.g. toothpaste or mouthwash) or applied to the lips (e.g. lipstick or lip balm). Pathogens can be ingested in this manner and cause disease via the gastrointestinal tract. Inhalation occurs when particulate matter or aerosols are released during the use of a product (e.g. deodorant, hairspray, powder, shower gel, bath foam, shampoo). In these products, it is mainly the respiratory pathogens that can cause disease (such as pneumonia).

Biocidal products are also used in cosmetic products, allowing selection for resistance. An example is *Pluralibacter gergoviae* in cosmetic products (Vincze et al., 2019).

High-risk products

Cosmetic products are rarely identified as a source of disease. No cases of disease were reported in the national surveillance of notifiable diseases where the source was traceable to a cosmetic product. No disease burden estimates have been attributed to cosmetic products. The RIVM report (De Jonge, 2019) described five outbreaks caused by cosmetic products (Table 43). What all five outbreaks have in common is that they involved a very vulnerable group of hospital patients for whom the product had been used.

Table 43 Outbreaks due to the microbial contamination of consumer products.

Product group	**Cases of disease**	**Microorganism and prevalence (/[concentration]/detection)**	**Origin**	**Reference**
Undiluted use on skin, including face				
Body milk as a source of nosocomial infections	5	*Burkholderia cepacia* positive in unopened bottles	Spain	(Álvarez-Lerma et al., 2008)
Direct use around or in the eyes				

Product group	Cases of disease	Microorganism and prevalence (/[concentration]/detection)	Origin	Reference
Use on skin and hair incl. diluted with water, possibly forming aerosols				
Baby shampoo in the neonatal ward	11	*Serratia* Marcescens positive	Saudi Arabia	(Madani et al., 2011)
Hand soap in the neonatal ward	9	*Serratia* Marcescens positive	France	(Rabier et al., 2008)
Washcloths in hospital	61	*Burkholderia cepacia* positive	Germany	(Martin et al., 2011)
Direct use in mouth with possibility of swallowing, inhalation and contact with wounds				
Mouthwash in intensive care units	12	*Burkholderia cepacian outbreak*, 5 batches positive	Germany	(Martin et al., 2012)

Products for undiluted use on skin, including face

The pathogens *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Enterobacter*, *Bacillus* spp., *E. coli*, and *Enterobacter gergoviae*, and the opportunistic pathogen *Burkholderia cepacia* were demonstrated in these products. When using these products, pathogens may be inhaled or they may enter the body via skin wounds or the eyes.

- If *Pseudomonas aeruginosa* enters the body via inhalation, it can cause pneumonia within a vulnerable population (cystic fibrosis); if it enters via damaged skin, it can cause skin infections; and if it enters via the eyes, it can cause eye infections (Michalek et al., 2019). If this involves a carbapenemase-producing strain, the infection is difficult to treat. From a public health perspective, this is an undesirable situation. These strains are rare in the Netherlands, but import via consumer products may occur.
- *Staphylococcus aureus* can cause skin infection via damaged skin, and in very exceptional situations, sepsis. *Staphylococcus aureus* is part of the normal microbiota of the skin and mucous membranes and contaminated products are not likely to cause an additional burden of disease in a healthy population via this route. In case of a vulnerable population, such as in a hospital or nursing home, there is a likelihood of infection.
- *Enterobacter,* including *Enterobacter gergoviae*, can cause pneumonia via inhalation, and if the natural barrier is breached, urinary tract infections may occur in a very vulnerable population (neonates, immunocompromised people). *Enterobacter gergoviae* resistance to preservatives in cosmetic products has been described, but there are no known cases of disease caused by creams and other such products (Michalek et al., 2019).
- *Bacillus spp.:* in case of *Bacillus anthrax*, there is a chance of infection via damaged skin. Exposure may lead to serious disease. The likelihood of exposure is minimal since *B. anthrax* is not specifically mentioned as a detected species. *Bacillus* spp. is not likely to cause disease via this route.
- *E. coli* is part of the normal microbiota of the human intestine, and this explains why it has been detected in used, rather than unused, cream. *E. coli* is not likely to cause disease by this route.
- Via inhalation, *Burkholderia cepacia* may cause pneumonia, and if the natural barrier is breached, urinary tract infections may occur in a vulnerable population. One outbreak is known to have occurred due to contaminated (unopened) body cream used in an intensive care unit, where five patients developed respiratory and urinary tract infections (Álvarez-Lerma et al., 2008).

Direct use around or in the eyes

The pathogens *Bacillus* spp. and *Staphylococcus* spp. were detected in these products.

- *Bacillus cereus* is associated with eye infections via eye makeup, although the risk has been assessed as minimal (Pitt et al., 2015).

- *Staphylococcus* spp*.* can cause eye infections and is found in eye makeup, but eye makeup has not been described as a source of these infections (Poluzzi et al., 2013).
- *Pseudomonas* spp*.,* including *P. aeruginosa*, can cause microbial keratitis and develop resistance to disinfectants used to clean lenses (Land et al., 2018).

Products for skin and hair (where dilution with water can lead to aerosol formation)

The pathogens *Bacillus spp*., *Pseudomonas spp*. and *Staphylococcus spp.* and the opportunistic pathogens *Serratia marcescens, Pseudomonas putida* and *Burkholderia cepacia* have been detected in these products (Table 41, Table 42Table 42 and Table 43). In addition to infection via wounds or the eyes, inhalation or ingestion is also a possible route of infection for these products. Based on the hazard descriptions, it can be deduced that the following pathogens can cause infections via these products along this route.

- *Bacillus* spp*.:* in case of *Bacillus anthrax*, infection via damaged skin is possible. Exposure via the skin and inhalation may lead to serious disease. The likelihood of exposure is minimal since *B. anthrax* is not specifically mentioned. If *Bacillus cereus* is involved, gastroenteritis may develop after ingestion of a large dose. The likelihood of significant amounts of *Bacillus cereus* being present in this product group is minimal. *Bacillus* spp. is not likely to cause disease via this route.
- *Staphylococcus aureus* may cause skin infection via damaged skin, and in very exceptional situations, sepsis. *Staphylococcus aureus* is part of the normal microbiota of the skin and mucous membranes and contaminated products are not likely to cause an additional burden of disease in a healthy population via this route. In case of a vulnerable population, such as in a hospital or nursing home, there is a likelihood of infection.
- After inhalation of *Pseudomonas aeruginosa*, there is a likelihood of pneumonia in vulnerable population such as persons with cystic fibrosis, and in rare cases, a likelihood of sepsis, if the pathogen enters the body via a wound in the skin. If this a carbapenemase-producing strain, the infection is difficult to treat. From a public health perspective, this is an undesirable situation. These strains are rare in the Netherlands but import via consumer products may occur.
- *Serratia marcescens* can cause infection via skin wounds in a susceptible population. There are two known outbreaks involving hand soap and baby shampoo used in neonatal wards in hospitals (Rabier et al., 2008; Madani et al., 2011), where 20 premature babies developed sepsis, eye infection, urinary tract infection, pneumonia and meningitis, with one fatal outcome.
- *Burkholderia cepacia* via inhalation may cause pneumonia in a vulnerable population, such as individuals with cystic fibrosis.
- *Pseudomonas putida* is mainly considered to be a causative infectious agent in hospital patients, possibly leading to urinary tract infection, wound infection, pneumonia and sepsis. The route of transmission is usually via medical devices, which break through the natural barrier. Infection via this product group is unlikely.

Products for direct oral use with possibility of swallowing, inhalation and contact with wounds

The pathogens *Pseudomonas spp*, *Enterobacter gergoviae, Klebsiella oxytoca, Bacillus spp, Burkholderia cepacia* have been detected in these products.

- *Pseudomonas spp.:* if *Pseudomonas aeruginosa* is involved, inhalation or ingestion during product use may result in pneumonia in a susceptible population (cystic fibrosis). If this involves a carbapenemase-producing strain, the infection is difficult to treat. From a public health perspective, this is an undesirable situation. These strains are rare in the Netherlands, but import via consumer products may occur. If it involves *Pseudomonas* spp*.,* there is not expected to be any risk via ingestion.
- *Enterobacter gergoviae* may cause pneumonia via inhalation in a susceptible population. *Enterobacter gergoviae* resistance to preservatives in cosmetic products has been described, but there are no known cases of disease caused by creams and other such products (Michalek et al., 2019).

- *Klebsiella oxytoca* is regularly found in humans in nasal, oral or intestinal tracts as part of the commensal microbiota and this can cause infections in immunocompromised persons. These usually involve wound infections or blood infections caused by contaminated invasive medical devices (Preventie, 2019). This bacterium is not likely to cause disease via oral products (Brzezinski & Craft, 2012).

Control and preservation

Microbial contamination of cosmetic products can be controlled by choosing high-quality raw materials and hygienic packaging. ISO 29621 describes the cosmetic products that pose a low risk of microbial contamination during manufacture and/or intended use. Physical barriers (such as presence of free water, pH, emulsion) and application of GMP (see also ISO 22716) also contribute to the safety of cosmetic products (Obrębska et al., 2008; Halla et al., 2018). The FDA has examined cosmetic products based on traditional and non-traditional preservatives and found that the pH (5--9) of the non-traditional preserved products allows for microbial growth. A positive correlation was also found between low a_w and microbial contamination. This is explained by the fact that the preservatives are specifically aimed at organisms that require high a_w and that the microorganisms that survive low aw are also less sensitive to these preservatives.

Preservatives or biocidal products (see also the biocidal products and plant protection products subdomain) can also result in the selection of resistant pathogens, as seen in the case of *P. aeruginosa* (Abu Shaqra et al., 2014) and *Pluralibacter gergoviae* (Vincze et al., 2019). Intrinsic resistance to common preservatives is also observed, e.g. in the case of *Bulkholderia cepacia (Leitão et al., 2010)*. This bacterium is therefore found in many different product groups, but its pathogenic potential is generally limited to immunocompromised persons.

A number of preservatives have been prohibited from cosmetic products in recent years, e.g. MI. The maximum permitted concentration of some preservatives has also been reduced. Almost no new authorised preservatives have been added. The range of preservatives to which a consumer is exposed is becoming smaller. Depending on the active ingredient in the preservatives, there is an increased likelihood of the selection of resistant microorganisms.

Conclusion

Pathogenic microorganisms regularly occur in unopened cosmetic products. In addition, pathogenic microorganisms may enter into and/or grow in cosmetic products during use, as a result of secondary contamination. Cosmetic products are used daily by almost the entire population. Disease cases for which cosmetic products are identified as a source are scarce, with the known cases involving opportunistic pathogens or highly susceptible populations. If the target population of the product is a potentially vulnerable population, the microbiological safety of this product group is of specific importance. Microbiologically, there is a risk of selection of resistant microorganisms against certain preservatives if the number of available preservatives is limited and may become more limited. For cosmetic products, the risk posed by human pathogenic microorganisms in the Netherlands is currently assessed as low to medium, based on likelihood (occasional) and severity (use by general population and easily reversible without medical treatment, while the risk is higher for vulnerable groups, sometimes with irreversible effects in very vulnerable people). The risk is partly inherent in the product, but behaviour (hygienic use, durability) contributes towards an increased risk.

Table 44 provides an overview of the risks broken down by pathogen and likely route of transmission.

Table 44 Relevance of the microbial risks of consumer products within the cosmetic products subdomain.

Use	***P. aerugosa***	***B. cepacia***	***E. gergoviae***	***Serratia marcescens***	***S. aureus***	***P. putida***	***Bacillus spp.***	***E. coli***	***K. oxytoca***
Skin/hair, undiluted	Average (vulnerable groups)	Low (vulnerable groups)	Negligible	N/A/unknown	Low	N/A/unknown	Low	Negligible	N/A/unknown
Skin/hair, diluted	Average (vulnerable groups)	Medium (vulnerable groups, inhalation)	N/A/unknown	Average (severe in vulnerable groups)	Low (vulnerable groups)	Negligible	Negligible	N/A/unknown	N/A/unknown
In mouth	Average (vulnerable groups)	N/A/unknown	Medium (high frequency, low likelihood)	N/A/unknown	N/A/unknown	Negligible	N/A/unknown	N/A/unknown	Negligible
In/around eyes	Low	N/A/unknown	N/A	N/A/unknown	Negligible	N/A/unknown	Low	N/A/unknown	N/A/unknown

6.4.6. Microbiological risks of portable climbing equipment

Portable climbing equipment consists of movable ladders, steps and step stools. Ladders are usually collapsible or extendable. Special designs include telescopic ladders and folding ladders, where the latter can sometimes be converted into low scaffolding. Reform ladders are extendable ladders that can stand alone (in an A position), but can also be used as a lean-to ladder (against the wall). Movable steps are usually kitchen steps or so-called household or cleaning steps. Step stools are usually small ladders with one or two steps and a platform to stand on and can vary from those that look more like a ladder to those that look like a stool or bench. The material can also vary, ranging from metal to wood or plastic.

