SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 21 October 2020

doi: 10.2903/j.efsa.2020.6306

Guidance on date marking and related food information: part 1 (date marking)

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Abstract

A risk-based approach was developed to be followed by food business operators (FBO) when deciding on the type of date marking (i.e. 'best before' date or 'use by' date), setting of shelf-life (i.e. time) and the related information on the label to ensure food safety. The decision on the type of date marking needs to be taken on a product-by-product basis, considering the relevant hazards, product characteristics, processing and storage conditions. The hazard identification is food product-specific and should consider pathogenic microorganisms capable of growing in prepacked temperature-controlled foods under reasonably foreseeable conditions. The intrinsic (e.g. pH and a_w), extrinsic (e.g. temperature and gas atmosphere) and implicit (e.g. interactions with competing background microbiota) factors of the food determine which pathogenic and spoilage microorganisms can grow in the food during storage until consumption. A decision tree was developed to assist FBOs in deciding the type of date marking for a certain food product. When setting the shelf-life, the FBO needs to consider reasonably foreseeable conditions of distribution, storage and use of the food. Key steps of a case-by-case procedure to determine and validate the shelf-life period are: (i) identification of the relevant pathogenic/spoilage microorganism and its initial level, (ii) characterisation of the factors of the food affecting the growth behaviour and (iii) assessment of the growth behaviour of the pathogenic/spoilage microorganism in the food product during storage until consumption. Due to the variability between food products and consumer habits, it was not appropriate to present indicative time limits for food donated or marketed past the 'best before' date. Recommendations were provided relating to training activities and support, using 'reasonably foreseeable conditions', collecting time–temperature data during distribution, retail and domestic storage of foods and developing Appropriate Levels of Protection and/or Food Safety Objectives for food–pathogen combinations.

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Keywords: date marking, best before date, use by date, food storage, shelf-life, reasonably foreseeable conditions, food donation

Requestor: European Commission

Question number: EFSA-Q-2019-00438

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Suggested citation: EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Koutsoumanis K, Allende A, Alvarez-Ordóñez A, Bolton D, Bover-Cid S, Chemaly M, Davies R, De Cesare A, Herman L, Nauta M, Peixe L, Ru G, Simmons M, Skandamis P, Suffredini E, Jacxsens L, Skjerdal T, Da Silva Felicio MT, Hempen M, Messens W and Lindqvist R, 2020. Guidance on date marking and related food information: part 1 (date marking). EFSA Journal 2020;18(12):6306, 74 pp. https://doi.org/10.2903/j.efsa.2020.6306

ISSN: 1831-4732

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The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

Summary

Following a request from the European Commission, the EFSA Panel on Biological Hazards (BIOHAZ) was asked for scientific opinions providing guidance on date marking and related food information in view of the application by food business operators (FBO) of Regulation (EU) No 1169/2011 on food information to consumers as an integrated part of their food safety management system (FSMS). The opinions should develop a risk-based approach to be followed by FBOs when deciding on the type of date marking, setting of shelf-life and the related food information that should be provided on the labelling in order to ensure food safety.

In particular, EFSA was requested to provide scientific advice in **ToR1** on the factors that make certain foods highly perishable and therefore likely after a short period, to constitute an immediate danger to human health and on how those factors should be considered by FBO when deciding whether a 'use by' date is required and setting the shelf-life and the required storage conditions, and in **ToR2**, on the factors that make certain foods become unfit for human consumption, but without constituting an immediate danger to human health. **ToR 3** provided advice, to avoid an increase in food safety risks, on the storage conditions and/or time limits for consumption after opening the package while **ToR 4** related to defrosting of frozen foods including good practices, storage conditions and/or time limits for consumption. ToRs 1 and 2 are addressed in this opinion (part 1 – Date marking), while ToRs 3 and 4 are covered in part 2 – Food information. Guidance is provided on the relevant microbiological hazards (pathogenic microorganisms) that should be taken into account by the FBO in determining whether a food is likely to constitute an immediate danger to human health and on the types of foods where these pathogenic microorganisms are more likely to be present. To assist in the identification of pathogenic microorganisms relevant for the shelf-life of perishable foods, data on pathogens of concern in different types of food categories and their ecological determinants for growth are reviewed, and information sources of food-borne outbreak data are indicated. Useful sources of information and a non-exhaustive summary of relevant bacterial pathogens capable of growing in prepacked temperature-controlled foods under reasonably foreseeable conditions are listed. The identification of relevant pathogenic microorganisms is food product-specific, and considering the huge variability in the food chain in terms of ingredients, product types, modes of processing and packaging, it is difficult to a priori exclude any of the pathogens able to grow at the currently used storage temperatures.

Guidance is also provided on the factors that might influence the growth of those pathogenic and spoilage (non-pathogenic) microorganisms and have an impact on: (1) the decision on whether a 'use by' date is required (only in case of pathogenic microorganisms), (2) the shelf-life and (3) storage conditions throughout the food chain and the intended use of the food. The raw materials, the processing environment and the manufacturing steps determine the type and the levels of microorganisms in the food product when released to the market. The intrinsic (especially pH and a_w), extrinsic (especially temperature and atmosphere) and implicit factors (such as interactions with competing background microorganisms of the food product determine which microorganisms can grow and their growth potential during subsequent storage until consumption. Information on growth-limiting factors is provided as a basis for guidance for decisions on the types of appropriate date marking and shelf-life. It is important for the FBO to understand the purpose and effect of the processes applied in the steps during manufacture, and examples are given on the potential impact of manufacturing processes on the prevalence and levels of microorganisms in the food product.

Finally, guidance is also given on how the identified factors influence the date marking decision (i.e. whether a 'use by' date is required or a 'best before' date is appropriate). This decision needs to be taken on a product-by-product basis, considering the product characteristics (intrinsic, extrinsic and implicit factors), processing and storage conditions. A decision-tree (DT) consisting of a sequential list of 10 questions, and supported with examples, was developed to assist FBOs in deciding the type of date marking. The reasoning is that, in the case of food products processed in a way that eliminates pathogenic microorganisms and avoids recontamination, or which do not support their growth, the risk to consumer health would not increase during shelf-life and a 'best before' date is appropriate. If there is no pathogen elimination step, or the possibility of recontamination after such a treatment, and the food product supports the growth of the contaminating pathogens, the consumer risk is expected to increase during shelf-life and a 'use by' date is required. Overall, it is considered that the DT will result in appropriate and consistent outcomes on the type of date marking within the interpretations of regulations and the assumptions made. The identified uncertainties are considered to result in a DT that may overestimate risk ('best before' food will end up with 'use by' date) for some food products,

unless the FBOs make appropriate use of the opportunity in the DT (Question 10) to demonstrate that their product does not support the growth of pathogens under reasonably foreseeable temperature conditions of distribution and storage, irrespectively of the time frame. The potential overestimation is partly a consequence of the lack of risk assessments and acceptable levels of hazards at the time of consumption.

Guidance is also provided on the setting of shelf-life and the required storage conditions, and on the identification of factors influencing the setting of shelf-life. 'Reasonably foreseeable conditions', as described in Regulation (EC) No 2073/2005, refers to the conditions of distribution, storage and use that the food product is likely to be exposed to when it has left the immediate control of the FBO, and which need to be considered when setting the shelf-life. In the case of 'use by' date, the shelf-life of a product should never be longer than whichever is the shortest between the 'sensory shelf-life' or the 'safe shelf-life'. The first relates to quality changes, in this opinion due to microbial growth, and the latter relates to the safety of foods. Except for guidelines for laboratories and FBOs on how to carry out shelf-life studies with regard to the *Listeria monocytogenes* microbiological criteria for RTE food established by Regulation (EC) No 2073/2005, and the ISO 20976-1, 20196-1:2009 guideline on how to conduct challenge tests, general guidelines with a wider scope regarding which factors to consider, and how to define the reasonably foreseeable conditions, have not been found. A case-by-case procedure to determine and validate the shelf-life of a food product should be applied and key steps are:

- to identify the relevant pathogenic/spoilage microorganism and estimate its initial levels,
- to characterise the intrinsic, extrinsic and implicit factors of the food product affecting the growth behaviour of the pathogenic/spoilage microorganism and,
- to assess the growth behaviour of the pathogenic/spoilage microorganism in the food product during storage, from retail to consumption to determine the time at which the pathogenic/spoilage microorganism will reach maximum acceptable levels under the appropriate reasonably foreseeable conditions.

Guidance is also given on the indicative time limits to be applied at EU level to facilitate marketing or donation of foods past the 'best before' date, provided that before the end of that period those foods shall not become unfit for human consumption. The available guidelines on food donations commonly cover a wider range of foods (not only 'best before' marked foods) and situations (e.g. donation of meals) than those within the scope of the present opinion, and do not cover marketing of foods past the 'best before' date. Food products eligible for donation are categorised based on their shelf-life with: (a) the most common characteristics of spoiled food for each shelf-life category indicated, (b) the recommended storage temperatures and an estimation of the time frame within which the food remains fit for distribution by food banks and charities once it has exceeded its date of minimum durability and (c) guidance on labelling and traceability of the donated food. Marketing of food past the 'best before' date is allowed in several countries under the responsibility of the seller provided that the food is fit for human consumption. Indicative time limits are either not provided, other than by highlighting the sensory properties of the food, or, when time limits are indicated, without providing their scientific basis. Due to the variability, among MS, between food products, and consumer habits, it was not considered appropriate to present indicative time limits for food donated or marketed past the best before date. However, the general principles, as outlined in EFSA BIOHAZ Panel (2018a) and Commission Notice 2020/C 199/01, can be applied across the EU.

Recommendations were provided relating to (a) training activities and support, particularly for small food businesses and laboratories, aimed at contributing to a better understanding of the microbial ecology of food and on the procedures to characterise the relevant factors determining shelf-life of perishable food, (b) collecting time–temperature data during distribution, retail and domestic storage of foods and carrying out consumer-based studies to generate better data to characterise reasonably foreseeable storage conditions of foods, (c) providing guidelines on how to use reasonably foreseeable conditions in date marking decisions and (d) developing appropriate level of protection (ALOP)/food safety objective (FSO) for most food–pathogen combinations.

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1. Introduction

1.1. Background and Terms of Reference as provided by the European Commission

1.1.1. Background as provided by the European Commission

Food waste prevention is a priority set out in the EU Action Plan for the Circular Economy adopted by the European Commission in December 2015.[1] As part of that Action Plan, the Commission has been called upon to examine ways to improve the use of date marking by actors in the food chain and its understanding by consumers. 'Date marking' is used as an umbrella term to refer both to the 'best before' and 'use by' dates. It is a prerequisite that initiatives aiming to reduce food waste should never compromise food safety.

A Commission study published in February 2018[2] estimated that up to 10% of the 88 million tonnes of food waste generated annually in the EU is linked to date marking. With the support of the sub-group on date marking and food waste prevention[3] of the EU Platform on Food Losses and Food Waste,[4] an immediate priority is the development of EU guidance based on the existing EU requirements in order to ensure more consistent date marking and related food information practices. The study also concluded that the date marking is particularly relevant for food waste prevention for the categories dairy products, fruit juices, chilled meat and fish.

It is important that food business operators (FBO) follow a risk-based approach when deciding on the type of date marking (i.e. 'use by' date versus 'best before' date), setting of shelf-life and the related food information that should be provided on the labelling in order to ensure food safety. Such risk-based approach should be an integrated part of the FSMS that all FBO are obliged to develop and implement under the current EU food safety legislation, taking into consideration previous scientific opinions of the European Food Safety Authority (EFSA) and Commission guidance.

Especially, clarity is needed on the differentiation between foods that at the end of shelf-life might constitute 'an immediate danger to human health'/become 'injurious to health' due to growth of pathogenic microorganisms, and foods that at the end of shelf-life might become 'unfit for human consumption' due to growth of spoilage non-pathogenic microorganisms.[5]

Therefore, in order to support FBO and national authorities in implementing correct and consistent practices, there is a need for the scientific advice of EFSA.

1.1.2. Terms of Reference as provided by EC

In accordance with Article 29 of Regulation (EC) No 178/2002, the European Commission asks EFSA for scientific opinions providing guidance on date marking and related food information in view of the application by FBO of Regulation (EU) No 1169/2011 on food information to consumers as an integrated part of their Food Safety Management System (FSMS).

The opinions should develop a risk-based approach to be followed by FBO when deciding on the type of date marking (i.e. 'use by' date versus 'best before' date), setting of shelf-life and the related food information that should be provided on the labelling in order to ensure food safety.

In particular, EFSA is requested to provide scientific advice on:

ToR 1. The factors that, from a microbiological point of view, make certain foods highly perishable and therefore likely after a short period to constitute an immediate danger to human health, and on how those factors should be considered by FBO when deciding whether a 'use by' date is required and setting the shelf-life and the required storage conditions, particularly on:

a) The relevant microbiological hazards that should be taken into account by FBO in determining whether a food, from a microbiological point of view, is likely to constitute an immediate danger to human health;
b) The types of foods where it is more likely to find those pathogenic microorganisms;
c) The intrinsic/extrinsic factors that might influence the growth of those pathogenic microorganisms and consequently have an impact on: (1) the decision whether a 'use by' is required, (2) the shelf-life (the period up until when a food is not likely to constitute an

[1] http://ec.europa.eu/environment/circular-economy/index_en.htm
[2] https://publications.europa.eu/en/publication-detail/-/publication/e7be006f-0d55-11e8-966a-01aa75ed71a1/language-en
[3] https://ec.europa.eu/food/safety/food_waste/eu_actions/date_marking_en
[4] https://ec.europa.eu/food/safety/food_waste/eu_actions/eu-platform_en
[5] Article 24(1) of Regulation (EU) No 1169/2011 and Article 14(2) to (5) of Regulation (EC) No 178/2002.

immediate danger to human health), either linked to the composition of a food (e.g. pH, a_w, presence of food additives) or to the production process and/or the way a food is marketed (e.g. production processes like pasteurisation, type of packaging), and (3) the storage conditions throughout the food chain and the intended use of the food;

d) How the factors identified above influence the decision whether a 'use by' date is required, the setting of shelf-life and the required storage conditions.

ToR 2. The factors that, from a microbiological point of view and limited to foods intended to be stored at controlled temperatures, make certain foods become unfit for human consumption, but still without constituting an immediate danger to human health, and on how those factors should be considered by FBO when deciding whether a 'best before' date is appropriate and setting the shelf-life and the required storage conditions, particularly on:

a) The intrinsic/extrinsic factors that might influence the growth of spoilage non-pathogenic microorganisms and consequently have an impact on: 1) the shelf-life (the period up until when a food is not likely to become unfit for human consumption); either linked to the composition of a food (e.g. pH, a_w, presence of food additives) or linked to the production process and/or the way a food is marketed (e.g. production processes like pasteurisation, type of packaging), and 2) the storage conditions throughout the food chain and the intended use of the food);
b) How the factors identified above influence the setting of shelf-life and the required storage conditions;
c) The indicative time limits to be applied at EU level to facilitate marketing or donation of foods past the 'best before' date, provided that before the end of that period those foods shall not become unfit for human consumption. Certain Member States (MS) have developed national guidance on this.[6]

EFSA is also requested to provide guidance to be considered by FBO when deciding on the food information to be provided to consumers regarding the shelf-life and the required storage conditions, particularly on:

ToR 3. Storage conditions and/or time limit for consumption after opening the package in order to avoid increase of food safety risks, particularly on:

a) The characteristics of a food and the intrinsic/extrinsic factors which might change once the package is opened, and specifically on which of those factors that should be taken into consideration when providing such information
b) The factors to be considered in deciding whether it is appropriate, and consequently mandatory, to indicate the storage conditions and/or time limit for consumption after opening the package according to Article 25(2) of Regulation (EU) No 1169/2011.

ToR 4. Defrosting of frozen foods including good practices, storage conditions and/or time limit for consumption in order to avoid increase of food safety risks, particularly on:

a) Advice to be given to consumers regarding good practices, storage conditions and/or time limit for consumption to protect consumers from possible health risks.

1.2. Interpretation of the Terms of Reference

The above terms of reference were discussed with the requestor of the mandate (EC). Some aspects were clarified and interpreted as explained below. The opinions should develop risk-based guidance to be followed by FBO when deciding on the type of date marking (i.e. 'use by' date vs. 'best before' date, see glossary), on the setting of shelf-life and on related food information to provide on the labelling in order to ensure food safety. This includes storage conditions and time limits for opened packages as well as storage conditions (ToR 3), time limits and good practices for thawing (defrosting) frozen foods (ToR 4). In addition, guidance should address indicative time limits for marketing or donation of food past the 'best before' date.

ToRs 1 and 2 are addressed in this opinion (Guidance on date marking and related food information: part 1 (Date marking), while ToRs 3 and 4 will be covered in part 2 (Food information). The wording of

[6] Italy – Guide to good practice for charitable organisations, Caritas Italiana, Fondazione Banco Alimentare Onlus, March 2016 (p. 29). Belgium – Circular on the provisions applied to food banks and charity organisations (FR; NL), Belgian food safety agency (Agence fédérale pour la Sécurité de la Chaine Alimentaire), 2017.

the terms of reference is based on the legal texts of Regulation (EU) No 1169/2011 and Regulation (EC) No 178/2002. Article 9, point (1)(f) and Annex X, points 1 and 2 of Regulation (EU) No 1169/2011 require that food is labelled either with a date of minimum durability ('best before' date) or a 'use by' date. A date of minimum durability ('best before' date) is not required for certain foods, such as whole fresh fruit and vegetables, wines and other beverages containing 10% or more (by volume; v/v) of alcohol, certain bakery products, vinegar, cooking salt, solid sugar and certain confectionery products.[7] Some foods have date marking specified by EU regulations (see Appendix A). This does not mean that foods exempt from a 'best before' date cannot be given a date label, if considered useful.

