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To:
- the Minister of Health, Welfare and Sport
- the State Secretary of Economic Affairs

Advisory report from the Director of the Office for Risk Assessment & Research (BuRO)

Advisory report on the options to extend the list of foods that are exempted from the requirement to bear a date mark (English translation of "Advies over mogelijkheden voor de uitbreiding van de lijst met producten die uitgezonderd zijn van de verplichting voor een vermelding van een houdbaarheidsdatum")

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The Matter

The Ministry of Economic Affairs (EZ) is looking for ways to reduce food waste. In 2010 and 2013 Dutch consumers wasted 44 kg and 47 kg of food respectively, food that was fit for consumption. One of the reasons behind this waste is expiry of the use-by date stated on the product. Some of these products are likely to still be of an acceptable quality and present no risks in terms of food safety. EU-wide rules with regard to stating the durability of food products are set out in Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, the labelling directive. The basic principle is that all food products must indicate a shelf life, whereby a distinction is made between the date of minimum durability (best-before date, "best before...") and use-by date ("use by ..."). The labelling directive is designed to ensure a high level of health protection for consumers, and imposes obligations in relation to the information that must be provided about such things as the composition and safe use of a food, including durability and storage, as well as information on the protection of consumers' health. Food products featuring a use-by date can no longer be used after this date. Food products featuring a best-before date can be kept until at least the stated best-before date. The key question in this recommendation is whether there is an easy way to extend Annex X of the labelling directive without placing food safety at risk. Annex X of this directive features a list of products and product groups that are exempted from the obligation to indicate the date of minimum durability. These exempted products and product groups are divided into two categories: a) products for which deterioration is clearly visible for the consumer and that spoil at a faster rate than the rate at which the product becomes microbiologically or otherwise harmful, and b) products that do not spoil

and whose properties, such as water activity[1] and acidity (pH), prevent the growth of pathogens or even reduces them. It is important to point out that it should never be assumed that products that are not labelled with a shelf life are intrinsically safe in terms of pathogens. A product could expose a consumer to a number of pathogens exceeding the food safety limit as a result of its ingredients or due to cross-contamination during the production process. This risk can be easily managed via entry checks and/or HACCP (Hazard Analysis and Critical Control Points) based procedures.

Extending the list of products exempted from the requirement to indicate a durability date could therefore prevent unnecessary food waste. One option to regulate this by law is to extend Annex X.

This option is currently being discussed at European level by the European Commission's Working Group on Food Labelling. One of the options identified to simplify this issue is to extend the list of food products that are exempted from the requirement to indicate a date of minimum durability: Annex X of the labelling directive. The Working Group has produced a discussion document (Working Document[2]) to this end that proposes an extension of Annex X by adding a number of products and product groups. It has also been asked whether this list can be extended by one of the following options: a) the addition of products and product groups, b) criteria or c) the shelf life stated by the manufacturer.

Moreover, the subject of "exemption from the obligation to provide a durability date" is currently also being discussed by the FAO/WHO Codex Committee on Food Labelling (the Codex Committee): "General Standard for the Labelling of prepackaged Foods Codex Stan-1-1985 (GSLPF)".

The Nutrition, Health Protection and Prevention Department (VGP) of the Ministry of Health, Welfare and Sport has asked the Office for Risk Assessment & Research (BuRO) of the Netherlands Food and Consumer Product Safety Authority (NVWA) to examine whether there is a "quick win" solution to exempting additional products and/or product groups from the obligation to indicate a date of minimum durability, and to examine the criteria products must meet in order to qualify for exemption. For the VGP, this concerns products that are reliably proven to have a very long shelf life, and whose key product characteristics ensure that they do not present any health risks. The results of the research can be contributed to the international debate within the European Working Group and the Codex Committee.
BuRO has also been asked to address the questions posed by the Working Group. On 16 February 2015, a provisional response was sent to the VGP policy

[1] Water activity (aw) is a measure of the amount of “free” water molecules present in a product. By definition, the a_w value of pure water is equivalent to 1. The lower the value, the smaller the amount of micro-organisms that is able to grow.
[2] Not public

department of the Ministry of Health, Welfare and Sport to support the Dutch contribution towards the European Commission's Working Group on Food Labelling, dated 17 February 2015.

Questions to be addressed

Further to the above-mentioned request from the Ministry of Health, Welfare and Sport, the BuRO called in the Front Office for Food Safety of the National Institute for Public Health and the Environment (RIVM) and RIKILT-Wageningen UR (Institute of Food Safety) (Appendix 1) to provide a substantiated response to the following questions:

1. Is there a "quick win" solution to extending the list of exemptions in Annex X of Regulation (EU) No 1169/2011?
2. What criteria must products meet in order to qualify for exemption from the obligation to indicate a durability date as referred to in Regulation (EU) No 1169/2011? Only taking products with a long shelf life in to account.
3. Are the products listed in the Working Group's Working Document suitable for exemption from the obligation to indicate a durability date?
4. Are there any products that meet the criteria, but cannot be exempted?

The research

At the BuRO's request, the RIVM and RIKILT Front Office for Food Safety has drawn up a list of proposed food safety criteria that food products must meet in order to qualify for exemption from the obligation to indicate a date of minimum durability, based on a literature study. This proposal is attached to this document as Appendix 1 and forms the basis for this recommendation.

The proposal is supplemented by a literature and information study carried out by the BuRO itself. Where these other information sources have been used, this is stated in the recommendation. The assessment takes into account food safety and quality aspects, as well as the discussion points raised in the Working Document.

Ample scientific research has been published on preventing spoilage of food. Based on these publications, it is possible to produce a list of criteria that products must meet in order to be kept for a long period, under prescribed storage conditions, without presenting a risk to the consumers' health.

Apart from the legislation, food products only need to be provided with a durability date for food safety reasons if the risk to health can increase during the shelf life without this being evident to the consumer in the form of spoilage. Spoilage can be caused by biological, physical, chemical or microbiological factors. Biological spoilage, for instance due to pest infestation, is more dependent on storage conditions than on the storage period. A durability date has no influence on this and biological spoilage has therefore been disregarded in this recommendation. Physical/chemical deterioration, except for the formation of biogenic amines

(chemical deterioration), does not usually cause food to become hazardous to health during its shelf life. Microbiological spoilage plays the most important role with regard to food safety. The recommendation therefore focuses on this aspect.