Portable climbing equipment sold to the consumer is not always designed specifically for private purposes but may also sometimes be used for professional purposes. Since portable climbing equipment has to be transportable, it must be as light and compact as possible, yet sufficiently rigid, stable and strong to work on (NVWA, 2016f).

Legal framework

Portable climbing equipment must comply with the Commodities Act Decree on Portable Climbing Equipment[204]. Specific national legislation has been laid down for this type of equipment, since there is no specific European legislation for portable climbing equipment. Therefore, in terms of European legislation, this product category is covered by the European General Product Safety Directive 2001/95/EC[205]. This Directive sets out general safety requirements but does not contain any specific microbiological requirements.

Identification of relevant microbiological pathogens

From 2014 to 2018, there were 119 notifications in Safety Gate concerning microbiological contamination of consumer products in Europe. None of these notifications concerned products falling within the climbing equipment subdomain. In the RIVM report, no scientific literature concerning the microbiological contamination of climbing equipment was found (De Jonge, 2019). An additional literature search [climbing and micro*] did not yield any relevant articles. The microbiological safety of climbing equipment is not monitored. Inspections (NVWA website: climbing equipment, inspection results) are not focused on microbiological safety.

Exposure

Exposure to microbial hazards via climbing equipment is not a likely route of transmission. The frequency of use of climbing equipment is unknown.

High-risk products

There are no high-risk products from the perspective of microbial safety within the portable climbing equipment subdomain. The RIVM report (De Jonge, 2019) does not describe any outbreaks or infections via this route. An additional literature search [climbing and (infection or outbreak)] did not yield any relevant articles.

Conclusion

The frequency of microbial contamination of portable climbing equipment is not known, but such equipment is not a likely source of microbial infections. It is not known how often portable climbing equipment is used. For portable climbing equipment, the risk posed by human pathogenic microorganisms in the Netherlands is assessed as low, based on likelihood (unknown but rare) and severity (unknown but probably easily reversible without medical treatment).

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[204] Decree of 29 January 1986 laying down rules for certain types of ladders and steps; Commodities Act Decree on Portable Climbing Equipment. Bulletin of Acts and Decrees 1986-86

[205] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. OJ L 11, 15.1.2002, p. 4-17

6.4.7. Microbiological risks of electrical equipment

Electrical equipment are products that operate on electrical voltage. This involves a very large and diverse range of products that are used very frequently in both the private and work sphere. The most common group of products - the group operating on 230V mains power supply intended for private purposes- can be roughly divided (NVWA, 2016f) into:

- Household appliances: washing machines, dryers, dishwashers, refrigerators, freezers, ovens, hobs (including built-in), microwaves, extractor hoods, vacuum cleaners, irons, coffee makers, toasters, food processors, deep fryers and kettles
- Personal care appliances: for hair care, e.g. hairdryers and curling tongs; for facial care, e.g. shavers, trimmers and hair clippers; and for oral care, e.g. toothbrushes and oral irrigators and sunbeds
- Heating and hot water equipment: central heating, electric boilers, individual heaters such as radiators and fan heaters, and electric blankets
- Audio and video equipment: CD, DVD, Blu-ray players and recorders, televisions, and audio equipment
- Office equipment: computers, copiers, and printers
- Lighting equipment: LED, halogen and FL lamps, light fittings, and Christmas lights
- Solar panels
- Adapters

Legal framework

Electrical equipment must comply with safety requirements, as outlined in the section explaining the physical risks. The legislation for this is not the same for all products. This legislation does not define any specific microbiological requirements.

Identification of relevant microbiological pathogens

From 2014 to 2018, there were 119 notifications in Safety Gate concerning microbiological contamination of consumer products in Europe. None of these notifications concerned products falling within the electrical equipment subdomain. In the RIVM report (De Jonge, 2019), three scientific studies were found concerning the microbiological contamination of electrical equipment. One article describes the presence of fungi (including *C. parapsilosis*) in 47 (47%) of 99 washing machines examined in Turkey (Döğen et al., 2017) and 55 (79%) of 70 washing machines examined in Slovenia. This is attributed to washing at lower temperatures (<40°C) and the use of biodegradable detergents (Babič et al., 2015) (see also the biocidal products and plant protection products subdomain). Nix et al. (Nix et al., 2015) determined the microbiome in a biofilm originating from rubbers and detergent trays of washing machines and found a wide range of Proteobacteria and fungi *(Ascomycota*). The NVWA carries out inspections of electrical equipment, such as sunbeds in tanning studios, in the Netherlands. This monitoring is not focused on microbiological safety. An additional search in PubMed focused on sunbeds [sun-bed and micro*] yielded no relevant articles. Inspections (NVWA website: electrical appliances, inspection results) are not focused on microbiological safety.

Exposure

Household appliances (refrigerators, blenders, washing machines) and personal care appliances are used on a daily to weekly basis and these may become contaminated with microbial pathogens during use. If these appliances are not cleaned or not cleaned properly, a biofilm may form in which microorganisms can survive and grow. In the case of washing machines, it is important to eliminate microbial contamination that may occur during use. To do this, industrial and institutional processes use high temperatures (60°C and above) and set requirements for the effectiveness of the used detergents. The trend among consumers is towards energy efficiency and hence washing at lower temperatures (<40°C) and the use of biodegradable detergents is common (De Jonge, 2019). This can result in pathogens remaining in clothing, which can subsequently cause infection via skin wounds or inhalation.

Another possible route of exposure to pathogenic microorganisms is via aerosol formation from aquarium pump systems, where inhalation of microorganisms is possible (De Jonge, 2019). Exposure to *Legionella* spp. may occur via this route (Smith et al., 2012).

High-risk products

The RIVM report did not include any literature on cases of disease caused by microbial contamination of washing machines or aquaria. An additional specific search [*Legionella* aquarium (infection or outbreak)], [washing machines micro* (infection or outbreak)] and [sun-bed micro* (infection or outbreak)] did not yield any relevant articles for aquariums or sunbeds. However, it did produce some articles in which outbreaks in hospitals among very vulnerable groups (neonatal ward) are attributed to contaminated washing machines: with resistant *Klebsiella oxytoca* (Schmithausena et al., 2019) and bacteraemia from bedding contaminated with *Bacillus cereus* in a hospital (Sasahara et al., 2011).

Conclusion

Pathogenic microorganisms regularly occur in electrical equipment as a result of its use. Cases of disease where electrical equipment has been identified as the source are scarce. Reported cases involve the use of washing machines in connection with vulnerable populations. If the target population of the product is a potentially vulnerable population, the microbiological safety of this washing machines, and possibly that of other household appliances (refrigerators, blenders) as well, is of specific importance. For electrical products, the risk posed by human pathogenic microorganisms in the Netherlands is currently assessed as low to medium, based on likelihood (occasional, due to use that can be frequent) and severity (in a very vulnerable population, ranging from usually reversible with medical treatment to long-term effects). The risk is not inherent in the product, but behaviour (washing temperature, hygienic use) contributes towards an increased risk.

6.4.8. Microbiological risks of gas appliances

A gas appliance runs on energy that is generated by burning gaseous fuels. When used for private purposes, gas appliances are mainly used for cooking, heating houses and producing hot water. Gas appliances are mainly distinguished from one another based on their dependence on the gas network. There are those that are connected to the gas network and those that can operate independently of the gas network with a separate gas cylinder. The most common appliances dependent on the gas network are heating appliances such as central heating boilers, appliances for producing hot water such as geysers and gas boilers, and appliances for cooking, baking and roasting such as gas cookers and gas ranges. The most common appliances not dependent on the gas network are recreational appliances, such as camping stoves, gas lights and stoves, gas barbecues and patio heaters (NVWA, 2016f).

Legal framework

Entrepreneurs who sell gas appliances are responsible for offering safe products. They must therefore ensure that these gas appliances comply with the Gas Appliances (Commodities Act) Decree 2018[206]. This Decree implements the European Regulation (EU) 2016/426[207].

The Gas Appliances (Commodities Act) Decree 2018 only covers gas appliances that are used for space heating, hot water production, washing and drying, lighting or food preparation. Other gas appliances, such as soldering torches and paint burners, fall under the General Product Safety (Commodities Act) Decree (*Warenwetbesluit algemene productveiligheid*). This legislation does not define any specific microbiological requirements.

[206] Gas Appliances (Commodities Act) Decree 2018. Bulletin of Acts and Decrees 2018-217
[207] Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC. OJ L 81, 31.3.2016, p. 99-147

Identification of relevant microbiological pathogens

From 2014 to 2018, there were 119 notifications in Safety Gate concerning microbiological contamination of consumer products in Europe. None of these notifications concerned products within the gas appliances subdomain. In the RIVM report, no scientific literature concerning the microbiological contamination of climbing equipment was found (De Jonge, 2019). An additional literature search [(gas appliance) and micro*] did not yield any relevant articles on the microbial contamination of gas appliances. The microbiological safety of gas appliances is not monitored. Inspections (NVWA website: inspections, gas appliances subdomain) are not focused on microbiological safety.

Exposure

Gas appliances are used daily by a part of the population. When gas appliances are used for cooking, baking and frying, the temperatures (>100°C) reached are high enough to kill pathogenic organisms. Therefore, it is unlikely that these gas appliances are contaminated with microorganisms or that their use poses a risk of contamination with microorganisms. If gas appliances for heating water (boilers, central heating boilers) do not function properly or if the temperature is reduced to prevent the risk of burning in vulnerable groups (such as elderly people with dementia or children) (Durand et al., 2012), the temperature may remain low enough (<50°C for one minute) for microorganisms to survive and grow, whether or not in the form of a biofilm in the water pipes. When hot water from the tap is used, e.g. when showering, aerosols containing microorganisms may be released and inhaled.

High-risk products

No cases of disease were reported in the national surveillance of notifiable diseases where the source was traceable to the microbiological contamination of gas appliances, whether properly functioning or not. No disease burden estimates have been attributed to the microbiological contamination of gas appliances. The overview of scientific literature (De Jonge, 2019) does not describe any outbreaks or infections via this route. An additional specific literature search [*Legionella* (boiler or hot-water tanks) (infection or outbreak)] yielded a study where the low temperature of a boiler led to infections in an apartment complex in Spain (Aldea et al., 1992) and homes in Canada (Dufresne et al., 2012).

Conclusion

Gas appliances are used daily by a large part of the Dutch population and do not in themselves present a microbial risk to consumers. The risk arises from the use of these appliances, when the choice is made to lower the temperature of an appliance (boiler) in order to avoid other negative effects (burns). For gas appliances, the risk posed by human pathogenic microorganisms in the Netherlands is currently assessed as low in case of correct use, based on likelihood (rarely occurring) and effect (easily reversible without medical treatment in the general population), and low to medium in case of incorrect use (no maintenance, too low temperature), based on likelihood (rarely occurring) and effect (potentially fatal in vulnerable groups). The risk is not inherent in the product, but behaviour contributes towards an increased risk.

6.4.9. Microbiological risks of machinery (for private purposes)

In lay terms, machinery are products with mechanically driven moving parts. Machinery can be powered by an electric motor, a combustion engine or compressed air. Machinery used for private purposes are intended to relieve human labour or effort. Examples of such machinery are drills, electric saws or lawn mowers (NVWA, 2016f).

Products not included in this subdomain are household appliances such as washing machines, tumble dryers, food processors and computers; these are considered to be electrical appliances.

Legal framework

Machinery must comply with the Machinery (Commodities Act) Decree[208]. This Decree implements the European Machinery Directive (Directive 2006/42/EC)[209]. This legislation does not define any specific microbiological requirements.

Identification of relevant microbiological pathogens

From 2014 to 2018, there were 119 notifications in Safety Gate concerning microbiological contamination of consumer products in Europe. None of these notifications concerned products within the machinery (for private purposes) subdomain. In the RIVM report, no scientific literature concerning the microbiological contamination of machinery (for private purposes) was found (De Jonge, 2019). An additional literature search [machine micro*] did not yield any relevant studies of microorganism-contaminated machinery used for private purposes. The microbiological safety of machinery (for private purposes) is not monitored. Inspections (NVWA website: machines, inspection results) are not focused on machinery (for private purposes), either in relation to their microbiological safety or otherwise.