The date of minimum durability ('best before' date) means the date until which the food retains its specific properties when properly stored.[8] In the case of foods which, from a microbiological point of view, are highly perishable and are therefore likely, after a short period, to constitute an immediate danger to human health, the date of minimum durability shall be replaced by the 'use by' date. After the 'use by' date, a food shall be deemed to be unsafe in accordance with Article 14(2) to (5) of Regulation (EC) No 178/2002[9]. According to Article 14 point 2 of Regulation (EC) No 178/2002, food shall be deemed to be unsafe if it is considered to be: a) injurious to health; b) unfit for human consumption.

For the purpose of this opinion, it was agreed that, in relation to decisions on 'use by' date, foods described by the phrasing *'highly perishable and therefore likely after a short period to constitute an immediate danger to human health'* are interpreted as temperature-controlled foods that may carry pathogenic and/or toxigenic microorganisms and can support their growth during storage and before consumption, and therefore may be injurious to health.

In Regulation (EC) No 178/2002, unsafe food also includes food that is unfit for human consumption. In the present opinion, and *'from a microbiological point of view'*, the term 'unfit for human consumption' is considered related only to sensory food quality due to microbial growth not affecting health. Thus, the growth and levels of spoilage bacteria and the associated deterioration of sensory properties are the basis for decisions concerning food to be labelled with a 'best before' date. The shelf-life related to growth of non-pathogenic, spoilage causing, microorganisms will be referred to as the 'sensory shelf-life'.

Importantly, the decision on which type of date marking to apply is interpreted as being related only to whether the risk to human health can increase with time or not, i.e. growth of pathogenic microorganisms and/or toxin production can take place during transport and storage. This decision depends on the use and characteristics of the food and the relevant hazards. The shelf-life related to the potential growth of pathogens or toxin production will be referred to as the 'safe shelf-life'.

The foods of interest for both opinions are prepacked foods, both raw and processed, that are stored at controlled temperatures, i.e. lower than ambient temperature. This includes refrigeration temperatures and freezing temperatures. The indicative time limits for donation or marketing past the shelf-life in ToR 2c relate only to prepacked, temperature-controlled foods with a 'best before' date.

Since the ToRs are interpreted to relate to microbial growth during shelf-life, the pathogenic microorganisms of interest are bacteria, yeasts, moulds and their toxins (including biogenic amines/ histamine). Thus, hazards of relevance, hereafter referred to as pathogenic microorganisms, are those present in foods after processing and packaging, and which can potentially increase during shelf-life, i.e. growth and/or toxin production under reasonably foreseeable conditions. Secondary contamination of opened packages is not considered. Pathogenic microorganisms that cannot grow in food, such as food-borne viruses and food-borne parasites, are not of relevance for decisions on date marking.

1.3. Additional information

1.3.1. Considerations for decisions on date marking in relation to Regulation (EU) No 1169/2011

Several of the expressions used in Regulation (EU) No 1169/2011[10] to refer to food needing 'use by' date instead of date of minimum durability (i.e. 'best before'), e.g. 'highly perishable', 'short period',

[7] Annex X point (1)(d) of Regulation (EU) No 1169/2011.
[8] Article (2) point (2)(r) of Regulation (EC) No 1169/2011.
[9] Article 24 point (1) of Regulation (EC) No 1169/2011. According to Article 14 of Regulation (EC) No 178/2002, food shall be deemed to be unsafe if it is considered to be: a) injurious to health; b) unfit for human consumption.
[10] 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, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. OJ L 304, 22.11.2011, p. 18–63.

'immediate danger', are not explicitly defined. The probability of illness in any given host is a function of exposure, or the dose, and it will, in general, increase with increasing dose. The relation between the dose and the probability of illness is quantified by a dose–response relationship. The dose–response relationship for infectious microorganisms and human illness is usually continuous, i.e. there is no threshold below which the microorganism does not present a certain risk, although this risk may be very low. This means that if pathogens are present and growth is possible during storage, the human health risk will increase. This is also true for pathogens where legislation mandates absence (not detected) from food, commonly because these can cause illness without prior growth. If these pathogens are present, risk will increase if growth is possible. Thus, the answer to the question of when an 'immediate danger to human health' is present, will be a value-based decision according to acceptable probabilities of illness.

Microbial food safety criteria have been implemented for *L. monocytogenes* in ready-to-eat (RTE) foods, based on the concept of food safety objective (FSO) providing an appropriate level of protection (ALOP) in the population (European Commission, 1999; FAO/WHO, 2002; Gram, 2004), but such levels are not defined for most pathogens. For other pathogens, especially toxin-producing bacteria such as *Staphylococcus aureus* and *Bacillus cereus*, different threshold levels have been applied. These levels have often been based on concentrations detected in outbreak samples or data on levels consistent with appropriate application of prerequisite programmes (Notermans et al., 1997; Lund et al., 2000). Part of the problem in defining safe, i.e. acceptable, vs. unsafe levels of microorganisms constituting a risk to human health, is the wide variation in susceptibility between consumers. For some pathogens, the probability of severe illness is largely associated with specific consumer risk groups, e.g. for *L. monocytogenes*, these risk groups include the elderly, the immunocompromised and pregnant women (also affecting their fetuses/children) (EFSA BIOHAZ Panel, 2018b).

Acknowledging the general lack of legally defined acceptable levels of microorganisms in foods, linked to considerations of ALOP and risk assessments, the term 'acceptable level' has been used throughout this opinion to describe any level of microorganisms relevant for decisions on date marking taken by FBOs for their food product considering food characteristics and reasonably foreseeable use (see glossary). The term may refer to the limit levels defining a microbiological criterion (m or M), e.g. 100 colony-forming unit (CFU)/g of *L. monocytogenes* in RTE foods, to general threshold levels considered safe, e.g. levels of toxin producing *S. aureus* or of a pathogen target level, or to spoilage microorganism levels not leading to a spoiled food.

Based on existing international regulations and guidelines, the wording 'highly perishable and are therefore likely after a short period to constitute an immediate danger to human health', used in regulation (EU) No 1169/2011, relates to foods that need time/temperature control for safety. This term is related to the concept of time/temperature control for safety (TCS) in the US Food Code (US FDA, 2013, 2017). Further, the expression 'short period' indicates that the time between 'safe' and 'unsafe' is short, which implies that a 'best before' date is used not only for foods that would never constitute a risk but also for those that may constitute a risk after a 'long period' (Soethoudt et al., 2013). Thus, a limited guarantee of safety would be given by the FBO who is responsible for the label information depending on how the term 'short period' is interpreted. The concept of 'short period' is open to different interpretations. Apart from the problem of scientifically defining the demarcation between safe and unsafe in terms of the number of microorganisms in the absence of such criteria as mentioned above, the understanding of what is a 'short period' can also be interpreted differently. For instance, in the WRAP guidance (WRAP/FSA/DEFRA, 2017), it was explained that 'short time period' has not been defined but could be considered in terms of days rather than longer, as applied in the food industry. The existing food safety criterion for *L. monocytogenes*[11] states that the level should be less than 100 CFU/g during the whole shelf-life. However, shelf-life for some products for which this criterion is applicable can be quite long (several weeks), and it can be argued as to whether this is appropriately described as a highly perishable product that after a 'short period' may constitute an immediate danger to human health.

Guidance on how the 'intended use' may impact the decision on the setting of shelf-life (type of date marking and shelf-life) should also be considered (ToRs 1 and 2). The intended use of a given food must be defined by the FBO as the third preliminary step when developing a HACCP plan. According to the Codex Alimentarius guidelines (CAC/RCP, 1997) and the Commission Notice (2016/C278/01), the intended use should be based on the normal and expected uses of the product by the consumer target

[11] Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. OJ L 338, 22.12.2005, p. 1–26.

groups and end users. Unless specifically targeted to certain consumers (e.g. infant food or for medical purposes), the intended use can be considered as consumption by the non-specified (general) population (Commission notice 2016/C278/01). However, vulnerable consumers (such as pregnant women, elderly, etc.) need to be considered from the microbiological food safety point of view as they consume the same food as the general population. Food targeted to particularly vulnerable consumer groups such as infant food or food for medical purposes are subjected to specific regulations (e.g. Regulation (EU) No 609/2013[12]) and have more stringent food safety criteria (Regulation (EC) No 2073/2005). The term end user refers either to the customer (e.g. business-to-business, mass caterers etc.) or the final consumer. In the frame of the present opinion, food donation is considered a normal or envisaged end use of food. The concept of 'intended use' in the current regulation is also used with reference to whether food is RTE, to be eaten raw, to be eaten cooked, to be reconstituted etc. (Regulation (EU) No 1169/2011; Regulation (EC) No 2073/2005).

Some decision tools, e.g. ReFED standardisation (ReFED, online), the WRAP decision tree (DT) (WRAP, FSA, DEFRA, 2017), make a distinction between RTE and non-RTE foods using the rationale that consumer cooking of non-RTE foods may control any hazards present (vegetative bacteria and toxins) and that a 'best before' date is warranted. However, hazards may remain after heat treatment or other processing methods, considering both the variability in consumer behaviour and preferences (e.g. undercooked food), and the thermal resistance of some hazards (e.g. spores and thermoresistant toxins). How to address this issue is open for further consideration. For instance, the WRAP tool addresses this possibility and also has the option to still consider a 'use by' date, whereas the ReFED tool does not.

Storage and distribution conditions, including transport and handling should be included in the full description of a food product (preliminary activity 2 within the HACCP, Commission Notice (2016/C278/01), Van Boxstael et al., 2014; Bover-Cid et al., 2015). Within the control measures that an FBO should implement, the correct determination of the type of date marking and shelf-life (sensory or safe shelf-life) should take into consideration reasonably foreseeable conditions during distribution, transport or consumer handling of the food, e.g. storage temperatures and heat treatments (see Section 3.4) (Regulation (EC) No 178/2002[13]; Regulation (EC) No 2073/2005; European Commission, 2013[14]; EURL *Lm*, 2019).

This introduction illustrates some difficulties with using the terms in the regulation as a starting point for a practical tool of use to FBOs since 'highly perishable', 'immediate danger to human health', 'short period', 'safe vs. unsafe', 'reasonably foreseeable conditions' and 'intended use' are not defined. Another limitation is the absence of risk assessments to support value-based decisions on safe vs. unsafe hazard levels. This is the reason why the question of growth of pathogenic microorganisms or not, is taken as the basis for the development of a DT to support decisions on the appropriate type of date marking.

1.3.2. Role of food business operator (FBO) in attributing shelf-life as part of their Food Safety Management System (FSMS)

Each FBO along the agri-food chain needs to develop an FSMS, based on prerequisite programmes (PRPs) and HACCP-principles (the latter is not required for primary production) (Regulation (EC) No 852/2004, Commission Notice 2016/C278/01[15]). This opinion covers the food chain from food producers, distribution of food and to the consumer stage. Thus, the correct identification of the type of date marking ('best before' vs. 'use by'), the determination of the proper information provided to consumers regarding the shelf-life (i.e. time), storage conditions (e.g. temperature) and instructions

[12] Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/European Commission, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009. OJ L 181, 29.6.2013, p. 35–56.

[13] 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. OJ L 31, 1.2.2002, p. 1–24.

[14] Commission Staff Working Document, Guidance Document on *Listeria monocytogenes* shelf-life studies for ready-to-eat foods, under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs, 2013. Draft. Available online: https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_mc_guidance_document_lysteria.pdf

[15] Commission Notice on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses (2016/C 278/01). OJ C 278, 30.7.2016, p. 1–32.

for use of the food product, including time limits and good practices for thawing (defrosting) frozen foods and cooking, are part of the activities of an FSMS of the FBOs. Setting a proper shelf-life date to a given food product is considered a measure to be taken by the FBO to ensure the compliance with microbiological criteria of the product in case these are available (Regulation (EC) No 2073/2005).

Within the FSMS, any control measure must be validated, monitored and verified (Commission Notice 2016/C278/01; CAC, 2008). Therefore, as part of the setting of the shelf-life (decisions on the type of date marking and the date) and instructions for storage and use, an FBO must perform a validation study to demonstrate that the shelf-life is correct for the food and the foreseen food supply chain, and prevents the relevant pathogenic microorganisms exceeding the acceptable level.

Studies to validate shelf-life (i.e. time) and other information to be provided to consumers (i.e. storage temperature, instructions for use) need to be performed *a priori*, i.e. before putting a new product on the market or when modifications of an existing product are applied (e.g. formulation/ recipe, production process and/or packaging type are to be implemented or when no shelf-life studies have been carried out). Once a shelf-life and required information are determined, monitoring ensuring that this information is correctly included on the food label is required. A last step associated with any control measure in the HACCP-plan and FSMS, done *a posteriori*, is to implement a verification procedure. The implementation of the set shelf-life and information to be provided to consumers includes verifying that the attributed shelf-life is valid and the processor must ensure that no changes are made to the recipe, process, packaging, food chain etc. which could impact the shelf-life (type of date marking and the date) or the proper instructions for use of the food.

When setting up their FSMS, some flexibilities are allowed for small FBOs with retail activities (e.g. fishmonger, restaurant, catering, café, butcher shop, ice cream vendor, bakery shop and fruit/vegetable selling point) (EFSA BIOHAZ Panel, 2017, 2018a; Commission Notice 2020/C199/01[16]). Mainly non-prepacked foods are sold to consumers in these establishments, where no indication of the shelf-life is required. However, it is recommended, in the frame of the prerequisite programme (PRP) dealing with consumer information (i.e. PRP 13), to give advice to the consumer on how to store the food and, when appropriate, for how long (e.g. in case of non-prepacked fresh fish or meat) (EFSA BIOHAZ Panel, 2017, 2018a). PRP 14 in Commission Notice 2020/C199/01 is related to the control of the shelf-life of prepacked foods within supermarkets, restaurants, food distribution and other retailers, and is especially applicable to all retailers involved in food donations. Moreover, to facilitate food donations of non-prepacked foods by retailers, the donated food can be packed by the retailer to make transportation and further storage possible. These donated foods are not considered to be 'prepacked foods', so no indication of shelf-life is necessary, and they are not covered in the present assessment.

2. Data and methodologies

2.1. Literature review

Relevant documents were identified and reviewed based on the knowledge and expertise of the members of the established expert Working Group and of the BIOHAZ Panel. These documents included scientific papers, book chapters, non-peer review papers, regulations, guidance documents from national and international authorities, scientific opinions and reports known by the experts themselves or retrieved through searches. The reference list of these documents was further screened in order to identify additional relevant publications until reaching a coverage of the subject considered sufficient by the WG.

Use was also made of relevant documents included under the Resources library available in the 'EU platform on food losses and food waste' at https://ec.europa.eu/food/safety/food_waste/library_en.

2.2. Approach to answering ToRs

Since there is overlap between issues to provide guidance on date marking in ToRs 1 and 2, the only difference being that ToR 1 relates to pathogenic microorganisms and ToR 2 to spoilage non-pathogenic microorganisms, several of the questions were addressed together in the same section of the assessment.

Guidance relating to ToR 1a (the relevant pathogenic microorganisms) and ToR 1b (the types of foods where it is more likely to find those pathogenic microorganisms) was based on a literature

[16] Commission Notice providing guidance on food safety management systems for food retail activities, including food donations 2020/C 199/01. OJ C 199, 12.6.2020, p. 1–57.

review and is presented in Section 3.1 (Microorganisms in foods). In addition, to give a suitable background for the other ToRs, a brief overview of spoilage microorganisms was also included in this section.

A summary addressing ToR 1c (factors that may influence growth of pathogens and may impact decisions on date marking, shelf-life and storage conditions) and ToR 2a (factors that might influence growth of spoilage non-pathogenic microorganisms and may have an impact on shelf-life and storage conditions) is presented together in Section 3.2 (Factors influencing the occurrence and growth of pathogenic microorganisms or spoilage non-pathogenic microorganisms). This section gives an overview of relevant concepts, and guidance on how different factors, such as the raw materials and manufacturing processes, affect the types and levels of microorganisms present in different foods, and how the intrinsic (product characteristics)/extrinsic (storage conditions)/implicit (effects due to microbiota in food) factors of the foods may affect their subsequent growth.

To address the subquestion of ToR 1d, relating to giving guidance on the decision on which type of date marking to apply, a decision tree was developed based on the information presented in the other ToRs. This decision tree and its rationale are presented in Section 3.3 (Guidance on the decision to apply a 'use by' or a 'best before' date).

To address ToR 1d and ToR 2b, guidance on different approaches for setting shelf-life and required storage conditions is summarised in Section 3.4 (Approaches for setting shelf-life and required storage conditions).

