Nederlandse Voedsel- en Warenautoriteit
*Ministerie van Landbouw, Visserij, Voedselzekerheid en Natuur*

> Return address P.O. Box 43006 3540 AA Utrecht

**To the Minister Mrs. S.T.M. Hermans of Public Health, Welfare and Sport and the Inspector General Mrs. A.T.A.J. van Dijk of the Netherlands Food and Consumer Product Safety Authority**

**Advice from the Director of the Office for Risk Assessment & Research**

**on the food safety risks of food contact materials**

**Office for Risk Assessment & Research**

Catharijnesingel 59
3511 GG Utrecht
P.O. Box 43006
3540 AA Utrecht
The Netherlands
www.nvwa.nl

**Contact**
risicobeoordeling@nvwa.nl

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# Advice from BuRO

Food Contact Materials (FCM) are materials and articles that come into contact with food. The EU has a focus on the transition towards a circular economy. There is also legislation to reduce the environmental impact of FCM, such as a ban on certain single-use plastic-containing articles. These developments have an impact on the use of raw materials, the reuse of products and the recycling of materials and therefore possibly also on the food safety of FCM.

BuRO has mapped out the current system of legislation and surveillance, investigated these developments in the field of environmental measures and identified food safety risks. This leads to the following advice.

**To the Minister of Public Health, Welfare and Sport**

- Amend national legislation for food contact materials to ensure the food safety of bio-based and recycled materials, such as paper and board.
- Make a Declaration of Compliance mandatory for all categories of food contact materials, so that information is available about the substances present in these materials within the production chain and for the authorities.
- Strengthen cooperation with the Ministry of Economic Affairs and Climate in the area of food contact materials, for an integrated approach to both sustainability and food safety.

**To the Inspector General of the Netherlands Food and Consumer Product Safety Authority**

- Ensure a sound development of the NVWA's data position with regard to substances in food contact materials by collecting information from inspections about the substances present, as well as conducting screening analyses at the laboratory. Expand the scope of the screening analyses to non-volatile substances.
- Explore the possibility of using bioassays to test the food safety of food contact materials.
- Strengthen cooperation with the Human Environment and Transport Inspectorate in the field of food contact materials, for example by coordinating surveillance and exchanging data.

Yours sincerely,

Prof. dr. Dick T.H.M. Sijm
Director of the Office for Risk Assessment & Research

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# Introduction

For food safety, it is important that food contact materials (FCM) do not release substances to the food in amounts that are harmful to public health. FCM may only be manufactured from authorised substances (Intentionally Added Substances, IAS). In addition, Non-Intentionally Added Substances (NIAS) can also be present in FCM, such as contaminants of raw materials.

Developments in the field of sustainability stimulate recycling and reuse of FCM and have an impact on the use of raw materials. A revision of the current FCM legislation has been launched at EU level, as the current legislation is considered inadequate by the European Commission and does not sufficiently respond to market innovation.

A good system of legislation and surveillance is important for ensuring FCM's food safety. The Netherlands Food and Consumer Product Safety Authority (NVWA) supervises the food safety of FCM.

# Research questions and answers

In 2021, the NVWA's Office for Risk Assessment & Research (BuRO) published the advice on risks in the consumer products domain, which describes 16 subdomains, including FCM. BuRO wants to update the risk profile of FCM based on emerging risks and also investigate how the current system of legislation and surveillance functions and where it can be improved. To this end, the following research questions have been formulated:

*1. How does the current system of legislation and surveillance regarding food safety risks of FCM function?*

The current system of legislation is based on authorisation of starting substances and to a limited extent on the final product. Authorisation is a time-consuming process and only a limited number of material categories are regulated at EU level. EU and national FCM legislation do not sufficiently respond to new developments, such as the use of bio-based materials and the use of recyclate other than plastics.

Surveillance often focuses on mandatory checks and checks where non-compliance is suspected. Monitoring by means of chemical analyses is made more difficult by the fact that the Control Regulation (EU) No 2017/625 requires an accredited method. Furthermore, NIAS poses a challenge, because of the identification of the substance and the often lack of certified standards. Screening methods for unknown non-volatile substances is difficult, due to the lack of a good library[1] for liquid chromatography (LC-MS). High-resolution LC-MS may provide a solution for this in the future. Due to the limited data position of the NVWA regarding all substances present in the FCM (both IAS and NIAS), it is difficult to determine the food safety of FCM by means of chemical analyses. Also, not all of these substances have (sufficient) toxicity and migration data available for a risk assessment.

[1] A mass spectrum of an unknown substance is compared to spectra in the library. For LC-MS, there are multiple variables that affect the ionisation and fragmentation of a substance, so that a general library is not sufficient.

*2. How can this system of legislation and surveillance be improved with food safety as a starting point? What are the likely effects of FCM's market developments on food safety, especially with a focus on the national level?*



A revision of the FCM legislation is currently taking place at EU level, considering the aforementioned aspects. Improvement is possible at national level by setting requirements for the expected NIAS in materials that are not regulated at EU level. In addition, specific requirements should be set for bio-based raw materials. At the moment, no further requirements are imposed on the use of recycled paper as raw material or on the use of bio-based raw materials. Because recycled paper and bio-based raw materials may contain NIAS, it is advisable to set specifications for the input, the decontamination process and/or the final product.

Currently, a Declaration of Compliance (DoC) is not mandatory for all material categories. For monitoring, it is important to have information on which substances (IAS and NIAS) are present in FCM. This information can be obtained through inspection of the DoC. National legislation can be adapted accordingly. Analytical screening methods for non-volatile substances should be developed. Research into the application of bioassays can offer a solution to map the food safety of FCM, because it is practically impossible to analyse and characterise all migrants.

# Approach

First an overview was created of how the food safety of FCM is ensured through the current legislation, both at European and national level. The different ways of supervising food safety are described. Subsequently, the impact of developments in the field of sustainability on FCM's food safety was investigated, such as a ban on certain single-use plastic-containing articles and the transition towards a circular economy. In addition, the current compliance monitoring system has been mapped out. We looked at the European notifications of unsafe FCM and NVWA monitoring data. The conceptual assessment framework (BuRO, 2024a) has been applied and a risk matrix for FCM has been drawn up.

FCM also has an impact on the environment, during the production stage, use stage and waste stage. These effects of FCM are not considered in this advice. However, developments in environmental legislation for FCM affect the food safety aspects and are taken into account.

The content of this advice was subjected to external peer review.

# Findings

## Legislation

- The food safety legislation of FCM is the responsibility of the Ministry of Public Health, Welfare and Sport (VWS). This legislation is supervised by the NVWA.
- At EU level, there are the Framework Regulation (EC) No 1935/2004 and the GMP (Good Manufacturing Practice) Regulation (EC) No 2023/2006, which apply to all FCM. The main requirement of the Framework Regulation is that migration of substances to food should not pose a health risk. In addition, there is EU legislation for a limited number of material categories, of which plastic is the most extensively regulated. Legislation for specific material categories is based on authorisation of starting substances, whereby a specific requirement may be imposed based on their toxicity, for example in the form of a specific migration limit.

- The Netherlands has additional national legislation for a large number of other materials, such as paper and board, rubber, metals, textiles, wood, cork and coatings. This national legislation is based on positive lists of authorised starting substances and materials and requirements for the final product.
- FCM is also subject to requirements regarding their environmental impact and sustainability. This is the responsibility of the Ministry of Economic Affairs and Climate. The Human Environment and Transport Inspectorate supervises compliance with this legislation.
- EU legislation that is not specifically drafted for FCM also contains requirements relating to FCM, including the REACH Regulation (EC) No 1907/2006, the POP Regulation (EU) No 2019/1021, the SUP Directive (EU) 2019/904 and the Packaging and Packaging Waste Regulation (EU) No 2025/40.

## Food safety assurance

- FCM must be produced according to good manufacturing practices and the use of authorised starting substances. The GMP Regulation (EC) No 2023/2006 requires, among other things, the setting of specifications for the procurement of materials and substances and the maintenance and cleaning of production areas.
- Under the Framework Regulation, it is mandatory for businesses to provide a Declaration of Compliance (DoC), which shows that the material complies with the legal requirements per production step. For a number of materials, it has been determined which specific information must be present in the DoC. The aim is to communicate this information in the production chain, so that later in the production chain it can be checked whether the FCM is suitable to package the specific food. For some material categories, it is mandatory to have supporting documentation that the FCM complies with the legal requirements.
- Businesses must have systems and procedures in place where they can trace one step back and one step forward. In the event of an unsafe product, a recall can be carried out quickly.
- Conformity tests, such as specific migration testing, can be used to demonstrate that the FCM complies with the legal requirements.

## Surveillance of food safety of FCM

- At FCM manufacturers (including semi-finished products), the NVWA can check whether businesses use authorised starting substances by means of an inspection. This only applies to material categories for which there is specific legislation. In addition, the NVWA can inspect whether the businesses produce in accordance with the requirements of good manufacturing practice, and if the final product meets the requirements. In the case of food industry, the NVWA can check whether the packaging is suitable for the food by checking the DoC.
- Self-regulation of FCM businesses can be ensured through participation in private control systems. The NVWA has accepted several private control systems, allowing businesses that participate to be eligible for adapted surveillance.
- FCM can be tested by the NVWA laboratory by determining the migration of substances into food (simulants). However, the NVWA often does not know which substances are present; this applies to both IAS and NIAS. Screening methods can be used to investigate which potentially migrating substances are present. However, the screening methods available do not cover all possible substances present. For non-volatile substances, good screening methods are not yet available at the NVWA laboratory. The data position of the NVWA is therefore insufficient to obtain a good insight into the food safety of the FCM on the Dutch market.

- Enforcement through chemical analysis requires certified standards of substances to confirm their identity, but these are not available for all NIAS. The Control Regulation (EU) No 2017/625 requires the use of an accredited method for enforcement. The NVWA laboratory has a flexible scope accreditation, including for analysis of FCM. This means that the laboratory can add validated methods to the list of methods covered by this accreditation. The Dutch Accreditation Council ensures that these methods meet all criteria.
- Bioassays can also be used to demonstrate the toxicological effects of migrating substances. This quantitatively determines the harmful effect of the substances that migrate. The advantage of bioassays is that individual migrating substances do not need to be analysed and characterised. FCM testing requires further standardisation regarding sample preparation, sensitivity of the bioassay, use of which bioassays (which toxicological endpoints should be covered) and interpretation of the results to demonstrate the absence of a negative health effect.

## Impact of the transition towards a circular economy

- The transition towards a circular economy is underway within the European Union. This topic is reflected in the European Green Deal. In a circular economy, products must be reused and raw materials recycled. As a result, a shift is taking place towards the application of recyclate and the use of bio-based raw materials.
- The Single Use Plastic (SUP) Directive (EU) 2019/904 entered into force in 2019. This Directive includes, among other things, a ban on certain single-use plastic products. In addition, the Directive lays down requirements with regard to the content of recyclate for certain products. As a result, a shift is taking place towards reuse of products and recycling of plastic, but also towards replacing plastic with other materials.
- For recycling of plastic FCM, the European Regulation (EU) No 2022/1616 is in force, which lays down specific rules regarding the collection and sorting of the plastic waste input, the efficiency of the decontamination of the plastic waste and the treatment of the recyclate. Only recycling processes authorised by the European Commission may be used to recycle plastic into FCM.
- In the Netherlands, for paper and board, it is regulated at national level that recycled paper may be used as a raw material. No further requirements have been imposed on this recycled paper. Possibly impurities (NIAS) may be present. There are requirements for the final product.
- Due to the transition towards a circular economy and the ban on certain single-use plastic-containing articles, FCM based on bio-based raw materials is on the rise. Research by the NVWA has shown that substances may be present, which pose a potential health risk to consumers, including residues of plant protection products, per- and polyfluoroalkyl substances (PFAS), heavy metals and plasticisers. Current national legislation does not provide specific requirements for these potentially present contaminants (NIAS).

## Food safety aspects of FCM

- In the European Rapid Alert System for Food and Feed (RASFF) unsafe FCM are notified by national authorities of European countries. A total of 900 RASFF notifications related to migration of a substance from FCM were published in the period 2021-2025. These notifications provide an insight into what the national authorities within the EEA (European Economic Area) are monitoring. Of these 900 RASFF notifications, 641 concerned plastic FCM (melamine, polyamide, plastic containing plant-based fibres, inlay of lids, coatings and other plastics).

- BuRO's 2021 risk profile of FCM showed that there are health risks due to migration of substances from FCM. In 2023, at the request of the Enforcement Directorate of the NVWA, BuRO issued a signal advice on the risk-oriented drafting of the national control plan for FCM. This signal advice concluded that migration of plasticisers, bisphenol-A and analogues, mineral oils and per- and polyfluoroalkyl substances (PFAS) may pose a health risk.
- BuRO has developed a conceptual assessment framework for optimising risk management. For FCM, the largest risks have been mapped out schematically in a so-called risk matrix. The effect and probability are plotted in a two-by-two matrix (see Figure 1). Annex 3 describes how this risk matrix was created. This risk matrix shows that surveillance should focus on polyamide kitchenware, recycled paper and board, canned coatings and aluminum water bottles.

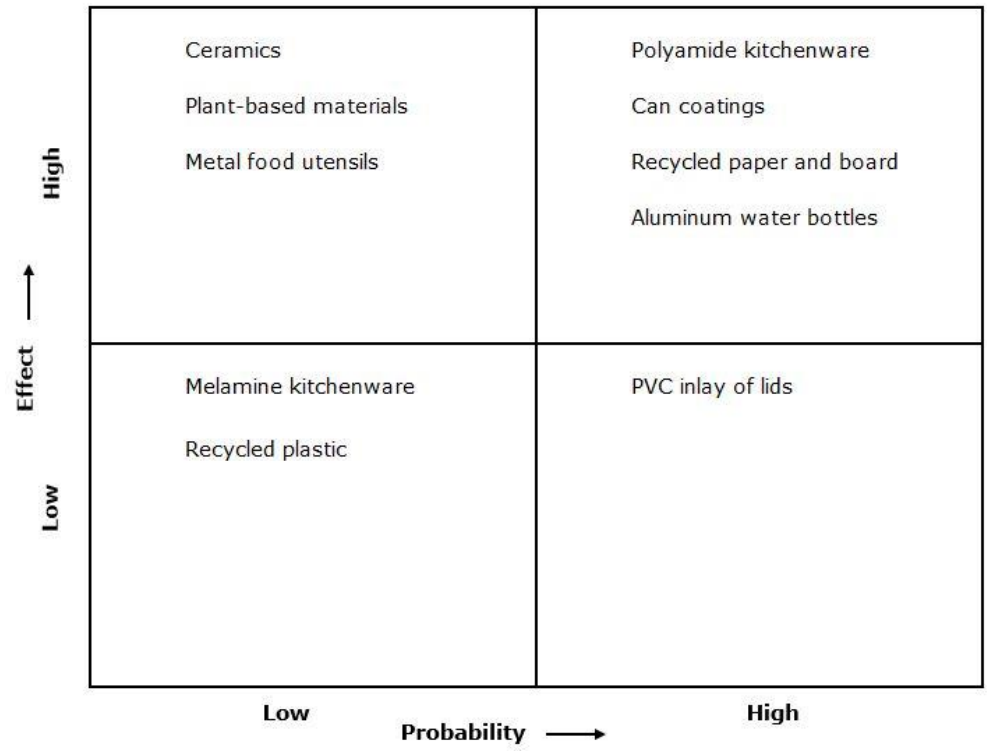



**Figure 1:** Risk matrix FCM

## Conclusions

- FCM must be produced according to good manufacturing practices. For material categories that are regulated, only authorised starting substances may be used. FCM must be traceable, to which and from which businesses materials are supplied. For only a few material categories, it is mandatory to have a DoC, containing information about the composition of the material.
- Legislation regarding sustainability and environmental impact affects FCM. An integrated approach requires effective cooperation at both the policy and supervisory levels.
- The ban on certain single-use plastic-containing articles and the transition towards a circular economy partly replace plastic. There is a shift towards the use of recyclate, reuse of materials but also the use of bio-based raw

materials. Research has shown that substances may be present, which pose a potential health risk.