Finally, this recommendation also examines the proposal in the Working Document to add certain products to the above-mentioned Annex X. Whether, and on what grounds, the proposed products could be included in Annex X is examined on a case-by-case basis.

Results of the research

Products are microbiologically safe/stable in the following situations: a) if they do not contain (pathogenic) micro-organisms, or b) if the number of (pathogenic) micro-organisms does not present a health risk, and the growth of (pathogenic) micro-organisms present also does not reach harmful levels. Based on this information, products could be exempted from the obligation to indicate a durability date if:

I. they are and remain sterile (no pathogens)
II. under normal conditions, the shelf life after production is so short that no spoilage can occur, as in the case of fresh products that are supplied daily (no pathogen growth);
III. spoilage is evident to the consumer before the product becomes (microbiologically) harmful (no pathogen growth)
IV. the growth of (pathogenic) micro-organisms is not supported (pathogen growth impossible), or the micro-organisms even die off, due to the product characteristics, e.g. acidity (pH) and water activity (aw), or storage conditions, such as temperature.

Categories II and III feature products that do indeed support microbiological growth. Therefore, these categories are not included in the current question regarding "quick win" options. The "quick win" options being examined in the context of this recommendation fall within categories I and IV above. It can be concluded from the literature study that more precise criteria can be inferred for these categories. If a food product meets these criteria, it can be regarded as microbiologically stable. The safety of public health is therefore guaranteed and the product qualifies for addition to Annex X of the labelling directive. The criteria are as follows:

A. food sterilised in a can: food safety is guaranteed by heating, sometimes in combination with the pH, and the fact that it is impossible for the product to be subsequently contaminated by micro-organisms;
B. food sterilised in other hermetically sealed packaging;
C. water activity (aw) <0.60;
D. acidity (pH) <3-4 (depending on the type of acid: organic or inorganic);
E. products with a lower aw plus with an additional inhibiting factor: aw <0.85 + low pH or use of preservative;

F. storage temperature < -18°C, provided the cold chain remains unbroken.

The types of products referred to under A and B fall within category I above and the other types of products under category IV. However, it is important that the products and their packaging remains undamaged and that the products are stored according to the instructions. These instructions must be indicated on the label. The above-mentioned product and process characteristics ensure that the products have a reliably long shelf life with no adverse effects on public health.

In addition to these "quick win" options, a more extensive risk assessment may lead to more products or product and/or process criteria to extend the list of food products in Annex X of the labelling directive. The Working Group has included a number of proposals in the Working Document of food products that could be exempted:

a. shelf-stable dry fermented sausages (pepperoni, salami not labelled as “keep refrigerated”);
b. preserved fish products such as pickled herring, dried or salted cod;
c. salt-cured products;
d. hard cheeses such as pecorino;
e. deli salads;
f. canned foods;
g. dry pasta (macaroni, spaghetti, etc.);
h. couscous, semolina and similar foods;
i. coffee, tea;
j. rice;
k. instant powder (low in fat);
l. dried spices;
m. flour;
n. water.

Some of these proposed products or product groups are also exempted from the obligation to indicate a durability date in other countries. In the US, for instance, products a to e are exempted from the obligation to provide a durability date because they comply with (scientific) research-based criteria, such as pH, aw, salt, nitrite and/or nitrate content. The focus here is on preventing growth and toxin formation by pathogenic micro-organisms, and not on spoilage in general.
Deli salads in the US have been shown to be acidified to such an extent and to contain sufficiently high concentrations of preservatives that they do not promote the growth of *Listeria monocytogenes*. The situation with regard to these types of salads in the EU, and whether these products can be regarded as having a very long shelf life, is unknown. It should also be noted that not all canned products have a long shelf life and that only sterilised canned products qualify, as referred to in the category A proposed in this recommendation. Water must be of drinking water quality, so that it contains no nutrients to support growth of micro-organisms. The

remaining products have a very low water activity and therefore all meet the limit of aw < 0.60 proposed in this recommendation.

One point to consider is that some of the above products are sensitive to biogenic amine formation (chemical spoilage), including fermented food products such as cheese and sausages. However, there is a lack of clarity regarding the toxicity of these amines and the amounts that occur in the various food products. Finally, it may be noted that the products currently listed in Annex X of the labelling directive belong to the previously specified categories II to IV.

Not only food safety but also loss of quality plays a role during storage, such as loss of vitamins. Providing a durability date is also relevant for other aspects, such as the retention of chemical and/or physical properties, which can be important for consumers adhering to a special medical or other type of diet. These quality aspects are crucial for the health of vulnerable target groups. Furthermore, failure to comply with the food product information on the label is a punishable offence. Durability is therefore not always determined exclusively by microbiological aspects. In such cases, the date of minimum durability is primarily useful in terms of the quality of the product, and not in terms of food safety.

Conclusions

- In the context of food safety, only microbiological spoilage is relevant. Any criteria for adding new products to the list of those exempted from the obligation to indicate a date of minimum durability would need to be based exclusively on this type of spoilage.
- In the interests of maintaining the desired quality, foods designed for specific groups of people whose health is affected by the deterioration of the product other than by microbiological spoilage should bear an indication of the date of minimum durability. Examples include dried infant formulae and dietary foods for special medical purposes.
- If the durability depends on the storage conditions (cool, dry, dark, etc.), instructions must be indicated on the label.
- Product and process characteristics can be formulated with which food products must comply to ensure that they can be stored for a very long time without presenting a significant health risk, and thus can be exempted from the obligation to indicate a durability date. These characteristics are listed under A to E in this recommendation.
- The freezing of food products (referred to under F) prevents microbiological spoilage, which means that these products could also be included in Annex X. The cold chain must remain unbroken at all times.
- "Deli salads", as referred to in the Working Document, have not been reliably proven to have a very long shelf life.
- The following products referred to in the Working Document: dry pasta, couscous/semolina and other similar foods, coffee/tea, rice, instant powder (low

in fat), dried spices and flour, meet the product criteria proposed in this recommendation and can therefore be added to Annex X of the labelling directive. Water, provided it is of drinking water quality, which also does not support bacteria growth, could also be added to the list of exemptions.