Guidance relating to ToR 2c (indicative time limits for marketing or donation of foods past their 'best before' date) is addressed in Section 3.5, by summarising, and critically appraising and adapting existing literature on the subject, including previous EFSA opinions and various national guidance documents.

2.3. Uncertainty assessment

In applying the EFSA guidance on uncertainty analysis in scientific assessments (EFSA Scientific Committee, 2018), special attention was given to discussing if assessment questions could be defined in relation to the ToRs, to identifying relevant sources of uncertainty and to evaluating their impact on the assessment question.

The main bulk of the opinion is a summary of relevant literature based on a review of the identified information sources. The most important assessment question identified was the decision on the type of date marking, which uses the DT developed in Section 3.3. This DT is based on assumptions, methods and data. All of these may be sources of uncertainty and may contribute uncertainty to the decision of the type of date marking.

To assess uncertainties in the decision of the type of date marking to use, sources of uncertainties were listed related to the decision tree itself and assessed based on expert knowledge (Appendix C.1). The structure of the decision tree was evaluated considering whether any relevant questions were missed, and whether any questions were included without being relevant. The impact (direction and magnitude) of the sources of uncertainty on the date marking decision was also assessed. Since the outcome of the decision tree is binary, the impact's direction was expressed as underestimation of risk, overestimation of risk or inconclusive, where the former corresponds to a scenario where a food requiring a 'use by' date ends up having a 'best before' date, and overestimation when a food for which a 'best before' date is appropriate ends up having a 'use by' date, and inconclusive when it could be either or. The impact of the uncertainty on the decision (magnitude) was assessed using an ordinal three-level scale from lower to higher importance.

Uncertainty relating to the date marking decision will also depend on how the DT is applied by FBOs. Although not relevant for the development of the decision tree, it was considered useful to highlight some important sources of uncertainty related to how the tree is applied by the FBOs and to the food data informing the response to the questions in the decision tree (Appendix C.2). The latter data on processing and other food parameters will be based on measurements and should have been carried out with appropriate (and validated) methods.

3. Assessment

3.1. Microorganisms in food (ToR 1a, b)

3.1.1. Relevant pathogenic microorganisms

According to Article 5, points 1 and 2 (a) from Regulation (EC) No 852/2004, it is the responsibility of the FBO to identify the relevant hazards, e.g. pathogenic microorganisms including toxin producing microorganisms, in their foods as part of the HACCP-plan. Identification of pathogenic microorganisms is case-specific and to assist in this task, there are different types of information and evidence available, which is summarised and referenced here with the focus on the relevance for the shelf-life of perishable food. Pathogens of concern in different types of food categories and their ecological determinants for growth, such as minimum temperature, pH and a_w for growth, can be found, for instance, in the book series of ICMSF, especially books 5 and 6 (ICMSF, 1996, 2005). Other examples are the overview in the IFT/US FDA (2003), where appropriate control processes are identified, and Uyttendaele et al. (2018). An important source of evidence is outbreak data indicating the association of illnesses and number of outbreaks between different food commodities and implicated hazards (EFSA and ECDC, 2018, 2019). These types of information and the information in Table 1 are used in this scientific opinion to guide the selection of the type of date marking (Sections 3.2 and 3.3).

The growth potential of pathogenic microorganisms is affected by the intrinsic and extrinsic factors of the food. In addition, the pathogens are not necessarily good competitors, and are often subjected to interactions with the background microbiota (implicit factors) limiting their growth. Thus, pathogenic microorganisms, in general, do not constitute the numerically dominating microbial group unless the food matrix is processed in a way to drastically reduce the background microbiota (e.g. pasteurisation). Consequently, pathogenic microorganisms do not generally cause spoilage of food.

The relevance of a pathogen for the shelf-life of a perishable food will depend on different factors (Section 3.2), including the prevalence and levels in the different sources of contamination, such as raw materials, ingredients and processing environment, and the behaviour (inactivation, survival and/or growth) during the different steps of the food processing and supply chain. In addition, there are dose-response related factors, in particular the need for sufficient growth in the product to produce toxin and/or exceed acceptable levels at the point of consumption.

Table 1 provides a summary, based on the literature, of major food-borne pathogenic microorganisms that may be relevant, i.e. able to grow and/or produce toxins at reasonably foreseeable temperatures, for some perishable food categories during the shelf-life. For instance, bacteria of public health significance considered not relevant in this context include thermophilic *Campylobacter* spp. and *Clostridium perfringens* since their minimum growth temperatures are 32°C and 12°C, respectively (ICMSF, 1996). Although not relevant in the context of this opinion, because thermophilic *Campylobacter* (jejuni/coli) do not grow at reasonably foreseeable conditions during the shelf-life of perishable food, they may survive during storage and contribute to food-borne cases via cross-contamination and/or undercooking (EFSA BIOHAZ Panel, 2020). Another bacterium considered not relevant for the present opinion is *Vibrio parahaemolyticus*. The reported growth temperatures of *V. parahaemolyticus* range from 5°C to 43°C (ICMSF, 1996), but in food matrices, growth has not been observed at temperatures below 12–15°C, and there is a decrease in survival with time (Yoon et al., 2008; Yang et al., 2009; Kim et al., 2012). Therefore, *V. parahaemolyticus* is not expected to grow under reasonably foreseeable conditions.

The information provided in Table 1 is not exhaustive, as any pathogen can be relevant for several food categories and specific food products within a general food category, or a specific food can be associated with different pathogenic microorganisms. This is because the factors influencing their occurrence and growth (as described in Section 3.2), are usually food product specific, and need to be taken into consideration in the hazard identification step of the HACCP development plan.

Based on the available evidence, mycotoxin production due to growth of moulds during the shelf-life of prepacked and temperature-controlled foods is not considered a main hazard to be addressed in relation to decisions on 'use by' date (IFT/FDA, 2003a,b; FSAI, 2019). The main health problems associated with moulds and mycotoxins in food are related to consumption of food contaminated with mycotoxins: (i) already present in raw materials (Fink-Gremmels and van der Merwe, 2019; Haque et al., 2020), (ii) formed due to growth of moulds during manufacturing (Wolf-Hall, 2007; Montanha et al., 2018) or (iii) formed due to secondary contamination and fungal growth after opening the

package. These three situations are not relevant for the assessment of ToR1. In contrast to the assessment of bacterial hazards, if there is any mould growth during the shelf-life, this will be detected in most cases by consumers seeing the visible mycelia in the food as sign of spoilage and thus the ingestion of mouldy food will generally be avoided (see Section 3.1.2) (Fink-Gremmels and van der Merwe, 2019).

Table 1: Non-exhaustive summary of pathogenic microorganisms of relevance for date marking for different perishable food categories (including raw and processed prepacked foods)

	Group Genera/species	Food category of concern	Examples of food type
Gram-negative (enteric) bacteria	**Mesophilic**		
	Salmonella spp., pathogenic *E. coli*	Meat and products thereof	Raw pork meat, raw beef
		Fish and seafood	Shellfish
		Fruits and vegetables	Fresh cut/RTE vegetables (sprouts, spinach, . . .) and fruits
		Milk and dairy products	Fresh/cottage cheese, raw milk
		Prepared/mix food	Prepared salads, sandwiches
	Psychrotrophic		
	Yersinia enterocolitica	Meat and products thereof	Raw minced meat
Gram-positive bacteria	**Non-toxicogenic** *Listeria monocytogenes*	Prepacked raw RTE food	Salads, fruit juices, fresh cut vegetables and fruits
		RTE food exposed to contamination after a processing step causing microbial inactivation	Cooked meat products, smoked fish, soft/semi-soft and fresh/ cottage cheese
	Toxicogenic **Non spore forming** *Staphylococcus aureus*	Meat and products thereof	Cooked meat products
		Fish and seafood	Cooked fish products
		Cheese and dairy products	Raw milk cheese, soft cheese
		Bakery products	Cream-filled pastries, pies
		Prepared meals	Fish dishes, meat dishes, cheese containing dishes
	Spore forming aerobic *Bacillus cereus* (Diarrheic and emetic)	Food of non-animal origin, particularly heat treated	Cooked dishes/meals containing pasta or rice, such as tabbouleh, rice salad, semolina, rice pudding
		RTE prepared/mix food/meals (REPFED)	Cooked vegetables and potatoes, vegetable puree Meat-based meals with non-animal components (sauce, vegetables)
		Milk and dairy products	Pasteurised milk and dairy products and desserts
	Spore-forming anaerobic psychrotrophic non-proteolytic *Clostridium botulinum* **mesophilic** proteolytic *Clostridium botulinum*	Reduced atmosphere packed food, particularly heat treated (REPFED)	Salted fish, cooked meat products (pâté, sausages), hummus
		Seafood and meat products	Canned fish (sardines, anchovies, tuna) and meat products (corned beef, pâté)

Note: Foods exempt from the requirements to indicate a 'best before' date or covered by other EU provisions imposing other type of date marking, and excluded from this opinion, are listed in Appendix A.
RTE: ready-to-eat; REPFED: refrigerated (minimally) processed foods of extended durability.

Gram-negative enteric bacterial pathogens such as *Salmonella* spp. and pathogenic *E. coli* are major causes of foodborne diseases in humans and constitute an important public health issue in the EU (EFSA and ECDC, 2018, 2019). Proper cooking of food before its consumption is considered to eliminate these hazards and, if recontamination is avoided, eliminate the risk. However, the consumption of undercooked food (by mistake or due to consumer preferences) or raw food products, as well as cross-contamination from raw to cooked or RTE foods, are common causes of foodborne illness due to enteric pathogens (Pitout and Church, 2004). Therefore, and linked to relatively low ID_{50}, the occurrence of these pathogens in food constitutes a public health concern even if the pathogen does not grow during the shelf-life. Proper refrigeration temperature (e.g. < 4°C) during storage prevents the growth of mesophilic pathogens, as their minimum growth temperature (T_{min}) is usually higher (e.g. 5–7°C for *Salmonella*, 6.5°C for pathogenic *E. coli*). However, reasonably foreseeable conditions at retail and consumer stages (Section 3.4.1) include temperatures higher than the T_{min} of some of these pathogens, which makes storage time and conditions significant factors for increasing the risk of foodborne disease in perishable foods that support their growth (Cassin et al., 1998).

Psychrotolerant/psychrotrophic enteric pathogens such as *Y. enterocolitica* (T_{min} = –1.3°C, ICMSF, 1996) and *A. hydrophila* (T_{min} = 0–2°C, ICMSF, 1996) are able to grow under refrigeration conditions. Therefore, an increase in the level of the pathogens and of the associated risk could be expected during the shelf-life period, unless other environmental factors (as described in Section 3.2.2) inhibit their growth.

Among the Gram-positive non-spore-forming pathogens, *L. monocytogenes* is a relevant pathogen found in RTE foods. *L. monocytogenes* is a psychrotrophic organism, T_{min} ranging from –0.4°C (ICMSF,1996) to –1.5°C (EURL *Lm*, 2019), and may grow in food during refrigerated storage. *L. monocytogenes* growth constitutes a key factor determining the risk of human invasive listeriosis associated with the consumption of RTE packed smoked or gravad fish, packed heat-treated meat products and soft or semi-soft cheese (EFSA BIOHAZ Panel, 2018b). Several fresh produce products can also support the growth of *L. monocytogenes* during the product's shelf-life (Hoelzer et al., 2012), increasing the risk of listeriosis due to the consumption of RTE food of plant origin (e.g. packed pre-cut leafy green salad, celery etc.) so are also relevant (Garner and Kathariou, 2016; Self et al., 2019). There is no growth of *L. monocytogenes* in blanched frozen vegetables kept frozen, but the pathogen can grow if blanched frozen vegetables are thawed and subsequently stored. The growth rate increases with temperature and is affected by the type of vegetable (EFSA BIOHAZ Panel, 2020).

Staphylococcus aureus is a vegetative mesophilic halotolerant bacterium able to produce thermoresistant enterotoxins responsible for staphylococcal food-borne intoxication. Growth and toxin production can occur above the T_{min} of 7°C and 10°C, respectively (ICMSF, 1996). Time and temperature conditions before cooking (failure of temperature control) and after cooking, following e.g. contamination by a human carrier, of meat-based prepared meals, as well as salads, dairy products are identified as important factors increasing the probability of staphylococcal intoxication (ICMSF, 1996; Kim et al. 2009). For raw milk cheeses, storage time and temperature have been recognised as significant factors contributing to unacceptable *S. aureus* concentrations (Lindqvist et al., 2002).

Bacillus cereus is the causative agent of a foodborne intoxication due to the production of thermostable toxins in the food (emetic), or due to toxico-infections caused by enterotoxin production following ingestion of cells or spores (diarrhoeic) when the bacterium has grown sufficiently on the food (e.g. to 10^5 CFU/g). The psychrotrophic strains of *B. cereus* (T_{min} = 4°C, ICMSF, 1996) are relevant when dealing with the shelf-life of RTE foods, in particular of foods that undergo a thermal treatment such as pasteurisation, which does not inactivate *B. cereus* spores, and have properties that support the growth and the toxin production during refrigerated storage, e.g. refrigerated processed foods with an extended durability (RePFED) (EFSA, 2005; EFSA BIOHAZ Panel, 2016).

Non-proteolytic *C. botulinum* is an anaerobic spore-forming psychrotrophic (T_{min} = 3.3°C, ICMSF, 1996) organism, which produces botulinum toxin. The pathogen is relevant for chilled foods under reduced oxygen packaging (ROP), in particular foods of the RePFED category that have not been processed to eliminate the spores (see Section 3.2.1.2) or the physico-chemical characteristics do not inhibit their growth (see Section 3.2.2) (Notermans et al., 1990; Peck, 1997; FSA 2017). Compared to other bacterial toxins, those of non-proteolytic *C. botulinum* can be heat inactivated by normal food cooking procedures (Licciardello et al., 1967; Wachnicka et al., 2016).

Finally, since the association between a food and a pathogenic microorganism will be dependent on the specific raw materials and hygienic environmental conditions of the processing environment as sources of microorganisms, as well as on processing and preservation technologies, intrinsic, extrinsic

and implicit characteristics of the food affecting microbial inactivation and growth, it is important to emphasise that the final identification of pathogenic microorganisms will be food specific.

3.1.2. Spoilage microorganisms

A key concept for understanding the microbial spoilage of food is 'specific spoilage organisms' (SSO). This term is used to identify/define the fraction within the total food microbiota that is responsible for the spoilage of a given foodstuff in a given 'spoilage domain'. The latter refers to the range of conditions regarding intrinsic, extrinsic and implicit factors (food product characteristics, storage conditions and microorganisms in the food) within which the SSO grow faster than other microbial groups and/or generate sufficient amounts of metabolites causing the off-flavours and undesirable changes to the food matrix. Changing the food characteristics due to processing or storage conditions, i.e. the spoilage domain, the SSO may also change and therefore also the time and signs of spoilage. In refrigerated fresh meat without packing or just wrapped (air atmosphere), *Brochothrix thermosphacta* typically dominates the early stages of storage but is eventually displaced by *Pseudomonas* spp. (Doulgeraki et al., 2012). If the same fresh meat is vacuum packed (limiting the growth of pseudomonads and other aerobic organisms), a selective pressure in favour of other bacteria, such as lactic acid bacteria is created, which will result in the production of off-odours and changes to the product (acidification). The signs of spoilage become apparent when the SSO reach a sufficient level, often considered to be between 10^6 and 10^8 CFU/g (e.g. Dalgaard et al., 1997; Koutsoumanis et al., 2002; Nychas et al., 2008), which is linked to the production of metabolites. The occurrence of these metabolites can be used as an objective chemical index of freshness/spoilage (Dalgaard, 2000; Nychas and Panagou, 2011). However, in some cases, bacteria can be responsible for spoilage of foods even if they do not dominate the overall microbial population (Nychas et al., 2008; Smith and Farms, 2008; Gribble et al., 2014). Spoilage bacteria that preferentially ferment carbohydrates switch to protein hydrolysis only when carbohydrate sources are depleted. This proteolysis causes 'spoilage' mostly due to off-flavours. Thus, in some products, the numbers causing spoilage can be low while in others, the numbers can be high but without signs (odour, off-flavours etc.) of spoilage (Uyttendaele et al., 2018). Regarding the application of microorganisms as food spoilage indicators, either the levels of the dominating microbiological groups (e.g. yeasts, lactic acid bacteria) or of a specific species (e.g. *Lactobacillus sakei*, *Leuconostoc mesenteroides* etc.) can be considered (Uyttendaele et al., 2018; Odeyemi et al., 2020). Table 2 shows some of the major microbial groups which have been associated with the spoilage of particular food types (single or in combination). More detailed information about the relevance of these and other SSO, for different types of food, as a function of storage conditions (packing, temperature etc.) are reviewed in the literature (e.g. Koutsoumanis et al., 1998; Nychas et al., 2008; Doulgeraki et al., 2012; FAO 2014; Odeyemi et al., 2020).