- The current system of authorisation of starting substances is time-consuming and does not specifically apply to the use of bio-based raw materials. For the use of recyclate, this is only specifically regulated for plastics.
- Surveillance is carried out by the NVWA through inspections at the businesses involved, from the manufacturer of materials to the user (food industry). Compliance with the GMP Regulation (EC) No 2023/2006 and the presence of a DoC (if required) can be monitored and enforced.
- An enforcement or testing laboratory can test whether the material complies with the legal requirements by means of chemical analyses. However, the laboratory usually does not know which substances (IAS and NIAS) are present. For enforcement, the method must be accredited.
- Partly because the data position of the NVWA is insufficient with regard to the presence of migrants in FCM, securing the safety of the FCM through chemical analyses is inadequate. The use of bioassays may offer a solution, in which the toxicological effect of migrating substances is quantitatively mapped. However, this requires further standardisation regarding sample preparation, necessary testing and interpretation of the results.

# Substantiation

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# 1 Introduction

Food contact materials (FCM) are used for the preparation, packaging and consumption of food. FCM broadly fall into two categories: packaging materials and utensils (articles). Various materials are used for FCM, such as plastic, paper and board, wood, glass, metals and ceramics. Examples of packaging are bottles, boxes, cans and containers. Among other things, packaging is important for extending the shelf life of the food. Examples of utensils include products used in the preparation and consumption of food and drink (cutlery, kitchen utensils, tableware), as well as materials intended to come into contact with food during the production of food (e.g. conveyor belts).

As a result of migration, FCM can release chemical substances to food. The degree to which they migrate depends, among other things, on the properties of the FCM material, the migrant and the food, the contact surface, the contact time and the temperature. The chemical safety of FCM is important for food safety. This means that the FCM should not release substances to the food in such quantities that a health risk arises.

A large number of chemicals are used in the production of FCM: raw materials such as monomers, catalysts, additives, adhesives and printing inks. These substances are called intentionally added substances (IAS). IAS are individual chemicals intentionally added for the manufacture of a food contact material to perform a specific technical function. Residues of this IAS may be present in the final product. NIAS (non-intentionally added substances) may also be present in the FCM. NIAS refers to an impurity in the substances used, an intermediate formed during the production process, or a decomposition or reaction product.

Currently, FCM is regulated partly at EU level and partly at national level. The main requirement is that these materials are safe, i.e. no food safety risk arises from migration of substances to the food. This applies to both IAS and NIAS. Some NIAS are known to be present in a certain material, so that the final product can be tested on it. Other NIAS must first be identified analytically and then migration to food must be determined. However, the identification, quantification and characterisation of all unknown substances is not feasible in practice.

There are societal developments, such as the transition towards a circular economy and the combating of plastic litter. These societal developments have consequences for the use of raw materials for FCM, namely the shift to renewable bio-based raw materials. In addition, the focus is on the reuse and recycling of materials. The question is what influence these developments have on the food safety of FCM and to what extent the legislation for FCM has responded to these developments.

In 2021, the Netherlands Food and Consumer Product Safety Authority (NVWA) Office for Risk Assessment & Research (BuRO) published the advice on risks in the consumer products domain (BuRO, 2021a). This document describes 16 subdomains, including the FCM subdomain. Scientific publications and other reports published before 1 November 2019 have been used to substantiate this subdomain. To update the risk profile of non-food consumer products, it was decided to do this per subdomain. In addition to updating the risk profile for FCM, it is now also being investigated how the current system of legislation and surveillance functions and where improvements might be possible.

# 2 Approach

This advice is based on the current FCM legislation, both European and national, and on the literature review carried out by BuRO. The search strategy for literature review is described in Annex 1. In addition, NVWA monitoring data was used.

First, the current legislation for FCM regarding food safety has been mapped out in section 3. It describes what measures are in place to ensure food safety.

Section 4 describes the different options for supervising FCM's food safety. It has been investigated what possibilities there are to ensure the safety of the food regarding migration of components from FCM and where the gaps are.

In Section 5 the impact of societal developments on FCM was examined, such as the ban on certain single-use plastic products and the transition towards a circular economy.

Section 6 provides an overview of FCM's food safety. For this purpose, the European system of notifications on unsafe FCM and NVWA monitoring data for FCM were used. The conceptual assessment framework developed by BuRO has been applied to these results. The material types are placed in a so-called risk matrix.

# 3 Legislation for FCM

FCM food safety legislation is partly regulated at European level. Several Member States, including the Netherlands, have additional national legislation. In the Netherlands, the (food) safety of FCM is the responsibility of the Ministry of Health, Welfare and Sport (VWS). The NVWA is responsible for surveillance of compliance with this legislation.

Legislation provides several ways to manage food safety risks, including the authorisation of raw materials and processing aids, the communication of information regarding substances within the production chain, and the retrospective verification of conformity through laboratory analyses.

In the waste stage, packaging materials, including food packaging, is the responsibility of the Ministry of Economic Affairs and Climate Policy (EZK). Surveillance of the applicable legislation is carried out by the Human Environment and Transport Inspectorate (ILT). To reduce the environmental impact of packaging materials and the amount of litter, there is specific legislation, which also applies to FCM, see 5.1 Legislation on environmental impact of FCM.

## 3.1 European FCM legislation

### 3.1.1 Overview of legislation

At European level, there is various legislation relating to FCM. An overview of legislation on FCM's food safety can be found on the European Commission's website. In addition, other EU legislation also applies to FCM. Table 1 provides an overview of all EU legislation for FCM.

**Table 1:** Overview of FCM legislation in the EU

| Name | Material category | Short description |
|---|---|---|
| **Regulation (EC) No 1935/2004** | All | Framework Regulation: general requirements FCM |
| **Regulation (EC) No 2023/2006** | All | Good manufacturing practices (see 3.3.4) |
| **Regulation (EC) No 1907/2006** | All | Restriction on C9-C14 perfluorocarboxylic acids and undecafluorohexanoic acid |
| **Regulation (EU) 2019/1021** | All | Restriction on perfluorooctane sulphonic acid, perfluorooctanoic acid and perfluorooctane sulphonic acid |
| **Regulation (EU) 2025/40** | All | Packaging and Packaging Waste Regulation (see 5.1.2) |
| **Regulation (EU) 2023/1230** | All | Requirements for food processing machinery |
| **Regulation (EU) 2023/988** | All | Safety requirements for consumer products |
| **Directive (EU) 2019/904** | Plastic | Restrictions on single-use plastic containing products (see 5.1.1) |
| **Regulation (EU) No 10/2011** | Plastic | List of permitted starting substances, test methods, final product requirements |
| **Regulation (EU) 2022/1616** | Plastic | Conditions for the recycling processes and conditions for the use of recycled plastic |
| **Directive 78/142/EEC** | Vinyl chloride polymers and copolymers | Maximum content for vinyl chloride monomer |
| **Regulation (EU) No 284/211** | Melamine and polyamide | Import of polyamide and melamine kitchenware from China and Hong Kong |

| Name | Material category | Short description |
|---|---|---|
| **Regulation (EC) No 450/2009** | Active and intelligent materials | Requirements for active and intelligent FCM, including a Community list of authorised substances |
| **Regulation (EC) No 1895/2005** | Plastics, coatings and adhesives | Restriction on bisphenol-A-diglycidyl ether, ban on bisphenol-F-diglycidyl ether and Novolac glycidyl ethers |
| **Regulation (EU) 2024/3190** | Adhesives, rubber, ion exchange resins, plastics, printing inks, silicones, varnishes and coatings | Restriction on bisphenol-A and other hazardous bisphenols |
| **Directive 84/500/EEC** | Ceramics | Lead and cadmium migration limits, test methods |
| **Directive 2007/42/EC** | Regenerated cellulose films | List of authorised substances and restrictions |
| **Directive 93/11/EEC** | Rubber (fop) teats | Release of nitrosamines and N-nitrosatable substances |

### 3.1.2 General FCM legislation in the EU

The general European legislation for FCM consists of Framework Regulation (EC) No 1935/2004[2] and Regulation (EC) No 2023/2006[3] on good manufacturing practice (GMP). See 3.3.2 Good manufacturing practices.

Regulation (EC) No 1935/2004 sets out the general requirements for FCM in article 3, paragraphs 1 and 2:

1) materials and articles, including active and intelligent materials and articles, shall 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 which could:

   a) endanger human health.
   b) bring about an unacceptable change in the composition of the food.
   c) bring about a deterioration in the organoleptic characteristics.

2) The labelling, advertising and presentation of a material or article shall not mislead the consumers.

The Framework Regulation (EC) No 1935/2004 also includes requirements on labelling of FCM, traceability and documentation (see 3.3.3 Declaration of Compliance and 3.3.4 Traceability).

The Framework Regulation identifies the following 17 material groups for FCM:

- Active and intelligent materials and articles
- Adhesives
- Ceramics
- Cork
- Rubbers
- Glass
- Ion-exchange resins
- Metals and alloys
- Paper and board
- Plastics
- Printing inks
- Regenerated cellulose
- Silicones
- Textiles

[2] 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, pp. 4–17.
[3] 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, pp. 75–78.

- Varnishes and coatings
- Waxes
- Wood

For NIAS, the FCM (finished product) must meet the general safety requirement: Article 3 of Framework Regulation (EC) No 1935/2004; namely, that the migration of NIAS into foodstuffs shall not pose a health risk.

### 3.1.3 Specific FCM legislation in the EU

Specific legislation has been drawn up for some of these material groups. Often this specific legislation for a material group consists of positive lists, which are lists of authorised substances. Only these substances may be used to manufacture the material. Specific EU legislation is in place for the following material groups:

- Plastics: Regulation (EU) No 10/2011[4]. This Regulation contains positive lists of monomers and additives for the manufacture of plastic FCM. Restrictions are included for a number of substances. This Regulation also describes how migration tests should be carried out.
- Active and intelligent materials: Regulation (EC) No 450/2009[5]. Active packaging extends the shelf life of food. They contain components that release substances to the packaged food or absorb substances from the food or the environment surrounding the food. Intelligent packaging monitor the condition or environment of packaged food, e.g. shelf life. For this active and intelligent FCM there is a register of authorised substances that can be used herein.
- Recycled plastic: Regulation (EC) No 2022/1616[6]. To produce recyclate that is subsequently used to manufacture plastic FCM, the process must be authorised by the European Commission. This Regulation sets out the requirements to be met by the recycling process.
- Ceramics: Directive 84/500/EEC[7] for ceramic materials. This Directive describes how ceramic materials should be tested for lead and cadmium migration and what these migration limits are.
- Regenerated cellulose films: Directive 2007/42/EC[8]. This Directive contains a list of authorised additives for regenerated cellulose films, with or without a coating. Restrictions are included for a number of additives, such as a maximum content.

Finally, there is legislation for several specific substances, driven by concerns regarding their specific toxicological effects. There is also a special Regulation for the import of kitchenware from China and Hong Kong, because of the large number of European notifications about non-compliance with the migration limits.

- Epoxy derivatives: Regulation (EC) No 1895/2005[9]. Migration limits are included for migration of bisphenol-A-diglycidyl ether and reaction products with water and hydrochloric acid. Bisphenol-F-diglycidyl ether and Novolac-glycidyl ethers (NOGE) are banned as starting substances.
- Bisphenols: Regulation (EU) No 2024/3190[10]. This Regulation prohibits the use of bisphenol-A, hazardous bisphenols and hazardous bisphenol derivatives in FCM.
- Nitrosamines in rubber teats and soothers: Directive 93/11/EEC[11]. This Directive sets migration limits for nitrosamines and nitrosatable substances from rubber teats and soothers. In addition,

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[4] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L 12, 15.1.2011, pp. 1–89.
[5] 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, pp. 3–11.
[6] Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008. OJ L 243, 20.9.2022, pp. 3–46.
[7] 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, pp. 12–16.
[8] 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, pp. 71–82.
[9] 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. OJ L 302, 19.11.2005, pp. 28–32.
[10] Commission Regulation (EU) 2024/3190 of 19 December 2024 on the use of bisphenol A (BPA) and other bisphenols and bisphenol derivatives with harmonised classification for specific hazardous properties in certain materials and articles intended to come into contact with food, amending Regulation (EU) No 10/2011 and repealing Regulation (EU) 2018/213. OJ L, 2024/3190, 31.12.2024.
[11] 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, pp. 37–38.

this Directive prescribes how the migration test is to be carried out. This migration test has been further elaborated in a standard: EN 12868[12].
- Vinyl chloride monomer in polymers and copolymers: Directive 78/142/EEC[13]. The residual content of vinyl chloride shall not exceed 1 mg/kg of plastic.
- Polyamide and melamine kitchenware from China and Hong Kong: Regulation (EU) No 284/2011[14]. This Regulation sets strict rules and border controls for importing polyamide and melamine plastic kitchenware and tableware from China and Hong Kong.

### 3.1.4 Intended revision of FCM legislation

In 2016, the European Parliament voted in favour of a new resolution[15] on the implementation of Framework Regulation (EC) No 1935/2004. The need for a re-evaluation of the current EU regulatory framework was highlighted by the report on the implementation of this Framework Regulation.

Based on the evaluation of the EU legislation for FCM, the European Commission identified the following shortcomings of the current legislation:

- Lack of clarity regarding safety and functioning of the EU market in the absence of specific EU harmonised rules for FCM other than mainly plastics;
- Weaknesses and limitations of legislation relying primarily on a list of authorised starting substances and lack of sufficient focus on the final FCM article;
- Lack of prioritisation of the most hazardous substances in all FCM;
- Poor quality, availability and transparency of information in supply chain, hampering the ability to ensure compliance and undertake official controls;
- The current rules do not sufficiently support small and medium-sized businesses nor the development of safe and more sustainable alternatives.

The European Commission has therefore started the revision of the European FCM legislation. This initiative aims to modernise the rules, to:

- Ensure food safety & a high level of public health protection
- Reduce the presence and use of hazardous chemicals
- Take account of the latest science & technology
- Support innovation & sustainability by promoting safe reusable and recyclable solutions, and help reduce the sector's environmental impact.

The proposal is expected to be published in 2027.

### 3.1.5 Other EU legislation related to FCM

There is also EU legislation that is not specifically drawn up for FCM but does apply to FCM. This legislation is also included in Table 1 and briefly explained below.