- Canned products must meet the criteria set out in this recommendation.
- The other products mentioned in the Working Document (a to d) only qualify for addition to Annex X of the labelling directive if they can be demonstrably classified in category IV.
- More extensive research into product and process characteristics, such as the combination of pH, aw and concentrations of salt and/or nitrite/nitrate, could produce additional criteria for updating the exemptions from the obligation to indicate a date of minimum durability. The basic principle here is once again to prevent microbiological spoilage. It will then need to be determined on a case-by-case basis which group of food products can be included in Annex X of the labelling directive without leading to health risks.
- Biogenic amine formation could occur in fermented products – such as cheese and meat – however, it is unclear what risk this poses to human health.
- The products listed in Annex X of the labelling directive can continue to be exempted from the obligation to indicate a durability date.

On the basis of these conclusions, the answers to the questions posed are as follows:

Re 1. There are "quick win" options for extending the exemption list in the labelling directive as described in this recommendation under I to IV.
Re 2. Criteria that products must meet in order to qualify for an exemption from the obligation to provide a durability date as referred to in Regulation (EU) No 1169/2011 are listed under A to F.
Re 3. Not all products in the Working Group's Working Document are by definition suitable for exemption from the obligation to indicate a durability date. The BuRO particularly has doubts about "deli salads".
Re 4. There are some products that meet the criteria, but that cannot be exempted. In order to guarantee their desired quality, foods designed for specific groups of people and which deterioration, other than microbiological spoilage, affects this groups health, must bear a date mark. Examples include dried infant formulae and dietary foods for special medical purposes.

Recommendation

Date
21 June 2016

Our reference
NVWA/BuRO/2016/152

To the Minister of Health, Welfare and Sport and the State Secretary of Economic Affairs

- Base the extension of Annex X of the labelling directive regarding products that are exempted from the obligation to indicate a durability date on objective process and/or product criteria that products or product groups must meet and lay down these criteria.
- Do not base the composition of Annex X on exemptions that apply in other countries outside the EU until it is clear whether these other countries apply the same objective process and/or product criteria as the Netherlands or the European Union.
- Encourage the provision of information to consumers on the durability of food products in general and about the storage of food products without a durability date in particular in order to combat food waste without placing food safety at risk.

Yours sincerely,

Prof. Dr. A. Opperhuizen
Director of the Office for Risk Assessment and Research

EVIDENCE USED AS A BASIS FOR THIS ADVISORY REPORT

Background: food waste

The Dutch government is looking for different options to combat food waste in the context of sustainability. For instance, the government commissioned an initial study in 2010 and a follow-up study in 2013 into food waste by consumers (van Westerhoven & Steenhuisen, 2010; van Westerhoven, 2013). These studies show that, in 2010 and 2013 respectively, consumers wasted 44 kg and 47 kg of food per year that was still fit for consumption, not including the inedible parts of a product such as bones, peelings and coffee grounds. One of the reasons mentioned for avoidable food waste is expiry of the durability date indicated on the product. The starting points for combating food waste will need to focus on this and other aspects. According to Van Westerhoven and Steenhuisen (2010), "conducting a review of the policy on durability dates and taking action on the basis of the outcome, for instance with a different presentation and/or with accompanying information" would have the greatest impact.

Background: Best-before date

In order to make a recommendation on the extension of the list of products that do not need to be labelled with a date of minimum durability, it is important to know why food products need to be provided with such a date. This obligation is laid down in the above-mentioned Regulation (EU) No 1169/2011. The Regulation distinguishes between two different types of durability dates: the date of minimum durability and the 'use by' date. The date of minimum durability is the date up to which the food product retains its specific characteristics, provided it is stored correctly. In the Netherlands, this is indicated by the words *"ten minste houdbaar tot (einde)" (THT)* ("best before (end)" (BBE)) preceding the date. For food products that are highly perishable from a microbiological perspective and can therefore present an immediate risk to human health after a short period of time, the date of minimum durability is replaced with a 'use by' date. In the Netherlands, this is indicated by the words *"te gebruiken tot" (TGT)* ("use by " (UB)) preceding the date. After the 'use by' date, a food product is deemed unsafe in accordance with Article 14, paragraphs 2 to 5 inclusive, of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. One of the aims of the labelling directive is to ensure a high level of health protection for consumers. Where this food information legislation makes food information mandatory, this concerns information about aspects such as

1. the identity and composition, properties or other characteristics of the food product;
2. the nutritional characteristics; and
3. the protection of consumers' health and the safe use of a food product, including durability and storage.

If we disregard the legislative framework, strictly speaking it is only necessary to provide a durability date for food products whose specific characteristics change (in a negative sense) during their shelf life. This can involve quality aspects (flavour, smell, texture, loss of vitamins and so on) or food safety. Food safety has a negative definition in law, in the sense that a food product must not be unsafe. The term "unsafe" is defined as (Regulation (EC) No 178/2002, Article 14, paragraph 2):

a) injurious to health; or
b) unfit for human consumption.

However, the labelling directive also features a list of product and product groups that are exempted from the obligation to provide a date of minimum durability; this list appears in Annex X of the regulation. The food products and groups of products are as follows:

1. fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated; this derogation shall not apply to sprouting seeds and similar products such as legume sprouts;
2. wines, liqueur wines, sparkling wines, aromatised wines and similar products obtained from fruit other than grapes, and beverages falling within CN code 2206 00 obtained from grapes or grape musts;
3. beverages containing 10 % or more by volume of alcohol;
4. bakers' or pastry cooks' wares which, given the nature of their content, are normally consumed within 24 hours of their manufacture;
5. vinegar;
6. cooking salt;
7. solid sugar;
8. confectionery products consisting almost solely of flavoured and/or coloured sugars;
9. chewing gums and similar chewing products.