Exposure

It is not known how frequently machinery for private purposes is used. It is assumed that a small part of the Dutch population uses such machinery on a monthly basis. Exposure to microbial hazards via machinery used for private purposes is not a likely route of transmission.

High-risk products

There are no known cases of disease attributable to the microbial contamination of consumer products that fall within the machinery (for private purposes) subdomain. No disease burden estimates have been attributed to the microbiological contamination of machinery (for private purposes) The overview of scientific literature (De Jonge, 2019) does not describe any outbreaks or infections via this route. An additional specific literature search [machine micro* (infection or outbreak)] did not yield any relevant studies on disease caused by the microbial contamination of machinery (for private purposes).

Conclusion

The extent of microbial contamination of machinery used for private purposes is not known, but it is assumed that such machinery is not a likely source of microbial infection. There are no known cases of disease occurring via this route. For machinery (for private purposes), the risk posed by human pathogenic microorganisms in the Netherlands is assessed as low, based on likelihood (unknown but rarely occurring in case of less frequent use by a part of the population) and severity (easily reversible without medical treatment).

6.4.10. Microbiological risks of food contact materials

Food contact materials include packaging and packaging materials as well as products used in the private sphere for the preparation and consumption of food and drinks. They also include materials that are intended to come into contact with food during the professional preparation or production thereof.

Food is packaged in a wide variety of materials. The most common examples of packaging materials are plastic, paper and paperboard, rubber, metal, glass and ceramic, textile, wood and cork or combinations thereof. Packaging may contain substances that help extend the shelf life of food. This kind of packaging is called active packaging. In addition, packaging can be provided with labels or materials that indicate the temperature, i.e. so-called intelligent packaging.

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[208] Decree of 30 June 1992 laying down rules on the safety of machinery. Bulletin of Acts and Decrees 1992, 379, last amended by Bulletin of Acts and Decrees 2018-465

[209] Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC. OJ L 157, 9.6.2006, p. 24-86

Temporary packaging may also be used within the food production and transport domain, such as jute bags for cocoa beans or storage barrels.

In addition, there are consumer products, also referred to as consumer articles, that are used for food preparation or consumption. Examples include plates, pans, cutlery, cutting boards, storage boxes, kettles, food processors and cooking pots as well as water filters designed for outdoor activities to filter natural water for use. Machinery used for food production on an industrial scale also contains materials that come into contact with food. Examples include conveyor belts and mixers (NVWA, 2016f).

Legal framework

The safety of food contact materials is regulated in the Commodities Act Decree on Food Contact Materials and the Framework Regulation (EC) No 1935/2004. The aim of the laws and regulations is to prevent harmful substances from packaging and products that are intended for processing or for coming into contact with food from entering the body via food. In addition, packaging or consumer articles must not alter the composition, odour, taste, colour, firmness or fluidity of the food. The Commodities Act Decree on Food Contact Materials and the European Regulation do not set specific microbiological requirements. Substances and contaminants that have entered the material during use and that can subsequently contaminate the food are not taken into consideration here.

Identification of relevant microbiological pathogens

Notifications of microbial contamination of food contact materials are not made in Safety Gate but via RASFF. A total of 722 RASFF notifications were made for food contact materials between 10/12/2014 and 31/12/2018. One of these concerned microbial contamination, in the case of reusable ice cubes in which aerobic mesophilic microbiota from the liquid could potentially leak into the drink to be consumed. Although this is not a microorganism that is pathogenic to humans, the aerobic mesophilic colony-forming unit count is used as a hygiene indicator and an indicator of the pathogens that can survive along this route. The RIVM report cited scientific literature on the microbiological contamination of water filters (De Jonge, 2019), which said that filters can become contaminated during use and the filtered water may contain more bacteria than unfiltered water. For example, in Italy, 93 unfiltered water samples demonstrated no bacterial contamination, but 20 of 93 filtered water samples demonstrated *P. aeruginosa* and three of 93 samples demonstrated other pathogens *(E. coli, S. aureus, Enterococci*). The RIVM report also included an article on microbially contaminated paper and paperboard of Polish origin, intended for food packaging. This showed contamination with bacteria, yeast and fungus. It is possible that the use of starch for thickening contributed to the contamination. Another possibility is the use of contaminated water or reuse of water during the production process (Guzińska et al., 2012). Monitoring and inspections (NVWA website: food contact materials foodstuffs, all documents) do not focus on microbial safety. However, the NVWA has conducted research into the effectiveness of small drinking water filters that are used by wild campers and hikers in places where the drinking water is of doubtful quality. Only one of the three water filters was assessed to be of sufficient quality (Reus & Nab-Vonk, 2005). The NVWA has also carried out a study on the hygiene of food packaging, where 40 unused packages were tested for the total colony-forming unit count, number of coliforms and yeasts and fungi on the inner surface. Fungi were found on 35% of the packages examined, with a low rate of contamination (between 1 and 28 cfu/package) (Bouma & Nab-Vonk, 2000).

A new development on which there is not much scientific literature as yet is the circular economy, where materials, such as bamboo, recycled paper and plastic, are processed into food contact materials. As a result of the Single-Use Plastics (Supreeyasunthorn et al.) Directive (EU) 2019/904, single-use plastics will be phased out and the practice of reusing materials is expected to increase[210]. In this way, the circular economy introduces new hazards in addition to or in the place of known traditional hazards. In case of processes or biobased products that do not

[210] Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019 on the reduction of the impact of certain plastic products on the environment. OJ L 155, 12.6.2019, p. 1-19

completely eliminate microbial hazards, it is conceivable that new hazards will be introduced. Furthermore, an accumulation of microbial hazards is conceivable, if the process steps are not capable of eliminating the microbiological risks. The scientific literature on this subject focuses mainly on chemical contaminants and microplastics, rather than on the microbiological risks; a specific search [food contact material and ((circular economy) or recycling)] did not produce any relevant studies.

Exposure

Almost the entire Dutch population comes into daily contact with various food contact materials. Microbial contamination of food contact material can contaminate the food it comes in contact with. If the food product in question does not require further processing before consumption, such as filtered water or smoked salmon, exposure to microorganisms via ingestion is likely.

High-risk products

Reusable materials in the packaging process

In 2012, an outbreak with almost 1,200 registered *Salmonella* Thomson cases was attributed to reusable transport trays (chosen for sustainability purposes) on which salmon was collected after cutting, in order to be transferred to the next process step (packaging). The material was found to be suitable as a food contact material in accordance with EU certification. When these transport trays were put into use, their porosity was an area of concern. In response, the cleaning procedure (in Greece) was modified to prevent contamination, but this has proved to be insufficient (OVV, 2012).

No disease burden estimates have been attributed to the microbiological contamination of food contact materials. The overview of scientific literature (De Jonge, 2019) does not describe any outbreaks or infections via this route. Additional literature searches [micro* (EFSA Panel on Food Contact Materials et al.) (infection or outbreak)] and [micro* (reusable ice cubes) (infection or outbreak)] did not result in any relevant hits.

Conclusion

Based on some studies, it is known that pathogenic microorganisms occasionally occur in food contact materials and that they are associated with cases of disease. Although food contact materials were only once clearly identified as sources, the effects of this outbreak were enormous and also affected the 'healthy' population. It is expected that outbreaks due to microbially contaminated food contact materials will occur more frequently given the societal developments in which sustainability, circular economy and recycling play an important role. For food contact materials, the risk posed by human pathogenic microorganisms in the Netherlands is currently assessed as low to medium, based on likelihood (low prevalence but frequent use by large part of the population) and severity (ranging from easily reversible without medical treatment to reversible with medical treatment in the general population; long-term effects, possibly irreversible for vulnerable individuals). The risk is inherent in the product and behaviour contributes towards an increased risk.

6.4.11. Microbiological risks of personal protective equipment

Personal protective equipment (PPE) is equipment intended to protect a person engaged in an activity involving a risk of injury. The protective equipment may be worn (e.g. life jacket, safety goggles) or held (e.g. a protective hood, shoes, gloves) by a person to protect the head, hand, hearing, face or limbs (NVWA, 2016f).

Examples of such products are teeth protection, respiratory apparatus, diving masks, helmets, climbing harnesses, carabiners, gloves, dust masks, earplugs or sunglasses. Personal protective equipment is used both for professional and private purposes.

Legal framework

Since 21 April 2018, Regulation (EU) 2016/425 is in effect with respect to the marketing of personal protective equipment in the European Union[211]. This Regulation has replaced Directive 89/686/EEC. In the Netherlands, this Directive was incorporated into the Personal Protective Equipment (Commodities Act) Decree (*Warenwetbesluit persoonlijke beschermingsmiddelen*). With the introduction of the Regulation, this Decree has lapsed and been replaced by the Personal Protective Equipment (Commodities Act) Decree 2018[212].

Identification of relevant microbiological pathogens

From 2014 to 2018, there were 119 notifications in Safety Gate concerning microbiological contamination of consumer products in Europe. None of these notifications concerned products falling within the personal protective equipment subdomain. In the RIVM report, no scientific literature concerning the microbiological contamination of personal protective equipment was found (De Jonge, 2019). An additional literature search [(personal protection) micro*] yielded a number of relevant studies on the use of mosquito repellents (Iliou et al., 2019), the use of protective clothing for staff in hospitals (Mitchell et al., 2015), and the use of protective mouth masks to prevent infection by microorganisms (Lee et al., 2005; Coia et al., 2013). The microbiological safety of personal protective equipment is not monitored. Inspections (NVWA website: personal protective equipment, inspection results) are not focused on the microbiological safety of personal protective equipment. However, the bird flu outbreak in 2014 is mentioned, where it is noted that there has been an improvement in the quality of personal protective equipment since the bird flu outbreak in 2003[213].

Exposure

Personal protective equipment for microbial protection is used during activities involving a potential microbial risk. Therefore, proper use and selection of appropriate protective equipment is important. In general, such equipment is not used daily by consumers but, for example, during a period of illness (of a family member) or a holiday. Exposure to microorganisms may occur if the filters are too coarse to keep out pathogens (face masks), gloves are not worn or removed at the right time (during contact with infected persons), eyes or face are rubbed with contaminated gloves or mosquito repellents are used that mosquitoes, such as tiger or malaria mosquitoes, have become resistant to.

High-risk products

The RIVM report does not include any literature on cases of disease due to microbial contamination resulting from personal protective equipment or the incorrect use thereof. An additional literature search [(personal protection) micro* (infection or outbreak)] yielded a few relevant studies: one on the role of protective clothing and textiles in the spread of microorganisms or prevention thereof in hospitals (Mitchell et al., 2015) and a few on the correct choice (gradation) of face masks and face shields in specific situations, such as during the influenza pandemic caused by H1N1 (te Beest et al., 2010; Coia et al., 2013; Brown et al., 2019).

Conclusion

Personal protective equipment can pose microbiological hazards for the user. This kind of equipment is used only occasionally but usually in high-risk situations. Cases of disease where PPE is identified as the cause occur with some regularity. In exceptional cases, these may involve

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[211] Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC. OJ L 81, 31.3.2016, p. 51-98

[212] Decree of 11 April 2018 establishing the Personal Protective Equipment (Commodities Act) Decree and amending the Administrative Fines (Commodities Act) Decree (*Warenwetbesluit bestuurlijke boeten*), the Working Conditions Decree and the Pressure Equipment (Commodities Act) Decree 2016 (*Warenwetbesluit drukapparatuur 2016*). Bulletin of Acts and Decrees 2018-104

[213] https://www.nvwa.nl/over-de-nvwa/organisatie/jaarverslagen-en-jaarplannen-nvwa/jaarverslag-2014/vogelgriep

serious pathogens that affect the healthy population (Ebola, influenza). Here, the hazard is not inherent in the product; the way it is used is the primary factor. For personal protective equipment or the incorrect use thereof by consumers in the Netherlands, the risk posed by human pathogenic microorganisms is currently assessed as low, based on likelihood (rarely occurring due to low frequency of use) and severity (usually reversible with medical treatment, long-term effects that are possibly irreversible or fatal effects).

6.4.12. Microbiological risks of toys

Toys may be made of various materials such as plastic, wood, textile, rubber or paint. There are relevant chemical substance groups for each material category. For example, wood may contain preservatives and plastic may contain plasticisers. Another categorisation of toys is by age. It is generally accepted that children up to the age of three put toys into their mouths and suck on them, and therefore the oral route is significant.