- The REACH Regulation (EC) No 1907/2006[16] restricts the content of C9-C14 perfluorocarboxylic acids and derivatives in articles of 25 ppb in entry 68 of Annex XVII. This also applies to FCM. Entry 79 states that from 10 October 2026, undecafluorohexanoic acid (PFHxA) shall not be placed on the market or used in a concentration equal to or greater than 25 ppb in FCM of paper

[12] 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.
[13] Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs. OJ L 44, 15.2.1978, pp. 15–17.
[14] 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, pp. 25–29.
[15] European Parliament resolution of 6 October 2016 on the implementation of the Food Contact Materials Regulation (EC) No 1935/2004 (2015/2259(INI)). OJ C 215, 19.6.2018, pp. 57–64.
[16] 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, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. OJ L 396, 30.12.2006, pp. 1–849.

and board, or 1000 ppb for the sum of PFHxA-related substances. From 10 October 2027, this restriction will apply to all homogeneous materials intended for consumers, including FCM.
- The POP Regulation (EU) No 2019/1021[17] includes a restriction of 0,025 % (250 ppm) by weight for perfluorooctane sulphonic acid, perfluorooctanoic acid and perfluorohexane sulphonic acid including their salts and all combinations of these products in articles. This also applies to FCM.
- The Packaging and Packaging Waste Regulation (EU) No 2025/40[18] applies to all packaging, both food and non-food (see 5.1.2). This Regulation lays down, amongst others, specific requirements for the content of heavy metals lead, cadmium, mercury, hexavalent chromium and per- and polyfluoroalkyl substances (PFAS) in FCM.
- SUP (single use plastic) Directive (EU) 2019/904[19] aims to reduce the environmental impact of certain disposable products containing plastic. In this context, the Directive includes, amongst others, a ban on certain single-use plastic-containing articles, including some FCM. Requirements are also set for the content of recyclate in plastic bottles. See 5.1.1.
- The Ecodesign Regulation (EU) No 2024/1781[20] (Ecodesign for Sustainable Products Regulation) has served as the EU legislative framework since July 2024, enabling the imposition of circularity requirements on products. The Ecodesign Regulation applies to utensils but not to packaging, because the Packaging and Packaging Waste Regulation has been drawn up specifically for this purpose. See 5.1.3 Ecodesign for Sustainable Products Regulation (Ecodesign).
- General Product Safety Regulation (EU) No 2023/988[21] states that only safe products may be placed on the market. According to this Regulation, a safe product is a product which, under normal or reasonably foreseeable conditions of use, including the actual duration of use, does not present any risk or only the minimum risks compatible with the product's use, considered acceptable and consistent with a high level of protection of the health and safety of consumers.
- The Machinery Regulation (EU) No 2023/1230[22] lays down essential health and safety requirements for machinery and related food processing products.

## 3.2 National legislation

There is no specific European legislation for various material categories. Member States can then draw up national measures. The Commodities Act Decree on Packaging and Consumer Articles [23] implements the general EU legislation. The Commodities Act Regulation on Packaging and Consumer Articles[24] contains national requirements for a total of 12 materials. These 12 materials largely but not entirely correspond to the 17 materials identified in the Framework Regulation. The Commodities Act Regulation contains a chapter for each of these materials. Each chapter contains positive lists of authorised raw materials, starting substances and additives. Only these authorised materials and substances may be used for the manufacture of FCM from this material. There are also requirements for the final product per chapter.

I. plastics
II. paper and board
III. rubber products

[17] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (recast). OJ L 169, 25.6.2019, pp. 45–77.
[18] Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC. OJ L, 2025/40, 22.1.2025.
[19] 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, pp. 1–19.
[20] Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC. OJ L, 2024/1781, 28.6.2024.
[21] Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC. OJ L 135, 23.5.2023, pp. 1–51.
[22] Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC. OJ L 165, 29.6.2023, pp. 1–102.
[23] Warenwetbesluit verpakkingen en gebruiksartikelen. 30-08-2005. Staatsblad 2005, 420.
[24] Warenwetregeling verpakkingen en gebruiksartikelen. 27-03-2014. Staatscourant 2014, 8531.

IV. metals
V. glass and glass ceramics
VI. ceramic materials and emails
VII. textile products
VIII. regenerated cellulose film
IX. Wood and cork
X. coatings
XI. dyes and pigments
XII. epoxy polymers

At national level, VWS can amend and draft the FCM legislation regarding non-harmonised materials.

### 3.2.1 Implementation of EU legislation

Chapters I, VIII and XII implement the European directives for FCM for these specific materials and substances or refer to European Regulations. Part B of the Commodities Act Regulations on Packaging and Consumer Articles prescribes how (migration) tests must be carried out. These tests are in accordance with the prescribed test method laid down in Regulation (EU) No 10/2011.

### 3.2.2 Benelux decisions

In 2022, the Benelux Ministers adopted the Council of Europe Resolution on metals and alloys[25] FCM (Benelux Comité van Ministers, 2022). It was implemented on 1 January 2025 in Chapter IV of the Commodities Act Regulation on Packaging and Consumer Articles[26].

In 2024, the Ministers of the Benelux adopted a Decision significantly lowering the migration limits for lead and cadmium from ceramic materials compared to Directive 84/500/EEC (Benelux Comité van Ministers, 2024), see Table 2. This was implemented on 29 May 2026 in Chapter VI of the Commodities Act Regulation on Packaging and Consumer Articles[27].

**Table 2:** Migration limits for lead and cadmium from ceramic materials

| Ceramic articles category | Cadmium | Lead |
|---|---|---|
| **Category 1: Articles which cannot be filled and articles which can be filled, the internal depth of which, measured from the lowest point to the horizontal plane passing through the upper rim, does not exceed 25 mm** | 4 µg/dm $^2$ | 6 µg/dm $^2$ |
| **Category 2: All other articles which can be filled** | 20 µg/L | 30 µg/L |
| **Category 3: Cooking ware; packaging and storage vessels having a capacity of more than three liters** | 7 µg/L | 10 µg/L |

## 3.3 Food safety safeguards

Ensuring the food safety of FCM is achieved in a number of ways. The first step is to authorise starting substances and to restrict them based on their toxicity. FCM must then be produced under good manufacturing practices. The presence of substances must be communicated in the production chain by means of a Declaration of Compliance. The mandatory traceability allows a possible recall in the event of an unsafe FCM to be carried out quickly. Conformity tests can be used to demonstrate whether a FCM complies with the legislation. Several strategies to ensure the safety of NIAS are described.

### 3.3.1 Authorisation of substances

The European and Dutch legislation for FCM is based on positive lists. Only (raw) materials authorised for this purpose may be used for the manufacture of a material category for which there is specific legislation. At European level, the European Food Safety Authority (EFSA) determines,

[25] CM/Res(2013)9 - Resolution on metals and alloys used in food contact materials and articles (Adopted by the Committee of Ministers on 11 June 2013 at the 1173rd meeting of the Ministers' Deputies)
[26] Wijziging Warenwetregeling verpakkingen en gebruiksartikelen, Staatscourant 2024, 42883.
[27] Wijziging Warenwetregeling verpakkingen en gebruiksartikelen, Staatscourant 2026, 16308.

based on toxicity and migration data, whether a substance is authorised for FCM and with what restriction. The following restrictions for authorised substances may be applied:

SML: specific migration limit
SML(T): Total specific migration limit (limit for a group of substances)
QMA(T): total residual content per surface area in contact with food (limit for a group of substances)

To ensure the overall quality of the material, a limit is set on the total migration to food of all substances together, the so-called total migration limit (TML). For most materials it is 60 mg/kg food, or 10 mg/dm$^2$ of the FCM. This conversion is based on 6 dm$^2$ per kg of food (a cube).

#### 3.3.1.1 Authorisation of substances at EU level

For material groups regulated at EU level, the application for authorisation of a substance must be submitted to a competent national authority in an EU Member State. Via the Member State, EFSA receives the dossier. A procedure has been drawn up by EFSA, whereby a dossier must be submitted containing information on, amongst others, the toxicity of the substance, the impurities, the possible reaction products, the intended use and the migration to food (simulants). It is assessed by EFSA and the outcome is published in a scientific opinion. Based on this opinion, the European Commission determines whether this substance is authorised and whether it is subject to a restriction, for example an SML or QMA.

#### 3.3.1.2 Authorisation of plastic recycling process at EU level

An application for authorisation of the recycling process of plastic FCM must be submitted to EFSA. EFSA has established criteria for the safety assessment of polyethylene terephthalate (PET) recycling processes (EFSA, 2024) and evaluates processes for which applications for authorisation are submitted on the basis of these criteria. The findings are recorded by EFSA in a scientific opinion. The European Commission then decides whether the recycling process is authorised. In addition, EFSA gives an opinion on whether new recycling technologies are suitable to be used for recycling processes based on the type of plastic input for which they are intended, and the principles they apply for decontaminating that input.

#### 3.3.1.3 Authorisation of substances at national level

In the Netherlands, for material groups for which no harmonised European legislation exists, an application must be submitted at national level to the Dutch Committee for safety assessment of food contact materials (CBVV). The templates for the application are the same for all material groups and are taken from EFSA templates. This means that the data required for the application at national level are comparable to an application to EFSA. CBVV assesses the completeness and content of the information in the dossier and presents the outcome of the safety assessment in an opinion document. This document then serves as the basis for decision-making by VWS. VWS then takes a decision on the inclusion of the substance in the relevant chapter of the Commodities Act Regulation on Packaging and Consumer Articles.

### 3.3.2 Good manufacturing practices

Good Manufacturing Practice (GMP) is important for consistent production and for safe FCM. This is regulated by Regulation (EC) No 2023/2006. This Regulation applies to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances.

This GMP Regulation lays down, amongst others, requirements for:

- Specifications, manufacturing formulae and processing which are relevant to compliance and safety of the finished material or article
- Staff powers and responsibilities.
- Maintenance and cleaning of the production areas.
- Procedures for, among other things, labelling, testing and packaging.
- Specifications should include the type of food (e.g. fat, solid, liquid, acid), shelf life, surface/food ratio. Based on the documentation provided by the supplier of the material or article, the buyer (user) can check whether these specifications are met.

A detailed rule on printing ink is set out in the Annex to this Regulation. The printed surfaces may not come into direct contact with food. In addition, care should be taken to ensure that no substances from the printing inks applied to the non food-contact side are transferred to the food at an amount that could pose a health risk (Article 3 of the Framework Regulation (EC) No 1935/2004). This can be due to migration to the food through the packaging material, or by set-off in the stack or the reel.

International standards are available for compliance with this Regulation, such as BRCGS Global Standard Packaging Materials[28] and ISO 22002-4[29].

### 3.3.3 Declaration of Compliance

To ensure the safety, quality and conformity of materials, these materials must be accompanied by a written declaration. This applies to every link in the production chain, up to and including the retail sector. For this purpose, a DoC must be provided, showing that the material complies with the legal requirements per production step. Article 16 of the Framework Regulation (EU) No 1935/2004 states that this applies to all 17 material categories listed in Annex 1 to this Regulation (see also 3.1.2). However, for each material category, it must be specifically determined and described what information this DoC should contain. At present, it is only regulated at EU level for plastics, ceramic materials and regenerated cellulose films. Annex 2 describes in more detail what information must be present in the DoC per material category.

In the Netherlands, the other materials categories are regulated at national level in the Commodities Act Regulation on Packaging and Consumer Articles. Annex A, Chapter 0.9 states that a DoC is mandatory if this is indicated in the relevant chapter (material category). In Annex 1 of Chapter 0 contains the description of the information that must be present in the DoC. For the material categories regulated at national level, currently only for metals (Chapter IV) and epoxy polymers (Chapter XII) a DoC is required.

### 3.3.4 Traceability

According to the Framework Regulation (EC) No 1935/2004, traceability must be ensured at all stages for all FCM in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.

With due regard to technological feasibility, businesses have systems and procedures in place that allow them to trace their product (FCM) one step back and one step forward. This information must be provided to the competent authority, the NVWA in the Netherlands, upon request. All FCM must be adequately labelled or identified to allow this traceability. The level of detail of traceability may be determined by an economic operator, for example based on the size of a lot.

### 3.3.5 Conformity tests

FCM final products must comply with the restrictions imposed on the starting substances, the total migration limit and the restrictions imposed on the final product as laid down for the relevant material category. This can be determined by, for example, a migration test or a screening approach. If the restriction concerns a maximum content (QM or QMA), the content in the material should be determined.

For plastic materials, Regulation (EU) No 10/2011 Article 16 stipulates that the company must have appropriate documentation to demonstrate that FCM from intermediate stages of their manufacturing as well as the substances intended for the manufacturing of those materials comply with the requirements of this Regulation. On request, these supporting documents must be made available to the national competent authorities. These supporting documents are the analytical reports of the conformity tests. This is not specifically stated for other materials.

[28] BRCGS. Global Standard Packaging Materials (Issue 7). 28 October 2024. SKU: 978-1-78490-494-4.
[29] ISO 22002-4:2025. Prerequisite programmes on food safety - Part 4: Food packaging manufacturing

#### 3.3.5.1 Migration tests

*Plastics*
Migration tests can be carried out to demonstrate that a plastic FCM complies with the specified restrictions. This can be done by determining the content of the migrant in the food. Another option is to use so-called food simulants. A food simulant is a test medium by which a food is imitated, such as 3% acetic acid solution in water or 10% or 50% ethanol solution in water. The behaviour of the food simulant mimics migration from FCM. Annex III to Regulation (EU) No 10/2011 lays down the food simulant to be used for each food. Annex V to this Regulation then describes how the migration test is to be carried out. The sample pre-treatment is prescribed, as well as the time and temperature of the migration test. The European Union Reference Laboratory for FCM (EURL-FCM) and the National Reference Laboratories (NRLs) have agreed on a set of test conditions, to ensure the comparability of measurement results reported in the frame of the implementation of official controls for FCM by authorities such as the NVWA (Beldi et al., 2023).

*Ceramic materials*
Directive 84/500/EEC describes how the migration test for lead and cadmium should be carried out, i.e. with 4% acetic acid solution for 24 hours at room temperature (for cadmium in total darkness).

*Other materials*
Annex B of the Commodities Act Regulation on Packaging and Consumer Articles describes the assessment methods. This corresponds to the selection of food simulants and test conditions for the migration test prescribed in the Annexes to Regulation (EU) No 10/2011. In the Netherlands, this applies to all other material categories, which are not regulated at EU level.

#### 3.3.5.2 Screening approaches for specific migration

*Plastic materials*
Article 18 paragraph 3 of Regulation (EU) No 10/2011 states that if a plastic FCM has not yet been brought into contact with food, a screening approach may be used to demonstrate compliance with the article if the result of the screening approach is below the specific migration limit. Annex V to this Regulation sets out screening approaches:

- Replacement of the specific migration by the overall migration. This only applies to non-volatile substances.
- The migration potential can be calculated based on the residual content of the substance in the material or article, assuming complete migration.
- The migration potential can be calculated from the residual content of the substance in the material or article applying generally recognised diffusion models based on scientific evidence that are constructed in a way that must never underestimate real levels of migration.
- Food simulants can be replaced by substitute food simulants if it is based on scientific evidence that the substitute food simulants result in migration that is at least as severe as migration that would be obtained using the prescribed food simulants.
- If the FCM is intended for a food contact application where it is successively subject to two or more time and temperature combinations, a single migration contact test time can be defined based on the highest contact test temperature according to the prescribed formula. The reasoning justifying that the resulting single test is at least as severe as the combined time and temperature combinations shall be documented in the supporting documentation.