Total viable count (TVC) is used to enumerate both vegetative cells and spores of bacteria, yeasts and moulds, that are present in a food and are able to grow in the culture media (nutrient agar) under the time/temperature/atmosphere conditions used to quantify them. Analytically, they are quantified in non-selective nutrient media but specific plate incubation conditions should be applied depending on the type of food and the intended conditions of storage, in order to quantify the most appropriate general indicator (Uyttendaele et al., 2018). For instance, the plate incubation conditions can be 30°C/ 3 days for mesophilic count or 20–22°C/4–5 days for psychrotrophic count (Quinto et al., 2020; Yuan et al., 2020). The latter is typically applied for refrigerated foods to follow potential growth of spoilage organisms in cold conditions (Macé et al., 2012; Uyttendaele et al., 2018). In case of psychrophilic count, an even lower incubation temperature can be applied (6–7°C) to measure the number of bacteria able to proliferate in cold storage conditions (Daraba, 2008; Laly et al., 2020). The total viable counts often need to be accompanied by the determination of more specific indicators (Table 2), according to the type of food and the foreseeable conditions of storage.

Aerobic or anaerobic spore-forming bacteria and/or spores, including genera *Bacillus*, *Clostridium*, *Alicyclobacillus,* are relevant in heat-treated foods, since spores may be able to survive the heat treatment (e.g. mild pasteurisation). Subsequent germination of spores and multiplication during the storage period may lead to spoilage associated with changes in pH, colour, gas accumulation, texture, odour and taste (e.g. *Alicyclobacillus*) (Jay et al., 2005; André et al., 2017; Pornpukdeewattana et al., 2020). In chilled vacuum-packed meat (not heat-treated) 'blown pack' spoilage may occur due to the occurrence and growth of psychrophilic and psychrotrophic *Clostridia* (non-pathogenic, mainly *Clostridium estertheticum* and *Clostridium gasigenes*) (Broda et al., 1996; Bolton et al., 2015; Húngaro et al., 2016).

Lactic acid bacteria (LAB) are relevant spoilage-causing bacteria in vacuum-packed and modified atmosphere packed food, where sensorial spoilage due to growth of homofermentative LAB and acid production will usually be detectable when the numbers exceed 10^7 CFU/g (Jacxsens et al., 2003). In cases where growth of heterofermentative species at such high levels occurs, off-odour, slime and gas formations may develop. It should be noted that LAB is a very diverse group (De Paula et al., 2015). Some of them cause spoilage (e.g. Schneiderbanger et al., 2020), some are bio-preservatives (e.g. Özogul and Hamed, 2018; Sadiq et al., 2019) and some are needed to give the desired sensory quality of the food (i.e. fermented foods). In the latter cases, this group is not an appropriate indicator of spoilage (e.g. Bautista-Gallego et al., 2020; Bungenstock et al., 2020). Yeasts and moulds mostly dominate the microbiota of a food when the conditions are less favourable for bacterial growth i.e. low pH, a_w (Tofalo et al., 2020). Significant changes in the sensorial attributes of foods will occur when yeasts numbers reach 10^5–10^6 CFU/g. Mould growth, forming a visual mycelium, is only possible in the presence of oxygen, although low residual levels may suffice (Uyttendaele et al., 2018). Mould spoilage is typical for sour, sweet, dry and fermented foods (Axel et al., 2017; Garcia and Copetti, 2019). Yeasts can also play a role in the spoilage of foods, especially if foods are heavily contaminated at the start of the shelf-life, such as in the case of fresh-cut fruits and vegetables (Hernández et al., 2018).

Table 2: Major spoilage microorganisms and relevant prepacked foods

Spoilage microorganisms	Relevant foods/comments
Aerobic or anaerobic spore-forming bacteria and/or spores, including genera *Bacillus*, *Clostridium*, *Alicyclobacillus*	In heat-treated foods (e.g. mild pasteurisation), spores may be able to survive the heat treatment which may lead to subsequent spoilage during the storage period In chilled vacuum-packed meat (not heat-treated), 'blown pack' spoilage due to the occurrence and growth of psychrophilic and psychrotrophic *Clostridia* (non-pathogenic)
Lactic acid bacteria, e.g. psychrotrophic genera such as *Leuconostoc, Weissella* and *Lactobacillus*	In vacuum-packed foods and MAP foods (e.g. *Photobacterium phosphoreum* in MAP fish products (Dalgaard et al., 1997)
Yeasts e.g. *Candida* spp., *Saccharomyces* spp. and moulds e.g. *Penicillium* spp., *Botrytis* spp., *Alternaria* spp.	Yeasts and moulds mostly dominate the microbiota of a food when the conditions are less favourable for bacterial growth i.e. low pH, a_w such as fruits and derived products (juices, marmalades and fresh-cut fruits), yoghurt, cheese or other fermented foods etc

In general, the microbiota in food, both pathogenic and spoilage microorganisms, reflects the microbiota in the ecosystem where the source material has been cultivated or raised, harvested and processed. Geographical areas with a high prevalence of specific pathogenic microorganisms will also have a higher likelihood of food contaminated with these pathogens. Some pathogenic microorganisms can survive in production facilities while others are related to live animals or faeces from these. The former group is more likely to be present in foods produced under poor hygienic conditions (see further under Section 3.2.1).

3.1.3. Concluding remarks

- The association between a food product and a specific pathogenic microorganism is dependent on the raw materials used, the hygienic environmental conditions and the processing technologies applied in its manufacture.
- To assist in the identification of pathogenic microorganisms of relevance for the shelf-life of perishable foods, data on pathogens of concern in different types of food categories and their ecological determinants for growth were reviewed, and information sources of outbreak data indicating the association between different food commodities and implicated pathogens were indicated. Guidance is presented in the form of useful sources of information and a non-exhaustive summary of relevant pathogenic microorganisms capable of growth in prepacked temperature-controlled foods under reasonably foreseeable conditions.
- The identification of pathogenic microorganisms is food product-specific. Considering the huge variability existing in the food chain in terms of product types, modes of processing, packing

and storage conditions, it is difficult to *a priori* exclude any of the pathogenic microorganisms able to grow, in packed temperature-controlled foods.

- The term-specific spoilage organism (SSO) is used to identify/define the fraction, a species or a group of microorganisms, within the total food microbiota that is responsible for the spoilage of a given food product under its product characteristics and storage conditions, i.e. the spoilage domain.
- Under the conditions of the spoilage domain, the SSO grow faster than other microbial groups and/or generate sufficient amounts of metabolites to cause the undesirable changes associated with spoilage. The microbiological levels at which this occurs in a food vary with the SSO, the properties of the food and storage conditions.
- Changing the product characteristics and storage conditions may also change the SSO and its growth potential, and, therefore, also the time and signs of spoilage.

3.2. Factors influencing the occurrence and growth of pathogenic or spoilage microorganisms (ToR 1c, 2a)

The decision on the appropriate type of date marking for a given food product (i.e. 'use by' or 'best before'), the shelf-life (time) and the storage conditions depend on the manufacturing process determining:

- the type and the levels of microorganisms in the product when released to the market (Section 3.2.1)
- the intrinsic, extrinsic and implicit factors of the food which determine the growth potential of these microorganisms in the food product during subsequent storage, until consumption (Section 3.2.2).

3.2.1. Factors determining the type and the levels of microorganisms in the end product

During a production process from raw material to end product, a variety of processes are applied in different steps, e.g. washing, blanching, mixing, cutting, cooking etc. Each process or step can have an impact on the initial microbiota of the raw materials (both in terms of prevalence and/or concentration of certain groups of bacteria or specific species). In a risk assessment modelling context, all product handling processes have been proposed to be identified as one, or a combination, of four basic processes (see below) considering their effect on the fraction of contaminated 'units' (prevalence), the number of microorganisms per 'unit' (concentration) and the 'unit' size (Nauta, 2002). Here, the 'unit' refers to the unit of food product considered, which can be for example the carcass of a slaughtered animal, a meat cut, a batch of minced meat, a retail package of meat products or a hamburger. In the context of an FBO, in the frame of their FSMS and HACCP plan, it is important to understand that some product handling processes can lead to (i) removal of microorganisms, (ii) addition of microorganisms by cross-contamination or from external sources and (iii) changes in the size of the food units by partitioning a larger food unit into smaller units (e.g. bulk tank milk to packages of milk), (iv) mixing of smaller food units to a larger unit (e.g. mixing different vegetables into a vegetable mix) (Nauta, 2002). All these processes may be associated with changes in the type of microorganisms present but also in the distribution of microorganisms over the units, affecting the prevalence and concentrations per food unit, and in the end influencing the decisions on the setting of the shelf-life (type of date marking and shelf-life date) (Table 3).

3.2.1.1. Raw materials and intermediate ingredients

Raw materials and ingredients but also intermediate products (e.g. business-to-business, B2B) can be contaminated by pathogenic and/or spoilage-causing microorganisms, thus constituting a source of contamination of the end product. The information provided in Sections 3.1.1 (pathogens) and 3.1.2. (spoilage microorganisms) can be useful to identify the relevant microorganisms. As part of the prerequisite programme 'supplier control' and sampling of raw materials, an FBO will gain insight in which groups of microorganisms (or SSO) are present and in the variability of the contamination levels of the supplied raw materials (Commission Notice 2016/C278/01).

3.2.1.2. Processing environment

The processing environment will also impact the microorganisms present in the end product. Hygienic environmental conditions during production until the food is packed (and protected) are a cause/risk factor for re-/cross-contamination. Therefore, many prerequisites in an FSMS are aimed at preventing transfer of contamination from the broader production environment to the processed foods, as documented in (Luning et al., 2009; Commission Notice 2016/C278/01; EFSA BIOHAZ Panel, 2018a, 2020):

a) Hygienic design of food contact surfaces, equipment and utensils and zoning of processing plants
b) Material flow and process lines for rapid production and minimisation of cross-contamination between lines.
c) Cleaning and disinfection
d) Air flow and air control (dust extraction, control of aerosols)
e) Water flow and water control, including drainage
f) Pest control
g) Technical maintenance
h) Personnel hygiene and training on hygienic practices

3.2.1.3. Manufacturing steps

Manufacturing steps applied during the production process will impact the microbiological ecology of the processed foods. A differentiation is made between steps involving i) handling and preparation which do not necessarily cause microbiological lethality nor growth inhibition, but contamination or re-distribution of microorganisms may occur, ii) steps with inactivation effects, iii) steps with growth inhibiting effects on the microbiota (growth inhibiting factors are described in Section 3.2.2). In a HACCP system, it is therefore important to know which impact the manufacturing steps have on the microorganisms, and to consider the total impact of the consecutive processing steps on the microorganisms, e.g. recontamination due to handling (slicing, dicing, assembling etc.) and packing of heat-treated foods (Commission Notice 2016/C278/01).

i) Manufacturing steps involving handling, preparation and treatment but not aimed at inactivation

Steps involving a mild heating, sometimes referred to by FBOs as blanching, pre-grilling or pre-frying, are addressed in this section. The reason is that although a decrease in microbiological levels will be achieved, these steps are not designed to achieve a full elimination/inactivation of target microorganisms as in the case of full cooking, pasteurisation or sterilisation. As a consequence, pathogenic microorganisms may remain after such manufacturing steps (Table 3).

The impact of manufacturing steps on the microbiological levels of a food may be a decrease, an increase, a re-distribution/homogenisation of microorganisms in the food matrix, or no effect. Table 3 illustrates the potential impact that manufacturing steps (not aiming at full inactivation of microorganisms) may have on the prevalence and concentration of microorganisms. Some scenarios where an increase or a decrease may occur are described.

Table 3: Potential impact of 'manufacturing steps' (not aiming at full inactivation of bacteria) on the prevalence and concentrations of target pathogenic and spoilage microorganisms, and examples of scenarios where this may happen

Manufacturing step	Potential impact on prevalence	Scenario where this may happen	Potential impact on concentrations	Scenario where this may happen
Washing Rinsing	Decreasing	Microbial removal and inactivation during washing may occur resulting in levels below detection, i.e. a decrease of prevalence	Decreasing	Microbial removal and inactivation during washing may lead to a decrease in the microbial concentration of the product
	Increasing	Washing in a washing tank where large volumes of product are continuously washed might lead to cross-contamination between contaminated and non-contaminated product units resulting in an increase of prevalence	Increasing	The use of contaminated wash water or water loaded with microorganisms from contaminated products from other batches (reuse), may spread microorganisms throughout the washed product resulting in an increase of the microbial concentrations of the product
Mixing[(a)] Assembling	Increasing	Redistribution of microorganisms may occur during mixing or combining of non-contaminated products with contaminated products, or by mixing or combining with contaminated ingredients	Decreasing	Dilution of microorganisms may occur during mixing or combining of contaminated product with non-contaminated ingredients
Partitioning[(b)] Splitting	Decreasing	A food unit with low concentration of contamination is split up into smaller units, of which some are no longer contaminated or below detection limit		
Mincing Cutting Handling Packing	Increasing	Contamination may occur during these steps by personnel, foods and/or food contact materials	Increasing	Contamination may occur during these steps by personnel, foods and/or food contact materials
Storing	Increasing	Contamination of unpacked ingredients/food may occur from personnel, food contact materials, other foods, ingredients, and/or drip water	Increasing	Growth may occur during storage (depending on storage conditions e.g. time, temperature, a_w)
	Decreasing	Some reduction may occur depending on species and initial contamination concentration if the product characteristics and storage conditions lead to inactivating effects resulting in concentrations below detection limit	Decreasing	Some reduction may occur depending on species if the product characteristics and storage conditions lead to inactivating effects
Fast cooling (after heating)	Increasing	Contamination of unpacked food may occur from personnel, food contact materials and/or drip water	Increasing	If cooling time/temperature profile is not fast enough and may allow growth of cells/spores surviving the heat treatment

Manufacturing step	Potential impact on prevalence	Scenario where this may happen	Potential impact on concentrations	Scenario where this may happen
Mild heating, pre-cooking not validated for elimination of target microorganisms (Blanching, 'pre-grilling' 'pre-frying')	Decreasing	Reduction due to inactivation of bacteria can occur depending on the species, initial contamination concentration and time–temperature conditions	Decreasing	Some reduction due to inactivation can occur depending on the species and the time–temperature conditions. Although in most cases, it will not be the aim, full inactivation of target pathogens (e.g. 6 Log_{10} reduction of *L. monocytogenes*) can be achieved via these steps depending on the species and the time/temperature conditions. The FBO is responsible to demonstrate this
Freezing and thawing	Decreasing	Some reduction due to inactivation of bacteria may occur depending on the species, initial contamination concentration, and freeze/thaw conditions (e.g. time, and temperature profiles)	Decreasing	Some reduction due to inactivation may occur depending on the species and freeze/thaw conditions
	Increasing	Contamination may occur during these steps by personnel, foods and/or food contact materials	Increasing	Growth may occur in case of temperature abuse during slow freezing process and/or thawing at growth permitting temperature conditions

(a): When mixing/assembling smaller units of food product into a larger one, the unit size of the food product increases, and as a consequence, the percentage of contaminated units (prevalence) increases (Nauta, 2002).
(b): If a larger unit of a contaminated food product is split up in smaller ones, it may be that some of these smaller ones are not contaminated. In that case the prevalence decreases (Nauta, 2005).

The physico-chemical characteristics of a food may change during handling and preparation steps, e.g. an equilibrium in pH between acid/non-acid components, due to the addition of ingredients and/or additives such as acidulants in spreads, fermentation resulting in a pH drop, lowering of the a_w due to ripening and drying or a change in the gas composition due to MAP packaging which can affect the microbial behaviour in subsequent steps of the food manufacturing and storage (see intrinsic and extrinsic properties of foods, Section 3.2.2).

ii) Process steps with inactivation effects on the target microorganisms

Several food processing and preservation technologies applied during the manufacturing of the food have inactivation (lethal) effects against microorganisms, thus decreasing their prevalence and/or concentration. The conditions applied in the treatments determine, together with the initial microorganism concentration, the probability of a product to be contaminated with pathogenic and/or spoilage microorganism, and consequently, if the end product is microbiologically shelf-stable or perishable. The higher the intensity of the treatment the lower will be the concentration of microorganisms in the end product.

Inactivation can be achieved by thermal and non-thermal processes, which are normally part of a control measure in the HACCP plan and that need to be properly validated according to recognised standards. During the daily running of the production process, the performance of such control measure must be monitored and subsequently verified (CAC, 2008).

Thermal processes consist of the application of heating technologies usually having immediate inactivation effects. A wide range of treatment intensities can be applied, the different impact on the concentration of microorganisms (pathogenic and spoilage microorganisms) has a direct consequence on the durability/perishability of the food and the storage conditions needed to ensure the product safety and quality. Table 4 summarises the most relevant features associated with the thermal process steps within the food production: sterilisation, pasteurisation and post-lethality treatments for RTE food.

Sterilisation aims to achieve a 'commercial sterile' food, i.e. shelf-stable not requiring refrigeration (stored at ambient temperature) provided that the sealed container or the aseptically filled package remains intact. The target pathogenic microorganism is the mesophilic proteolytic *C. botulinum* and the performance criterion to be achieved is 12 Log_{10} reductions (in low-acid foods, pH $\geq$ 4.6), which equals a survival probability of 10^{-12}.