Legal framework

The safety of toys is regulated by the European Toy Safety Directive[214]. In general, toys should not present any health hazards. Requirements regarding the microbiological safety of toys are set out in Annex II, Chapter V of the Toy Safety Directive. Hygiene and cleanliness must be adequate so as to avoid any risk of infection, sickness or contamination. Further microbiological requirements for toys containing aqueous media have been published via a test protocol (EC-type approval protocol No. 2), see Table 45. These requirements apply to toys containing aqueous media (e.g. some types of rattles), finger paints, modelling clay and water-based toys such as toy-slimes, putty and gels.

Table 45 Microbiological requirements for toys containing aqueous media (EC-type approval protocol No. 2)

Microorganism	**Requirement (cfu per gram or ml)**
Total aerobic colony-forming unit count	$\leq 1 \times 10^3$
Yeasts and fungi	$\leq 1 \times 10^2$
Staphylococcus aureus	Absent
Pseudomonas aeruginosa	Absent
Candida albicans	Absent
Escherichia coli	Absent
Salmonella spp.	Absent
Enterobacteriaceae	$\leq 1 \times 10^2$

Another requirement is that toys for children under three must be sold in a clean condition. Textile toys must be washable. It is important that the toy continues to meet the safety requirements even after the cleaning or washing process. Instructions must be provided for how to wash and dry the toys (within the framework of safety testing) (EC-type approval protocol No. 4). Cosmetic toys, such as face paints or makeup, must comply with the legislation for toys as well as that for cosmetic products.

Identification of relevant microbiological pathogens

Of the 119 notifications in Safety Gate in Europe from 2014 to 2018, 51 concerned the microbiological contamination of toys (Table 46).

[214] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys. OJ L 170, 30.6.2009, p. 1-37

Table 46 Safety Gate notifications in the area of microbiology relating to toys in the period from 2014 to 2018

Product group	Number of notifications	Deviation	Origin	Notifying country	Related to NL
Undiluted use on skin, including face					
Paint/face paint/makeup	10	Aerobic mesophilic colony-forming unit count (8) Coliforms (1) *S. aureus* (1) Fungus (3) Yeast (2) *P. aeruginosa* (2) *Enterobacteriaceae* (2)	China (9) Peru (1)	Italy (3) Czech Republic (1) France (2) Hungary (2) Spain (2)	No
Use involving mostly hand contact					
Clay/toy-slime	4	Aerobic mesophilic colony-forming unit count (4) Fungus (1)	China (4)	The Netherlands (1) Spain (1) Italy (1) France (1)	Yes
Chemistry set	1	Aerobic mesophilic colony-forming unit count	China (1)	France (1)	No
Plastic ball with liquid	5	Aerobic mesophilic colony-forming unit count (4) *P. aeruginosa* (1)	China (5)	Italy (3) Spain (2)	No
Use with likelihood of swallowing/inhalation					
Bubble mixture	31	Aerobic mesophilic colony-forming unit count (28) *P. aeruginosa* (10) *Enterobacteriaciae* (2) *S. maltophilia* (1)	China (17) Spain (3) Hong Kong (2) France (1) Unknown	Spain (8) France (6) Latvia (3) The Netherlands (1) Hungary (1) Italy (3) Germany (2)	Yes

The scientific literature overview prepared by the RIVM includes 46 articles describing the microbial contamination of products (De Jonge, 2019). One of these articles contained prevalence data or positive findings in used or unused products within the subdomain of toys, i.e. a recalled teething ring where the liquid contained therein was possibly contaminated with *Pseudomonas* (US FDA). An additional literature search [toys micro*] yielded a relevant study on the disinfection of toys in day care centres, where it was possible to reduce the respiratory viruses in the environment (Ibfelt et al., 2015). The microbiological safety of toys is not monitored. In 2016, the NVWA conducted a study on the safety, microbiological or otherwise, of bubble mixture products (NVWA, 2016a). The study focused on yeasts, fungi, *P. aeruginosa*, *S. aureus* and *Enterobacteriaceae*. Of the 38 bubble mixture products tested, five (13%) failed to meet microbiological safety requirements because too many aerobic mesophilic microorganisms were detected. It is suspected that the contamination occurs through the use of contaminated water.

Exposure

Almost all children in the Netherlands come into contact with toys on a daily basis. The way in which a product is used determines whether the pathogens can actually end up at the particular place in the human body where they can cause disease.

Toys such as cosmetic kits/face paint, finger paint or other paints come in contact with the skin after being smeared on the skin or allowed to remain on it, as a result of which it can be absorbed into the skin (leave-on products). Other toys, such as clay or squeezies, are frequently kneaded with the hands. Invasive opportunistic or other pathogens may therefore enter the body via this

route through the eyes or small wounds in the skin and cause infection or enter the eyes through hand-eye contact and cause infection. Oral exposure occurs via products that are put into the mouth, e.g. because they resemble food or are drinkable (bubble mixtures), and in case of hand-to-mouth contact, which occurs frequently among children. Pathogens can be ingested in this manner and cause disease via the gastrointestinal tract. Inhalation occurs when vapours or aerosols are released during the use of a product (e.g. bubble mixture). In these products, it is mainly the respiratory pathogens that can cause disease (such as pneumonia).

High-risk products

Toys are rarely identified as a source of disease. No cases of disease were reported in the national surveillance of notifiable diseases where the source was traceable to toys. No disease burden estimates have been attributed to toys. The RIVM report (De Jonge, 2019) described one outbreak caused by toys. This involved children who developed sepsis after playing with a bubble mixer that turned out to be microbiologically contaminated. This was followed by an in-depth study of the legislation on toy safety requirements, notifications in Safety Gate and identification of the production areas. This revealed that almost all bubble mixtures come from China and that untreated, contaminated water was used at a key production site (Amoruso et al., 2015).

Conclusion

Almost all children in the Netherlands come into contact with toys on a daily basis. Pathogenic microorganisms occur regularly in toys, where the most well-known case is that of microbial contamination in bubble mixtures imported from China. In the case of toys, this always concerns a vulnerable population, namely children. Cases of disease in which toys are identified as the source are scarce. For toys (bubble mixture), the risk posed by human pathogenic microorganisms in the Netherlands is currently assessed as low, based on likelihood (occasional for certain product groups, with frequent use) and severity (usually reversible with medical treatment). Here, the risk is inherent in the product and behaviour contributes towards an increased risk.

6.4.13. Microbiological risks of playground equipment

Playground equipment consist of structures or elements used for the purpose of recreation and amusement. If there are moving parts involved, these are propelled exclusively by muscular effort. Examples are air cushions, slides, sandboxes, ball pits and trampolines (NVWA, 2016f).

Legal framework

The safety of playground equipment is regulated in the Commodities Act Decree on Amusement Devices and Playground Equipment[215]. Playground equipment must be designed and manufactured in such a way that, when used under reasonably foreseeable conditions, they do not endanger the safety or health of persons. No further microbiological requirements have been specified in this Decree.

Identification of relevant microbiological pathogens

From 2014 to 2018, there were 119 notifications in Safety Gate concerning microbiological contamination of consumer products in Europe. None of these notifications concerned products within the playground equipment subdomain. In the RIVM report, no scientific literature concerning the microbiological contamination of playground equipment was found (De Jonge, 2019). The microbiological safety of playground equipment is not monitored. Inspections focusing on microbiological safety have been carried out for ball pits (NVWA, 2002b; Nab-Vonk, 2010) and sandboxes (NVWA, 2002a). The hygiene of 19 ball pits was inspected in 2001, where 13 were assessed as good, five as moderate and one as poor. Fungi, yeasts, *S. aureus* and *Enterobacteriaceae* were found; *Pseudomonas* spp. and *Streptococci* were not found. Ball pits near

[215] Decree of 3 September 1996 establishing a general order in council for the implementation of the Dangerous Equipment Act (Safety of Amusement Devices and Playground Equipment Decree (*Besluit veiligheid attractie- en speeltoestellen*)). Bulletin of Acts and Decrees 1996, 474, last amended by Bulletin of Acts and Decrees 2016-189

restaurants scored the lowest (NVWA, 2002b). A repeat study in 2009 demonstrated high numbers of *Enterobacteriaceae* (Nab-Vonk, 2010). In 2001, microbiological safety inspections were conducted in 17 sandboxes in public playgrounds, which lead to fungi and yeasts being detected in 14 sandboxes, *Clostridium* spores and *Bacillus* spores in 13 sandboxes and *Enterobacteriaceae* in three sandboxes. *Salmonella* and *Campylobacter* were not present in detectable quantities. An additional specific search in Pubmed for these products ([sandbox micro*] and [(ball pit) micro*] did not yield any relevant articles. Playground equipment in indoor playgrounds is inspected, but these inspections do not focus on microbiological safety (NVWA website, [keyword 'playground equipment', type 'inspection results indoor playgrounds']).

Exposure

Sand pits are not used daily, but perhaps monthly or temporarily during the summer by part of the population, namely by children. All kinds of biological contaminants are found in sandboxes. The two main groups found are food leftovers and natural materials (e.g. leaves, mushrooms or grass). Mice, rats and birds may be attracted to these food leftovers, as a result of which droppings (containing possible pathogens) may end up in the sand (NVWA, 2002a). In uncovered sandboxes, contamination may occur due to parasites *(Toxocara*) from cat or dog faeces. Very young children (under the age of three) also play in sandboxes. Children in that age group tend to put everything in their mouths. It is estimated that a child consumes an average of 0.2 g of sand per day. Through this, they may ingest pathogens that lead to infections via the oral route. This may happen directly by ingestion via the mouth or indirectly during eating, if one eats with unwashed hands.

Ball pits are not used daily, but perhaps monthly by part of the population, namely by children. Ball pits can become contaminated when used by infected children, or if contaminated by diapers, vomit or food. Pathogenic microorganisms can be transferred to the balls via this route and other children playing in this ball pit can become infected (NVWA, 2002b). Infection may occur via oral ingestion, inhalation or contact with skin wounds. A comparable route of transmission is also conceivable for bouncy castles, slides and trampolines, although to a lesser extent.

High-risk products

No cases of disease were reported in the national surveillance of notifiable diseases where the source was traceable to playground equipment. No disease burden estimates have been attributed to playground equipment. The RIVM report does not describe any outbreaks or infections via this route (De Jonge, 2019). An additional literature search in Pubmed [(sandbox) (infection or outbreak)] and [(ball pit) (infection or outbreak)] yielded one article describing play activities in a sandbox in the Netherlands as a risk factor for infection with *Salmonella* Typhimurium (Doorduyn et al., 2006), and another article that recognised ball pits as potentially high-risk sites for bacterial infection but did not mention any cases of disease (Davis et al., 1999).

Conclusion

The frequency of use of ball pits and sandboxes is not known, but it is assumed that this may be monthly, to even weekly or daily in warmer seasons. Based on several studies, it is known that pathogenic microorganisms regularly occur on playground equipment, especially in ball pits and sandboxes. These pathogens can cause infection and disease through ingestion or contact with the mouth, contact with hands or skin or after inhalation, although there are few reports of this route as a source of disease. The population that uses playground equipment is vulnerable, mostly children aged up to five (6% of the Dutch population), including very young children (<3 years old; 3% of the Dutch population). The main risk is that of infection with *Toxocara* or *Salmonella* (sandboxes), or pathogens that follow the faecal-oral route such as norovirus and *E. coli* (ball pits). For playground equipment, the risk posed by human pathogenic microorganisms is assessed as low to medium, based on likelihood (occasional based on average prevalence, moderately frequent use by about 6% of the Dutch population) and severity (easily reversible without medical treatment or usually reversible with medical treatment). The risk is not inherent in the product, but behaviour contributes towards an increased risk.

6.4.14. Microbiological risks of tattooing and piercing

Tattoos are permanent markings on the skin made using ink and a needle. Tattooing involves the puncturing of the epidermis and injection of ink into the dermis. The cells in the dermis then encapsulate the ink. Applying permanent makeup is also a form of tattooing, but here the ink is only applied to the epidermis and will fade after a few years. Permanent makeup (PMU) is mainly used for correcting minor physical imperfections. Aftercare ointments are applied to a wound after the application of a tattoo. They have a protective effect. In addition, generally available disinfectants are used.

In case of piercings, the skin is punctured with a needle. A small bar, ring or other piercing jewellery is inserted into the hole. Sometimes the piercing penetrates not just skin but also cartilage. Piercings can be done in many places on the body, e.g. through the tongue, eyebrow or navel (NVWA, 2016f).