The European Commission's Joint Research Centre (JRC) is the European Reference Laboratory for Food Contact Materials. JRC has published a guideline on how to apply migration modelling for plastic FCM (JRC, 2015).

*Other materials*
Paragraph 4.1.1.2 of Annex Part B of the Commodities Act Regulation on Packaging and Consumer Articles states that the same rules apply to the examination of materials that do not or do not solely consist of plastics as for plastic materials as described in Regulation (EU) No 10/2011. This means that for materials regulated at national level, screening approaches including migration modelling may also be applied to demonstrate compliance with legislation.

### 3.3.6 NIAS

NIAS stands for non-intentionally added substances. The definition of NIAS is according to Regulation (EU) No 10/2011: an impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product. For the application for an authorisation of a new substance, the contaminants must also be specified, which can be impurities, but also reaction and degradation products. There is no specific legislation for NIAS. Article 3 of the Framework Regulation (EC) No 1935/2004 applies, i.e. migration from NIAS to the food must not endanger human health.

There is no legally prescribed method for assessing the safety of NIAS. Annex Part B of the Commodities Act on Packaging and Consumer Goods contains a chapter: Chapter III. Risk assessment of non-intentionally added substances (NIAS) based on the Threshold of Toxicological Concern (TTC) principle. However, this chapter has not yet been filled in.

Based on knowledge of the chemistry of the IAS and raw materials present, production conditions, literature and experience, there are NIAS that are suspected to be present. These NIAS can be measured with targeted analytical methods. There are also unknown NIAS. Non-targeted screening methods must be used to identify these unknown substances. However, good screening methods are not yet available for all substances (see 4.4.4 Analytical screening).

EFSA published an opinion on the risk assessment of substances from FCM (EFSA, 2016). Reaction and degradation products and impurities frequently occur as structurally inter-related multiple chemical species and are often related to the parent substance. Non-testing methods may be taken into account on a case-by-case basis, for priority setting and for a preliminary toxicological assessment. Applicable methods include grouping and read-across, or structure-activity relationships and quantitative structure-activity relationships, and the TTC principle (EFSA, 2019a).

The TTC approach may be applicable with regard to genotoxicity. The EFSA Scientific Committee concluded that a threshold of 0.15 µg/person per day would provide sufficient protection against (genotoxic) carcinogenic and heritable effects when it can be ruled out that the compounds are part of the exclusion category (EFSA, 2012a). Therefore, no genotoxicity data are needed for NIAS if exposure is below 0.15 µg/person per day. This threshold of 0.15 µg/person per day is derived from the threshold of 0.0025 µg/kg body weight per day and based on a standard body weight of 60 kg.

# 4 Surveillance of food safety FCM

In the Netherlands, the NVWA is the competent authority for food safety of FCM. This surveillance can be carried out in different ways: by means of inspections at the businesses involved, but also by carrying out analytical tests of the FCM in the laboratory.

## 4.1 Production chain FCM

Various sectors are involved in the different stages of the FCM production chain: producers of raw materials, intermediate products, the final product, and, ultimately, the packaged foodstuff. These businesses can be producers, distributors and importers. Figure 2 shows a schematic representation of the production chain for food packaging. Figure 3 shows a schematic representation of the chain for food-contact articles. The NVWA supervises businesses in the yellow framework for compliance with the FCM legislation.

ILT supervises the businesses that produce the raw materials and during the waste stage. Businesses are required to have a so-called Packaging File. This includes information on the sustainability of the packaging (minimum adequate weight, recyclability, reusability). The Packaging and Packaging Waste Regulation (EU) 2025/40 requires an EU Declaration of Conformity demonstrating that the packaging complies with all the requirements of this Regulation. This Regulation comes into force on 12 August 2026. ILT monitors how businesses pass on information about their packaging, including to businesses in the yellow framework.

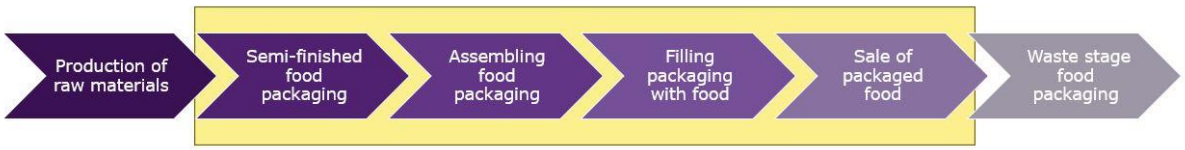



**Figure 2:** Schematic representation of the food packaging production chain




**Figure 3:** Schematic representation of the production chain of food contact articles

Knowledge regarding the substances used to manufacture FCM is greatest at the upstream end, the producer of the raw materials. At each stage of the supply chain, information regarding the substances present must be communicated via a DoC. Not all these links in the chain are located in the Netherlands or within the EU. For example, packaged food or utensils are also imported into the EU.

In the case of recycling, waste is processed into a new product. Consumers and businesses separate waste, such as plastic, paper, glass, and metal cans. This is collected and transported to a recycling plant. At the plant, the waste is cleaned, sorted, and reprocessed. This process can take the form of mechanical recycling, where plastic is processed without chemical modification; PET bottles are an example of this. Chemical recycling can also take place, whereby the plastic is reduced to the starting materials from which plastics can be produced again.

## 4.2 Inspections at businesses

Article 24 of Framework Regulation (EC) No 1935/2004 requires Member States to carry out official controls to enforce compliance with this Regulation. Article 25 states that Member States are obliged to lay down the rules on sanctions applicable to infringements of the provisions of this Regulation. To this end, the NVWA Food Contact Materials Specific Intervention Policy (IB02-SPEC 61, version 01) was published in the Government Gazette[30].

The NVWA, as national authority, can check whether they comply with the legal obligations regarding good manufacturing practice, which are set out in Regulation (EC) No 2023/2006. This Regulation applies both to the producers of the FCM and to the businesses that subsequently use the FCM (food industry). Furthermore, the mandatory documentation can be checked, such as a DoC.

According to Regulation (EC) No 1935/2004, FCM must be traceable by means of an indication on accompanying documents, label, packaging, or on the article itself. Businesses must have systems in place to allow identification of the businesses from which and to which materials or articles were supplied. The NVWA can check during an inspection whether businesses comply with this obligation of traceability.

Businesses that recycle plastic into FCM, or a raw material for FCM, are subject to the surveillance of the NVWA. For plastic recycling, Regulation (EC) 2022/1616 applies. Businesses must draw up a DoC for each production batch of recycled plastic. For plastic recycling, there is a special authorisation per recycling process, see3.3.1 Authorisation of substances.

## 4.3 Self-regulation

There are private organisations that offer independent control systems. FCM businesses can participate on a voluntary basis to demonstrate that they meet certain quality requirements and comply with legislation. This can be done through inspections, audits and/or analyses of samples. The NVWA has accepted a number of these private control systems (PCS), including for FCM. FCM

[30] Staatscourant 2022, 28524

businesses participating in this can be eligible for adapted surveillance: they are inspected less frequently and for shorter duration by the NVWA.

## 4.4 Chemical analyses of FCM

Another way to check the safety of the FCM is to test the material by chemical analysis. The migration of substances present, such as monomers and additives, can be determined and then checked against the legal limit. See3.3.5 Conformity tests.

### 4.4.1 Control Regulation

The Control Regulation (EU) No 2017/625[31] requires the use of an accredited analytical method for the enforcement of FCM. Accrediting a method is a time-consuming process. The method and the associated validation dossier must be assessed during an internal audit and subsequently during an audit conducted by the Dutch Accreditation Council.

On 11 December 2019, the Chemical and Microbiological Product Safety Laboratory of the NVWA was designated as an official laboratory, as referred to in of Article 37 of Regulation (EU) No 2017/625[32]. One of the conditions for the designation is that a laboratory for the applied methods must be ISO 17025[33] accredited. The NVWA laboratory is accredited according to ISO 17025 with registration number L104. For FCM, the following analytical techniques are accredited under the flexible scope:

- Sample preparation; destruction, extraction, migration
- Determination of the content of organic compounds; Gas chromatography (GC-MS)
- Determination of the content of organic compounds; Liquid chromatography (LC-DAD, LC-MS, LC-MS-MS)
- Determination of the content of elements; Inductively Coupled Plasma – Mass Spectrometry (ICP-MS)

### 4.4.2 National control plan

In 2019, the European Commission[34] published a Recommendation on a coordinated control plan to establish the prevalence of certain substances migrating from food contact materials. Substances to be investigated (in certain types of FCM) are: primary aromatic amines; formaldehyde and melamine; phenol; bisphenols; plasticisers; fluorinated compounds and metals. In addition, overall migration is also mentioned in this recommendation. Member States are requested to draw up a national control plan for FCM and to report annually to the European Commission.

At the request of the Enforcement Directorate, BuRO drew up a signal advice in 2023 to prioritise substances in FCM on the basis of the health risk, so that the national control plan for FCM can be drawn up in a risk-oriented manner (BuRO, 2023). Based on the database of authorised substances, literature, RASFF notifications and NVWA surveillance data, a risk assessment has been carried out by BuRO and a prioritisation has been established. For the national control plan for FCM, the following substance(s) are recommended:

- Migration of plasticisers from inlays of lids, PVC packaging and paper and board
- Migration of bisphenol-A (and substitutes) from polycarbonate packaging and paper and board
- Migration of bisphenol-A (and substitutes including cyclo-di-BADGE: reaction product of BPA and BADGE) from epoxy can coatings
- When specific legislation comes into force for mineral oils and for PFAS, it is advised to include these substance groups in the national control plan.

[31] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products. OJ L 95, 7.4.2017, pp. 1–142.
[32] Staatscourant 2019, 69789.
[33] ISO 17025: 2018. General requirements for the competence of testing and calibration laboratories.
[34] Commission Recommendation (EU) 2019/794 of 15 May 2019 on a coordinated control plan to determine 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.

### 4.4.3 Import surveillance of kitchenware from China and Hong Kong

There is a mandatory import control of melamine and polyamide kitchenware from China and Hong Kong, as laid down in Regulation (EU) No 284/2011. These articles must be accompanied by a DoC and a laboratory report. There is a 100% check of the DoC and the laboratory report. 10% of consignments are sampled on a random basis and analysed by the NVWA laboratory. Melamine kitchenware is checked for migration of formaldehyde (SML=15 mg/kg); polyamide kitchenware is checked for migration of primary aromatic amines (PAAs). PAAs listed in entry 43 of Appendix 8 to Annex XVII to Regulation (EC) No 1907/2006 shall not be allowed to migrate, with a detection limit of 0,002 mg/kg. For PAAs not listed in this Annex and for which no SML is specified in Regulation (EU) No 10/2011, a migration limit of 0,01 mg/kg applies to the sum of these PAAs.

### 4.4.4 Analytical screening

The NVWA also analyses FCM samples in response to consumer reports or to support or verify business-focused surveillance. The NVWA does not always have information about the composition of the material, such as which starting substances and additives have been used. The analyses are often focused on substances that are likely to be present based on literature or experience. Another option is to first perform a screening test to determine which substances are present.

For FCM, it is generally assumed that only substances with a molecular weight below 1000 Da are relevant for chemical safety, as substances with a higher molecular weight usually cannot be absorbed in the body (preamble 8 of Regulation (EC) No 10/2011). Screening FCM for unknown substances, including NIAS, is difficult to implement. Identification of the substance poses an analytical challenge, especially when it is present in a low content. Currently, gas chromatography coupled with mass spectrometry (GC-MS) is often used to identify migrants. A requirement for GC-MS analysis is that the substances are volatile or semi-volatile, so that they can be separated with a gas chromatograph and then identified using a mass spectrometer. Good libraries are available for GC-MS identification of substances. GC-MS screening is feasible for substances with a molecular weight up to 500 Da.

For non-volatile substances and substances with a molecular weight between 500 and 1000 Da, liquid chromatography coupled with mass spectrometry (LC-MS) would be suitable. For LC-MS, however, identification of unknown substances is much more difficult. There are more variables that affect the ionization and fragmentation of a substance, making it difficult to identify using a library. High-resolution LC-MS may offer a solution in the future, as it facilitates easier identification due to highly accurate mass determination. LC-MS is now used by the NVWA laboratory for targeted analysis purposes and not for screening for unknown substances. As a result, it is not possible to obtain a complete overview of unknown substances present.

The NVWA laboratory is currently carrying out the screening of FCM for unknown substances by extraction in an ultrasonic bath in both a polar and apolar solvent. These extracts are then analysed with GC-MS. Many substances can be detected in this way, but non-volatile substances remain out of sight.

Simoneau and colleagues have determined that a total of 8,030 authorised substances are present in national FCM legislation for non-harmonized material categories, (Simoneau et al., 2016), whereas there are an estimated 40,000 to 100,000 NIAS for FCM (Grob et al., 2006).

Legal limits have been set for several NIAS, such as PAAs and several heavy metals. For the remaining NIAS, it shall be demonstrated by means of a risk assessment that no health hazard arises from migration of these substances to the food. Enforcement requires the availability of a certified analytical standard of the substance in question, which can confirm the identity of the substance. In addition to the difficulty of identifying the substance, it is often difficult to determine its toxicological effect. Given the large number of authorised substances (IAS) and NIAS, it is impossible to determine them all analytically and carry out a risk assessment. In practice, this means that the analytical testing is limited to the known substances that may be present.

## 4.5 Bioassays

Another analytical way to characterize biological effects and toxic activity of FCM is by using bioassays. A bioassay is the quantitative effect measurement of biological active substances by administering these substances to biological test systems under standard conditions. Bioassays are

available for various harmful effects. Bioassays are currently being used for various applications. For example, the Water Laboratory in Haarlem uses bioassays to test the safety of drinking water. Bioassays are also used for food safety testing, for example by Wageningen Food Safety Research (WFSR). Bioassays are not yet used by the NVWA laboratory.

An advantage of bioassays is that the toxicological effect of the mixture of migrants is determined. When chemical analyses are performed, the toxicity of a mixture is often estimated based on the individual substances.

Article 3 of the Framework Regulation requires that migration of substances from the FCM does not pose a health risk. This could potentially also be demonstrated using bioassays.

### 4.5.1 Bioassays for testing FCM

The following types of bioassays are common for FCM (Groh & Muncke, 2017):

- Cytotoxicity
- Genotoxicity
- Endocrine activity

Limitations of bioassays for testing FCM include the fact that the substances tested *in vitro* are not subject to the influence of food components or human digestion. The first limitation can be addressed by using food simulants or in vitro digestion models; the second limitation applies to bioassays in general.