Pasteurisation aims to reduce the most resistant non-spore-forming microorganisms of public health significance to a concentration that is not likely to present a public health risk under normal conditions of distribution and storage and to extend the food shelf-life by reducing the concentration of spoilage microorganisms (NACMCF, 2006). Since some spoilage bacteria and spores of pathogens may remain, spore germination and subsequent growth may be induced, and therefore, pasteurised food needs refrigeration. Despite pasteurisation being designed to eliminate relevant vegetative pathogens (*Salmonella, E. coli, L. monocytogenes*, etc.), in relevant foods (e.g. crabmeat, REPFED), it may also be used for inactivation of spores of psychrotrophic non-proteolytic *C. botulinum* (ECFF 2006; NACMCF, 2006; FSA, 2017).

Thermal treatments can also be applied to RTE foods in the final package in order to eliminate potential *L. monocytogenes* re-contaminating the product after a previous lethal treatment, e.g. during slicing, dicing, sampling, packing etc. The result of these post-lethality treatments would be equivalent to pasteurisation in the sense that the relevant pathogen will be eliminated (safety of the product ensured) but refrigeration is needed to maintain the microbiological quality and/or to avoid germination of spores. The performance criteria are usually lower than for general pasteurisation since microorganism concentrations are lower and located on the surface of the end product, compared to the contamination of raw materials and ingredients (Murphy et al., 2005).

Process criteria to achieve a specific performance criterion for a given pathogen can be found in guidelines and specific international regulations, either in form of accumulated lethality targets (i.e. F_0 or p^z_{Tref} values, see glossary) or as temperature/time combinations with equivalent lethality. In Table 4, some examples are provided. More examples of international regulations and guidelines are reviewed in Peng et al. (2017). Thermal resistance of microorganisms is highly dependent on the physico-chemical characteristics of the food such as pH and a_w. Specific and global parameters to determine accumulated lethality can be obtained from the scientific literature (van Asselt and Zwietering, 2006a,b; EFSA BIOHAZ Panel, 2012). Importantly, the characterisation of pH and a_w in multicomponent food should be done after equilibrium has been reached in physico-chemical

properties between the food components, and also taking into account inter- and intra-batch and product variability (FDA/CFSAN 2010).

The setting up and validation of the thermal treatment should be performed case-by-case (product-processor specific) following international guidelines (CAC/RCP 23, 1979, CAC/RCP 40, 1993, CAC/RCP 46, 1999, FSAI 2006) ensuring the requirements set in the Regulation (EC) No 852/2004 (annex II, chapter XI):

1) Any heat treatment procedure used to process an unprocessed product or to further process a processed product should: a) raise every part of the product treated to a given temperature for a given period of time; and b) prevent the product from becoming contaminated during the process;
2) To ensure that the process employed achieves the desired objectives, FBO should regularly check the relevant parameters (particularly temperature, pressure, sealing and microbiology), including by the use of automatic devices;
3) The process used should conform to an internationally recognised standard (e.g. pasteurisation, ultra-high temperature or sterilisation).

Thermal treatment of food may result in products with a higher susceptibility to pathogen growth during subsequent storage (e.g. involving spores or surviving organisms or new contaminants) or if recontamination occurs (e.g. from processing environment, packing material/equipment or is mixed with other food). The higher susceptibility to microbial growth is mainly associated with a lower concentration of competing background microorganisms but other factors, such as destruction of heat-labile antimicrobial compounds (e.g. as shown in carrots by Beuchat and Brackett (1990)), texture changes making water and nutrients more available, may also be relevant.

Table 4: Impact of thermal processes on microbiological inactivation

Thermal process	Aim, target pathogenic microorganism and impact on concentration (performance criterion[f], PC)	Product and process criteria
Sterilisation[a] (batch, continuous) (retort, UHT direct/indirect)	Inactivation of vegetative cells and spores of pathogenic and spoilage microorganisms capable of growth in the product at room temperature PC: 12 Log_{10} reduction of mesophilic proteolytic *C. botulinum*	Examples • Low acid food, i.e. pH > 4.6[b], require treatments at > 100°C with an accumulated lethality[c] of F_0 = 3 min (i.e. 3 min at 121.1°C known as 'botulinum cook'). However, in practice higher intensity (F_0 6–10) is usually applied to assure inactivation of thermophilic spoilage sporulated bacteria (Richardson, 2004); Holdsworth (2009) Remize, 2017) • Acid and acidified food (pH < 4.6), treatments at reference temperature from 90 to 110°C and lower lethality can also achieve shelf-stability of food (different process criteria were set by FDA/CFSAN 2010) • Ultra high temperature (UHT) processed milk involve a short time at no less than 135°C (Regulation (CE) 853/2004)
Pasteurisation[d] (batch, continuous)	Inactivate vegetative pathogens and reduce the concentration of vegetative spoilage bacteria during food processing/ manufacturing PC: usually 6 Log_{10} reduction (ranging from 4 to 8 Log_{10} reduction) of relevant vegetative pathogen depending on the type of commodity/raw materials used *L. monocytogenes, Salmonella* spp. *etc.* (see Table 3)	Examples: e.g. $P_{7.0}^{7.5}$ = 2min to achieve 6 Log_{10} reduction of *L. monocytogenes* (Gaze et al., 1989; ECFF 2006) or as equivalent time/ temperature combinations (e.g. ECFF 2006; FSANZ 2009; FSIS 2017) e.g. Milk and dairy products pasteurised at least 72°C for 15 s (High Temperature Short Time, HTST) or at least 63°C for 30 min (for low temperature for a long time) (Regulation (EC) 853/2004), e.g. Fruit juices HTST processed at 71.5°C for 15–30 s to reducing 5 Log_{10} reduction of *E. coli* O157:H7 and *L. monocytogenes* (Duan et al., 2011) e.g. Cooked poultry products minimum of 60°C/12 min or 65°C/91 sec to decrease by 7 Log_{10} *Salmonella* spp. (other combinations also available (Appendix A, FSIS, 2017)
	Inactivate spores of non-proteolytic psychrotrophic *Cl. botulinum*, other vegetative pathogenic bacteria and reduce the concentration of vegetative spoilage bacteria PC: 6 Log_{10} reduction psychrotrophic non-proteolytic *Cl. botulinum* spores	Food under reduced oxygen atmosphere (vacuum, MAP) packaging requires an accumulated lethality of P_{90}^{10} = 10 min, unless other antimicrobial hurdles are implemented to inhibit the growth of non-proteolytic *C. botulinum* (i.e. pH ≤ 5.0; $a_w \leq 0.97$; or a combination of factors including preservatives consistently showing to prevent growth and toxin formation by the pathogen) (ECFF, 2006; FSA, 2017)
Post-lethality treatment[d] (batch)	Inactivate *L. monocytogenes* PC set by international health authorities such as 1-2[e] Log_{10} reduction of *L. monocytogenes* (FSIS (2014) Listeria guideline for RTE food, operating Alternative 2a); 3 Log reduction of *L. monocytogenes* (Health Canada Listeria Policy for RTE food)	Foods exposed to surface contamination after a lethal treatment during e.g. slicing, cutting, assembling, packing etc. (i.e. post-lethal exposed RTE foods)

(a): Sterilisation principles are described in Holdsworth (2009).

(b): Low acid foods include also products with $a_w > 0.85$. The pH and a_w threshold to distinguish low acid from acid/acidified foods is focussed on the growth of pathogenic microorganisms. It should be noted that, contrary to low pH, low a_w protects microorganisms from thermal effects. Therefore, higher microbial resistance in low a_w (low moisture foods) has to be taken into account.
(c): See glossary.
(d): Pasteurisation principles are described in Da Silva and Gibbs (2009).
(d): Post-lethality treatments can be thermal or non-thermal (e.g. High-pressure processing, see Table 5).
(e): 1 log reduction is the minimum inactivation required to consider the processing a 'lethality' treatment, while 2 Log_{10} reduction allows to the document an increased concentration of control of *L. monocytogenes* in RTE food.
(f): Performance criterion is the change in hazard level required at a specific step in order to reduce the hazard level at the start of the step to a level at the end of the step that complies with the performance objective or the Food Safety Objective (Gorris, 2004; http://www.icmsf.org/wp-content/uploads/2018/02/021-027_Gorris.pdf).

Non-thermal technologies include a variety of processes with immediate inactivation impact (e.g. high-pressure processing), as well as the combination of mild hurdles with gradual but long-term inactivation effects as a result of the changes in the physico-chemical characteristics of the food matrix (Table 5).

Table 5: Examples of some non-thermal processes and their impact on microbiological inactivation

Processes	Aim, target pathogenic microorganisms and impact on concentration	Comment
Single hurdle		
High-Pressure Processing (HPP)	Inactivation of vegetative pathogens and spoilage microorganisms to a variable extent. No inactivation effect on spores	The extent of Log_{10} reductions depends on the type of microorganisms, the processing parameters as well as the physico-chemical characteristics of the food. Some spoilage bacteria and spores may survive, thus HPP treated food usually needs to be stored under refrigeration (Considine et al., 2008)
Multiple hurdles[(a)]		
Fermentation	Growth inhibition and potential inactivation of vegetative pathogens	The production of organic acids reduces pH which alone, or in combination with other factors (e.g. temperature, preservatives, microbial interactions, etc.), inhibits the growth of pathogens in the end product and can lead to inactivation. However, the inactivation may be slow or partial. The use of starter cultures to control and standardise the fermentation is advisable (Sperber and Doyle, 2009)
Ripening and/or drying	Growth inhibition and potential inactivation of vegetative pathogens	Reduces a_w to a value that alone, or in combination with other factors (pH, temperature, preservatives etc.), does not favour the growth of pathogens in the end product and can lead to inactivation. However, the inactivation may be slow or partial (Sperber and Doyle, 2009)

(a): Hurdle technology to combine several techniques mainly limiting the growth of the pathogenic microorganisms (which is described in next section) but also leading to inactivation due to metabolic exhaustion of the microorganisms (Leistner, 2000).

Within the FSMS, the FBO has to carry out validation activities to collect solid scientific and technical evidence that the control measures are effective in controlling the hazards and that the required Log_{10} reduction of the target microorganisms can be achieved under all production circumstances. The Codex Alimentarius Commission issued the Guidelines for the validation of food safety control measures (CAC, 2008).

(iii) Steps/processes with growth inhibiting effects on the microorganisms

Growth inhibiting factors and their impact on growth is described in the next section (3.2.2).

3.2.2. Factors influencing the growth behaviour of microorganisms during the storage of the end product

Processing factors may consist of a single or a combination of the above-mentioned factors, including other physical treatments (Section 3.2.1) such as heating and pressure, as well as the addition of ingredients and preservatives resulting in changes in pH (e.g. due to addition of acids or generation of fermentation products), in a_w (e.g. due to addition of sugar, salt or other solutes) or the concentration of antimicrobial substances (e.g. organic acids, curing salts etc.). In relation to microbiological safety and spoilage, the factors affecting the shelf-life of foods are those determining the growth of microorganisms in foods. Once the end product is released to the market, including storage, distribution, sale to the consumer etc., the probability of growth and, in case of growth, the growth rate, will determine the time needed for the relevant microorganism to exceed the acceptable level.

The growth affecting factors may be classified into those that are intrinsic or associated with the food material and those that are extrinsic or associated with the environment surrounding the food (Jay, 2000; Ray, 2004). Implicit factors cover effects depending on the microbiota that initially develops according to intrinsic and extrinsic factors.

A source of information for minimum limits for growth of pathogenic microorganisms is summarised in Table B.1 and reports combinations of pH and a_w values that may allow their growth. Data are collected by the NACMCF (2010).

In relation to considerations on whether the observed growth of a microorganism is microbiologically relevant, the estimated uncertainty associated with the analytical enumeration (usually plate count) ranges from 0.5 to 1 Log_{10} unit. Similar to the EU, Canada and Australia consider the threshold as 0.5 Log_{10} units (Health Canada, 2011; FSANZ, 2013; EURL *Lm*, 2019), equivalent to twice the standard deviation (i.e. 0.25) associated with the experimental enumeration colony count technique, as also reported by the Codex Alimentarius (CAC, 2007). A food in which *L. monocytogenes* does not increase in numbers by 0.5 Log_{10} throughout the stated shelf-life under reasonably foreseeable conditions of distribution, storage and use is considered not to support growth of the organism (EURL *Lm*, 2019). In comparison, in the US, a 1 Log_{10} increase for a given period of time is the threshold for considering the microbial growth of biological relevance (NACMCF, 2010). The term 'antimicrobial agent or process' (AMA/P) is used by the US regulations to refer to technological/ processing operating alternatives integrated within the FSMS aiming to reduce or limit the growth of *L. monocytogenes*. As a preventive measure, the AMA/P allows no more than 1 Log_{10} increase (increased level of control) or 2 Log_{10} increase (minimum level of control) of the hazard during the product shelf-life.

3.2.2.1. Intrinsic factors

Intrinsic factors are those associated with the characteristics of the food material (Jay, 2000; Ray, 2004; Mossel et al. (1995), which can be natural, induced and/or added in food processing operations. Intrinsic factors include water activity (a_w), pH and buffering capacity, nutrients, oxidation–reduction (redox) potential (*Eh*) and redox buffering capacity, antimicrobial substances naturally present in foods, added as preservatives or produced by biological processes such as fermentation. Other biological intrinsic factors include the tissue structure of foods. Overall, pH and a_w are the most important intrinsic factors to consider in assessing whether pathogenic microorganisms will grow in foods during their shelf-life. In food products formulated with preservatives with antimicrobial activity (e.g. organic acids and their salts such as lactate, acetate, propionate, sorbate, curing agents (nitrites), sulfites etc.), the type and concentration of the antimicrobial substance/s added are also relevant intrinsic factors reducing the growth potential of sensitive microorganisms (e.g. reducing the growth rate and/or extending the lag phase). The extent of the antimicrobial effects of preservatives depends on the microorganism and also on the dose and its interactions with other components (e.g. proteins, lipids) and factors (e.g. pH, a_w) of the food to which they are added (Davidson and Branen, 2005).

Generally, it is accepted that foods with a pH below 3.9 or a_w below 0.88 do not support the growth or toxin production of foodborne pathogenic microorganisms, irrespectively of the storage conditions (temperature, atmosphere…) (NACMCF, 2010; EFSA BIOHAZ Panel, 2012), though other microorganisms, such as yeast and moulds, could grow and cause spoilage. Combinations of pH and/ or a_w of non-heat-treated food (or heat treated but exposed to re-contamination) that inhibit the growth of any pathogen (vegetative or sporulated) include (NACMCF, 2010):

- $a_w \leq 0.88$ or
- pH ≤3.9 or
- $a_w \leq 0.96$ and pH ≤ 4.2
- $a_w \leq 0.92$ and pH ≤ 4.6
- $a_w \leq 0.90$ and pH ≤ 5.0

For pH and/or a_w values above those just mentioned, time/temperature control for safety is required unless proved to the contrary. It is worth mentioning that the conditions specified in Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs, for foods not supporting growth of *L. monocytogenes* (i.e. pH ≤ 4.4 or $a_w \leq 0.92$, or pH ≤ 5.0 and $a_w \leq 0.94$) will not inhibit all pathogenic microorganisms, e.g. *S. aureus* can grow at lower a_w (> 0.88).

In pasteurised foods, where vegetative pathogens have been eliminated, the growth of pathogenic spore-forming bacteria and/or the toxin production is prevented when (NACMCF 2010; US FDA, 2017):

- pH ≤ 4.6 (i.e. acid or acidified food)
- $a_w \leq 0.92$
- $a_w \leq 0.95$ and pH ≤ 5.6

For foods with pH and/or a_w values above those just mentioned, time/temperature control for safety (TCS) is required unless the FBO can show that other hurdles (such as natural antimicrobial substances or added preservatives) contribute to prevent microbial growth and/or toxin production (NACMCF, 2010).

Combining materials or ingredients to form multicomponent food products also modifies the intrinsic parameters, throughout or at the interface of components, depending on the type of product, resulting in new equilibria of intrinsic parameters that also influence microbial growth. Multicomponent food products present more complex situations, especially at the interface of the dissimilar components, where there will be an equilibrium established in properties that affect microbial growth, which may alter the expected behaviour of pathogens during storage in either the food components or their composite. This might be especially of concern when one food component provides the contaminants (e.g. bacterial spores or vegetative pathogens) and another modifies the properties (e.g. pH, a_w, etc.) at the interface of components allowing growth of contaminants (Glass et al., 2015). Further, microenvironments allowing growth of bacterial pathogens may be established within multicomponent products through growth of non-pathogenic species of microorganisms (e.g. mould growth in acidic products raising the microenvironment pH through metabiosis and allowing subsequent microbial and spore growth).

3.2.2.2. Extrinsic or environmental factors

One of the most relevant extrinsic or environmental factors affecting a food is temperature. The lower the temperature the lower the microbial growth rate. At temperatures below –6 to –10°C, microbial growth does not occur, and at freezing temperatures (–18°C), spoilage will be associated with chemical and physical processes, such as oxidation and/or desiccation (Brown, 1991).

In non-packed food or food packed using a permeable packing material, the relative humidity can play a role as it affects the a_w of the surface of the food. In packed food, gas composition of the package atmosphere (which is affected by the permeability of the packing material) modifies microbial growth depending on the concentration of gases with antimicrobial activity (i.e. CO_2) or reduction/ elimination of O_2 concentration (Uyttendaele et al., 2018).