Legal framework

There is no European legislation for tattoo ink. In the Netherlands, safety requirements are set out in the Commodities Act Decree on Tattooing colourants)[216]. Article 4(1)(g) stipulates that tattooing colourants must be sterile. In addition, they must not contain any preservatives. Since 2007, regulations have also been in effect stating that tattoos and piercings may only be done if certain hygiene requirements are met[217]. A licensing requirement has been introduced for this, for which the Municipal Health Services (GGD) carries out hygiene inspections. Tattoos and piercings may be done from the age of 16 onwards, and for children aged between 12 to 16 years, these may be applied after obtaining permission from and in the presence of their parents.

Identification of relevant microbiological pathogens

Tattoo inks generally contain water, which allows for microbial contamination. Contamination may occur during production, while using the product, or if contaminated raw materials or containers are used (Bonadonna, 2015). For piercings, the surface of the ornament should not be porous so as to prevent the growth of microorganisms (NVWA, 2013).

Among the 119 notifications in Safety Gate in Europe from 2014 to 2018, one was about microbiological contamination of a non-sterile single-use tattoo needle and six were about non-sterile tattoo ink (Table 47). Minghetti *et al.* indicate that more than 10% of notifications about tattoo ink in Safety Gate in the period 2007-2017 (dd. 18 January 2018) involved microbial hazards (Minghetti et al., 2019).

Table 47 Safety Gate notifications about microbiological contamination relating to tattoos and piercings in the period from 2014 to 2018

Product group	Number of notifications	Deviation	Origin	Notifying country	Related to NL
Tattoo needle	1	Non-sterile packaging			
Tattoo ink	6	Total aerobic colony-forming unit count (6) Fungus (2)	Germany (1) UK (4) UK (1)	Germany (2) Italy (4)	No

[216] Decree of 14 August 2003 on establishing rules concerning the safety of tattooing colourants (Tattooing Colourants (Commodities Act) Decree). Bulletin of Acts and Decrees 2003, 342, last amended by Bulletin of Acts and Decrees 2013, 177.

[217] Regulation of the Minister of Health, Welfare and Sport of 23 May 2007, no. VGP/PSL 2770998, containing rules concerning the use of tattooing and piercing materials. Government Gazette 2007, 99, last amended by Government Gazette 2019-35496

For piercings, there were no notifications of microbiological contamination in Safety Gate.

The scientific literature overview prepared by the RIVM includes 46 articles describing the microbial contamination of products (De Jonge, 2019). This included four articles with prevalence data or positive findings in used or unused tattoo ink (Table 48).

Table 48 Microbiological hazards in tattoo ink or permanent makeup reported in scientific literature (De Jonge, 2019).

a	Microorganism and prevalence (/[concentration]/detection)	Country	Reference
-	*P. aeruginosa*, fungus; product withdrawn from the market	USA	(Bonadonna, 2015)
16	No contamination found in 16 inks	France	(Bonadonna, 2015)
39 unopened, 106 opened	In 4/145 (39 unopened, 106 opened)>10,000 CFU/ml aerobic mesophilic colony-forming unit count, *Bacillus*	Germany	(Bonadonna, 2015)
58 unopened, 6 opened	6/58 (10%) unopened and 1/6 (17%) opened, non-sterile, including yeast, fungus, *Pseudomonas spp*., *Staphylococcus spp*. *Enterococci*	Via internet, various countries	(Hogsberg et al., 2013)
34	Opened and unopened; total 31/34 (91%) not sterile, unopened 86% not sterile *Bacillus* (unopened), *Staphylococcus spp.* (open)	Italy	(Bonadonna, 2015)
85 unopened	42/85 (49%) not sterile, of which 40 were bacterial, 9 with fungus (7 double infected) incl. Bacillus spp.	USA	(Nho et al., 2018)
26	3/26 not sterile	France	(Verdier, 2015)

The NVWA monitors tattoo and permanent makeup inks based on the Commodities Act Decree on Tattooing colourants (2003) and the Resolution of the Council of Europe (ResAP(2002)1). This is partly focused on microbiological safety, i.e. the sterility aspect (NVWA, 2014c;2017f). In the period 2004-2008, after the legislation came into effect, the microbiological condition of ink originating from Dutch manufacturers and importers was found to have improved from 11% non-sterile in 2004 to 2% non-sterile in 2007 (NVWA, 2014c). In the period 2008-2013, 698 samples were subjected to microbiological testing during inspections. Of these, 42 (6%) samples were found to be non-conforming from the microbiological perspective, with a significant number in 2009 and 2010 (26 out of 175 samples (15%) and 10 out of 128 (8%) respectively) being attributable to a manufacturer with a bacteriological problem in the production process. In 2015, the NVWA sampled 52 different black tattoo inks offered by Dutch importers and traders. Of these, two (4%) samples were non-sterile (mesophilic colony-forming unit count >100 cfu/g) but no *Pseudomonas* or *S. aureus* was detected (NVWA, 2017f).

Besides the NVWA, the GGD also carries out inspections focused on hygienic working methods. If the requirements are met, a licence is issued. Based on unannounced inspections in 2012 of 119 (20% of the total number) licensed tattooists and/or piercers, shortcomings were found among 30% of this group. Two deviations were found in inks, i.e. an expired and an unreadable use-by date. During a repeat inspection, all shortcomings had been resolved (NVWA, 2013). The NVWA

has continued to carry out annual inspections. Inspections in the period 2012-2017 in 250 tattoo and piercing shops revealed deviations (which led to the imposition of certain measures) varying between 30% and 59%, based on 461 tattoo and piercing shops (NVWA, 2019e).

For microbial contamination of aftercare articles: see the cosmetic products subdomain.

Exposure

It is estimated that 6% of the Dutch population has at least one tattoo and 3% has at least one piercing (Urbanus et al., 2011). Since tattooing and piercing involve puncturing the skin, pathogens in the ink, on the needle or on the jewellery can cause infections via the invasive route. Normal skin microbiota can also get into the deeper parts of the skin or bloodstream via the puncturing of the skin, and thus cause infections. In case of piercings, the material remains in the skin, with microbial growth and infection possible if the inserted material has a porous surface. The application of a tattoo or piercing creates a wound that needs to be taken care of to prevent infections. The care products used for this may also be contaminated and enter the body via the wound. Besides the use of sterile products, a hygienic working method is also important. These actions are usually performed by non-medically trained persons. Unhygienic working practices can result in secondary contamination of opened products or lead to an infection hazard due to damaged treatment chairs, incorrectly used disinfectants or hand contact with the wound (NVWA, 2013).

High-risk products

Infections caused by tattoos are known to occur. However, it is not precisely known to what extent tattoos lead to infection, since people report these to their tattooist and generally do not visit their GP (Bonadonna, 2015). Moreover, it is not known what proportion of infections can be attributed to contaminated opened or unopened products of tattoo ink or aftercare products. Outbreaks of infections with nontuberculous *Mycobacterium chelonae* have been reported, which were attributed to the use of tap water instead of sterilised water (Bonadonna, 2015). In another outbreak of *M. chelonae* with 19 cases among people aged between 18 and 48 years, the contamination was detected in unopened, pre-diluted ink (Kennedy et al., 2012). In an internet survey, 68% of respondents reported skin problems, 7% systemic reactions, 1% fever and less than 1% wounds with pus. These symptoms may be related to bacterial infections (Bonadonna, 2015). In general, both young and older adults get tattoos and piercings.

Cases of disease caused by piercings are not mentioned in the scientific literature overview made by the RIVM. An additional search in Pubmed [piercing, (infection or outbreak), micro*] yielded many (>100) relevant articles. After narrowing this down to the Netherlands, the remaining case reports concerned rare and sporadic cases in which a piercing resulted in a *Staphylococcus epidermidis* infection of a breast implant (Cornelissen et al., 2017), a tongue piercing led to a *Streptococcus endocarditis* infection (Kloppenburg & Maessen, 2007), and an ear piercing led to pyogenic spondylitis (pus-like inflammation of the vertebra) (Sewnath et al., 2007).

On the other hand, studies among blood donors show that tattoos and piercings do not lead to an increased risk of transmission of pathogens via blood products (Prinsze et al., 2019) and that people in the Netherlands with multiple tattoos do not have an increased risk of hepatitis B virus infection or hepatitis C virus infection (Urbanus et al., 2011). It should be noted, however, that the population allowed to donate blood is not a representative sample of the Dutch population due to certain exclusion criteria.

For possible infections due to microbial contamination of aftercare articles: see the cosmetic products subdomain.

Conclusion

Several studies show that microorganisms occur regularly (about 5%) in tattoo ink; however, it is not known to what extent pathogenic microorganisms occur in tattoo ink. There are scarcely any reported cases of disease in which products within the tattooing and piercing subdomain have been identified as sources. Although these products can be a source of infection ('product failures'), infections are mainly caused by secondary contamination, as a result of unhygienic

practices (behaviour) during the application and aftercare of tattoos and piercings. In 30-60% of the inspected tattoo and piercing shops, deviations were found with respect to hygienic working methods. The target population for the products are young and older adults and this is not considered as a vulnerable group. For tattoos and piercings, the risk posed by human pathogenic microorganisms in the Netherlands is currently assessed as low to medium, based on likelihood (rare in case of good hygiene, occasional in case of moderately good hygiene) and severity (usually reversible with medical treatment).

6.4.15. Microbiological risks of textiles

The word 'textile' literally means 'that which is woven'. A piece of textile consists of endless threads or short threads that have been woven, knitted, knotted, braided or felted. It may be used as a raw material on the roll from which an end product is made, such as clothing, or the end product itself. When intended for private purposes, it includes a range of end products such as clothing, linen, bed linen, home textiles, furnishing fabrics, carpets and rugs. It also includes haberdashery, yarns and knitting yarns. The term 'clothing' should be considered very broadly: leather clothes, baby clothes, underwear, everyday clothes, work clothes, sportswear, swimwear, as well as accessories such as scarves, bags, gloves and footwear (NVWA, 2016f).

Legal framework

There are several articles of law in Dutch legislation and European regulations that are applicable to clothing and textiles. This legislation does not define any specific microbiological requirements.

Identification of relevant microbiological pathogens

From 2014 to 2018, there were 119 notifications in Safety Gate concerning microbiological contamination of consumer products in Europe. None of these notifications concerned products within the textiles subdomain. In the RIVM report, no scientific literature concerning the microbiological contamination of textiles was found (De Jonge, 2019). An additional specific search [textile micro*] yielded many irrelevant hits (microplastics); a narrower search [textile micro* contamination] yielded no relevant articles. The microbiological safety of textiles is not monitored. Inspections (NVWA website: textiles, inspection results) are not focused on microbiological safety.

For textiles contaminated after use of a washing machine: see the electrical appliances subdomain.

Exposure

Microbial contamination of textiles can cause infections via skin contact, presence of wounds in the skin (*porte d'entrée*) or inhalation. It is conceivable[218] that the products could get contaminated when clothes are tried on/worn and then returned with insufficient attention to personal hygiene. This also applies to second-hand clothing (De Liberato et al., 2019). If these products are subsequently purchased and not washed before use, there is a risk of infection if a pathogen is able to survive in the environment for a long time. It is not known with what frequency people are exposed to newly purchased garments that are not washed before wearing. It is assumed that this will not be more than a few times each year.

High-risk products

There are no known cases of disease attributable to the microbial contamination of textiles. No disease burden estimates have been attributed to the microbiological contamination of textiles. The overview of scientific literature (De Jonge, 2019) does not describe any outbreaks or infections via this route. An additional specific search [textile micro* (infection or outbreak)] did not yield any relevant hits for microbial contamination, but there were some hits for the antimicrobial effect of textiles (silk, hospital bedding) (Ricci et al., 2006; Borkow & Gabbay, 2008) where resistance development might occur. In 2012, the BfR made an overview of potential problems relating to clothing. If clothing is to be finished with antimicrobial substances, the BfR states that the

[218] https://www.nu.nl/lifestyle/3956438/nederlander-negeert-hygiene-bij-passen-van-online-bestelde-kleding.html

advantages and disadvantages must be assessed (possible development of resistance). In particular, the BfR stated that triclosan should no longer be used (BfR, 2012). In 2014, the EU prohibited the use of triclosan as an active substance in products for the purpose of preserving fibrous or polymerised materials, such as leather, rubber, paper or textiles[219]. When textiles treated with biocidal products are washed, these active substances may be released. KEMI is concerned about the potential for bacteria to develop resistance through exposure to low concentrations of biocidal products. This may affect the development of antibiotic resistance. Therefore, KEMI has recommended that unnecessary use of biocidal products in textiles should be avoided (KEMI, 2014).