Groh and colleagues provided an overview of the available bioassays that are being used (Groh & Muncke, 2017). They conclude that the use of bioassays allows for a rapid assessment of FCM safety. Combined chemical and biological tests frequently demonstrated that the total effect of the detected chemical substances could not account for the entire observed biological effect (Groh & Muncke, 2017). Possible explanations for this are that:

- Effects on lower concentrations are taken into account
- There are effects of substances that were not identified
- There are combination effects from the substances present

Commissioned by BuRO, Maastricht University conducted research into the use of bioassays to test recycled paper and cardboard for FCM (Kourkopoulos, 2025), see also below in 4.5.2. Kourkopoulos and colleagues developed a testing strategy in which bioassays are combined with chemical analyses, see 4.5.4.

### 4.5.2 Bioassays for paper and board

Swedish research of paper and board FCM using bioassays showed that an effect-based approach is a valuable tool to identify the hazards of the substances present in FCM (Selin et al., 2021). They examined methanol extracts of paper and board from a total of 23 samples of widely used paper and board on the Swedish market. Bioactivities were observed in a high proportion of the samples: oxidative stress, genotoxicity, xenobiotic metabolism, antiandrogenity and antiestrogenicity.

Kejlová and colleagues examined the safety of paper and board FCM (Kejlová et al., 2019). The combination of bioassays and chemical research was used. A high content of phthalates, photoinitiators, polycyclic hydrocarbons was found from a black printed sample using chemical analyses. This explained the toxicity observed with bioassays.

Kourkopoulos and colleagues (Kourkopoulos et al., 2025) investigated the impact of sample preparation methods (migration and extraction), the addition of liver metabolic enzymes, endogenous ligands, and various cell lines on the *in vitro* toxicity of FCM from paper. Food simulants were used for migration as required by Regulation (EU) No 10/2011. For extraction, a Soxhlet extraction was used with a 50/50 v/v% mixture of ethanol and acetone. Their research data demonstrated that sample preparation has a significant influence on the toxicological potential of the FCM. This indicates that different substances migrate or are extracted from the material depending on the sample preparation method used. The addition of metabolic enzymes also has an effect.

### 4.5.3 Results bioassays for plastic

Arcega and colleagues (Arcega et al., 2025) used bioassays to assess the toxicity of new and recycled plastic FCM at different recycling stages. For this purpose, migration solutions have been used in four food simulants (water, 20% ethanol, 4% acetic acid and n-heptane). For polyethylene terephthalate (PET), renal toxicity was observed in the food simulants, probably caused by migration of antimony (catalyst). In HepaRG cells, antimony showed a negative correlation with cell viability and a positive correlation with cell surface area, indicating a role in rPET-induced necrosis.

### 4.5.4 Combination of bioassays and chemical analyses

Kourkopoulos and colleagues proposed a testing strategy for paper and board FCM, combining chemical analyses and bioassays to map FCM safety (Kourkopoulos et al., 2022). The compatibility of sample preparation for both bioassays and chemical analyses is a challenge.

According to Severin and colleagues, combining both chemical analyses and bioassays offers a promising and pragmatic tool for the risk assessment of unknown substances such as NIAS (Severin et al., 2017). NIAS often cannot be identified and therefore cannot be characterised toxicologically. Literature review by Severin and colleagues showed that in polyethylene terephthalate (PET) water bottles, estrogenic activity had been demonstrated in most of this water using bioassays, but also in other plastics.

Schilter and colleagues state that identifying and toxicologically characterizing all substances migrating from FCM is not practically feasible (Schilter et al., 2019). Their proposal is to apply the TTC approach to unidentified substances and classify them as Cramer Class III substances. For Cramer Class III substances, a limit value of 1,5 µg/kg body weight per day has been set as a generic threshold for chronic exposure (EFSA, 2019a). Classification in Cramer Class III is only allowed if the substance is not a DNA reactive mutagen and/or carcinogen and does not meet the general exclusion criteria for the TTC approach. A migration solution or FCM extract may be tested using a bioassay, possibly with a concentration step, to demonstrate the absence of these effects. A prerequisite is that this bioassay is sufficiently sensitive.

For FCM, various protocols are available for the sample preparation of bioassays. A migration extract can be used, but a worst-case extraction of the material can also be used. The food simulants prescribed in Regulation (EU) No 10/2011 may be used for a migration extract. To be able to use bioassays to demonstrate that the FCM complies with the safety requirements of Article 3 of the Framework Regulation (EC) 1935/2004, it is necessary to standardise this, as for migration tests. Research by Kourkopoulos and colleagues (Kourkopoulos et al., 2025) showed that sample preparation affects *the in vitro* test results, therefore standardised methods of sample preparation are needed. It should be prescribed which bioassays should be used and the sensitivity of those bioassays. Finally, it is necessary to establish how the results of the bioassays are to be interpreted: when is the FCM considered safe for food contact.

# 5 Circular economy - impact on FCM

The EU has the ambition to be climate neutral and circular. The European 'Green Deal' was drawn up within that framework. In 2015, the Commission adopted an EU action plan for a circular economy and identified plastics as a top priority (European Commission, 2015). In 2017, the Commission confirmed that it would focus on the production and use of plastics and work towards the objective of ensuring that all plastic packaging is recyclable by 2030 (European Commission, 2018). For FCM, this requires that they are designed in such a way that they are easy to recycle. In a circular economy, products must be reused and raw materials recycled, creating a closed loop. For the recyclability of multi-layer packaging, it is necessary that these different layers can be easily separated.

Due to these developments, there has been a shift towards the use of recyclate, but also towards the use of renewable bio-based raw materials instead of fossil raw materials. The planned revision of the European legislation for FCM aims to make these materials and technologies possible, while ensuring food safety, in order to reduce the environmental impact of FCM.

In addition, there is also legislation banning certain single-use plastic-containing articles and legislation on the waste stage of food packaging.

Legislation is also in place that applies to the design phase of products (consumer goods) to ensure the creation of sustainable (reusable, repairable, recyclable) products.

## 5.1 Legislation on environmental impact of FCM

### 5.1.1 SUP Directive

Plastic litter increases annually and is harmful to the environment. The European government therefore wants to reduce the environmental impact of single-use plastic. In 2019, the Single Use Plastics (SUP) Directive was published: Directive (EU) 2019/904. This SUP Directive focuses on the replacement of plastic materials, the reuse of plastic products and the recycling of plastic. It concerns both FCM and other plastic products. The SUP Directive has been implemented in the Netherlands in the Single-Use Plastic Products Regulation[35].

The most important national measures to prevent plastic litter are:

- A ban on the sale of certain single-use products containing plastic, including plates, cutlery, beverage stirrers, straws, cotton bud sticks, balloon sticks, and beverage and food containers made of so-called expanded and extruded polystyrene (EPS and XPS). The ban also applies to products made of oxo-degradable plastic.
- A requirement for producers to collect at least 90% of all plastic beverage bottles up to 3 liters for recycling by 2029. For implementation, the Netherlands opted for a deposit-refund scheme for these plastic beverage bottles.
- Mandatory labeling on certain plastic products to indicate that they contain plastic.
- Fishermen must collect at least 23% of fishing gear waste, with the percentage increasing annually.
- Producers of plastic products frequently found as litter must pay the costs for cleaning up litter.
- An obligation for Member States to take measures to achieve an ambitious and sustained reduction in the consumption of single-use cups and containers containing plastic. In the Netherlands, a measure has been introduced to charge an additional fee for the use of single-use cups and containers containing plastic for on-the-go drinks and meals. Additionally, reusable tableware is mandatory for food and drinks consumed on-site.
- Caps must remain attached to plastic bottles and beverage containers.
- By 2025, PET bottles must contain at least 25% recycled plastic; by 2030, this figure must be at least 30% for all plastic bottles.

### 5.1.2 Packaging and Packaging Waste Regulation

On 12 August 2026, the Packaging and Packaging Waste Regulation (PPWR) (EU) no. 2025/40 will enter into force. This Regulation aims to reduce packaging waste, increase the use of recyclable packaging, and decrease the use of virgin materials in packaging. The scope of this Regulation covers all packaging, both food and non-food, and covers all types of material. This Regulation addresses the entire lifecycle of packaging across the following themes:

- Safe, sustainable and recyclable packaging. Targets have been set for 2030 and 2040 regarding the minimum percentage of recycled material in plastic packaging (up to 65% for single-use plastic bottles by 2040). Furthermore, packaging weight and volume must be minimized, and requirements are in place to limit the presence of substances of concern to a minimum. Specific requirements apply to FCM regarding the content of heavy metals lead, cadmium, mercury, hexavalent chromium and PFAS.
- Restrictions on single-use plastic grouped packaging, single-use plastic packaging for pre-packaged fruit and vegetables of less than 1.5 kg; single-use plastic packaging for serving and consuming food and drinks in hotels, bars, and restaurants (on-site consumption); individual portions of condiments, sauces, coffee creamer, and sugar in hotels, bars and restaurants; small single-use cosmetics and toiletries used in the accommodation sector (e.g. shampoo or lotion bottles); and very lightweight plastic bags (e.g. bags used at markets for bulk purchases).
- Reuse targets and refill obligations. Binding reuse targets have been set for 2030, along with indicative targets for 2040. These targets vary depending on the type of packaging and its use:

[35] Regeling kunststofproducten voor eenmalig gebruik. Staatscourant 2022, 8376.

40% for transport and sales packaging and 10% for bulk packaging. Takeaway restaurants must offer customers the option to bring their own containers to fill with cold or hot drinks or ready-to-eat food at no extra cost.

### 5.1.3 Ecodesign for Sustainable Products Regulation (Ecodesign)

With the Ecodesign Regulation (EU) No 2024/1781, the EU aims to ensure that sustainable products become the standard on the European market. These products must be easy to re-use, repair and recycle. This means that the design of these products must consider, among other things, the choice of materials and which substances the material contains. This Regulation applies to food articles, but not to packaging, as packaging is regulated through the PPWR.

The Digital Product Passport (DPP) is an important measure of the Ecodesign Regulation. The DPP serves as a vehicle for incorporating the information requirements set out in the Ecodesign Regulation. In addition to information about the composition and origin of a product, this passport can also provide insight into how the product can be used, reused and recycled. This is expected to make it easier for consumers to make responsible choices and select products with a lower environmental impact. The DPP is also useful for collectors, sorters, recyclers, and authorities; processors can gain insight into the materials contained in products, while authorities can use the information to verify compliance with specific requirements.

## 5.2 Effects of circular economy on FCM

The scope of the SUP Directive, the PPWR, and the Ecodesign Regulation extends beyond FCM. The SUP Directive only concerns single-use plastic containing products, whereas the PPWR covers packaging made from all materials. The Ecodesign Regulation applies to food contact articles. The SUP Directive, the PPWR, and the Ecodesign Regulation fall under the responsibility of the Ministry of Economic Affairs and Climate Policy (EZK), while the Human Environment and Transport Inspectorate (ILT) is the responsible authority for supervision. The requirements of this Directive and the PPWR have an impact on FCM, such as the replacement of virgin plastics with renewable materials, and recyclate, and the reuse of FCM. BuRO has conducted research into the possible impact of these developments on food safety.

### 5.2.1 Replacement of certain single-use plastic products

For certain disposable plastic products, such as plates, cutlery, beverage stirrers, straws, cotton bud sticks, balloon sticks, a sales ban applies from July 2021. In 2022, commissioned by BuRO, the RIVM conducted research into substitute materials for single-use plastic items (plates, cutlery, stirrers, cups, and straws) (Zwartsen et al., 2023). The substitute materials were paper and board, wood, bamboo, sugarcane, palm leaves and wheat. Through a literature review, the RIVM identified six potential migrants in these materials as highest priority, based on health effect and presence: formaldehyde, bisphenol-A, diisobutyl phthalate, dibutyl phthalate, diethyl hexyl phthalate and lead.

In addition to chemical risks, physical risks can also occur. An example of this is the replacement of plastic straws with paper straws. Reports to the NVWA indicated that, upon becoming wet, small clumps of paper could detach and pose a choking hazard.

### 5.2.2 Reuse

In 2023, commissioned by BuRO, the RIVM conducted a study into the chemical, microbiological, and physical health risks associated with reusable FCM on the Dutch market (McKeon et al., 2024). RIVM investigated materials used in reusable products designed to replace single-use plastic items. This study focused on straws, paper cups with a plastic coating, drinking bottles, and party or festival cups. The three most commonly used materials across all product categories were plastic, stainless steel, and silicone.

In 2023, commissioned by BuRO, the RIVM conducted a study into the chemical, microbiological, and physical health risks associated with reusable FCM on the Dutch market (McKeon et al., 2024). The RIVM investigated materials used in reusable products designed to replace single-use plastic items. This study focused on straws, paper cups with a plastic coating, drinking bottles, and party

or festival cups. The three most commonly used materials across all product categories were plastic, stainless steel, and silicone.

A literature review was conducted to identify substances that could potentially migrate from these materials. Based on reported migration data and hazard classifications, a number of substances were prioritised for each material category. These included certain heavy metals, bisphenol-A, melamine, formaldehyde, dibutyl phthalate, and PAAs.

Reusing drinking utensils without proper cleaning and/or disinfection can lead to hygiene issues. Reuse can cause material wear, such as scratches and cracks. Plastics are more susceptible to wear than stainless steel and silicone, and these worn areas are harder to clean; bacteria can colonize them. RIVM concluded that there is no significant (additional) microbiological safety risk compared to single-use plastic products. Saliva contains few or no pathogenic microorganisms, and their growth is limited. Furthermore, the bacteria found in reusable products most likely originate from the user themselves.

Several incidents have occurred in which young children sustained injuries from falling while using stainless steel straws. Fall-related injuries pose a potential health risk when straws are replaced by hard materials such as stainless steel or hard plastic.

### 5.2.3 Recycling

For plastic recycling, Regulation (EC) No 282/2008[36] was published in 2008, regulating the use of plastic recyclate for FCM. This Regulation was repealed and replaced by Regulation (EU) No 2022/1616 in 2022. The latter Regulation lays down specific rules for the recycling process, including the collection and sorting of the plastic input, the efficiency of plastic waste decontamination and the processing of the recyclate. Authorisation from the European Commission is required to produce plastic recyclate intended for food contact (see3.3.1 Authorisation of substances).

In the Netherlands, the use of wastepaper as a raw material for paper and paperboard FCM has been allowed for several decades. No specific requirements are imposed regarding the waste paper, such as its source or acceptable contamination levels, nor are there requirements concerning the efficiency of the decontamination process. However, requirements do apply to the finished product regarding certain substances; these are the same requirements that apply to virgin paper and paperboard. FCM manufactured from waste paper may come into direct contact with food in the Netherlands.

### 5.2.4 Renewable materials

A renewable material is a material that regenerates or is replenished, either naturally or through human intervention, within a human timescale (approximately 100 years). Unlike fossil-based raw materials, they are not depleted, provided they are managed sustainably. Renewable materials can be of either plant or animal origin and are also referred to as bio-based raw materials.

In 2019, Bonwick and colleagues conducted a study on bio-based raw materials used to manufacture FCM (Bonwick et al., 2019). Key examples of natural polymers that can be derived from bio-based raw materials include starch, cellulose, lignocellulose, gluten, zein, alginate, pectin, and carrageenan. Chitin, casein and gelatin can be extracted from animal biomass. These polymers can be chemically modified. In addition to these natural polymers, whether modified or not, there are also conventional plastics that can be produced from bio-based raw materials. A well-known example of this is polylactic acid (PLA).