3.2.2.3. Implicit factors

Implicit factors refer to those depending on the particularly dominant microbiota that initially develop according to intrinsic and extrinsic factors and determine the co-existence with other microorganisms. Microbial interactions can result in an increased or decreased growth of technological microbiota (e.g. in fermented foods), pathogenic or spoilage microorganisms, with symbiotic (Furukawa et al., 2013) and antagonistic effects (Kostrzynska and Bachand, 2006; Jordan et al., 2014), respectively.

Microbial growth can modify some intrinsic factors through its metabolic action, consuming and/or releasing substances capable of modifying the pH, redox potential, nutrient availability, structure etc. Consequently, the subsequent growth of the microbial groups in the food can also be affected. The effects of interacting factors can be synergistic or antagonistic; examples of synergistic effects: one organism removing a substance or changing the pH that is inhibitory to another, or an organism producing growth factors required by another. Antagonistic mechanisms include non-specific competitive exclusion and the production of metabolites (e.g. organic acids, bacteriocins etc.) able to inhibit the growth and sometimes inactivate some microorganisms (Jordan et al., 2014).

Combining food materials to form multicomponent products may also modify the microbiota of the food through cross-contamination, as microorganisms, including pathogens, from different food materials might be introduced in the multicomponent product (see Table 3).

The reduction or elimination of background microbiota by pasteurisation constitutes better conditions for the growth of non-competitive psychrotrophic pathogens, either spore formers resistant to the heat treatment (*B. cereus*, non-proteolytic *C. botulinum*) or re-contaminating the product if exposed after the heat treatment (e.g. *L. monocytogenes*). In addition, pasteurisation may induce spore germination to a more abundant development of germinated spores compared to the non-heated products.

3.2.3. Concluding remarks

- The raw materials, the processing environment and the manufacturing steps determine the type and the concentration of microorganisms in the food product when released to the market.
- The intrinsic (properties of the food), extrinsic (properties of the environment outside the food) and implicit (effects due to other microorganisms, often the dominating microorganisms present in the food) factors determine which microorganisms can grow in the food product, and the growth potential during subsequent stages of distribution and storage from retail to consumption.
- Different pathogenic and spoilage microorganisms can grow only under a specified set of conditions, e.g. temperature, pH, a_w. Growth limiting factors of microbiological pathogens can be found in the literature and/or determined experimentally. The impact of implicit factors (interactions with competing background microbiota) will often need to be assessed experimentally.
- It is important for the FBO to understand the purpose and effect of the processes applied in the steps during manufacture. Some processes are not designed for inactivation of microorganisms (e.g. washing, mincing, mixing) while others are (e.g. UHT, pasteurisation), but all may have an impact on the concentration and distribution of microorganisms in the food product.
- Adequate data of the extrinsic, intrinsic, implicit factors of the food, but also conditions of the manufacturing processes influencing the occurrence and growth of microorganisms in the food product, is a necessity for informed decisions on the type of date marking, shelf-life and storage conditions. Validation activities to collect scientific and technical evidence that the control measures are effective in controlling the target pathogens under all production circumstances are also needed.

3.3. Guidance on the decision to apply a 'use by' or 'best before' date (ToR 1d)

The decision on whether a food should have a 'use by' or a 'best before' date needs to be taken on a product-by-product basis, considering the product characteristics (including processing) and storage conditions as described in Section 3.2, taking into account variability and reasonably foreseeable conditions (see Section 3.4.1), as well as its intended use (Section 1.3.1).

A DT was developed to assist FBOs in deciding whether a 'use by' or 'best before' date is appropriate for a certain prepacked food product. The DT is based on the interpretation of the definitions of the 'use by' and 'best before' dates in Regulation (EU) No 1169/2011 and the considerations in Section 1.3.2. In particular, the underlying assumptions for the DT are that:

1) the decision about the type of date marking is based on whether any pathogenic microorganisms may be present at the end of processing, and if they can grow or produce toxin during the shelf-life
2) in the absence of defined acceptable levels of pathogenic microorganisms, any significant growth during shelf-life may increase the risk of illness for the consumers including normal and susceptible populations
3) cooking alone, before consumption, may not eliminate the risk, due to the possibility of cross-contamination post-cooking and/or undercooking at the consumer stage
4) if both spores and vegetative cells of pathogenic microorganisms are present in a food product, growth limits targeting vegetative cells apply as these will also ensure spores do not germinate, grow and form toxin.

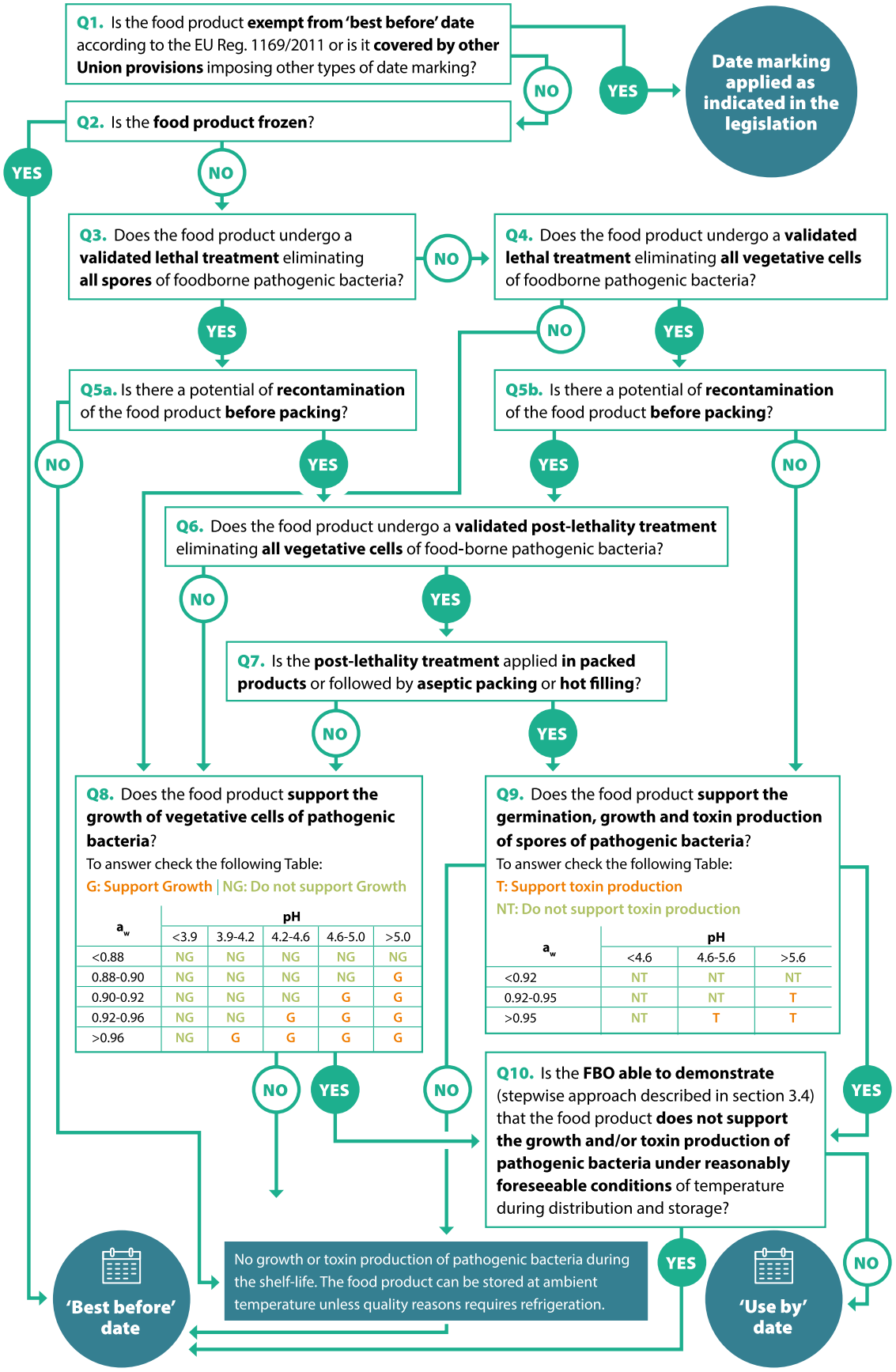
In the case of food products with either an absence of pathogens at the end of processing or the presence of pathogens in a food that does not support growth or toxin production, the risk of illness for the consumers would not increase during shelf-life and a 'best before' date is appropriate. In contrast, if growth of the pathogen(s) or toxin production is possible in the food product, the risk is expected to increase during shelf-life and thus a 'use by' date is required. Growth of pathogenic microorganisms during storage may lead to a higher risk also for products that are intended to be cooked before consumption. In the latter case, the potential increase of the risk is affected by several factors including the extent of pathogen growth during distribution and storage, the possibility of

cross-contamination during preparation (before cooking), as well as the variability in cooking time–temperature conditions among recipes and consumers which provides a certain probability of undercooking, which will not eliminate the microorganisms or their toxins before consumption.

Based on the rationale and assumptions above, the intended use of a food product (described in Section 1.3.1) does not impact on the outcome of the current DT. According to assumptions (2) and (3), no distinction is made based on whether the food is RTE, to be eaten raw, to be eaten cooked, to be reconstituted or the consumer target group (general population or food targeted to particularly vulnerable consumer groups such as infant food or food for medical purposes) and end users (business to business, mass caterers or final consumer).

3.3.1. Development of the decision tree

The DT consists of a sequence of ten questions (Q1–Q10) which lead to the decision on the selection of a 'use by' or a 'best before' date marking for a specific product (see Figure 1).



a_w	pH				
	<3.9	3.9-4.2	4.2-4.6	4.6-5.0	>5.0
<0.88	NG	NG	NG	NG	NG
0.88-0.90	NG	NG	NG	NG	G
0.90-0.92	NG	NG	NG	G	G
0.92-0.96	NG	NG	G	G	G
>0.96	NG	G	G	G	G

a_w	pH		
	<4.6	4.6-5.6	>5.6
<0.92	NT	NT	NT
0.92-0.95	NT	NT	T
>0.95	NT	T	T

Figure 1: Decision tree on the appropriate date marking for temperature controlled prepacked foods

Question 1 (Q1) refers to the exemption from 'best before' date according to Annex X in Regulation (EU) No 1169/2011 (Appendix A) or the case of a food product which is covered by other EU provisions imposing a specific date marking (Appendix A).

If the food is not exempt or it is not covered by other EU provisions, the FBO should proceed to Q2, which is related to the frozen storage of the product. When a product is distributed and stored frozen, growth of pathogenic microorganisms during the shelf-life is not expected, and a best before date is appropriate.

For non-frozen foods, the FBO must evaluate the effect of processing on the contamination of the end product by answering questions Q3–Q10.

Q3–Q4 ask if the food product undergoes a validated lethal treatment eliminating all spores (Q3) or all vegetative cells (Q4) of food-borne pathogenic bacteria, respectively. The FBO must answer these questions considering the effect of the processing conditions (e.g. time and temperature of a thermal treatment) on the inactivation of pathogens (see Table 4 of Section 3.2.1). For example, if a food product undergoes a pasteurisation treatment targeted towards the most thermally resistant vegetative pathogenic bacterium but does not eliminate the bacterial spores, the answer to Q3 is 'No' and the answer to Q4 is 'Yes'. In the case of mixed or multicomponent products a 'Yes' to Q3 or Q4 should refer to all ingredients of the end product.

Q5 (Q5a or Q5b) relates to the potential for recontamination before packing. In this question, 'before packing' refers to the steps after the 'validated lethal treatment' mentioned in Q3 or Q4. For example, for in-package lethal treatment or aseptic packing or hot filling the answer to Q5a is 'No' while it is 'Yes' if there is any handling after the lethal treatment and before packing. Similarly, for in-package treatment or aseptic packing or hot fill the answer to Q5b is 'No' while it is 'Yes' if there is any handling after the lethal treatment and before packing which leads to a potential of microbial contamination.

Q6 covers food products that undergo a validated post-lethality treatment. Post-lethality treatment refers to a second lethal treatment after the primary treatment mentioned in Q3–Q4 eliminating all vegetative cells of the relevant pathogenic bacteria such as a high-pressure processing (HPP). As for Q3–Q4, Q6 should be answered based on the effect of the processing conditions (e.g. time and pressure of the HPP) on the inactivation of pathogens. Depending on this effect, the end product (after processing) can be: (i) free of pathogens (i.e. below detection), (ii) potentially contaminated only with spores of pathogenic bacteria or (iii) potentially contaminated with spores and vegetative cells of pathogenic bacteria. For example, if the food undergoes a validated treatment eliminating all vegetative cells (but not all spores) of food-borne pathogenic bacteria and potential recontamination before packing is not possible, then potential contamination of the end product is limited only to spores of pathogenic bacteria. In contrast, if recontamination after a heat treatment but before packing is possible (e.g. slicing of cooked ham before packing) then contamination of the end product may also include vegetative cells of pathogenic bacteria.

Q7 refers to the conditions after the post lethality treatment and before packing and evaluates the potential of recontamination. For in-package treatment or aseptic packing or hot filling the answer to Q7 is 'Yes' while it is 'No' if there is any handling after the post lethality lethal treatment and before packing which leads to a potential of microbial contamination.

Depending on the type of contamination in the end product (spores or vegetative cells), the FBO should further evaluate whether the food product supports growth or toxin production of the pathogenic bacteria by answering Q8 or Q9. The ability of a food product to support growth of pathogenic bacteria is evaluated based on its pH and a_w (IFT 2003), through tables provided in the DT (see Section 3.2.2.1). It needs to be noted that the tables presented in Q8 and Q9 refer to an optimum growth temperature and optimum conditions for all other factors affecting microbial growth (e.g. the absence of preservatives and no presence of MAP or vacuum-packing). If a food product has a combination of pH and a_w which does not allow growth of pathogenic bacteria, it can be stored at ambient temperature unless it requires refrigeration for quality reasons. In this case, a 'best before' date marking is appropriate.

For products with a combination of pH and a_w that allows the growth or toxin production of pathogenic bacteria a 'use by' date is required unless the FBO is able to provide evidence that the food product does not support growth or toxin production of pathogens under reasonably foreseeable conditions of temperature during distribution and storage, due to, for instance, additional hurdles (such as preservatives, storage atmosphere) (Q10). The evidence should refer to the intrinsic and extrinsic factors of the food product irrespective of the time of storage (i.e. should be valid even after the food product passes the 'best before' date). Demonstration of the latter may require specific studies, e.g. challenge tests focusing on the relevant pathogenic microorganisms based on the food,

its characteristics and the storage conditions (see Section 3.4.2). For example, in the case of a fish product packed under MAP in which only spores of pathogenic bacteria may be present at the end of processing and which is distributed under refrigeration, the evidence provided by the FBO should focus on non-proteolytic *Cl. botulinum*.

For mixed foods where intrinsic factors such as pH and a_w may evolve/change when the ingredients are mixed and/or during the subsequent storage, the answers to Q8 and Q9 and Q10 should be based on the ingredients with the more favourable intrinsic factors for microbial growth. In case an equilibrium is reached before the food leaves the control of the FBO then the answer to Q8, Q9 and Q10 can be based on the intrinsic factors at equilibrium.

3.3.1.1. Application examples of the decision tree for date marking to specific food products

Table 6 presents some examples of applying the DT for date marking to specific food products. As mentioned before, the answers to the questions of the DT depend on the processing/packing conditions and the intrinsic and extrinsic factors of the specific food product. This means that the outcome of the DT can be different even for products with the same generic name (see e.g. in Table 6 UHT milk examples). Thus, certain assumptions regarding processing/packing conditions and intrinsic factors were made. In the following paragraphs, the application examples presented in Table 6 are discussed showing how small differences in processing/packing conditions and intrinsic/extrinsic factors can affect the outcome of the DT.

Milk and dairy products

UHT milk is not exempt from the 'best before' date according to Annex X to Regulation (EU) No 1169/2011 (Q1: No) and is not distributed or stored as frozen food product (Q2: No). UHT treatment (> 135°C for 2–5 s) is expected to eliminate all spores of food-borne pathogenic bacteria (Q3: Yes). Normally the dairy industry uses aseptic filling units for packing the milk and so there is no potential for recontamination after the heat treatment and before packing (Q5a: No). Based on the above, the in-package product is free of food-borne pathogenic bacteria and the milk can be stored at ambient temperature unless quality reasons require refrigeration, and thus a 'best before' date marking of UHT milk is appropriate. However, when the packing is not aseptic, there is a potential for recontamination with vegetative cells of pathogenic bacteria before packing (Q5a: Yes). When the milk is not undergoing a validated post-lethal treatment (Q6: No) and considering that the pH (> 6.5) and a_w (> 0.99) of UHT milk support growth of vegetative pathogenic bacteria microorganisms (Q8: Yes), the milk should be distributed and stored under refrigeration and requires a 'use by' date, unless the FBO has evidenced that the product does not support growth of pathogenic bacteria under reasonably foreseeable conditions of temperature during distribution and storage (Q10: No).