For textiles contaminated after use of a washing machine: see the electrical appliances subdomain.

Conclusion

Unworn textiles are not a likely source of microbial infections. However, infection is possible in the case of worn textiles (second-hand, via online shopping or otherwise), if these clothes are not washed before use and if the pathogens can survive in the environment for a long time. It is not known to what extent this route leads to infections. Biocidal products that are prohibited in the EU, such as triclosan, may still be present in imported textiles. The use of biocidal products in textiles can lead to the development of resistant bacteria that may influence the development of antibiotic resistance. For textiles, the risk posed by human pathogenic microorganisms in the Netherlands is assessed as low, based on likelihood (rare if washed in advance) and severity (easily reversible without medical treatment). The risk is not inherent in the product, but behaviour contributes towards an increased risk.

For textiles contaminated after use of a washing machine: see the electrical appliances subdomain.

6.4.16. Other - general product safety

Consumer products that do not fall under one of the earlier mentioned subdomains are categorised by the NVWA as general consumer products. This is a very diverse segment. including, for example, garden soil or potting soil, scented candles, jewellery, tools, tampons, toothbrushes, and sporting goods.

Legal framework

General consumer products must comply with the General Product Safety Directive (Directive 2001/95/EC)[220]. This Directive sets out general safety requirements but does not contain any specific microbiological requirements. In general, the requirement states that these products must not pose any risk to human safety or health during their intended and foreseeable use.

Identification of relevant microbiological pathogens

From 2014 to 2018, there were 119 notifications in Safety Gate concerning microbiological contamination of consumer products in Europe. None of these notifications concerned products within the 'Other consumer products' subdomain. In the RIVM report, nine scientific articles were found concerning the microbiological contamination of products in the 'Other consumer products' subdomain (De Jonge, 2019). One study describes a low microbial contamination of 14-15 tested, packaged tampons where pathogens, especially *Bacillus,* were demonstrated in 6% of the samples (Briancesco et al., 2018); another study describes the microbial contamination of 19 of 40 (48%) unused toothbrushes (Do Nascimento et al., 2011). One study describes the presence of *Legionella* spp. (including *L. pneumophila, L. bozemannii, L. longbeachae*) in 61 of 88 (69%) compost samples and in 9 of 47 (19%) dust/aerosol samples from compost in Switzerland (Conza et al., 2013). The remaining six articles describe the microbial contamination of compost and its

[219] 2014/227/EU: Commission Implementing Decision of 24 April 2014 on the non-approval of certain biocidal active substances pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council. OJ L 124, 25.4.2014, p. 27-29

[220] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. OJ L 11, 15.1.2002, p. 4-17

derivatives, thus drawing attention to the circular economy. The risk of recycling waste for compost was identified as early as in 1995, where the condition known as pica (a craving to consume unusual or inedible things), which is experienced by small children and pregnant women (Déportes et al., 1995), may give rise to a risk. In the case of biomass (which can be used as manure) generated from 93 pulp and paper mills, *Salmonella, Campylobacter, Shigella, and Cryptosporidium* were found in 6-8% of the mills in Canada (Flemming et al., 2017). *Giardia*, *E. coli/enterococci* were found more frequently: in 19% and 50-75% of all samples, respectively (Flemming et al., 2017). Cancelado et al. indicate that compost from animal remains can be used as manure, but not on plants for human or animal consumption (Cancelado et al., 2014). A study on the survival span of pathogens in compost based on paper or paperboard, fruit, vegetables and green waste showed that *Salmonella* could survive for three months; *E. coli* and *Listeria* monocytogenes did not survive this period (Lemunier et al., 2005). Longhurst et al. assessed the risks of compost in the context of the circular economy in the UK using the worst-case scenario of an *E. coli* O157 contamination via compost on vegetables intended to be consumed raw, and based on this, concluded that the risk is negligible provided the relevant protocols and standards are followed (Longhurst et al., 2019).

In the context of the circular economy, it is also important to follow the developments in the area of struvite. As described by Grinten and Spijker (2018), struvite derived from wastewater is currently labelled as waste by law. This makes it possible to place complex derivatives of this on the market as raw materials for new products. The water authorities want to label it as a raw material rather than as waste. The product made from it will then be worth more and the processors will no longer have to be designated as waste processors. However, in order to bring about this change in the label, struvite must meet certain safety criteria. Microbial risks with respect to *Clostridium, E. coli* and viruses can be expected.

The microbiological safety of the products falling under 'Other consumer products' is not monitored. Inspections are not focused on the microbiological safety of products falling under 'Other consumer products'. In 2009, the NVWA performed an exploratory study on erotic articles (sex toys), including the biocidal products used for disinfecting the articles and edible cream. The active substance in nine delivered biocidal products was assessed, and it was found that the active substances were not present in all biocidal products at the optimal concentration. In a few cases the claimed active substance could not be demonstrated. All the three biocidal products that were tested for antibacterial activity demonstrated antibacterial activity (VWA, 2009a). An antiviral effect was claimed in only one biocidal product, but this effect was not tested. An additional targeted literature search [(sex toys) and micro*] [(erotic toys) and micro*] did not yield any relevant articles.

Exposure

The frequency of use of other consumer products is not known but is expected to vary widely (daily, monthly, seasonally), given the diversity of products. Direct exposure to pathogens, especially *Legionella spp*. in garden soil or compost, occurs via hand-to-mouth contact or via inhalation of aerosols. Indirect exposure to pathogens in garden soil or compost occurs when the product is used on plants intended for human consumption and specifically on plants that are consumed raw. Exposure to pathogens via toothbrushes can occur after ingestion, inhalation or invasively, if wounds occur while brushing teeth. Exposure to pathogens via tampons occurs vaginally and via erotic articles both vaginally and anally, where the pathogens can grow and cause an infection at the specific location or can be absorbed via mucous membranes, and from there they can reach other parts of the body.

High-risk products

The RIVM report does not include any literature on cases of disease caused by microbial contamination of products falling under 'Other consumer products'. An additional literature search on [tampon* micro* (infection or outbreak)] resulted in reviews regarding the rare but very serious toxic shock syndrome (Lodén et al.), which could previously be caused by use of a specific type of tampon (highly absorbent). Since this type of tampon has been withdrawn from the market, TSS due to tampon use scarcely occurs (Ross & Shoff, 2019). An additional literature

search on [(toothbrush* or (tooth brush*)) micro* (infection or outbreak)] yielded articles on the risks of poor oral hygiene, but not as a result of contaminated toothbrushes.

An additional literature search on [*Legionella* (potting soil) (infection or outbreak)] yielded several articles demonstrating a relationship between potting soil and disease in the United States (CDC, 2000), New Zealand (Cramp et al., 2010), the Netherlands (Den Boer et al., 2007) and Scotland (Pravinkumar et al., 2010). *Legionella longbeachae* via compost is a potential public health problem in the UK (Currie et al., 2014).

An additional literature search on [(erotic toys) and (outbreak or infection)] yielded several relevant articles. Here, the use of sex toys is identified as a risk factor for infection by sexually transmitted pathogens such as the human immunodeficiency virus (HIV) and human papillomavirus (HPV) (Armstrong et al., 2018; Plummer et al., 2019). It is not known to what extent this route contributes to infections as compared to other routes of transmission.

Conclusion

Pathogenic microorganisms occur regularly in products falling under the 'Other consumer products' subdomain, and cases of disease in which products within this subdomain are identified as a source are mainly known for potting soil and compost, and to a lesser extent, for tampons and toothbrushes. For sex toys, the products are not initially contaminated, but infected persons may contaminate them during use. If these toys are shared and/or the additionally supplied biocidal products are insufficiently effective, the pathogen may spread. The frequency of use of the products in the 'Other consumer products' subdomain is not known, but it is assumed that this varies widely, ranging from daily for toothbrushes by the entire population, weekly to monthly for sex toys by a small part of the population, to occasionally (seasonally) for potting soil. With regard to sex toys, the risk is assessed as medium to high, based on likelihood (occasional) and severity (long-term effects, possibly irreversible). Here, the risk is not inherent in the product, but behaviour contributes towards an increased risk. With regard to potting soil, cases of disease or outbreaks as a result of microbially contaminated potting soil are expected to occur more frequently, given the societal developments in which sustainability, circular economy and recycling play an important role. The target population for such products is adults working in the garden, and this is not considered to be a vulnerable group. In case of - the usually rare - condition of pica, exposure via ingestion may occur within a vulnerable population, i.e. small children and pregnant women. The risk of intake of human pathogenic microorganisms via potting soil or compost in the Netherlands is currently assessed as low, based on likelihood (rare) and severity (usually reversible with medical treatment). The risk is inherent in the product and behaviour (pica) also contributes towards an increased risk.

7. Survey on consumer products

7.1. Introduction

Consumers make an assessment, whether consciously or unconsciously, of the risks associated with the use of products. People mainly do this by assessing how serious the possible injuries will be. This is what appears from studies of people's perception of risk on viewing warning texts and symbols on consumer products (van Duijne, 2005). The perception of the hazard, perceived familiarity with the product and the costs of safe behaviour appear to be three important factors associated with the safe or unsafe handling of products.

To gain more insight into this, consumer perception of the safety of consumer products was studied. In the period from 16 March to 3 April 2020, the market research agency Motivaction conducted a survey on behalf of BuRO (Motivaction, 2020). The survey was conducted online via Motivaction's ISO 26362-certified online research panel StemPunt. The target group consisted of Dutch people aged 18 to 75. A representative sample of 3,199 Dutch people aged between 18 and 75 was created. This sample was representative of age, gender, education, Nielsen region, Mentality milieu[221] and interactions between these variables. The questionnaire was prepared in cooperation with (BuRO).

Later it appeared that the survey had been conducted at the beginning of the period in which drastic coronavirus (COVID-19) measures came into force, such as the closure of schools, childcare centres, hotels, restaurants and cafes, sports clubs, with the advice to stay at home and maintain a distance of one-and-a-half metres from other people. During that period, the number of people who were infected with the virus, falling ill and dying also increased. Each survey also asks questions about safety perceptions relating to general issues, such as neighbourhood safety, food safety, health care and road safety. The general feeling of safety was even scored slightly higher than in previous surveys. This indicates that the extensive coronavirus-related measures did not have a negative impact on the risk perception of consumer products.

7.2. Purchase of consumer products

Place of purchase

Almost nine out of ten Dutch people (87%) usually buy their consumer products (such as magazines, washing powder, cosmetic products, paint, electrical appliances and clothing) at a physical shop. Four out of ten Dutch people (40%) sometimes buy consumer products from Dutch online shops and 8% also buy such products from foreign online shops.

If consumers buy products from online shops in the Netherlands, the NVWA can monitor this. The NVWA also monitors the import of consumer products from outside the EU. It cannot take direct action against sellers based outside the Netherlands. Within the European Union and the European Economic Area, it can take the assistance of fellow market surveillance authorities. The central government has launched an information campaign to raise awareness regarding the risks consumers take when ordering directly from online shops based outside the EU: #laatjenietinpakken, which roughly translates to 'Don't get taken in'[222].

Reason for purchase

Three-quarters of the Dutch population (76%) indicate that price is one of the most important factors for them when choosing a new consumer product. Seven out of ten Dutch people (70%) also cite quality as an important factor in their choice. The Dutch find reviews (28%), the appearance of a product (26%) and its durability (23%) less important factors in their choice of a new consumer product. What they hear within their social environment (10%) and TV advertisements (3%) are the least often chosen as important factors.

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[221] Mentality milieus are segments of the population with their own specific value orientation and outlook on daily life.

[222] https://www.rijksoverheid.nl/onderwerpen/bescherming-van-consumenten/vraag-en-antwoord/kopen-bij-webwinkels-buiten-de-eu

Information on the label

For most consumer products, there are legal requirements for what must be included on the label with regard to safety information or instructions for safe use. Examples of such information are age indications for toys, hazard symbols on household chemicals or a declaration of the substances used as ingredients.

A quarter of the Dutch population (25%) frequently or always pays attention to the general symbols on labels when buying a new product. Most (45%) do this sometimes and 24% never do this. A quarter of the Dutch population (25%) also frequently or always read the list of ingredients on labels. Again, most read them sometimes (45%) and a quarter never do (25%). Instructions on safety and use are read more often: 47% do this frequently to always, 41% do this sometimes and 9% never read the instructions on labels.