The government is exploring the possibility of no longer stating this date for food products with a (very) long shelf life as one of the options for changing the rules on indicating a durability date. After all, food products that fall into this category are not unsafe for consumption the day, week or month after expiry of their durability date. Even after the currently mandatory date of minimum durability, products with a long shelf life remain safe for consumption for some time. In the context of reducing food waste, it is important to be aware that only four – five kg of avoidable food waste by consumers consists of unopened products (van Westerhoven & Steenhuisen, 2010). This category includes products with a long shelf life, but also pre-packaged (highly) perishable food products. Furthermore, research has shown that product groups for which expiry of the durability date is a key reason for waste are meat, fish, sauces, cheese, dairy products, fruit juices and beer. The top five products responsible for avoidable food waste in the Netherlands in 2013 were dairy, bread, vegetables, fruit and sauces & fats (van Westerhoven, 2013). Only a

small percentage of these products (hard cheese, dry sausage and sauces) could qualify for exemption from the obligation to provide a durability date.
It is therefore still unclear how great a reduction in food waste can be achieved by extending the list in Annex X of the labelling directive with products that have a very long shelf life. For this reason, in order to reduce food waste one also needs to look at other options relating to the use of durability dates and consumer action based on these dates.

Background: different types of food spoilage
Food products become unsafe as a result of spoilage (in Dutch "bederf"). The Dutch dictionary ("Van Dale"; den Boon & Hendrickx, 2015) gives the following definition of "bederf":

1) the contamination of organic matter by mould, bacteria, etc. -> putrefaction, rot, rotting, decomposition;
2) to degenerate, to become worse -> deterioration.

In English the word "perish" is also used, defined as "lose its normal qualities"

Food products can be affected by different types of spoilage (Wijtzes et al., 2007). The definition of spoilage provided under point 1) refers to the microbiological spoilage of food products. The definition under point 2) also includes chemical, biological and physical deterioration. It is also important to understand that a spoilt (in the broadest sense) food is not necessarily unsafe. For example, wine that has become sour can still be consumed without any health effects. And vice versa – an unsafe food product is not always visibly spoilt. Just a few pathogenic micro-organisms such as bacteria or viruses are all it takes to make a person ill (Atmar et al., 2013; Schmid-Hempel & Frank, 2007). These quantities are invisible to the naked eye.

Physical deterioration
Physical deterioration of food products can often be detected through the senses and does not necessarily result in a harmful product. Examples of physical deterioration include drying out or absorbing water, damage resulting from freezing, crystallisation and settling, but also mechanical damage (Wijtzes et al., 2007). This has no impact on consumer health, however it can indirectly affect the occurrence of other types of spoilage. A dry product that has absorbed water may consequently become a breeding ground for (pathogenic) micro-organisms. Or an apple bruised by a fall can turn mouldy (microbiological spoilage).

Biological deterioration
Biological deterioration refers to infestation by pests such as maggots, worms or mice (Wijtzes et al., 2007). This type of deterioration is more dependent on storage conditions than on the storage period. This type of deterioration is not affected by a durability date, therefore biological deterioration has not been taken into account in this recommendation.

Chemical deterioration

This type of spoilage involves a reduction in the quality of the food product due to chemical reactions (Wijtzes et al., 2007). For example, chemical deterioration can occur under the influence of light and oxygen, leading to discolouration and changes in the flavour of a product. Other examples are bleaching of preserved vegetables, loss of flavour in beer caused by glass or lupulin, or the development of a rancid taste. High-acid canned products, such as tomato products, are known to undergo a sensory deterioration as well as a reduction in nutritional value over time as a result of corrosion of the can (USDA-FSIS, 2015).
Chemical deterioration is sometimes caused by enzymatic reactions: enzymatic browning of fruit (discolouration), breakdown of pectins in fruit (loss of texture), loss of vitamins; or oxidative reactions: greening in potatoes, rancidity (fax oxidation, e.g. of crisps) (Wijtzes et al., 2007).

Chemical and physical reactions during a food product's shelf life often lead to reduced quality, which can make the product unfit for consumption. If the product is already potentially harmful, the organoleptic changes that have taken place will in most cases prevent consumption (Wijtzes et al., 2007). One exception to this is biogenic amine formation. This is a type of enzymatic deterioration involving enzymes from micro-organisms. The most toxic biogenic amines are histamine and tyramine.

Based on consumer exposure to these biogenic amines, the most important products in terms of food safety that contain histamine are fish and fish products, fermented vegetables, cheese and fermented sausage. The main products that contain tyramine are fermented sausage, fish and fish products, cheese and fermented vegetables (Office for Risk Assessment, 2010; EFSA BIOHAZ Panel, 2011). However, there is still a lack of clarity on the toxicity of the various biogenic amines and the associated concentrations in different food products.

Microbiological spoilage

Microbiological spoilage can cause food products to become harmful.
Microbiological spoilage involves the undesired growth or metabolic activity of bacteria, mould or yeast (Wijtzes et al., 2007). This can eventually be detected through the senses, such as a mouldy piece of bread or cheese, strong-smelling fish or curdled milk.
However, food products can be microbiologically unsafe without any visual or olfactory evidence of growth or metabolic activity of micro-organisms. This concerns disease-causing micro-organisms, known as pathogens, which include bacteria (e.g. *Salmonella*, *Listeria*, STEC, *Campylobacter*), viruses (e.g. hepatitis A virus, norovirus), parasites, including protozoa (e.g. *Giardia*, *Cryptosporidium* and *Toxoplasma*) and helminths (worms; e.g. *Anisakis* and *Trichinella*). These pathogens can cause illness in humans even at low numbers (Atmar et al., 2013; Schmid-