Yoghurt is not exempt from the 'best before' date according to Annex X to Regulation (EU) No 1169/2011 (Q1: No) and is not distributed or stored as frozen food products (Q2: No). The processing involves pasteurisation of milk which does not eliminate spores of pathogenic bacteria (Q3: No) but is expected to eliminate vegetative cells (Q4: Yes). During inoculation of the starter culture and packing, there is a potential for recontamination (Q5b: Yes). As the yoghurt does not undergo a validated post-lethal treatment (Q6: No) and assuming a pH > 4.2 and a_w > 0.990, the product can support growth of pathogenic bacteria (Q8: Yes). If the FBO cannot demonstrate that the food product does not support growth of pathogens under reasonably foreseeable conditions of temperature during distribution and storage (Q10: No), the product requires a 'use by' date. However, if the FBO, by applying the stepwise approach described in Section 3.4.2, is able to demonstrate that, due to the presence of a certain starter culture in the yoghurt and considering the reasonably foreseeable temperatures during refrigerated storage, yoghurt does not support growth of pathogenic bacteria (Q10: Yes) then a 'best before' date is appropriate.

Meat and meat products

Fresh meat (e.g. fresh pork) is not exempt from the 'best before' date according to Annex X to Regulation (EU) No 1169/2011 (Q1: No) and is not distributed or stored as frozen food product (Q2: No). This food product is not heat treated (Q3: No, Q4: No) and can support growth of vegetative cells of pathogenic bacteria (Q8: Yes) based on pH (5.7) and a_w (0.99). If the FBO is not able to demonstrate that the fresh meat does not support growth of pathogens under reasonably foreseeable conditions of temperature during distribution and storage (Q10: No), the fresh pork would require a 'use by' date.

Vacuum-packed sliced thermally treated meat product (e.g. Genoa Salami) are not exempt from the 'best before' date according to the Regulation (EU) No 1169/2011 (Q1: No) and are not distributed or stored as frozen food products (Q2: No). The validated heat treatment does not eliminate spores of food-borne pathogenic bacteria (Q3: No) but is expected to eliminate vegetative cells (Q4: Yes). When the product is sliced after the primary validated heat treatment (Q3–4), there is a potential for recontamination (Q5b: Yes). Assuming no validated post-lethal treatment (Q6: No), a pH = 5.0 and a_w = 0.94, the meat product can support growth of pathogen's vegetative cells (Q8: Yes). If the FBO is not able to demonstrate that the meat product does not support growth of pathogens under reasonably foreseeable conditions of temperature during distribution and storage (Q10: No), the product requires a 'use by' date. The outcome of the DT can change if the processing/ packing conditions and the intrinsic/extrinsic factors of the meat product are different. For example, in the case of a vacuum-packed sliced thermally treated meat product, which is treated after slicing once in the final package with high pressure (HHP) thereby eliminating all vegetative cells of food-borne pathogenic bacteria (Q6: Yes), and the HHP treatment is in the package (Q7: Yes), while the combination of pH and a_w (pH = 5.0 and a_w = 0.94) does not support germination, growth and toxin production of spores of pathogenic bacteria (Q9: No), the output of the DT would indicate that a 'best before' date is appropriate.

Products derived from fruits and vegetables

Fresh fruit juice (e.g. orange juice) is not exempt from the 'best before' date according to Annex X to Regulation (EU) No 1169/2011 (Q1: No) and is not distributed or stored as frozen (Q2: No). There is no heat treatment that eliminates spores or vegetative cells of pathogenic bacteria in all ingredients (Q3: No, Q4: No). Assuming pH = 3.6 and a_w = 0.995, the juice does not support growth of pathogen's vegetative cells (Q8: No), and thus, the product can be stored at ambient temperature unless quality reasons require refrigeration, and a 'best before' date is appropriate.

Pasteurised fruit juice (e.g. orange juice) products are not exempt from the 'best before' date according to Annex X to Regulation (EU) No 1169/2011 (Q1: No) and are not distributed or stored as frozen food product (Q2: No). The first validated lethal treatment, pasteurisation, does not eliminate all spores of pathogenic bacteria (Q3: No) but is expected to eliminate their vegetative cells (Q4: Yes). If the product is not packed under aseptic conditions, there is a potential for recontamination (Q5b: Yes). If the product is not undergoing a validated post-lethal treatment (Q6: No) and assuming a pH = 3.6 and a_w = 0.995, the product cannot support growth of vegetative cells of pathogenic bacteria (Q8: No), the product can be stored at ambient temperature unless quality reasons require refrigeration and a 'best before' date is appropriate. The outcome would have been the same for an aseptically packed pasteurised fruit juice (with Q5b: No and Q9: No).

Frozen vegetables (e.g. frozen carrots) are not exempt from the 'best before' date according to Annex X to Regulation (EU) No 1169/2011 (Q1: No) but are distributed or stored as frozen food product (Q2: Yes). Thus, a 'best before' date is appropriate.

Other food products

Mixed salad with fresh and canned ingredients is not exempt from the 'best before' date according to Annex X to Regulation (EU) No 1169/2011 (Q1: No) and is not distributed or stored as frozen food product (Q2: No). If there is no heat treatment that eliminates spores or vegetative cells of pathogenic bacteria in all ingredients (Q3: No, Q4: No), and assuming a combination of pH of 5.5 and a_w of 0.94 after equilibration between ingredients (important since mixed product), growth of pathogen's vegetative cells, is supported (Q8: Yes). If the FBO cannot demonstrate otherwise (Q10: No), then the product requires a 'use by' date. When convergence to equilibrium occurs after the food has left the control of the FBO, the answers to Q8, Q9 and Q10 should be based on the ingredients with the more favourable intrinsic factors for microbial growth.

Table 6: Application examples of the decision tree on the appropriate date marking for temperature controlled prepacked foods

DT question	Milk and dairy products				Meat and meat products			Products derived from fruits and vegetables			Other food products
	UHT milk (e.g. pH = 6.6, a_w = 0.995)		Yoghurt (e.g. pH = 4.3 and a_w = 0.995)		Fresh meat (e.g. fresh pork with pH = 5.7 and a_w = 0.99)	Vacuum-packed sliced thermally treated meat product (e.g. Genoa Salami (e.g. pH = 5.0 and a_w = 0.94)		Fresh fruit juice (e.g. fresh orange juice with pH = 3.6 and a_w = 0.995)	Pasteurised fruit juice (e.g. pasteurised orange juice with pH = 3.6 and a_w = 0.995)	Frozen vegetables (e.g. frozen carrots)	Mixed salad with fresh and canned ingredients (e.g. leafy salad with canned corn, with a combination of pH = 5.5, a_w = 0.94 for at least one ingredient)
	Aseptic packing	No aseptic packing	With starter culture and conditions which does not inhibit growth of pathogens under refrigeration	With starter culture and conditions inhibiting growth of pathogens under refrigeration		No HPP	In package HPP				
Q1. Is the food product exempt from best before date according to the EU Reg. 1169/2011 or is it covered by other Union provisions imposing other types of date marking?	No	No	No	No	No	No	No	No	No	No	No
Q2. Is the food product frozen?	No	No	No	No	No	No	No	No	No	Yes	No
Q3. Does the food product undergo a validated lethal treatment eliminating all spores of food-borne pathogenic bacteria?	Yes	Yes	No	No	No	No[(g)]	No[(g)]	No	No		No
Q4. Does the food product undergo a validated lethal treatment eliminating all vegetative cells of food-borne pathogenic bacteria?	NA	NA	Yes[(c)]	Yes[(c)]	No	Yes[(g)]	Yes[(g)]	No	Yes		No[(o)]

DT question	Milk and dairy products				Meat and meat products			Products derived from fruits and vegetables			Other food products
	UHT milk (e.g. pH = 6.6, a_w = 0.995)		Yoghurt (e.g. pH = 4.3 and a_w = 0.995)		Fresh meat (e.g. fresh pork with pH = 5.7 and a_w = 0.99)	Vacuum-packed sliced thermally treated meat product (e.g. Genoa Salami (e.g. pH = 5.0 and a_w = 0.94)		Fresh fruit juice (e.g. fresh orange juice with pH = 3.6 and a_w = 0.995)	Pasteurised fruit juice (e.g. pasteurised orange juice with pH = 3.6 and a_w = 0.995)	Frozen vegetables (e.g. frozen carrots)	Mixed salad with fresh and canned ingredients (e.g. leafy salad with canned corn, with a combination of pH = 5.5, a_w = 0.94 for at least one ingredient)
	Aseptic packing	No aseptic packing	With starter culture and conditions which does not inhibit growth of pathogens under refrigeration	With starter culture and conditions inhibiting growth of pathogens under refrigeration		No HPP	In package HPP				
Q5a. or Q5b. Is there a potential of recontamination of the food product before packing?	No[(b)]	Yes	Yes[(d)]	Yes[(d)]	NA	Yes[(h)]	Yes[(h)]	NA	Yes[(m)]		NA
Q6. Does the food product undergo a validated post-lethality treatment eliminating all vegetative cells of food-borne pathogenic bacteria?	NA	No	No	No	NA	No	Yes[(j)]	NA	No		NA
Q7. Is the post-lethality treatment applied in packed products or followed by aseptic packing or hot fill?	NA	NA	NA	NA	NA	NA	Yes[(j)]	NA	NA		NA
Q8. Does the food product support growth of vegetative cells of pathogenic bacteria?	NA	Yes[(a)]	Yes[(e)]	Yes[(e)]	Yes[(f)]	Yes[(i)]	NA	No[(l)]	No[(n)]		Yes[(p)]
Q9. Does the food product support germination, growth and toxin production of spores of pathogenic bacteria?	NA	NA	NA	NA	NA	NA	No[(k)]	NA	NA		NA

DT question	Milk and dairy products				Meat and meat products			Products derived from fruits and vegetables			Other food products
	UHT milk (e.g. pH = 6.6, a_w = 0.995)		Yoghurt (e.g. pH = 4.3 and a_w = 0.995)		Fresh meat (e.g. fresh pork with pH = 5.7 and a_w = 0.99)	Vacuum-packed sliced thermally treated meat product (e.g. Genoa Salami (e.g. pH = 5.0 and a_w = 0.94)		Fresh fruit juice (e.g. fresh orange juice with pH = 3.6 and a_w = 0.995)	Pasteurised fruit juice (e.g. pasteurised orange juice with pH = 3.6 and a_w = 0.995)	Frozen vegetables (e.g. frozen carrots)	Mixed salad with fresh and canned ingredients (e.g. leafy salad with canned corn, with a combination of pH = 5.5, a_w = 0.94 for at least one ingredient)
	Aseptic packing	No aseptic packing	With starter culture and conditions which does not inhibit growth of pathogens under refrigeration	With starter culture and conditions inhibiting growth of pathogens under refrigeration		No HPP	In package HPP				
Q10. Is the FBO able to demonstrate (stepwise approach described in Section 3.4) that the food product does not support the growth and/or toxin production of pathogenic bacteria under reasonably foreseeable conditions of temperature during distribution and storage?	No	NA	No	Yes	No	No	NA	NA	NA		No
Date marking	Best before	Use by date	Use by date	Best before	Use by date	Use by date	Best before	Best before	Best before	Best before	Use by date

NA = not applicable; DT = decision tree.
(a): Based on the combination of pH = 6.6 and a_w = 0.995, the product can support growth of pathogen's vegetative cells (see table in Q8 of the DT).
(b): Aseptic packing does not allow microbial contamination.
(c): The validated thermal treatment refers to the pasteurisation of milk.
(d): Yoghurt cup filling may allow microbial contamination.
(e): Based on the combination of pH = 4.3 and a_w = 0.995, the product can support the growth of pathogen's vegetative cells (see table in Q8 of the DT).
(f): Based on the combination of pH = 5.7 and a_w = 0.99, the product can support the growth of pathogen's vegetative cells (see table in Q8 of the DT).
(g): Thermal treatment of the product is equivalent to pasteurisation which eliminates vegetative cells of pathogenic bacteria but not their spores.
(h): Slicing after thermal treatment allows recontamination.
(i): Based on the combination of pH = 5.0 and a_w = 0.94, the product can support the growth of pathogen's vegetative cells (see table in Q8 of the DT).
(j): HHP is applied in packed product.
(k): Based on the combination of pH = 5.0 and a_w = 0.94, the product cannot support the growth of pathogen's spores (see table in Q9 of the DT).
(l): Based on the combination of pH = 3.6 and a_w = 0.995, the product cannot support the growth of pathogen's vegetative cells (see table in Q8 of the DT).

(m): Contamination may occur during filling if no aseptic packing is applied.
(n): Based on the combination of pH = 3.6 and a_w = 0.995, the product cannot support the growth of pathogen's vegetative cells (see table in Q8 of the DT).
(o): If at least one ingredient does not undergo a validated lethal treatment, the answer is 'No'.
(p): If the combination of pH = 5.5 and a_w = 0.94 of at least one ingredient can support the growth of pathogen's vegetative cells (see table in Q8 of the DT).

3.3.2. Uncertainty analysis of the date marking decision tree

Potential sources of uncertainty associated with the date marking DT, i.e. assumptions, methods, data, questions included and the structure of the DT, are presented in Table C.1 (Appendix C). The impact of the source of uncertainty in terms of the direction of the decision was expressed as overestimation of risk, i.e. that some foods for which a 'best before' date is appropriate end up having a 'use by' date, or underestimation, i.e. that some foods requiring a 'use by' date end up having a 'best before' date, or inconclusive, i.e. could be either/or. Sources of uncertainty affecting the decision on the type of date marking but related to the application of the DT by the FBO are listed in Table C.2 (Appendix C).

Based on discussions and evaluations of examples of food products using the DT, it was considered that all the relevant questions were identified and included in the DT. During the development of the DT, the phrasing, relevance and relation between questions were discussed. The structure of the tree was deemed logical, and to reflect the relevant events that may take place and influence the outcome of the DT, but to some extent also determined by convenience and graphical layout. The outline of the tree can be modified in an elaborated version tailored to specific uses and/or food products if considered appropriate.

The largest potential impact on the decision is the uncertainty related to Q10 – if FBOs can demonstrate that food products do not support growth. This makes Q10 a pivotal question that can reverse the decision from 'use by' date to 'best before' date, or vice versa, and places high demands on the data and methods used to inform this decision. If not done properly, this may lead to underestimation (or overestimation) of risk as defined here.

Next in terms of potential impacts are the uncertainties related to basing microbial growth/no growth decisions on growth limiting pH and a_w, at otherwise optimum conditions, and the data used for growth limits representing the most pH and a_w growth tolerant vegetative microorganisms and spores. These uncertainties may potentially contribute to an overestimation of risk, since these limits would presumably be less strict if temperature, etc. was also suboptimal, and for less tolerant microorganisms. However, Q10 is used as a check for overestimations, where FBOs can use detailed information for their product to modify the decision to become a 'best before' date or 'use by' date as appropriate. An underestimation is possible as well with the data used but is considered less likely than overestimation since this would only occur in the case of emergence or the existence of hyper-tolerant microorganisms.

The uncertainties related to the assumption of not considering inactivation at the consumer stage may contribute to an overestimation of risk. However, the impact of these uncertainties is considered to be low and is only relevant for some non-RTE products, such as cuts of prepacked fresh meat. However, this assumption was considered necessary in the absence of microbiological risk assessment and defined acceptable microbiological levels at the time of consumption.

Overall, it is considered that the relevant questions are included in the DT and in a logical and consistent manner to result in appropriate outcomes on date marking within the assumptions and interpretations of regulations made in its development. The main sources of uncertainty which may impact on the direction of the decisions are the assumptions on growth limiting pH and a_w for worst-case microorganisms at optimum conditions, which can lead to an overestimation of risk, and the structure of the DT, where the outcome of a single question (Q10) can reverse the decision on the type of date marking. The latter may contribute to either under- (more serious from a public health perspective) or overestimation if not applied correctly, illustrating the importance of how the DT will be understood and applied. Taken together, the uncertainties are considered to result in a DT that may overestimate risk for some food products, unless appropriate use of Q10 is applied. This is partly a consequence of the lack of risk assessments and defined appropriate levels of protection, food safety objectives and associated acceptable levels of pathogenic microorganisms at the time of consumption.

3.3.3. Concluding remarks

- The decision on the appropriate type of date marking, i.e. whether a food should have a 'use by' or a 'best before' date, needs to be taken on a product-by-product basis, considering the product characteristics, processing and reasonably foreseeable storage conditions.
- A decision tree (DT) consisting of a sequential list of 10 questions was developed, and supported with examples, to assist FBOs in deciding the type of date marking for a certain food product. The underlying assumptions for the DT are that:

  - the decision is based on whether any pathogenic bacteria may be present at the end of processing, and if they can grow or not during the shelf-life;
  - any increase in concentrations of the pathogenic bacteria is relevant for the decision in the absence of defined acceptable levels of pathogenic microorganisms;
  - heating of foods before consumption may not eliminate all the pathogenic bacteria or their toxins and may be associated with consumer risks; and
  - if both spores and vegetative cells of pathogenic bacteria may be present in a food product, the growth limits for vegetative cells apply since these are wider than for growth and toxin production of bacterial spore-forming species.