According to the NVWA, the legally mandatory safety labels must be present. However, this mandatory labelling has limited influence on purchasing behaviour and the use of consumer products. A distinction can be made between consumer groups, the degree of familiarity with a product and the perceived risk. Consumers with a certain allergy will, for example, pay attention to the ingredients declaration. If a product is being used for many years, the user will pay little attention to the safety information (van Duijne, 2005). When using a new product that is perceived as potentially risky (e.g. a drill), the buyer generally pays attention to the safety instructions.

Product failure

Among the Dutch, 58% checks whether they can repair a broken product themselves, while 46% take it to the separate refuse collection if they can, 41% try to use the product as long as possible, and 29% have the product repaired by someone else. Less than two out of 10 Dutch people immediately buy a replacement product (18%) or hand in the broken-down product to the thrift shop (17%). About one out of 10 persons throws the product away (11%) or takes it to a repair café (7%).

If a product is repaired by the consumer, another person or a repair café, there is a risk that faulty parts will be used or that the product will not be repaired properly. This may result in a safety risk. There is a potential safety risk when someone continues to use the product for as long as they can, despite a part of the product not working.

About refurbished products: see also Section 5.20.4 of the main text.

7.3. Information sources used and confidence in product safety

Confidence in information sources

When it comes to information on consumer products, about six out of 10 Dutch people indicate that they trust the Dutch consumers' association Consumentenbond (61%) and the NVWA (57%). The central government comes in third as a reliable source (43%). Moreover, the following are seen as reliable sources of information by the Dutch: information on the product itself (32%), reviews about the product (28%), and what others around them say about the product (25%).

The survey showed that most people consider the information provided by the NVWA and the central government to be reliable. In 2015, the NVWA started publishing its studies on consumer products. Any warnings about unsafe products are also posted on the NVWA website, Facebook and Twitter.

Responsibility for safe consumer products

More than three-quarters of the Dutch population (77%) believes that the producer is responsible for the safety of a product. Three-quarters thinks that the government should ensure safe internet commerce (74%). In addition, 66% trusts the government to provide sufficiently safe products. Most Dutch people understand that products will become more expensive if there are increased

safety controls (61%). Almost six out of 10 Dutch people (58%) agree that the media sometimes exaggerate risks in order to attract more readers and viewers.

Among the Dutch, 57% thinks that the risks of some products are underestimated, compared to 41% who thinks that risks are overestimated. Four out of 10 Dutch people find it unacceptable that some products cause allergic reactions (37%) or are unsafe (44%), compared to 37% who accepts that some products cause allergic reactions and 29% who accepts that products may be unsafe.

The majority of consumers believe that the responsibility for a safe product always lies with the producer. They also believe that the government should monitor this and have confidence in the safety of consumer products including those available via internet commerce. Perceptions of the risks associated with consumer products vary somewhat. In Section 1.4, we examine this in greater detail per product category.

Role of the government

A majority of Dutch people are confident that the Dutch government takes the safety of citizens sufficiently into account when it comes to product safety (59%) and that there are sufficient rules in the Netherlands to keep harmful effects under control (58%). Only a small proportion does not think so (12% and 9% respectively). In addition, just over half of those surveyed feel that the government is doing a good job with respect to product safety (55%) and that the government is competent enough to take decisions in this area (53%). Among the Dutch, 43% think that the government has sufficient knowledge about the risks of products and almost two in 10 (17%) do not.

However, 45% of Dutch people believes that the government is influenced by industry in decisions on product safety (vs. 13% believing that the government is not). One-third of the Dutch (33%) believes that the government is influenced by action groups when taking decisions about product safety (vs. 20% who believed it is not influenced).

One-third of the Dutch population thinks that the government listens to the feelings of citizens on the subject of product safety (35%) and what citizens think about product safety (33%). About two out of 10 people are unable to answer these questions (17% and 18% respectively). A similar percentage of the respondents does not feel that the government listens to citizens' feelings and what citizens have to say (18% and 19% respectively). Approximately half of the Dutch population (47%) is prepared to pay more for a product, if the government carries out stricter checks on the safety of non-food products. This varies between 10 euros to more than 100 euros per year.

There is confidence in the Dutch government with regard to product safety. The majority of respondents think that there are sufficient rules for safe products. However, almost half of the consumers feel that the government is influenced by the industry, and to a slightly lesser extent, by action groups. The influence of citizens themselves is not assessed as high. Almost half of the consumers are prepared to pay more for a consumer product, if the government carries out stricter safety controls.

7.4. Confidence in specific product groups

Consumers were asked to assess the health risk for various product groups and indicate the extent to which they have confidence in the safety of that product group.

Figure 6 visually displays the level of consumer confidence in various categories of products. Green colours indicate confidence; yellow is neutral; orange and red colour indicate no confidence. Confidence in fairground attractions and playground equipment is lowest, while confidence in electrical equipment, textiles, gas appliances, personal protective equipment and machinery is highest.

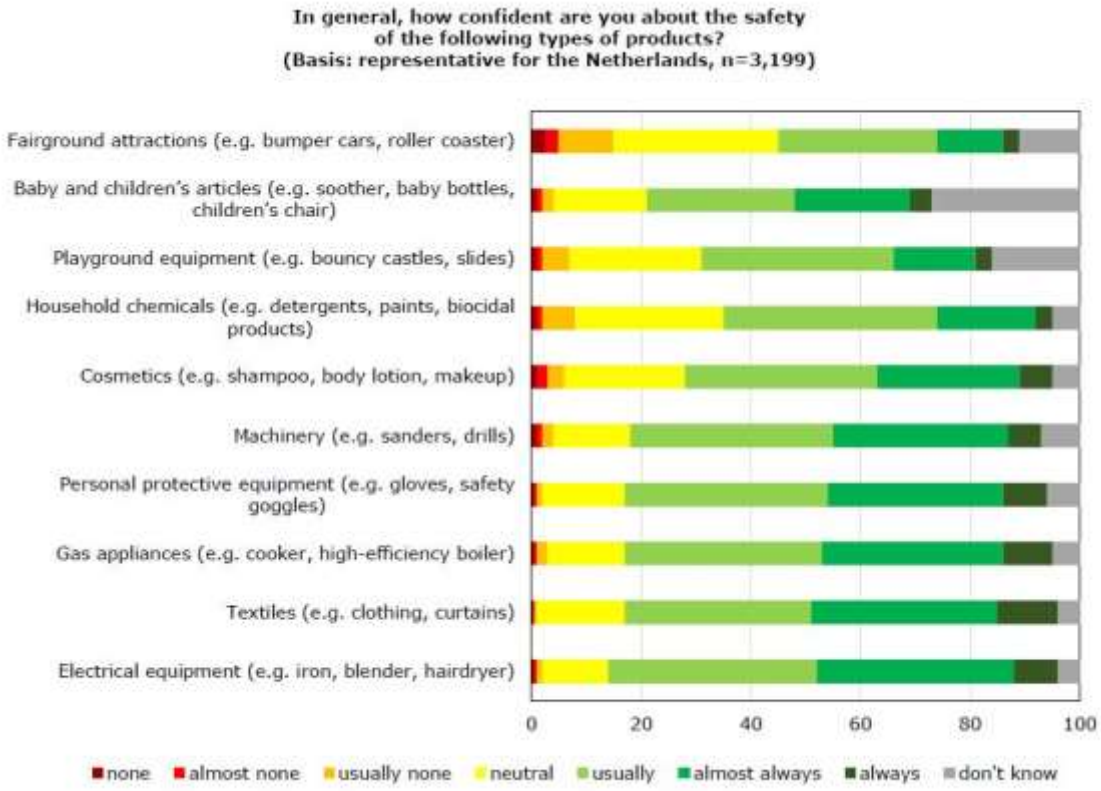

Figure 6 Confidence in consumer product safety

Table 49shows the percentage of consumers who are confident about the safety of consumer products, based on different age groups and levels of education. For a number of product categories, such as fairground attractions, playground equipment and child use and care articles, confidence is lower among older people. For gas appliances, it is the other way around. Consumers with lower levels of education have, on average, lower confidence in the safety of consumer products.

Table 49 Confidence in consumer products based on differences in age and level of education

% Usually + Almost always + Always	Male	Female	18 to 24	25 to 34	35 to 44	45 to 54	55 to 64	65 to 75	High	Medium	Low
Electrical equipment	83%	81%	82%	77%	80%	83%	85%	84%	88%	83%	71%
Textiles	77%	80%	83%	77%	80%	80%	77%	76%	84%	80%	69%
Gas appliances	79%	76%	72%	70%	74%	83%	82%	82%	83%	78%	70%
Personal protective equipment	79%	75%	78%	70%	78%	79%	77%	80%	82%	78%	67%
Machinery	80%	71%	73%	71%	73%	80%	80%	74%	82%	76%	65%
Cosmetics	66%	70%	74%	65%	69%	70%	67%	63%	71%	70%	59%
Household chemicals	62%	58%	64%	62%	58%	64%	58%	57%	62%	62%	53%
Playground equipment	54%	51%	62%	60%	60%	58%	42%	36%	60%	55%	36%
Baby and children's articles	50%	55%	55%	56%	61%	52%	49%	43%	59%	53%	43%
Fairground attractions	47%	40%	59%	47%	50%	47%	34%	29%	49%	45%	32%

Consumers assessed the health risk on a scale from 1 (very low) to 7 (very high). Consumers who assessed the health risk as high (6 or 7) were asked what they generally do about this. They were

also asked whether they have confidence in the safety of these types of products (None, Almost none, Usually none, Neutral, Usually, Almost always, Always, Don't know). Table 50 shows the score for various product categories and the percentage of consumers who are confident about safety.

Table 50 Assessed health risk of different categories of consumer products

Product category	Assessed health risk[1]	Confidence in safety
Household chemicals (detergents, paints, biocidal products)	4.41	60%
Fairground attractions (bumper cars, roller coaster)	4.08	44%
Playground equipment (bouncy castles, slide)	3.83	53%
Gas appliances (cooker, high-efficiency boiler)	3.57	78%
Machinery (sanders, drills)	3.61	75%
Cosmetics (shampoo, body lotion, makeup)	3.40	67%
Electrical appliances (iron, blender, hair dryer)	3.29	82%
Child use and care articles (soother, baby bottle, children's high chair)	3.31	52%
Personal protective equipment (gloves, safety goggles)	2.94	77%
Textiles (clothing, curtains)	2.75	79%

[1] Estimated risk on a scale from 1 (very low) to 7 (very high)

Household chemicals

Among consumers, 60% are confident about the safety of household chemicals; one-fifth consider the health risk to be relatively high. The majority of people who assess the risk as high, use the products despite the risk: 35% say they will use the product despite the risk but will take precautions; 21% say they are willing to take the risk; 20% say the benefits outweigh the risks. A number of consumers no longer use these products: 26% are looking for an alternative, 19% cite the reason that these products are bad for the environment.

Fairground attractions

Most consumers are neutral (30%) in assessing the risk or are confident about the safety (44%). Among consumers, 15% assess the health risk of fairground attractions as high; most of them avoid fairground attractions. The safety of fairground attractions depends to a large extent on the operator of the attraction. In addition, behaviour and compliance with safety instructions also play a role.

Playground equipment

Most consumers are neutral (24%) in assessing the risk or are confident about the safety of playground equipment (53%). Among consumers, 11% assess the health risk of playground equipment as high. They indicate that they avoid such playground equipment, look for an alternative or take precautions, for example, by actively supervising children at play.

Gas appliances

Consumers have a great deal of confidence in the safety of gas appliances (79%), but 11% assess the health risk as high. They say they use gas appliances mostly because of the benefits, or they take precautions by allowing periodic maintenance to be carried out, or they look for information on what it signifies for them, or they avoid these products.

Machinery

Three-quarters of the Dutch have confidence in the safety of machinery, while 9% assess the health risk as high. The majority indicate that they use them despite the risk for the following reasons: they take precautionary measures, they find the benefits more important or because they have searched for specific information on the internet. By taking precautions, such as wearing personal protective equipment, consumers can influence their own safety.

Cosmetic products

Among consumers, 67% have confidence in the safety of cosmetic products, but 8% assess the health risk of cosmetic products as high, where a majority of these people say that they do not use the products any more or are looking for an alternative. Unfortunately, it is not specified whether this refers to a specific product or to cosmetic products in general. Some people continue to use cosmetic products for the following reason: they take precautions, their friends use them as well, they also see the benefits, they are willing to take the risk. Among consumers, 11% indicate that they look for information, e.g. via the internet, about what it signifies for them personally. Cosmetic products include not only makeup but also products for general hygiene, such as shampoo, toothpaste and deodorant. Most consumers want to continue using this type of cosmetic products regardless of other factors. Some indicate that they choose an environmentally friendly product because it will contain less harmful substances.