In 2020, Zimmermann and colleagues published a study on the safety of bioplastics and other materials based on bio-based raw materials (Zimmermann et al., 2020). Forty-three bioplastics and other plant-based materials were examined using bioassays. Extracts from these packaging materials were studied *in vitro.* Two-thirds (67%) of the samples showed *in vitro* toxicity, 42% oxidative stress, 23% displayed anti-androgenic activity and one sample oestrogenic activity. Extracts from cellulose and starch-based materials generally caused strong *in vitro* toxicity. The

[36] 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, pp. 9–18

authors warned that when introducing new bio-based materials, attention should be paid to the safety of these materials.

In 2020, BuRO commissioned the University of Twente to conduct a literature study on bio-based FCM on the Dutch market (Van den Berg & ten Klooster, 2020). A wide variety of bio-based FCM were identified on the Dutch market. Common materials are PLA, sugarcane, paper, packaging made from plant fibers mixed with plastic, and starch-based materials. For the cultivation of plant fibres, it must be considered that these crops may have been treated with plant protection products and fertilizers. Although the EU has established strict registration procedures for plant protection products and maximum residue levels in food, EU legislation does not regulate their presence in FCM. In addition, these crops are produced outside the EU, where different regulations regarding the use of crop protection products may apply.

There is no specific EU or national legislation for the material category 'bio-based materials'. Bioplastics must comply with the Plastics Regulation (EU) No 10/2011 (Chapter I of Annex A, Commodities Act Regulation on Packaging and Consumer Articles (Staatscourant 2014, 8531)). National legislation exists for paper and paperboard, namely Annex A, Chapter II of this Commodities Act Regulation. Chapter IX of this Regulation sets out requirements for wood and cork. Other plant-based materials, such as bamboo, bagasse, and palm leaves, fall under Chapter VII (textiles); this chapter lists plant-based fibers as a raw material. There are limited legal restrictions regarding the substances identified in the NVWA study on plant-based FCM. Where such restrictions do exist, they are not always consistent across the different material categories. Many of these substances can be classified as NIAS (Non-Intentionally Added Substances). For NIAS, the rule is that migration of the substance must not pose a health risk.

# 6 Food safety from FCM

In a previously issued signal advice, BuRO established a prioritisation for the monitoring of substances in FCM based on their associated health risks (BuRO, 2023). This signal advice indicated that health risks could potentially arise from the migration of plasticisers, bisphenols, mineral oil and PFAS from FCM to the food.

To gain a better understanding of the food safety status of FCM, an overview of RASFF notifications from recent years was compiled. In addition, recent monitoring data from the NVWA were examined.

## 6.1 RASFF notifications

The European Rapid Alert System for Food and Feed (RASFF) is a system for the rapid exchange of information between national authorities regarding health risks associated with food and feed. Unsafe FCM are reported through this system. RASFF notifications provide a picture of what the national authorities within the EEA (European Economic Area) are monitoring.

BuRO has compiled an overview of RASFF notifications concerning FCM for the period 2021–2025. The RASFF notifications were selected based on the criteria of 'migrating substance' and material type. Notifications regarding issues such as exceeding the overall migration limit, missing documentation, altered organoleptic properties, coating detachment, or material breakage were excluded from the selection, as these are not specifically linked to a chemical substance. This resulted in a total of 900 RASFF notifications related to migration of a substance from FCM, of which 641 notifications concerned plastic FCM (melamine, polyamide, plastic with bamboo or other bio-based additives, lid inlays, coatings and other plastic). Table 3 provides an overview of the substances identified and the number of notifications.

**Table 3:** Overview of RASFF notifications 2021 to 2025 on FCM (n=900)

| Material | Number of RASFF notifications | Migrant substances |
|---|---|---|
| **Melamine** | 118 | Formaldehyde; melamine |
| **Polyamide** | 187 | Primary aromatic amines |
| **Bamboo** | 254 | Unauthorized additives in plastic |
| **Other bio-based materials** | 52 | Unauthorized plant additives in plastics |
| **Other plastics** | 26 | Plasticisers, lead; chromium, styrene, unauthorised recyclate; unauthorised additive |
| **Lid inlays** | 4 | Plasticisers |
| **Coatings** | 13 | Bisphenol-A, bisphenol-F-dyglycidyl ether |
| **Paper and paperboard** | 54 | 1,3-dichloropropanol; 1-hydroxy-cyclohexyl phenyl ketone; 3-monochloro-1,2-propanediol; lead; plasticisers; benzisothiazolinone; mineral oil; unauthorized additives |
| **Metal** | 95 | Aluminum; arsenic; manganese; Chromium; nickel; iron; lead; cobalt; copper |
| **Ceramics** | 35 | Aluminum; arsenic; cadmium; cobalt; lithium; lead; zinc |
| **Email** | 8 | Aluminum; antimony; cobalt; copper; manganese; nickel |
| **Glass** | 15 | Cadmium; lead; cobalt |
| **(Silicone) rubber** | 37 | Nitrosamines; cyclosiloxane, volatile organic compounds |
| **Wood** | 2 | Lead, plant protection products |

Melamine and polyamide kitchenware fall within the scope of Regulation (EU) No 284/2011, which includes a mandatory import control on migration of formaldehyde and PAAs from kitchenware from China and Hong Kong. In 2021-2022, the so-called 'Bamboo-zling' action took place, a coordinated EU enforcement action against plastic FCM containing bamboo powder or bamboo fibres. This bamboo-zling action resulted in a high number of RASFF notifications for bamboo food utensils.

Monitoring in the EU focuses primarily on mandatory checks and products suspected of non-compliance. Risk-based surveillance has the advantage that it is efficient in terms of the use of supervisory capacity.

## 6.2 NVWA monitoring results

The NVWA supervises compliance with the FCM legislation both by means of inspections and by means of lab research.

### 6.2.1 Inspections

In 2013, the NVWA conducted 186 inspections of food producers and importers of packaged food, during which the documentation was checked (NVWA, 2014). Larger food manufacturers were the most likely to have established specifications for FCM, i.e. in 75% of cases. This figure was significantly lower for smaller food manufacturers (30%). Larger food manufacturers also performed markedly better regarding the application of these specifications and the availability of a DoC. Furthermore, the content of these DoCs was better in terms of dating, food product specifications, and information regarding substances subject to restrictions.

In 2014, the NVWA conducted 210 inspections of food manufacturers, during which the documentation was checked (NVWA, 2015). Overall, the results from 2014 show an improvement compared to 2013. However, given the limited group of businesses examined per year and the fact that the majority of these businesses were inspected only once, this improvement should be viewed as indicative. The improvement is more evident among small manufacturers. Importers of packaged food were inspected in both 2013 and 2014. The number was too small to draw a conclusion.

In the period 2022-2023, the NVWA inspected 61 businesses supplying food packaging made of plastic or paper/board. This involved 46 manufacturers, 3 importers and 12 traders. Of these, 96%

complied with the requirements of the GMP Regulation (EC) No 2023/2006. Checks were carried out regarding the presence of a quality system, a procedure for traceability and corrective measures, work instructions for production and a complaint registration system. There were no noticeable differences between types of businesses. Company certification (BRC, ISO 9001, ISO 2022) and company size did not appear to influence compliance.

Among the companies supplying plastic packaging (31 out of 61), it was found that 90% met the requirement to have a DoC in place. The DoCs were also checked for compliance with the requirements set out in Regulation (EU) No 10/2011; over 90% met these requirements. In 63% of the checked DoCs, the supporting documentation required to demonstrate that the material meets the regulations was also present. Compared to 2013–2014, there has been a significant improvement regarding the availability of documentation (DoC). GMP requirements were not included in the assessment at that time.

In 2024-2025, the NVWA inspected businesses that trade in food utensils. This group included importers, distributors, and manufacturers, a total of 77 businesses. Non-compliance issues were identified, particularly among importers; for instance, 33% of the importers inspected lacked a DoC.

### 6.2.2 FCM lab research

The NVWA conducts examinations of FCM samples on a project basis approach whenever possible. A number of recent investigations are briefly described below. In addition to these projects, FCM samples are also analyzed in response to notifications or to support or verify business-focused surveillance.

#### 6.2.2.1 Import of melamine and polyamide kitchenware

Regulation (EU) No 284/2011 stipulates that 10% of consignments of melamine and polyamide kitchenware from China and Hong Kong are to be sampled on a random basis and analysed by the NVWA laboratory (see 4.4.3 Import surveillance of kitchenware from China and Hong Kong). Melamine kitchen utensils are examined for migration of formaldehyde, polyamide utensils for migration of PAAs. Table 4 provides an overview of the results of the sample analysis for the past seven years. These results show that most melamine samples comply with the legal limit. Although fewer polyamide samples were taken and analysed, a higher number of exceedances of the legal limit were found compared to melamine kitchenware. Furthermore, the exceedances of the legal limit observed for polyamide kitchenware are often substantial.

**Table 4:** Results of NVWA sample analysis under Regulation (EU) No 284/2011 in the period 2019-2025

| | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 |
|---|---|---|---|---|---|---|---|
| **Melamine** | | | | | | | |
| **Number of samples** | 73 | 52 | 43 | 59 | 59 | 57 | 28 |
| **Non-compliant** | 1 | 1 | 0 | 1 | 0 | 1 | 0 |
| **Polyamide** | | | | | | | |
| **Number of samples** | 9 | 9 | 7 | 3 | 14 | 9 | 10 |
| **Non-compliant** | 2 | 1 | 2 | 1 | 4 | 0 | 0 |

#### 6.2.2.2 Bamboo utensils

Bamboo utensils were gaining popularity, partly due to their eco-friendly image. These items were often marketed with claims such as ‘biodegradable’, ‘environmentally friendly’, ‘organic’, ‘natural’ or even ‘100% bamboo’. It was suggested that the products were made exclusively from bamboo, while they consist largely of plastic material (melamine-formaldehyde resin). EFSA's Expert Working Group on FCM discussed the legal aspects and safety of bamboo as an additive in FCM (EFSA, 2020a). Wood flour and wood fibres, if untreated, were allowed at that time as an additive for plastic FCM. The Expert Group concluded that bamboo fibres and bamboo powder do not fall under the definition of wood and are therefore not authorised as an additive for plastic FCM. This

means that the safety of this additive has not been assessed. In the meantime, 'Wood flour and wood fibres, if untreated' is no longer on the positive list of Regulation (EU) No 10/2011[37].

In 2019, the NVWA conducted a survey on bamboo/melamine food utensils and determined the migration of formaldehyde (Bouma et al., 2021). A total of 46 bamboo/melamine drinking utensils were sampled and examined in duplicate. The majority of the products (88%) complied with the migration limit of 15 mg/kg. However, some very high migration values have also been found, exceeding 200 mg/kg. The highest migration value found for formaldehyde is 247 mg/kg. In 2021, BuRO published an advice on the health risks of bamboo cups (BuRO, 2021c). Formaldehyde release exceeding 19 mg/kg can pose a health risk. Since 2021, the NVWA has banned bamboo/melamine FCM from the Dutch market because bamboo fibers or powder are not authorized as additives for plastic FCM.

#### 6.2.2.3 Plant-based FCM

In 2022, the NVWA conducted a study on plant-based FCM (Bouma et al., 2024). A total of 28 such FCM samples were collected, consisting of bioplastic, paper and board, wood, bamboo, bagasse, palm leaves, coconut, banana leaves, reed, and wheat. These plant-based FCM were analysed for residues of plant protection products, PFAS, heavy metals and subjected to generic GC-MS screening. Although only a limited number of samples per material category were examined, this study clearly indicates the presence of harmful substances, such as active substances from plant protection products, PFAS, heavy metals and plasticisers. These may have been added intentionally or were present as NIAS. No migration tests or risk assessments were performed.

#### 6.2.2.4 PFAS in paper and board

During the period 2019/2020, NVWA developed a screening method for PFAS in paper and board, which was subsequently used to conduct a market survey. Samples of baking paper, cardboard cups, fast-food packaging, and pizza boxes were collected and analysed. Significant levels of perfluorocarboxylic acids (C13 and C14) were detected in these paper and board packaging materials. In several samples, high concentrations were found (>1 mg/kg of paper). The migration of C13 and C14 perfluorocarboxylic acids was not determined.

In 2023, the NVWA conducted an investigation into the presence of PFAS in paper straws. PFAS may be used to make such straws water-repellent. It was found that 21 out of the 22 straws contained PFAS, specifically, perfluorocarboxylic acids. Perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA), and perfluorohexane sulfonic acid (PFHxS) were found. The concentrations ranged from 0.5 to 17 µg/kg. Denmark uses a total organic fluorine (TOF) content of 20 mg/kg as an indicator value for the intentional addition of PFAS (Danish Ministry of Environment and Food, 2020). The PFAS levels detected were significantly lower than this indicator value, suggesting that these substances were not intentionally added to the straws.

#### 6.2.2.5 Metal utensils

In 2020, the NVWA laboratory analysed a total of 54 metal utensils for the release of (heavy) metals. The sampling covered a wide range of items: cutlery, pans, baking tins, and baking trays. Some articles were lightweight models designed specifically for camping. A number of these metal utensils showed high levels of aluminum release, exceeding the current migration limit of 5 mg/kg. No migration of heavy metals (lead, cadmium, arsenic, and mercury) was detected.

In 2021, the NVWA investigated the release of metals from electric kettles and coffee makers (NVWA, 2021). For this study, 22 products from various brands and price ranges were sampled. Detectable migration of aluminum, barium, boron, chromium, iron, copper, manganese, rubidium, strontium, and zinc was observed, but levels remained below the migration limits. No migration of heavy metals (lead, cadmium, arsenic, and mercury) was detected.

#### 6.2.2.6 Aluminum drinking bottles

In 2023 and 2024, the NVWA tested aluminum drinking bottles for the migration of aluminum. A large number of the aluminum water bottles tested failed to comply with the migration limit for

[37] Commission Regulation (EU) 2023/1442 of 11 July 2023 amending Annex I to Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, as regards changes to substance authorisations and addition of new substances . OJ L 177, 12.7.2023, pp. 45–58.

aluminum (5 mg/kg). Furthermore, they did not meet the requirement of no increasing migration. A white precipitate also formed, which unacceptably altered the organoleptic properties (sensory characteristics) of the drinking water. This white precipitation consisted of 26% aluminum. When 3% acetic acid was used as a food simulant instead of tap water, a very high aluminum migration of nearly 50 mg/kg was observed. A risk assessment by BuRO indicated that exposure to aluminum resulting from migration from these water bottles did not exceed the health-based guidance value (BuRO, 2024b). However, if acidic beverages are used, the health-based guidance value may be exceeded.

#### 6.2.2.7 Plasticisers in PVC inlays of lids

In 2018/2019, the NVWA conducted an investigation into plasticisers in PVC inlays. A total of 27 lids were sampled from manufacturers, importers, and distributors. Documentation (DoCs and any test reports) was also requested. No phthalates were detected. However, other plasticisers have been found, namely: acetyl tributyl citrate (ATBC), dibutyl sebacate (DBS) and di-isononyl-1,2-cyclohexanoate (DINCH). According to the documentation provided, epoxidized soybean oil (ESBO) and polyadipates were also used as plasticisers, but these were not included in the NVWA's analytical scope. The NVWA did not measure the migration of these plasticisers; only their concentration within the PVC inlay was determined. ATBC levels exceeding 25% were found. Because concentration data for the inlay was available for only a limited number of samples, and the level in the foodstuff itself was not determined, an exposure assessment could not be carried out. Consequently, further risk assessment was not possible.