Hempel & Frank, 2007), which means that significant growth leading to high cell numbers is not always necessary. Food can easily get contaminated with these low numbers of micro-organisms from the environment, or via contact with humans or raw materials. For instance, meat can become contaminated with *Salmonella* and STEC during a poorly managed slaughtering process (faecal contamination) (Rhoades et al., 2009) and food can get contaminated with viruses via symptomatic or asymptomatic individuals involved in food preparation, or via contaminated water (Cliver, 1997). *Salmonella* and STEC can potentially grow in food, however this is of minor relevance given that even small numbers of these pathogens can cause illness (Schmid-Hempel & Frank, 2007). Viruses and parasites do not grow on food products at all, as they need a host cell. In the case of the hepatitis A virus and norovirus, the host is (usually) a human being (Duizer et al., 2015; Petrignani, 2015). However, there are also pathogenic micro-organisms that only become hazardous to health when present in higher numbers (Schmid-Hempel & Frank, 2007). These include pathogens such as *Listeria monocytogenes*, which presents a health risk from 100 colony-forming units (cfu)/g of product. This is therefore the standard that food products are required to meet (Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs). *Bacillus cereus*, *Clostridium perfringens* and *Staphylococcus aureus* also only become hazardous to health when higher number of cells are present in food. The standard for these pathogens in the Netherlands is 100,000 cfu/g (*Warenwetbesluit Bereiding en behandeling van levensmiddelen*). These numbers are usually only reached following growth in the product. However, this growth and any toxin formation (by *B. cereus* and *S. aureus*) does not lead to apparent spoilage of the product. Here too, environmental contamination alone can result in levels of contamination with the potential to cause illness in humans (CDC, 2015; Fitz-James et al., 2008).

Background: microbiological food safety

Food safety starts with preventing contamination of the food product by following good hygiene practices throughout the production process. Microbiological food safety, on the other hand, is based on eliminating the risks or reducing these risks to an acceptable level, for which it is necessary (and mandatory) to produce food products using HACCP (Hazard Analysis and Critical Control Points) based procedures (Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs).

Whether the number of bacteria present remain at an acceptable level depends on a food product's bacterial growth potential. This growth potential is determined on the one hand by the characteristics of the bacteria itself, and on the other by the intrinsic properties of the food product (e.g. pH, aw and so on) and extrinsic factors such as impact of the production process (heating, drying), the type of packaging (airtight, antimicrobial) and the storage conditions (light, temperature, humidity) (Wijtzes et al., 2007).

For many of these factors it is possible to specify growth/no growth limits with regard to microbiological spoilage or growth of pathogenic bacteria. For example, micro-organisms do not grow below a certain temperature, such as in a freezer. The same applies to the pH and aw of a product (Figure 1 and Table 1). A combination of various milder growth-inhibiting conditions can also sufficiently delay or prevent bacterial growth so as to ensure that a product has an acceptable shelf life. Table 2 provides an overview of the risk of growth and toxin formation of/by pathogenic micro-organisms; more stringent requirements apply to preventing spoilage. A product can also be made microbiologically safe by heating it to a temperature that eliminates vegetative cells, mould spores and, at much higher temperatures, bacterial spores (Wijtzes et al., 2007). To ensure that a product is microbiologically stable, any subsequent contamination must then be avoided. The same applies to spore growth, which means that the packaging must be hermetically sealed.

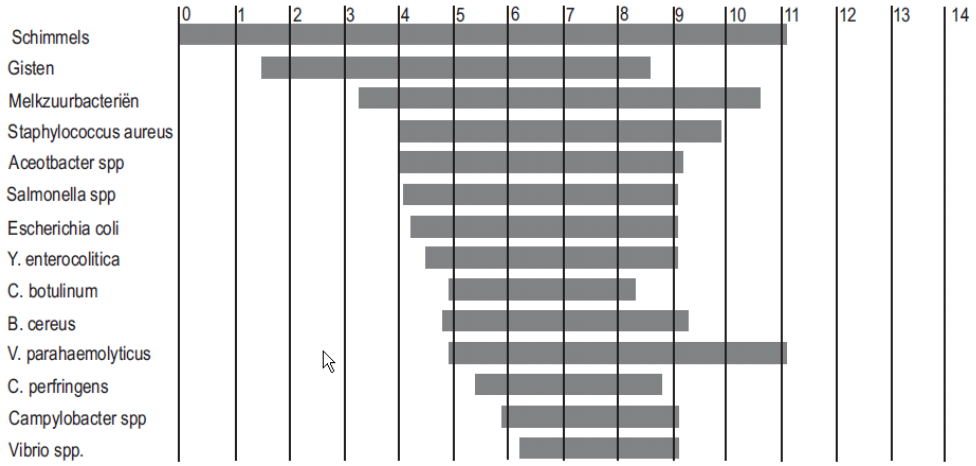

Figure 1. Overview of micro-organism pH ranges in terms of growth potential (taken from (Wijtzes et al., 2007)). Explanation: Schimmels = moulds; gisten = yeast; melkzuurbacteriën = lactic acid bacteria.

Table 1. Overview of micro-organism growth limits in relation to the water activity of a food product (adapted from (Beuchat, 1931))

a_w range	**Micro-organisms whose growth is inhibited by the lowest a_w value in this range**
1.00 – 0.95	*Pseudomonas*, *Escherichia*, *Proteus*, *Shigella*, *Klebsiella*, *Bacillus*, *Clostridium perfringens*, *C. botulinum* E and G, some yeasts
0.95 – 0.91	*Salmonella*, *Vibrio parahaemolyticus*, *C. botulinum* A and B, *Listeria monocytogenes*, *Bacillus cereus*
0.91 – 0.87	*Staphylococcus aureus* (*aerobic*), many yeasts (*Candida*, *Torulopsis*, *Hansenula*, *Micrococcus*)
0.87 – 0.80	Most fungi (*mycotoxigene penicillia*), *S.aureus*, most *Saccharomyces* (*bailii*) *spp.*, *Debaryomyces*
0.80 – 0.75	Most halophilic bacteria, *mycotoxigenic aspergilli*
0.75 – 0.65	*Xerophilic fungi* (*Aspergillus chevalieri*, *A. candidus*, *Wallemia sebi*), *Saccharomyces bisporus*
0.65 – 0.61	Osmophilic yeasts (*Saccharomyces rouxii*), some fungi (*Aspergillus echinulatus*, *Monascus bisporus*)
<0.61	All bacteria, fungi and yeasts

Table 2. pH/a_w combinations whereby products can be stored without refrigeration[a] and do not support the growth of pathogenic micro-organisms (U.S. Public Health Service & FDA, 2013)

A: Heated, packaged products: test for spores			
a_w	**pH**		
	<4.6	4.6 – 5.6	>5.6
<0.92			
0.92 – 0.95			
>0.95			

B: Unheated or unpackaged heated products: test for spores and vegetative cells				
a_w	**pH**			
	<4.2	4.2 – 4.6	4.6 – 5.0	>5.0
<0.88				
0.88 – 0.90				
0.90 – 0.92				
>0.92				

[a]: room temperature: <21°C;

green: unrefrigerated storage with no risk of growth;
red: risk of growth when stored unrefrigerated.
The sole aim of the research was to identify "quick win" options for the extension of Annex X of the labelling directive. The instruction was to focus the research on products that are reliably proven to have a very long shelf life, and whose key product characteristics ensure that they do not present any major health risks.