Electrical equipment

Among consumers, 82% have confidence in the safety of electrical equipment, while 7% assess the health risk of electrical equipment as high. Some indicate that they use the equipment despite the risk, but that they take precautions, accept the risks or use the equipment because it also has advantages. Some indicate that they no longer use the product, or are looking for information, e.g. via the internet, on what it signifies for them.

Child use and care articles

A relatively large group (27%) is unfamiliar with the degree of safety and health risk (possibly due to lack of experience with these articles). Among consumers, 17% are neutral about the safety of child use and care articles, 52% are confident about the safety, and 4% are not confident. Of those who have no confidence in the safety, some continue to use the products and others do not. The reasons for this are very diverse.

Personal protective equipment

Among consumers, 77% is confident about the safety of personal protective equipment; the health risk is assessed as relatively low. Most respondents continue to use the product despite the risk.

Textiles

Eight out of 10 (79%) have confidence in the safety of textiles (clothing, textiles); half of the Dutch population assess the health risk as low or very low. The 7% who assess the health risk as high, generally continue to use the product despite the risk. The reason given for this is that the risk does not apply to them, or that the benefits outweigh the risks or that friends also use it. Some indicate that they avoid these products or look for an alternative. The latter seems very difficult, because it includes not only home textiles, but also clothing.

7.5. Summary

Most Dutch people buy consumer products at a physical shop. Among the Dutch, 40% indicates that they also buy products online from a Dutch online shop, while 8% also orders from online shops outside the EU. The NVWA does not monitor direct purchases by consumers from outside the EU. Such products may not comply with the European safety requirements.

Both price and quality are important for the purchase. The symbols and lists of ingredients on labels are hardly read. The instructions for use are read with a little bit more attention. The legally

required information has a limited influence on the purchasing behaviour and use of products. The extent to which consumers pay attention to this will be influenced by the perceived severity of the injury and familiarity with the product.

When a product breaks down, consumers often try to repair it themselves, have it repaired or take it to a repair café. In this case, there is a risk that faulty parts are used for the repair or that it is not repaired correctly.

Consumers have the most confidence in information about consumer products received from the Consumentenbond and the NVWA (approximately 60%). The central government comes in third. Communication by the NVWA and the central government would therefore seem to be a suitable instrument for informing consumers about safe or unsafe products.

Consumers believe that the producer is responsible for safe consumer products. They generally have confidence in the government and its supervisory activities. A large group thinks that the government is influenced by industry with regard to decisions on product safety. This applies to a lesser extent to the influence of action groups. Some consumers are prepared to pay more for a stricter monitoring of consumer products.

Confidence in the safety of consumer products is generally high. The health risk of textiles is assessed as the lowest, while that of household chemicals is assessed as the highest. For some product categories, such as fairground attractions and playground equipment, it is easy to avoid these products if the health risk is assessed as high. For other product categories, such as textiles, cosmetic products as well as household chemicals (e.g. detergents), this is more difficult. For some products, it is possible for consumers themselves to influence the safety, e.g. by using personal protection equipment (for household chemicals) or by allowing periodic maintenance to be carried out (on gas appliances). Sometimes consumers indicate that the benefits outweigh the health risks.

8. Abbreviations

AIS	Abbreviated Injury Scale
BFR	Brominated flame retardants
BfR	German Federal Institute for Risk Assessment (*Bundesinstitut für Risikobewertung*)
BMD	Benchmark dose: dose at which a substance produces a particular effect, i.e. the benchmark effect
$BMDL_{10}$	Lower limit of 10% benchmark effect: dose at which there is a 95% confidence that a 10% effect will occur
BPA	Bisphenol A
BuRO	Office for Risk Assessment & Research (*Bureau Risicobeoordeling & onderzoek*)
CLP	Classification, labelling and packaging: Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures
CRF	Child Resistant Fastening
DNEL	Derived No Effect Level: daily dose of a substance at which no effect is expected in humans. Often derived from NOAEL for the critical effect, with interspecies (10) and intraspecies (10) assessment factors
EPA (DK)	Danish Environmental Protection Agency
FO	Front Office Food and Product Safety operated by the RIVM and the RIKILT Institute of Food Safety
GHS	Globally harmonised system: United Nations internationally harmonised system for the classification of chemical substances
LIS	Injury Surveillance System (*Letsel Informatie Systeem*, managed by VeiligheidNL)
LMR	National Medical Registration of hospital admissions (*Landelijke Medische Registratie*, managed by Prismant)
MAIS	Maximum Abbreviated Injury Scale
MOE	Margin of Exposure
MAR	Minimum Tolerable Risk [level]
NOAEL	No-observed-adverse-effect-level
NVWA	Netherlands Food and Consumer Product Safety Authority (*Nederlandse Voedsel- en Warenautoriteit*)
PAAs	Primary aromatic amines, may be released from azo dyes
PAHs	Polycyclic aromatic hydrocarbons
PFAS	Per- and polyfluoroalkyl substances
PFOS	Perfluorooctanesulfonic acid
RASFF	Rapid Alert System for Food and Feed
RIVM	National Institute for Public Health and the Environment (*Rijksinstituut voor Volksgezondheid en Milieu*)
Safety Gate	Rapid alert system for dangerous non-food products
SCCNFP	Scientific Committee on Cosmetic products and Non-Food Products intended for consumers: predecessor of SCCS
SCCPs	Short-chain chlorinated paraffins
SCCS	Scientific Committee for Consumer Safety
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCHEER	Scientific Committee on Emerging and Environmental Risks
A&E	Emergency department of a hospital
SML	Specific Migration Limit
STOT-SE/STOT-RE	Specific target organ toxicity on single exposure/repeated exposure
SVHC	Substances of Very High Concern
TCPP	Tris(2-chloro-1-methylethyl) Phosphate; flame retardant
TDCP	Tris(1,3-dichloro-2-propyl) Phosphate; flame retardant
TDI	Tolerable Daily Intake
TWD	*Tactile Warning of Danger*
TWI	Tolerable Weekly Intake [PTWI = Provisional TWI]
VOC	Volatile organic compounds
VSD	Virtually Safe Dose
WEEE	Waste electrical and electronic equipment

9. List of referenced standards

Amusement devices	
NEN-EN 13814:2004	Fairground and amusement park machinery and structures - Safety
NEN-EN 13814--1:2019	Safety of amusement rides and amusement devices - Part 1: Design and manufacture
NEN-EN 13814--2:2019	Safety of amusement rides and amusement devices - Part 2: Operation, maintenance and use
NEN-EN 13814--3:2019	Safety of amusement rides and amusement devices - Part 3: Requirements for inspection during design, manufacture, operation and use
Child use and care articles	
EN 12586:2007	Child use and care articles - Soother holders - Safety requirements and test methods
EN 12868:2017	Child use and care articles - Method for determining the release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers
EN 1400:2013	Child use and care articles - Soothers for babies and young children - Safety requirements and test methods
EN 14350--1:2004	Child use and care articles - Drinking equipment - Part 1: General and mechanical requirements and tests
EN 14350--2:2004	Child use and care articles - Drinking equipment - Part 2: Chemical requirements and tests
EN 14372:2004	Child use and care articles - Cutlery and feeding utensils - Safety requirements and tests
EN 14988:2017	Children's high chairs - Requirements and test methods
EN 16890:2017	Children's furniture - Mattresses for cots and cribs - Safety requirements and test methods
EN 1930:2011	Child use and care articles - Safety barriers - Safety requirements and test methods
NPR-CEN/TR 13387--2:2018	Child care articles - General safety guidelines - Part 2: Chemical hazards
NPR-CEN/TR 13387--3:2018	Child care articles - General safety guidelines - Part 3: Mechanical hazards
Cosmetic products	
EN 17516:2014	Cosmetics - Microbiology - Microbiological limits
EN 24443:2012	Determination of sunscreen UVA photoprotection in vitro
EN 24444:2010	Cosmetics - Sun protection test methods - In vivo determination of the sun protection factor (SPF)
ISO 22716: 2007	Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices
EN 29621:2017	Cosmetics - Microbiology - Guidelines for the risk assessment and identification of low-risk microbiological products
	International Sun Protection Factor (SPF) Test Method (2006)
Portable climbing equipment	
EN 14183:2004	Step stools
EN 131--1:2015	Ladders - Part 1: Terms, types, functional sizes
EN 131--2:2010	Ladders - Part 2: Requirements, testing, marking
EN 131--3:2018	Ladders - Part 3: Marking and user instructions
EN 131--4:2007	Ladders - Part 4: Single and multiple hinge-joint ladders
EN 131--6:2019	Ladders - Part 6: Telescopic ladders
EN 131--7:2013	Ladders - Part 7: Mobile ladders with platform
Electrical equipment	
EN-IEC 60335--1:2012	Household and similar electrical appliances - Safety - Part 1: General requirements
EN-IEC 60335--2--15:2016	Household and similar electrical appliances - Safety - Part 2--15: Particular requirements for appliances for heating liquids
Gas appliances	

EN 15502--1:2012	Gas-fired heating boilers - Part 1: General requirements and tests
EN 15502--2--2:2014	Gas-fired central heating boilers - Part 2-2: Specific standard for type B1 appliances with a nominal heat input not exceeding 70 kW
Personal protective equipment	
EN 352--1:2002	Hearing protectors - General requirements - Part 1: Ear-muffs
EN 352--2:2002	Hearing protectors - General requirements - Part 2: Ear-plugs
EN 352--3:2002	Hearing protectors - General requirements - Part 3: Ear-muffs attached to an industrial safety helmet
EN 352--4:2001	Hearing protectors - Safety requirements and testing - Part 4: Level-dependent ear-muffs
EN 352--5:2003	Hearing protectors - Safety requirements and testing - Part 5: Active noise reduction ear-muffs
EN 352--6:2003	Hearing protectors - Safety requirements and testing - Part 6: Ear-muffs with electrical audio input
EN 352--7:2003	Hearing protectors - Safety requirements and testing - Part 7: Level-dependent ear-plugs
EN 352--8:2008	Hearing protectors - Safety requirements and testing - Part 8: Entertainment audio ear-muffs
EN 166:2001	Personal eye-protection - Specifications
EN 174:2001	Personal eye-protection - Ski goggles for downhill skiing
EN 353--1:2014	Personal fall protection equipment - Guided type fall arresters including an anchor line - Part 1: Guided type fall arresters including a rigid anchor line
EN 353--2:2002	Personal protective equipment against falls from a height - Part 2: Guided type fall arresters including a flexible anchor line
EN 365:2004	Personal protective equipment against falls from a height - General requirements for instructions for use, maintenance, periodic examination, repair, marking and packaging
Toys	
EN 71--1:2014	Safety of toys - Part 1: Mechanical and physical properties
EN 71--2:2011	Safety of toys - Part 2: Flammability
EN 71--3:2019	Safety of toys - Part 3: Migration of certain elements
EN 71--4:2013	Safety of toys - Part 4: Experimental sets for chemistry and related activities
EN 71--5:2015	Safety of toys - Part 5: Chemical toys (sets) other than experimental sets
EN 71--7:2014	Safety of toys - Part 7: Finger paints - Requirements and test methods
EN 71--8:2018	Safety of toys - Part 8: Activity toys for domestic use
EN 71--9:2005	Safety of toys - Part 9: Organic chemical compounds - Requirements
EN 71--10:2006	Safety of toys - Part 10: Organic chemical compounds - Sample preparation and extraction
EN 71--11:2005	Safety of toys - Part 11: Organic chemical compounds - Methods of analysis
EN 71--12:2016	Safety of toys - Part 12: N-Nitrosamines and N-nitrosatable substances
EN 71--13:2014	Safety of toys - Part 13: Olfactory board games, cosmetic kits and gustative games
EN 71--14:2019	Safety of toys - Part 14: Trampolines for domestic use
EN 62115:2005	Electric toys - Safety
Textiles	
ASTM D1230-17	Standard Test Method for Flammability of Apparel Textiles
EN 1103:2005	Textiles - Fabrics for apparel - Detailed procedure to determine the burning behaviour
EN 8333:2018	Protective clothing - Body covering clothing that supports the protection against tick bites and is industrially treated with permethrine

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