## 6.3 Risk matrix

The RASFF notifications and NVWA monitoring data show that there are FCM on the European and Dutch market that do not comply with the legal requirements. These legal requirements are often SMLs, which are based on the toxicological properties of the substance. Exceeding the legal limit indicates a potential health risk. A previous BuRO signal advice concluded that health risks can arise from the migration of substances from FCM (BuRO, 2023). To bring structure to this issue, BuRO has developed a risk matrix based on its conceptual framework for risk assessment.

To optimise the management of the risks concerning the public interests safeguarded by the NVWA, the director of BuRO presented a so-called conceptual assessment framework (BuRO, 2021b;2024a). The major risks associated with a specific public interest are mapped out schematically in a risk matrix by plotting their effect against the probability.

This risk matrix can also be drawn up for the FCM subdomain. Risks have been identified based on NVWA data, RASFF notifications and literature. Annex 3 describes how this classification was established. Figure 4 presents the resulting risk matrix for FCM.

This risk matrix indicates that surveillance should primarily focus on polyamide kitchenware, recycled paper and board, aluminum water bottles and can coatings. Substances posing a health risk have also been identified in plant-based materials; however, there was insufficient data to conduct a qualitative risk assessment (Bouma et al., 2024). Due to the transition toward a circular economy, the use of these materials is on the rise, though they currently fall into the 'low' probability category. This could shift to a 'high' probability as this market segment grows. Both of these quadrants, high effect combined with low probability, and high effect combined with high probability, require active supervision.

In the case of PVC inlays in lids, high levels of exceedance have been found in some instances, particularly in relation to fatty foods. Randomized (non-selective) monitoring applies to the low effect/high probability quadrant.

Regular monitoring is appropriate for materials falling into the low effect/low probability quadrant; this includes melamine kitchenware and recycled plastics.

The number of materials included in this risk matrix is limited, due to a lack of further data. Should more monitoring data become available, the risk matrix can be revised.

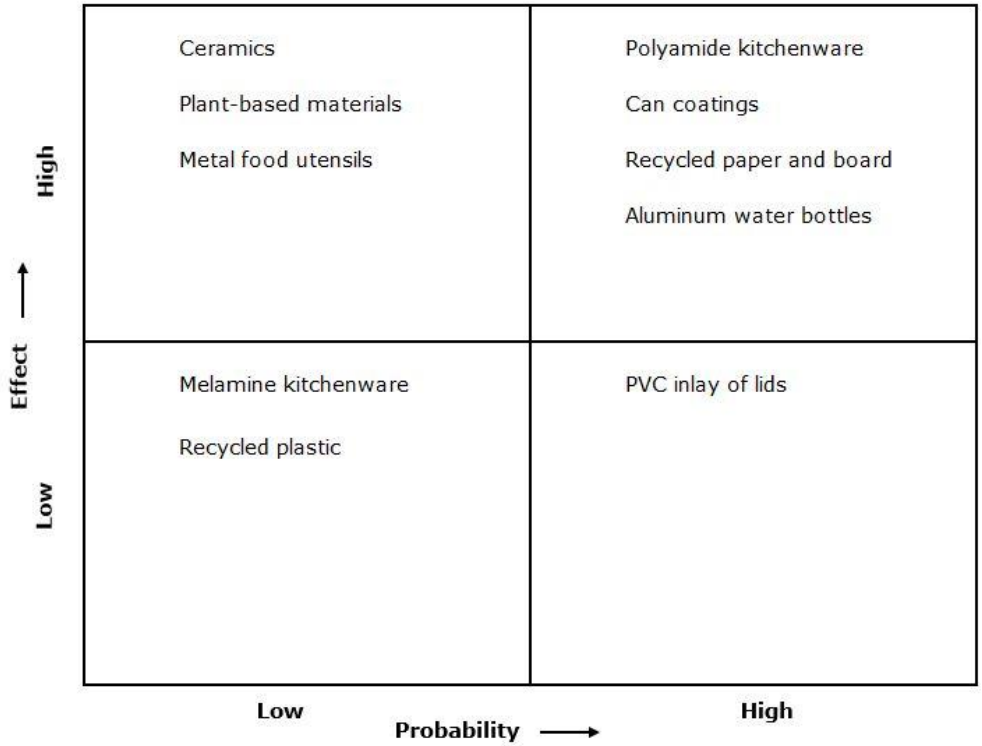



**Figure 4:** Risk matrix FCM

# 7 Conclusions

- The current system of FCM legislation has several shortcomings, including the fact that harmonized EU legislation exists for only a limited number of material categories. In addition, the Netherlands has national legislation in place for a number of other materials. FCM legislation is primarily based on positive lists of (starting) substances. Authorisation per substance is a time-consuming and costly process. The European Commission is currently working on a revision of the EU legislation. The Netherlands has the option to amend its legislation at the national level.
- Laboratory testing conducted by the NVWA and authorities in other European countries indicate that not all FCM placed on the market comply with legal requirements. Risk assessments carried out for a number of substances show that the migration of these substances into food can pose a food safety risk. These risks have been translated into material categories and placed in the risk matrix.
- The transition toward a circular economy, combined with a ban on certain single-use plastic products, has driven a shift toward the use of recyclate, the reuse of materials, and the use of renewable alternatives, such as bio-based materials. Research has shown that bio-based materials can contain harmful substances, such as heavy metals, PFAS, and active substances derived from plant protection products. There is no specific EU legislation governing FCM produced from bio-based materials, and Dutch legislation has not addressed this regarding specific requirements for potentially present harmful substances.
- Enforcement through chemical analysis can only be applied if an accredited method is available. The NVWA laboratory holds a flexible-scope accreditation for FCM regarding sample preparation and chemical analysis (GC, GC-MS, LC-DAD, LC-MS, LC-MS-MS). Specific methods must be validated under this flexible scope and added to the register of accreditation. Consequently, FCM enforcement focuses on several known substances where there is a suspicion that specific limit values are being exceeded. Based on RASFF notifications, it is suspected that other Member States also supervise in this manner.
- Inspections at businesses to monitor good manufacturing practices, material traceability, and documentation can be used to provide the NVWA with information regarding the production

chain and the substances used. Recent monitoring data concerning manufacturers of plastic and paper FCM show that 96% comply with the requirements set out in the GMP Regulation.

- The data position of the NVWA with regard to the migrants present in FCM is insufficient to map the food safety of the FCM by means of migration tests. Chemical screening techniques for unknown substances can be employed to gain insight into the overall composition of a material (IAS and NIAS). For non-volatile substances, the screening method (LC-MS) is currently difficult to deploy. Moreover, the number of IAS and NIAS is very large, making the identification of all substances present extremely difficult and time-consuming. Identification requires standards, which are by no means always available. In addition, there is often a lack of the toxicological and migration data necessary to conduct a risk assessment for these substances.
- The risk matrix Figure 4) is based on migration data obtained using food simulants and worst-case migration conditions (time and temperature). This is expected to result in an overestimation of migration compared to the foodstuff itself.
- Bioassays can be used to determine the toxicological effect of migrating substances. In this way, it is also possible to demonstrate whether or not the migration of substances from the FCM poses a health risk. This requires further standardisation of sample preparation as well as of interpreting results. Furthermore, the bioassays must be sufficiently sensitive.

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# 9 Abbreviations

| | |
|---|---|
| ATBC | Acetyl tributyl citrate |
| BADGE | Bisphenol-A-diglycidyl ether |
| GDP | Butyl benzyl phthalate |
| BMDL | Benchmark dose lower confidence limit |
| BPA | Bisphenol-A |
| BuRO | Office for Risk Assessment & Research |
| CBVV | Dutch Committee for safety assessment of food contact materials |
| CdB | Cyclo-di badge |
| Danish EPA | Danish Environmental Protection Agency |
| DBP | Dibutyl phthalate |
| DBS | Dibutyl sebacate |
| DEHP | Diethyl hexyl phthalate |
| DINCH | Diisononyl-1,2-cycholhexanoate |
| DINP | Diisononyl phthalate |
| DPP | Digital Product Passport |
| ESBO | Epoxidised soybean oil |
| EURL-FCM | European Reference Laboratory for Food Contact Materials |
| EZK | Ministry of Economic Affairs and Climate |
| FCM | Food Contact Material |
| GMP | Good Manufacturing Practice |
| IAS | Intentionally added substances |
| ILT | Environment and Transport Inspectorate |
| JRC | Joint Research Centre |
| MOAH | Mineral oil aromatic hydrocarbons |
| MOSH | Mineral oil saturated hydrocarbons |
| NIAS | Non-intentionally added substances |
| NRL | National Reference Laboratory |
| NVWA | Netherlands Food and Consumer Product Safety Authority |
| PAAs | Primary aromatic amines |
| PFAS | Poly- and perfluoroalkyl substances |
| PFOS | Perfluoro octane sulphonic acid |
| PPWR | Packaging and Packaging Waste Regulation. |
| QMA(T) | Total residual content per surface area in contact with food (limit for a group of substances) |
| RIVM | National Institute for Public Health and the Environment |
| SML | Specific migration limit |
| SML(T) | Total specific migration limit (limit for a group of substances) |
| SUP | Single Use Plastic |
| TTC | Threshold of Toxicological Concern |
| DoC | Declaration of Compliance |
| VWS | Ministry of Public Health, Welfare and Sport |
| WFSR | Wageningen Food Safety Research |

# 10 Annex 1 Literature research

## 10.1 Legislation

The European Commission's website has been used for the legislative overview.

The current Dutch legislation for food contact materials can be found via wet.overheid.nl

## 10.2 Bio-based materials

Commissioned by BuRO, the University of Twente conducted a literature study on bio-based food contact materials (Van den Berg & ten Klooster, 2020).

Prior to the publication of the NVWA study on plant-based FCM (Bouma et al., 2024), a supplementary literature search was conducted in PubMed in December 2023 using the terms 'food contact materials' and 'biobased'. This yielded 70 results. These were filtered for the analysis or migration of substances present in these materials, resulting in 3 relevant publications. Additionally, a search of grey literature identified 2 market studies by NGOs.

## 10.3 Bioassays

For this advice, BuRO searched PubMed with the terms 'food contact materials' AND 'bioassay'. This yielded 76 results. The results were filtered for recent publications (from 2014 onwards) and publications in which bioassays were used to demonstrate the safety of food contact materials. This resulted in 8 relevant publications.

## 10.4 other

In 2023, an extensive literature review was conducted to substantiate the signal advice (BuRO, 2023).

BuRO searched PubMed using the terms 'NIAS' and 'Food Contact Materials'. This yielded nine relevant publications. Most of the publications focus on a specific material (e.g., polyester baby bottles) or on an analytical technique, whether chemical or toxicological. The search identified one publication providing a literature review on NIAS and one reporting on NIAS detected in paper and board.

For BPS and BPF, BuRO searched PubMed using the terms 'migration' AND 'Bisphenol S' AND 'Bisphenol F.' This search identified relevant publications from the United States and China regarding exposure to these substances.

In addition, BuRO searched for published reports from authorities in EU Member States, such as BfR (Germany) and Danish EPA (Denmark), but also RIVM.

# 11 Annex 2: DoC by material category

## 11.1 Plastic

Annex IV of the Plastics Regulation (EU) No 10/2011 specifies the data to be included in the DoC:

1. the identity and address of the business operator issuing the declaration of compliance
2. the identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles
3. the identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles
4. the date of the declaration
5. confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet the relevant requirements laid down in this Regulation and in Article 3, 11(5), 15 and 17 of Regulation (EC) No 1935/2004
6. adequate information allowing the downstream business operators to ensure compliance with this Regulation relative to the substances used for which restrictions and/or specifications are set out in Annexes I and II, including adequate information on the presence of non-intentionally added substances if present in an amount that could cause non-compliance of a final material with Article 3 of Regulation (EC) No 1935/2004. At intermediate stages, this information shall include the identification and amount of the following substances contained in the intermediate material:
   - substances that are subject to restrictions and/or specifications in Annex II, or
   - substances for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate material and which could be present in an amount that foreseeably gives rise to an individual migration into food from the final plastic material or article exceeding 0,00015 mg/kg food
7. adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 2008/60/EC, 95/45/EC and 2008/84/EC to enable the user of these materials or articles to comply with the relevant EU provisions or, in their absence, with national provisions applicable to food
8. specifications on the use of the material or article, such as:
   - type or types of food with which it is intended to be put in contact
   - time and temperature of treatment and storage in contact with the food
   - the highest food contact surface area to volume ratio for which compliance has been verified in accordance with Article 17 and 18 or equivalent information
9. when a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of this Regulation.

## 11.2 Ceramics

In Annex III to Directive 84/500/EEC for ceramic materials, the following information is required in the DoC:

1. the identity and address of the company which manufactures the finished ceramic article and of the importer who imports it into the Community;
2. the identity of the ceramic article;
3. the date of the declaration;
4. the confirmation that the ceramic article meets the relevant requirements in this Directive and Regulation (EC) No 1935/2004.

## 11.3 Regenerated cellulose films

Directive 2007/42/EC for regenerated cellulose films states that the DoC must be drawn up in accordance with Article 16(1) of Regulation (EC) No 1935/2004. In concrete terms, this means:

1. Good identification of the product (e.g. description, item number, colour);
2. Confirmation that the product complies with Regulation (EC) No 1935/2004;

3. Confirmation that the product complies with Regulation (EC) No 2007/42;
4. The conditions of use to be taken into account.

## 11.4 Epoxy derivatives

The Regulation for certain epoxy derivatives (EC) No 1895/2005 states that materials and articles containing BADGE and its derivatives shall be accompanied by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004. In concrete terms, this means:

1. Good identification of the product (e.g. description, item number, colour);
2. Confirmation that the product complies with Regulation (EC) No 1935/2004;
3. Confirmation that the product complies with Regulation (EC) No 2007/42;
4. Declaration of compliance with the SML for BADGE and derivatives;
5. Statement that NOGE (Novolac glycidyl ether) and BFDGE (bisphenol-F-diglycidyl ether) are not present.