The literature study carried out for the purpose of answering this question shows that pathogenic micro-organisms are the most important factor to be taken into account when exempting products from the obligation to indicate a date of minimum durability in the context of food safety. Food is microbiologically safe/stable if it is free from (pathogenic) micro-organisms, or, if contaminated by bacteria in numbers that do not present a health risk, growth of (pathogenic) micro-organisms is not supported during shelf life. This concerns products that

I. are and remain sterile; or for which
II. under normal conditions the shelf life after production is so short that no spoilage can occur (fresh products that are supplied daily); or whose
III. spoilage is clearly visible to the consumer and occurs at a faster rate than the rate at which the product becomes (microbiologically) harmful; or in which
IV. the growth of (pathogenic) micro-organisms is not supported, or the micro-organisms even die off, due to the product characteristics, e.g. acidity (pH) and water activity (a_w), or storage conditions.

Based on the questions to be addressed, the literature study focused on products that fall within the above categories I and IV. It is possible to conclude that if a food product meets the following criteria, it can be regarded as microbiologically stable and may qualify for addition to the list of products in Annex X of the labelling directive that are exempted from the requirements to indicate a durability date:

A. sterilised in a can: food safety is guaranteed by the heating stage, sometimes in combination with the pH, and the fact that it is impossible for the product to be subsequently contaminated by micro-organisms; or
B. sterilised in other hermetically sealed packaging; or
C. water activity (a_w) <0.60; or
D. acidity (pH) <3-4 (depending on the type of acid: organic or inorganic); or
E. products with a lower a_w plus an additional inhibiting factor: a_w <0.85 + low pH or use of preservative; or
F. storage temperature < -18°C.

The products referred to under A and B fall within category I above and the other products under category IV. The product must be stored under suitable conditions, specifically at a temperature <21°C, humidity <50%, and the packaging must be undamaged. If the storage conditions are important for the durability of the product, this information must be indicated on the packaging. For instance, canned

products are known to be at risk of spoilage when stored at a higher temperature, therefore canned products destined for the tropics undergo a different production process to products destined for a non-tropical climate (Heinz & Hautzinger, 2007; USDA-FSIS, 2015).

Some pathogens (e.g. *Salmonella* and spore-forming bacteria) can survive for a longer period in food products that fall within the proposed product groups based on pH and/or a_w values. Like frozen products, these products are therefore microbiologically stable in the sense that no bacterial growth can occur, and in some cases bacteria will even die off, but this does not mean that they cannot contain (pathogenic) micro-organisms and therefore do not pose a health risk (CDC, 1999; FAO & WHO, 2014). However, the risk will not increase during the shelf life. In addition, category D products will still have the potential for mould and yeast growth. Yeasts only cause food spoilage, and mould growth will often eventually lead to visible deterioration. This spoilage will therefore not lead to any significant health risk, assuming that consumers throw away products with visible spoilage. The criteria proposed here (A to E) that food products must meet to qualify for exemption from the obligation to indicate a durability date are "quick win" options that reliably ensure that products have a very long shelf life without posing any major health risk. More extensive research may reveal room for manoeuvre in terms of the strict limits proposed here (Singh & Shalini, 2016). Moreover, products/product groups can also be exempted on a case-by-case basis (see also below under “Evaluation of the Working Document”). The above-mentioned room for manoeuvre can be sought in areas such as the term "potentially hazardous food" used in some countries, where food that does not belong to this category is therefore non-potentially hazardous. The types of criteria used correspond, amongst other things, with those used in this recommendation (pH, a_w), however they are not aimed at preventing microbiological growth in general, but solely on that of pathogenic micro-organisms. This means that the products will not become hazardous during their shelf life, however they may become unfit for consumption. According to the FDA Food Code (U.S. Public Health Service & FDA, 2013), "potentially hazardous food" in the United States includes products that must be refrigerated because they support the (rapid) growth of pathogenic micro-organisms. Products that do not fall within this category include food products with a a_w <0.85[3] or a pH <4.6, food products in an unopened hermetically sealed and industrially produced container designed to be and remain sterile during unrefrigerated storage and distribution, and food products proven by laboratory tests not to support the (rapid) growth of pathogenic micro-organisms, for instance products with a pH> 4.6 and a_w >0.85 containing an added preservative or other barriers to bacterial growth. Canada also uses a pH <4.6 and a_w <0.85 for food products that are not "potentially hazardous", however the pH value of some products with an extended shelf life must be lower due to the risk of *Salmonella* (Institute of Food Technologists, 2001).

[3] The Codex Alimentarius defines "low moisture food" as that with an a_w value <0.85 (Codex Alimentarius, 2015).

The pH and a_w values used in this recommendation are limits that result in food products that are reliably proven not to support the growth of (pathogenic) micro-organisms. Micro-organisms cannot grow at a_w <0.6, while the limit of 0.85 is based on the lower limit for pathogenic growth potential. *S. aureus* is the pathogen with the lowest known a_w lower limit, and can produce toxins from a_w=0.85. The pH lower limit for pathogenic micro-organisms is determined by *Salmonella spp*., which can grow from a pH as low as 3.8 (Institute of Food Technologists, 2001). The *S. Panama* strain, which caused an outbreak in the Netherlands via fresh fruit juice consumption, has even been known to grow from pH 3.4 (Noël et al., 2010).

However, in addition to the fact that food must not be hazardous in general, in other words must not cause illness or negative health effects, there are also products aimed at groups of people whose general health is almost entirely dependent on a special diet. This includes infant formulae and foods for special medical purposes. This food contains nutrients that are essential for general growth and development or improving the health of specific groups of people. Even if these products meet the criteria proposed in this recommendation and could therefore be exempted from the mandatory indication of a a durability date, it is unwise not to indicate a durability date on these products related to chemical and/or physical deterioration of the product. Products such as powdered infant formulae must always feature a durability date, including in the US, Australia and New Zealand: countries that exempt a broader range of food products from the obligation to provide a durability date than the EU. The basis for this decision in US law is that, unlike almost all other food products, powdered infant formulae is often the only source of nutrients for a vulnerable target group undergoing a phase of rapid growth and development (FDA). In the case of infant formulae, the durability date guarantees the retention of the nutritional values stated on the packaging. The product must also still have an acceptable quality, such as dissolving well (FDA, 2015b).

Evaluation of the Working Document

<u>List of products and product groups already exempted</u>

As previously stated, Annex X of the labelling directive lists food products that do not require an indication of the date of minimum durability. They are:

1. fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated; this derogation shall not apply to sprouting seeds and similar products such as legume sprouts;
2. wines, liqueur wines, sparkling wines, aromatised wines and similar products obtained from fruit other than grapes, and beverages falling within CN code 2206 00 obtained from grapes or grape musts;
3. beverages containing 10 % or more by volume of alcohol;
4. bakers' or pastry cooks' wares which, given the nature of their content, are normally consumed within 24 hours of their manufacture;
5. vinegar;

6. cooking salt;
7. solid sugar;
8. confectionery products consisting almost solely of flavoured and/or coloured sugars;
9. chewing gums and similar chewing products.

These products fall within the microbiologically safe product groups II to IV described earlier in this document, with some also falling within categories C and D proposed in this recommendation.

Proposed list of products and product groups to be added to Annex X

The following products and/or product groups are put forward in the Working Group's Working Document as potential additions to Annex X of Regulation (EU) No 1169/2011:

a) shelf-stable dry fermented sausages (pepperoni, salami not labelled as "keep refrigerated");
b) preserved fish products such as pickled herring, dried or salted cod;
c) salt-cured products;
d) hard cheeses such as pecorino;
e) deli salads;
f) canned foods;
g) dry pasta (macaroni, spaghetti, etc.);
h) couscous, semolina and similar foods;
i) coffee, tea;
j) rice;
k) instant powder (low in fat);
l) dried spices;
m) flour;
n) water.

Products a to e are exempted from the obligation to provide a durability date in the US, in those cases where there is indeed an obligation to provide a durability date, for instance in the catering industry once the packaging has been opened. At federal level, there is no obligation in the US to provide consumers with a durability date. The exemptions mentioned only apply to products produced by a food manufacturing company, in other words not a catering or artisanal establishment, which is inspected by the competent authority (U.S. Public Health Service & FDA, 2013). The focus is, furthermore, on preventing growth and toxin formation by pathogenic micro-organisms, and not on spoilage in general.

Re a

In the US, dry fermented sausages that can be stored at room temperature do not need to be labelled with a durability date or the instructions "keep refrigerated". The shelf life of these products is guaranteed by the added nitrite and salt and the

low pH resulting from the fermentation process. Products must meet objective criteria in order to be labelled "can be kept at room temperature" (U.S. Public Health Service & FDA, 2013). A number of criteria have been defined (USDA-FSIS, 2005); for dry sausage, this concerns a prescribed moisture-protein ratio. For semi-dry sausage, the criterion is also a prescribed moisture-protein ratio, possibly in combination with a low pH (<5.0) or, alternatively, the following criteria: pH <4.5 (or pH <4.6 and a_w <0.91), intact product (or, if cut, vacuum packed), internal brine concentration of >5%, preserved with nitrite or nitrate and wood-smoked. In Canada, fermented meat products must also meet certain criteria in order to be marketed without being labelled "keep refrigerated". The criteria relate to the concentration of nitrite/nitrate (100 ppm) and salt (2.5%) in order to prevent the growth and toxin formation of *C. botulinum*, in combination with either pH (<4.6) or a_w (<0.85) or a combination of pH/a_w (<5.3/0.9) (CFIA, 2014).
The FAO also applies objective criteria to the durability of dry fermented sausage. These products must have a moisture content below 35%, however in practice the content is often below 30%, with a corresponding a_w of 0.9 or less. The pH varies from 5.0 to 5.5. This means that the products, under moderate climatic conditions (approx. 20°C and humidity 70 – 75%) have a long shelf life at room temperature (> one year) (Heinz & Hautzinger, 2007).

In the Netherlands, guidelines for the production of dry fermented sausage are set out in the hygiene code(national guide to good practice) for butcher's, Hygiënecode voor Slagersbedrijf (Royal Dutch Association of Butchers (*Koninklijke Nederlandse Slagersorganisatie*), 2010). Various standards are met if the recipes provided are adhered to. These products must have a pH of at least 5.0 – 5.2 or lower depending on the calibre (Mulder & Lenssinck, 1987), and drying is defined as 20 – 30% or more weight loss from the original weight (Research Committee of the Butcher's Trading Organisation (*Bedrijfschap Slagersbedrijf*), 1993). Butchers in the Netherlands have been known to sell these dry fermented sausage not fully dried (pers. comm. Paul van Trigt, 2015). This is also evident from NVWA monitoring data (unpublished NVWA data, 2011), which revealed that 50% of the dry fermented sausage sold by artisanal sausage producers had a pH >5.0, 45% had a pH >5.2, and the a_w in 59% of cases was >0.85 and in 41% >0.90.

In addition to the fact that butchers (non-industrial producers) do not always comply with the standard pH and a_w values for dry fermented sausage, there is also a trend towards reducing salt levels. The amount of salt in meat products originating in the Netherlands and sold in Dutch supermarkets fell by 15% between 2013 and 2015 for "raw products"[4], including cervelat and salami (Kester, 2015). This reduction in salt could have an impact on the shelf life of these products.

[4] The "raw products" referred to in the research fall within the categories "minced meat and meat preparations intended to be eaten raw" and "meat products intended to be eaten raw" in Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs.