## 11.5 Epoxy polymers

Chapter XII of Part A of the Commodities Act Regulation on Packaging and Consumer Goods states that FCM manufactured from epoxy polymer, with or without a coating, and auxiliaries intended for the manufacture of epoxy-polymer FCM, shall be accompanied, when sold other than in retail, by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004 and Section 0.9 of Chapter 0, Annex A. The following information is required:

1. identity and address of the operator issuing the declaration of conformity
2. identity and address of the operator manufacturing or importing the materials or articles, intermediate products or semifinished products thereof, or substances intended for the manufacture of such materials or articles
3. identity of the materials or articles, intermediate products or semifinished products thereof, or substances intended for the manufacture of such materials or articles
4. the date of declaration;
5. a statement to the effect that the materials or articles, intermediate products or semifinished products thereof, or substances comply with the relevant requirements of this regulation and of Regulation (EC) No 1935/2004Confirmation that the FCM, intermediates or semi-finished products thereof, or substances comply with the relevant requirements of this Chapter and of Regulation (EC) No 1935/2004
6. adequate information about the used substances or metabolites thereof, for which Chapters I–XII of Annex A contain restrictions or specifications, so that downstream operators can ensure compliance with those restrictions or specifications
7. the use of substances permitted in foodstuffs
    i. adequate information about the substances for which a restriction applies in foodstuffs, obtained based on experimental data or theoretical calculations, about the specific migration of such substances
    ii. adequate information on purity criteria in accordance with Regulation (EU) No 231/2012, in the case of substances which may pose a risk to public health (e.g. mutagens)
    iii. adequate information on the migration of impurities in accordance with Section 0.4.2 (d), enabling the user of such materials and articles to comply with the relevant EU provisions or, if those are absent, with the national provisions for foodstuffs
8. the specifications for the use of the material or article, such as:
    i. the type(s) of food with which it is permitted to come into contact
    ii. maximum duration and temperature during treatment and storage of the foodstuffs
    iii. the ratio between the area coming into contact with foodstuffs and the volume, based on which it was found that the material or article meets the requirements.
9. If a substance as referred to in Section 0.3 (e) has been used, there must be a mention of the fact that the principle of "no migration" is used in respect of conformity with Article 3 of Regulation (EC) No 1935/2004.

## 11.6 Active and intelligent materials

Annex II of the Regulation on Active and Intelligent Materials (EC) No 450/2009 sets out the mandatory information to be contained in the DoC:

1. the identity and address of the business operator which issues the declaration of compliance
2. the identity and address of the business operator which manufactures or imports the active and intelligent materials and articles, or the components intended for the manufacturing of those materials and articles, or the substances intended for the manufacturing of the components
3. the identity of the active and intelligent materials and articles or the components intended for the manufacturing of those materials and articles, or the substances intended for the manufacturing of the components;
4. the date of the declaration;
5. the confirmation that the active or intelligent material or article complies with the relevant requirements laid down in this Regulation, Regulation (EC) No 1935/2004, and in specific Community measures applicable
6. adequate information relative to the substances which constitute the components, for which restrictions are in place under the Community or national provisions applicable to food and this Regulation; where appropriate, specific purity criteria in accordance with the relevant Community legislation applicable to food and, the name and quantity of the substances released by the active component, to allow the downstream business operators to ensure compliance with those restrictions
7. adequate information on the suitability and effectiveness of the active or intelligent material or article
8. specifications for the use of the component, such as:
    i. the group or groups of materials and articles in which the component may be added to or incorporated into
    ii. the conditions of use necessary to achieving the intended effect
9. the specifications for the use of the material or article, such as:
    i. the type or types of food intended to be put in contact with it
    ii. the time and temperature of treatment and storage in contact with the food
    iii. the ratio of food contact surface area to volume used to establish the compliance of the material or article;
10. when a functional barrier is used, the confirmation that the active or intelligent material or article complies with Article 10 of this Regulation.

## 11.7 Metals

Part A, Chapter IV of the Commodities Act Regulation on Packaging and Consumer Goods states that the conformity of the materials and articles shall be demonstrated by the operator by means of a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004 and Section 0.9 of Chapter 0, Annex Part A.

# 12 Annex 3: FCM risk matrix classification

## 12.1 Creation of the FCM risk matrix

The risk matrix is a two-by-two matrix. It plots probability and effect along its axes, using the categories high and low. The risk matrix forms part of the conceptual assessment framework for the public interests that are supervised by the NVWA (BuRO, 2021b;2024a).

First, a classification was made at substance level with regard to the effect. For the purpose of monitoring, it is more relevant to classify FCM at material level than at substance level. Based on the material category, it can then be selected which substances should be focused on.

It should be noted, as a disclaimer, that this is a snapshot in time. Other groups of substances may be identified, or new insights into health risks may emerge. There may also be a shift in exposure to other products and materials. This categorisation was developed by BuRO, with an explanatory note provided for each category.

## 12.2 Classification at substance level

The following sources were consulted as input for relevant substances:

- Signal advice prioritisation of substances in food contact materials (BuRO, 2023)
- RASFF data (see section 6.1)
- Recent NVWA monitoring data and data from literature (paragraph 5.2.4 and 6.2.2)

All substances that pose serious health hazards, such as carcinogenic, mutagenic, reprotoxic, neurotoxic and immunotoxic substances have been placed in the 'high' effect category. The other substances (groups) are placed in the 'low' effect category. This is shown in Table 5, which also includes an explanation as to why they have been assigned to these respective categories.

**Table 5:** Classification of substances for risk matrix FCM

| Substance(group) | Classification of effect | Explanation |
|---|---|---|
| **Melamine** | Low | Harmful to the kidneys |
| **Formaldehyde** | Low | Harmful to the stomach |
| **Glycidyl ethers** | Low | Harmful to the spleen, not carcinogenic or genotoxic |
| **Aluminum** | High | Neurotoxic |
| **Mineral oils** | High | Mutagenic and carcinogenic |
| **Primary aromatic amines** | High | Carcinogenic |
| **Bisphenols** | High | Immunotoxic |
| **PFAS** | High | Immunotoxic |
| **Plasticisers** | High | Reprotoxic |
| **Heavy metals** | High | Neurotoxic, carcinogenic |
| **Plant protection products** | High | Mutagenic and reprotoxic |

### 12.2.1 Melamine

EFSA assessed that for melamine the formation of stones in the kidneys or urinary tract is the critical effect (EFSA, 2010a). EFSA derived a TDI of 0.2 mg/kg bodyweight per day for melamine by applying a safety factor of 100 to the $BMDL_{10}$ (benchmark dose lower confidence limit) of 19 mg/kg bodyweight per day from a 13-week dietary study of male rats (National Toxicology Program, 1983).

### 12.2.2 Formaldehyde

When exposed to formaldehyde, the harmful effects occur primarily in the tissue or organs of first contact. This is caused by the rapid conversion of formaldehyde into formic acid. According to EFSA, there is no indication that formaldehyde is carcinogenic via oral exposure (EFSA, 2007). EFSA derived a TDI of 0.15 mg/kg body weight per day for formaldehyde. This TDI was adopted from the World Health Organisation (WHO, 2005) and is based on a 2-year study in rats, in which

formaldehyde was administered via drinking water (Til et al., 1989). The critical effect was damage to the gastric mucosa, often leading to hyperkeratosis and ulcer.

### 12.2.3 Glycidyl ethers

For the glycidyl ether BADGE (bisphenol-A-diglycidyl ether), effects on the spleen have been identified as a critical effect (EFSA, 2004). The health-based guidance value is based on this. For CdB (cyclo-di-BADGE), Burleigh-Flaye and colleagues derived a NOAEL of 1139 mg/kg bodyweight per day (Burleigh-Flayer et al., 2026). This NOAEL is derived from a 90-day study in rats, in which CdB was administered via corn oil. This was the highest test dose. No clinical signs were observed in the rats. The results of the genotoxicity tests (Ames test and micronucleus test) were negative.

### 12.2.4 Aluminum

In the signal advice on aluminum water bottles, BuRO (BuRO, 2024b) identified kidney damage and reduced grip strength as critical effects, based on a developmental neurotoxicity study in rats (Poirier et al., 2011)

### 12.2.5 Mineral oils

Mineral oils consist of two types: MOSH (mineral oil saturated hydrocarbons) and MOAH (mineral oil aromatic hydrocarbons). According to EFSA, MOSH is neither mutagenic nor carcinogenic (EFSA, 2012b). Within the MOAH group, there are substances with mutagenic and carcinogenic properties.

### 12.2.6 Primary aromatic amines

Most primary aromatic amines (PAAs) are classified as (suspected) carcinogens under the CLP Regulation (EC) No 1272/2008[38].

### 12.2.7 Bisphenols

Bisphenol-A (BPA) is considered an immunotoxic substance (EFSA, 2023). This substance has since been banned in FCM by Regulation (EU) No 2024/3190. Alternative bisphenols and bisphenol derivatives are also covered by the scope of this prohibition. Literature studies have shown that these substitutes may have similar toxicological properties, or that there is insufficient knowledge (den Braver-Sewradj et al., 2020).

### 12.2.8 PFAS

According to EFSA, effects on the immune system (reduced immune response) should be considered the most sensitive toxicological effect of PFAS exposure (EFSA, 2020b). These effects have been observed in both animals and humans. EFSA has derived a TWI of 4.4 ng/kg bodyweight per week for the sum of four PFAS: PFOA, PFOS, PFNA and PFHxS based on equipotency.

### 12.2.9 Plasticisers

Several plasticisers may be present in FCM (see also previous signal advice BuRO (BuRO, 2023)). In 2019, EFSA published an opinion regarding phthalates (EFSA, 2019b). DBP, BBP and DEHP are reprotoxic substances. In addition, other plasticisers have also been found, such as ESBO, DINCH, adipates and citrates. Based on the available toxicity data, these plasticisers are not carcinogenic, mutagenic, or toxic to reproduction.

### 12.2.10 Heavy metals

This includes lead, mercury, cadmium. According to an EFSA opinion, lead is neurotoxic (EFSA, 2010b). According to EFSA, cadmium causes renal failure and cadmium exposure has been statistically linked to an increased risk of cancer (EFSA, 2012c). According to EFSA, long-term exposure to methylmercury may lead to adverse effects on neurological development, liver, kidneys, immune system and reproductive system(EFSA, 2012d).

[38] 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, pp. 1–1355.

### 12.2.11 Plant protection products

In the NVWA study of plant-based materials (Bouma et al., 2024), a number of active substances of plant protection products of concern were found, including carbendazim at a high content (5.7 mg/kg). EFSA has assessed, on the basis of animal studies, that carbendazim is a mutagenic and reprotoxic substance (EFSA, 2010c). This substance is not authorised in the EU as an active substance in a plant protection product.

## 12.3 Classification at material level

There are various material categories for FCM. Based on the substances found therein, these materials are classified in an effect category low or high. For the probability component, an assessment is made regarding the extent to which a material is used and the frequency with which non-compliances (i.e., excessive migration of these substances) have been observed. This is shown in Table 6. For some material categories, this assessment is generic, while for others, it is broken down in greater detail, depending on the data available. Table 6 served as input for the risk matrix, which is illustrated in Figure 4.

**Table 6:** Classification of materials in FCM risk matrix

| Type of material | Probability | Effect |
|---|---|---|
| **Melamine kitchenware** | Low | Low |
| **Polyamide kitchenware** | High | High |
| **Recycled plastic** | Low | Low |
| **Lids with PVC inlay** | High | Low |
| **Recycled paper and board** | High | High |
| **Can coatings** | High | High |
| **Ceramic materials** | Low | High |
| **Aluminum drinking bottles** | High | High |
| **Metal food utensils** | Low | High |
| **Plant-based materials** | Low | High |

### 12.3.1 Melamine kitchen utensils

Formaldehyde and melamine can migrate from melamine kitchenware; both are classified in the low effect category. Table 4 shows that very few samples were found to be non-compliant. The probability is therefore estimated to be low.

### 12.3.2 Polyamide kitchen utensils

PAAs can migrate from polyamide kitchenware. These are (suspected) carcinogens, classified in the category high effect. Table 4 shows that, compared to melamine, samples exceeding the migration limit are found more frequently for polyamide kitchenware. When the SML is exceeded, this is often a high exceedance. The probability is therefore assessed as high.

### 12.3.3 Recycled plastic

Due to the transition towards a circular economy, the use of recycled plastic in FCM is on the rise. This is strictly regulated; there is a special Regulation (EU) No 2022/2016. Recycled plastic intended for use in FCM may only be produced via authorised recycling processes. The resulting FCM must meet the same requirements as virgin plastic FCM. Comprehensive legislation, Regulation (EU) No 10/2011, is already in place for plastic FCM. There is no evidence to suggest that substances migrating from recycled plastic pose a high health risk. Currently, the number of FCM products containing recycled material remains low; however, this is expected to increase in the coming years, driven by the targets set out in Regulation (EU) No 2025/40.

### 12.3.4 Lids with PVC inlay

The latest NVWA study (2018/2019) showed that these inlays do not contain phthalates, but do contain other plasticisers such as ESBO, DINCH, adipates and citrates. These fall into the low effect category. The migration to the food is not determined, but the levels in the lids were high. Previous European research has shown that migration particularly into fatty foods can be significant,

sometimes exceeding 60 mg/kg (total migration limit) (McCombie et al., 2012; McCombie et al., 2015). See also BuRO's signal advice for further explanation (BuRO, 2023) and the overview of RASFF notifications in Table 3. The probability is therefore assessed to be high.

### 12.3.5 Recycled paper and board

Research by the NVWA (BuRO, 2023) shows that recycled paper and board can contain PFAS, mineral oils, plasticisers and bisphenols. These substances are classified in Table 5 in the high effect category. Based on this risk assessment, the probability (BuRO, 2023) is estimated to be high. Furthermore, the use of recycled paper and paperboard is on the rise as a replacement for single-use plastics, which have since been banned (Zwartsen et al., 2023).

### 12.3.6 Can coatings

Cans normally are typically lined with an epoxy coating, which may contain both bisphenols and glycidyl ethers. Bisphenols fall into the high effect category; glycidyl ethers in the low effect category. According to BuRO's signal advice, literature research shows that the risk of migration of bisphenols and glycidyl ethers is high (BuRO, 2023). There is now a ban on the use of bisphenols (Regulation (EU) No 2024/3190), with a transition period allowing for their initial placement on the market until July 20, 2026.

### 12.3.7 Ceramic materials

Cadmium and lead can migrate from ceramic materials. These are classified as high effect. The current EU migration limits for lead and cadmium are quite high (Directive 84/500/EEC). ). In 2024, a decision was adopted within the Benelux region that sets significantly lower migration limits. In 2022-2023, the NVWA Product Safety Laboratory examined 28 samples of ceramics obtained through import controls. These products largely complied with these proposed limits for lead and cadmium. The probability is therefore assessed as low.

### 12.3.8 Metal food utensils

NVWA research showed that there was no detectable migration of heavy metals from metal utensils (pans, cutlery, baking molds) or from electric kettles and coffee makers (see 6.2.2.5). However, the migration of aluminum for several utensils was high, higher than the migration limit, which could potentially from a health risk. The effect is assessed as high (heavy metals and aluminum). The probability is estimated to be low, as there was no detectable migration of heavy metals and high aluminum migration occurred in only a limited number of samples.

### 12.3.9 Aluminum drinking bottles

Aluminum is classified as a high effect. The results of the NVWA study show that the migration limit is frequently exceeded, in such a way that a health risk may arise (BuRO, 2024b). The probability is therefore assessed as high.

### 12.3.10 Plant-based materials

NVWA studies have shown that plant-based materials may contain PFAS, metals (non-heavy) and residues of plant protection products (Bouma et al., 2024). PFAS and plant protection products are classified as high-effect. At present, plant-based materials are not yet widely present on the market, and the probability is therefore estimated to be low. However, the use of these plant-based materials is on the rise, driven by the transition toward a circular economy, as well as their role as a replacement for certain single-use plastics, which are now prohibited (Zwartsen et al., 2023).