The term "dry sausage" therefore needs be defined in greater detail using criteria if these products are to be included in Annex X. Drafting such criteria falls outside the scope of this research. Next to microbiological spoilage, fermented products, including this type of sausage, are high-risk products in terms of biogenic amine formation (Office for Risk Assessment, 2010; EFSA BIOHAZ Panel, 2011).

Re b
In the US, preserved fish products such as pickled herring and dried or salted cod are excluded from the obligation to provide a durability date due to the acidity and/or high salt content in these products. These properties prevent the growth of *L. monocytogenes* in these products. In acidified products, such as pickled herring, the eventual pH of the product must be <4.6 (FDA, 2015a).
This pH does not directly comply with a criterion as stipulated in this recommendation. Further research is required to determine whether this type of product qualifies for addition to Annex X.

Re c
Due to the current health trend towards a lower salt diet, the term "salt-cured products" could lead to products that fail to meet the expectations arising from the term "salt-cured products" as used in this document. For instance smoked meat, which is preserved by means of a drying and salt-curing process, previously tended to have a much longer shelf life, however the use of lower salt levels means that it is gradually becoming a chilled product (pers. comm. Paul van Trigt). Shelf life is also determined by the pickling method. Meat cured via the injection of brine, an accelerated pickling process, has a shorter shelf life than products that undergo a longer, traditional salt-curing process (Heinz & Hautzinger, 2007). It is no coincidence that the salt-cured meat products that are exempted from the obligation to provide a durability date or to be labelled "keep refrigerated" in the US are obtained through dry salting and not through brine injection or wet salting. These are products such as prosciutto, "country cured ham", Parma ham, pastirma, bresaola, coppa and capicola. The shelf life of these products is determined by their low moisture content, with a weight loss of >18% during the production process, and by the nitrite content and smoke. However, the inside of these products have a higher aw than the outside, which means that slices of these products can indeed support the growth of *S. aureus*. Slices must therefore be kept refrigerated with a recommended shelf life of two – three months (U.S. Public Health Service & FDA, 2013). It should also be noted that a whole country ham has a shelf life of at least one year, however loss of quality can occur after this period (CFIA, 2014).

Re d
In the US, cut hard cheese is exempted from the obligation to provide a durability date. These are cheeses with a moisture content lower than 39%, and that need to be kept refrigerated. This prevents the growth of *L. monocytogenes* (U.S. Public Health Service & FDA, 2013). It is not clear whether the growth of non-pathogenic

micro-organisms can still lead to spoilage. Spoilage can be caused by more or less stringent osmophilic fungi, for example in Pecorino Romano (Mangia et al., 2011). If the a_w value is less than 0.6, the risk of growth is almost zero. Cheeses, like fermented sausage, are also high-risk products in terms of biogenic amine formation (Office for Risk Assessment, 2010; EFSA BIOHAZ Panel, 2011).

Re e
The exemption of deli salads to bear a date mark in the US is based on a risk assessment study showing that industrially produced deli salads in the US do not support the growth of *Listeria monocytogenes* due to their acidity and added preservatives combined with refrigeration (U.S. Public Health Service & FDA, 2013). However, the Canadian inspection service removed various deli salads from the shelves in April 2016 due to possible *Listeria* contamination (FDA, 2016). The situation with regard to these types of salads in the EU, and whether these products can be regarded as having a very long shelf life, is unknown.

Re f
Not all canned products can necessarily be stored at room temperature, for example certain types of ham and fish (USDA-FSIS, 2015). The exemption can only apply to products such as those proposed under category A of this recommendation, namely sterilised canned products.

Re g to m
Products g to m all have an a_w<0.6 (Schmidt & Fontana, 2008), which means that they fall within category IV based on the limit proposed in this recommendation (C).

Re n
Finally, water (of drinking water quality) contains no nutrients to support growth of micro-organisms, and therefore also falls within category IV.

<u>Extension of Annex X</u>
As shown, many of the food types discussed that are exempt from the obligation to provide a durability date in certain countries often meet (or should meet) a reasonably limited set of criteria. To avoid a lack of clarity regarding the definition of different products, these criteria must be determined and laid down for each product or product group based on scientific evidence . During this process it is important to establish whether the focus should lie solely on harmfulness (pathogenic micro-organisms) or also unfitness (general spoilage caused by micro-organisms), whereby the latter will usually be apparent. The drafting of these criteria falls outside the scope of this recommendation. To prevent Annex X of the labelling directive from becoming a long list of specific products, it is also advisable to formulate, if possible, objective, measurable criteria that products must meet to quality for exemption from the requirement to indicate a durability date.

In addition to the process and product criteria put forward in this recommendation, the Working Document proposes that the storage period specified by the manufacturer should be used as a guiding principle. As storage periods are determined partly on the basis of product and process characteristics, both types of criteria should result in reasonably similar product types if the manufacturer were to base its durability date solely on food safety. However, the use of criteria provides manufacturers with a guideline when determining the durability date, whereas, as stated in the Working Document, there are currently no guidelines for determining an accurate and consistent shelf life. As discussed earlier in this document, the quality of a product can deteriorate during its shelf life. The previous examples relating to preserved vegetables, beer and rancidity all involve a loss of sensory quality. High-acid canned food, such as tomato products, are known to undergo a sensory deterioration as well as a reduction in nutritional value over time as a result of corrosion. Another example is that loss of vitamins can occur, meaning that the product may no longer comply with the information indicated on the label. This is a punishable offence. These are factors that are also taken into account when determining a product's shelf life, which means that products may be labelled with a shorter shelf life than is necessary for food safety reasons. Further research is required to identify the types of food products mentioned under points C, D and E in this recommendation. Consequently, monitoring the absence of a durability date on products or product groups that may be exempted from this obligation based on one or two (combinations of) product characteristics requires additional effort that is not necessary from the perspective of food safety: one of the basic principles of the labelling directive. On the other hand, it is important in precisely this context to check that appropriate durability dates are provided for vulnerable, perishable products that could, for example, support the growth of *L. monocytogenes* (Newsome et al., 2014).

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Appendix 1 Front Office for Food and Product Safety of the RIVM/RIKILT - Assessment of best-before date products NVWA/BURO/2016/152

Date
21 June 2016

Our reference
NVWA/BuRO/2016/152