- According to the DT, in the case of products that are processed in a way that results in the absence of pathogenic bacteria, or a processed product that does not support their growth, the consumer risk would not increase during shelf-life and a 'best before' date is appropriate. In contrast, if there is no pathogen elimination step, or the possibility of recontamination after such a treatment, and the food product supports the growth of the contaminating pathogen, the consumer risk is expected to increase during shelf-life and a 'use by' date is required.
- An uncertainty analysis of the potential sources of uncertainty characterised their potential contribution to the estimated consumer risk as overestimated, i.e. that some foods for which a 'best before' date is appropriate may end up having a 'use by' date, or underestimated, i.e. that some foods requiring a 'use by' date end up having a 'best before' date, or inconclusive, i.e. could be in either category.
- Overall, the uncertainty analysis considered that the DT will result in appropriate and consistent outcomes on date marking within the above interpretations of the regulations and the assumptions made in its development, e.g. using growth or no-growth as the basis for decisions.
- The main sources of uncertainty that can impact on the direction of the decisions are the assumptions and data on growth limiting pH and a_w for worst-case microorganisms at otherwise optimum conditions, and the structure of the DT, where the outcome of a single question can reverse the decision on the type of date marking. The latter may contribute to underestimation if not applied correctly, illustrating the importance of how the DT will be understood and applied.
- Taken together, the uncertainties are considered to result in a DT that may overestimate the risk for some food products, unless the FBOs make appropriate use of the opportunity in the DT (Question 10) to demonstrate that their product does not support the growth of pathogens under reasonably foreseeable temperature conditions of distribution and storage, irrespectively of the time frame. The potential overestimation is partly a consequence of the lack of risk assessments and defined acceptable levels of protection, FSOs and associated acceptable levels of pathogenic microorganisms at the time of consumption.

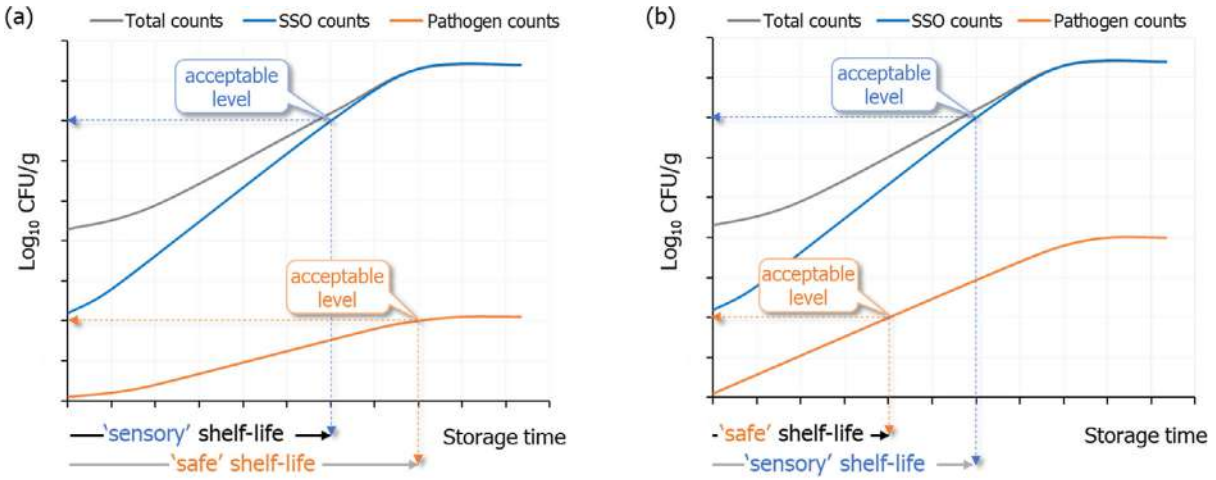
3.4. Approaches for setting shelf-life and required storage conditions (ToR 1d and ToR 2b)

The initial prevalence and concentration of pathogenic microorganisms present in the food product post-production, and how these microorganisms can grow during subsequent distribution and storage conditions, need to be considered in setting the shelf-life. The same type of food but produced under different levels of hygiene control can be associated with different initial levels of the relevant pathogenic and spoilage microorganisms. Moreover, several preservation technologies can be applied to the same type of food leading to different levels of pathogenic or spoilage microorganisms being associated with the final food product, despite appearing to be a similar product from a consumer perspective.

Shelf-life as defined in Regulation (EC) No 2073/2005 means either the time corresponding to the period preceding the 'use by' or the minimum durability ('best before') date. According to Regulation (EU) No 1169/2011, date of minimum durability ('best before' date) means the date until which the food retains its specific properties when properly stored. This period can therefore be considered as relating to the quality of foods. Regulation (EU) No 1169/2011 requires that in the case of foods which, from a microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health, the date of minimum durability shall be replaced by the 'use by' date. After the 'use by' date, a food shall be deemed to be unsafe in

accordance with Article 14(2) to (5) of Regulation (EC) No 178/2002. This period is related to the safety of foods.

Several factors related to either food quality or to food safety determine the shelf-life of a food product. Factors related to food quality include organoleptic changes due to physical (e.g. water loss (drying) or water gain leading to loss of crunchiness), chemical, biochemical/enzymatic and microbiological phenomena. Factors related to food safety include growth of pathogens and/or toxin production. Referring to these as 'sensory shelf-life' (here only changes due to microbial growth of spoilage causing microorganisms) and 'safe shelf-life' (based upon potential growth or toxin production of pathogens (NACMCF, 2005), respectively, the attributed shelf-life time (to be indicated in the labelling) should never be longer than the shortest of these. If the safe shelf-life is longer than the sensory shelf-life, then the sensory shelf-life should determine the length of the shelf-life for a 'use by' product, and vice versa (see Figure 2). Which of these situations is relevant, depends on several factors, such as types and initial levels of spoilage and pathogenic microorganisms, and may vary, depending on the intrinsic and extrinsic factors of the food. For instance, some factors may have inhibitory effects on the growth of spoilage microorganisms but be less effective in inhibiting the growth of the relevant pathogenic microorganisms. In these cases, the safe length of the shelf-life may be close to or even shorter than the sensory shelf-life.



In (a) sensory spoilage determines the shelf-life of food, i.e. SSO reach spoilage level before pathogenic microorganisms have reached maximum acceptable levels, while in (b) shelf-life is determined by the growth of pathogenic microorganisms to exceed acceptable levels before SSO reach the spoilage level.

Figure 2: Food characteristics and storage conditions support the growth of both pathogenic (hazard) and specific spoilage organisms (SSO) during storage (adapted from Dalgaard at ISOPOL, 2010 & 1993 paper)

3.4.1. Reasonably foreseeable conditions

Important in the setting of shelf-life is the interpretation of the term reasonably foreseeable conditions of distribution, storage and use in the post-processing stages of the food product used in Regulation (EC) No 2073/2005). Reasonably foreseeable conditions of distribution, storage and use of foods refer to the conditions that the food is exposed to after it has left the immediate control of the FBO. They may include temperature during storage at distribution centres, transportation, storage at retail and domestic level as well as consumer handling and preparation conditions (e.g. cooking temperature). Regulation (EC) No 2073/2005 also states that any studies conducted to determine shelf-life and storage conditions shall take into account the inherent variability linked to the product, the microorganisms in question and the processing and storage conditions. There is also inherent variability associated with factors influencing shelf-life but that are within the control of FBOs. These issues are addressed in Section 3.4.2.

The distinction between reasonably foreseeable conditions and misuse of food is a topic that has been much discussed between FBOs, retailers, consumers and competent authorities. The most extreme assumptions have been that reasonably foreseeable conditions should cover any use, e.g. storage at ambient temperature even if 4°C is indicated on the label, or an ideal situation with

storage temperatures limited to storage < 4°C, even though it is well known that consumers' refrigerators may operate at higher temperatures, as discussed below. Similarly, the issue associated with not applying a heat treatment or considering undercooking as a reasonably foreseeable condition when cooking instructions are given on the label, has also been discussed. This illustrates the difficulties in deciding which range of the variable conditions and habits existing in the consumer population to consider reasonably foreseeable, i.e. which fractions of the variation to include, when identifying the relevant hazard and setting shelf-life and storage conditions. The setting of the range to consider involves judgements that are to a large extent value-based and is in the domain of risk management. Thus, clarifications and general guidance on reasonably foreseeable conditions are needed.

Guidelines containing information related to reasonably foreseeable conditions of storage temperature, focusing on different percentiles of the variable storage temperatures and time, and less elaborated default lengths allocated to steps of the food chain, have been published. Some of these at EU (EURL *Lm*, 2019, ISO 20976-1:2019) and some at national level (Betts et al., 2004; FSAI, 2019), but decisions are often made by the individual FBO, with knowledge of the post-production chain. However, as many FBOs and even countries, each with their own consumer habits and practices, are involved along a food supply chain and practices can differ among various countries, an overview of approaches and conditions considered to be 'reasonably foreseeable' is not straightforward to obtain.

The *L. monocytogenes* microbiological criterion for RTE foods supporting growth, describes different microbiological limits, applicable at different stages of the food chain, in food samples depending on whether the FBO has demonstrated that growth does not exceed 100 CFU/g during the shelf-life or not, i.e. that the growth potential of the bacterium under reasonably foreseeable conditions has been considered or not (Reg. (EC) No 2073/2005). Two guideline documents addressing this criterion have been prepared, one for FBOs (European Commission, 2013) and one for laboratories (EURL *Lm*, 2019). In the latter document, the reasonably foreseeable conditions are related to time–temperature conditions as they can be foreseen by the FBO (professional actors), during food distribution, and by the consumer. In the absence of specific representative data on storage time, the default scenario is to distribute storage time between three stages (i.e. processing company, distribution/retail and consumers) in three equal periods (i.e. 1/3 each). Each stage in the food chain is associated with their reasonably foreseeable conditions, e.g. in terms of storage temperature, and thus it is important how shelf-life is partitioned to different stages of the food chain. The potential impact of this is illustrated by studies using product specific data, e.g. MAP cold-smoked salmon (Skjerdal et al., 2018) together with predictive microbiology growth models to illustrate how shelf-life, in terms of the time until 1 CFU/g of *L. monocytogenes* had increased to 100 CFU/g varied extensively depending on the reasonably foreseeable conditions used for the different stages (Skjerdal et al., 2018; EURL *Lm*, 2019). Thus, allocating a larger proportion of the shelf-life to the processing company stage, with presumably better temperature control than at later stages, is expected to promote a longer shelf-life.

It is well documented that the storage temperature conditions vary between countries and in the supply chain. For this reason, the guidelines to conduct shelf-life studies recommend the use of worst-case (conservative) storage temperatures (e.g. 7°C representing from the manufacture to the retail display cabinet, and 12°C to represent the consumer storage), unless the FBO can use data available specifically for the country where the stage of the cold chain is located. The temperature used for the shelf-life study should be justified by detailed information, e.g. 95% percentile of the temperature distribution (EURL *Lm*, 2019). Other percentiles (e.g. 75th) have been recommended by ISO 20976-1, 20196-1:2009.

In addition to the question of which percentile range to consider reasonably foreseeable conditions, is the matter of which factors to consider. Storage temperature and time are obvious, whereas the question of alternative use in opposition to the labelling instructions is less clear. An approach to integrate information on storage conditions and consumer behaviour into estimations of distributions of the time-to-consumption has been published (Daelman et al., 2013). Potential factors to consider in the determination of 'reasonably foreseeable conditions' for the determination of shelf-life include:

A) Consumer behaviour (unintended use of food)

Potential unintended use of food is a concern. In particular, foods which are not intended as RTE foods by FBOs may be used by the consumers without proper cooking to eliminate pathogenic microorganisms before consumption such as hot dogs consumed directly from the package, frikadelles as cold cut, raw meat for steak tartare or carpaccio or undercooked hamburgers and

meals only pre-cooked (e.g. pizza, lasagne) (Daelman et al., 2013), or frozen vegetables used directly without heating if labelled as a non-RTE food (EFSA BIOHAZ Panel, 2020). This makes it difficult to draw a clear line between unintended and intended use.

Reasons for unintended use vary. It may be a matter of preference, but several other reasons exist, including problems with understanding the label, which underlines the importance of clear and intelligible instructions on the label. Another reason may be that other aspects are prioritised, e.g. to reduce food waste (De Boeck et al., 2017). There may be ambiguity about whether the food needs to be thoroughly cooked or thoroughly reheated before consumption, in particular in the case of pre-cooked meals (FSAI, 2019, Skjerdal et al., 2017).

A survey of Belgian consumers by Van Boxstael et al. (2014) showed that 80% of the participants were familiar with 'best before' date and 'use by' date labelling and that 70% knew the difference between both labels. However, only half of the participants took the difference between these two types of dates into account when assessing the suitability of food for consumption. In addition, participants were flexible in interpreting the 'use by' date, 34.7% indicated they would sometimes eat expired refrigerated RTE products at home. In a survey performed in Spain (n = 396), 45% of the consumers declared they would eat expired prepacked sliced cooked meat products after the indicated expiring date if no signs of spoilage were evident (Bover-Cid et al., 2015).

Beside a lack of observation of the 'use by' date by some consumers, the reason for consuming a product after the 'use by' date might also be more straightforward. Johnson et al. (1998) reported that the majority of elderly people understood the date labels, but that 45% of the elderly consumers have difficulties finding or reading them.

B) Storage temperatures at distribution, storage and retail level

Conditions at the retail level are out of manufacturers' direct control. In general, storage temperatures at retail are lower than during domestic storage (EFSA BIOHAZ Panel, 2008; Mercier et al., 2017). Available survey studies on retail chilled storage temperatures in France, Slovenia, Greece, Spain and Finland reported a mean temperature ranging from 2.7 to 5.6°C (Pierre, 1996; Afchain et al., 2005; Derens et al., 2006; Likar and Jevsnik, 2006; Koutsoumanis et al., 2010; Lunden et al., 2014). Storage temperature may vary between retail cabinet types as well as between positions in the cabinet. In addition, a variation of temperature over time in retail cabinets has been reported in which periodic up-shifts of temperature may occur due to the defrost system of the refrigerators (Koutsoumanis et al., 2010).

Temperature data representative of the food distribution and retail level can be found in the cold-chain database developed in the frame of the EU project FRISBEE from real temperature profiles obtained from field tests in Europe (Gogou et al., 2015).

C) Storage temperature at consumer level

Studies on domestic refrigerator temperatures from eight European countries (Table D.1 Appendix D) show a mean temperature ranging from 5.4 to 10.43°C and a maximum temperature range from 9.3. to 21.8°C. Roccato et al. (2017) analysed data available from surveys on domestic refrigerator temperatures of chilled RTE food in European countries and suggested that there may be a geographical variation in mean domestic refrigerator temperatures. There is also variation in domestic storage temperature between refrigerators of different models and age as well as between positions in the refrigerator. In general, the middle shelf has been reported as the coldest spot of domestic refrigerators (Koutsoumanis et al., 2010; WRAP, 2010; Marklinder and Eriksson, 2015) and the door shelf as the warmest spot (Bakalis et al., 2004; Koutsoumanis et al., 2010; Jofré et al., 2019). The waste and reduction action programme (WRAP, 2010) reported that refrigerator compartments at the bottom of the refrigerator–freezer combination showed slightly higher mean refrigerator air temperatures than both stand-alone (larder) refrigerators and refrigerator freezers with the refrigerator compartment on top. The results from the above programme also suggest a general trend that older refrigerators have higher mean air temperature than newer models. Refrigerators between 1 and 2 years old showed mean temperatures of 3.7°C compared with mean temperatures of 6.4°C within refrigerators of 5+ years old.

3.4.2. Guidance on approaches to determine shelf-life

As described in Section 1.3.1, the FBO is responsible for setting and validating the safety of the food during the shelf-life as part of the activities of an FSMS. Validation of product shelf-life involves

obtaining and documenting any evidence that proves that the shelf-life of a food is accurate, and that the food will maintain its safety and quality until the end of it. More specifically, the objective of the studies to set the shelf-life is to compile the scientific evidence proving that the relevant hazard for the food product of interest will not exceed the acceptable level at the end of the set shelf-life, taking into account the intrinsic variability linked to the pathogenic or spoilage microorganism, the product and the processing as well as the reasonably foreseeable conditions of distribution, storage and use. In the particular case of the RTE food, 'safe' shelf-life studies contribute to demonstrate/document the compliance with the food safety criterion set for *L. monocytogenes* by the Regulation (EC) No 2073/2005.

Shelf-life studies, as for the validation of almost all control measures, are best carried out through a stepwise approach addressing the key aspects. In this context, it is not possible to establish a prescriptive common methodology to estimate the shelf-life of a food. Rather, a case-by-case procedure should be applied to identify the microorganism of concern and estimate the levels in the given food product immediately after production and release to the market (i.e. initial levels) and, subsequently, assess the growth behaviour of this microorganism in the food product during subsequent storage, from retail to consumption (Figure 3).

Several guidelines developed by public and private organisations are available and describe with a variable level of comprehensiveness the approaches to conduct shelf-life studies for perishable food (e.g. Regulation (EC) No 2073/2005-AnnexII, FSAI, 2019; EURL *Lm*, 2019; BRC/CFA, 2018; CFA 2010; BRC/CFA 2018; Betts et al., 2004; NACMCF, 2010; MPI, 2016). The main steps and key aspects of the procedures to set the shelf-life are described below, with particular focus on the 'safe' shelf-life (i.e. use by date), but the same steps apply to determination of sensory shelf-life although laboratory methods will cover a wider range of approaches.

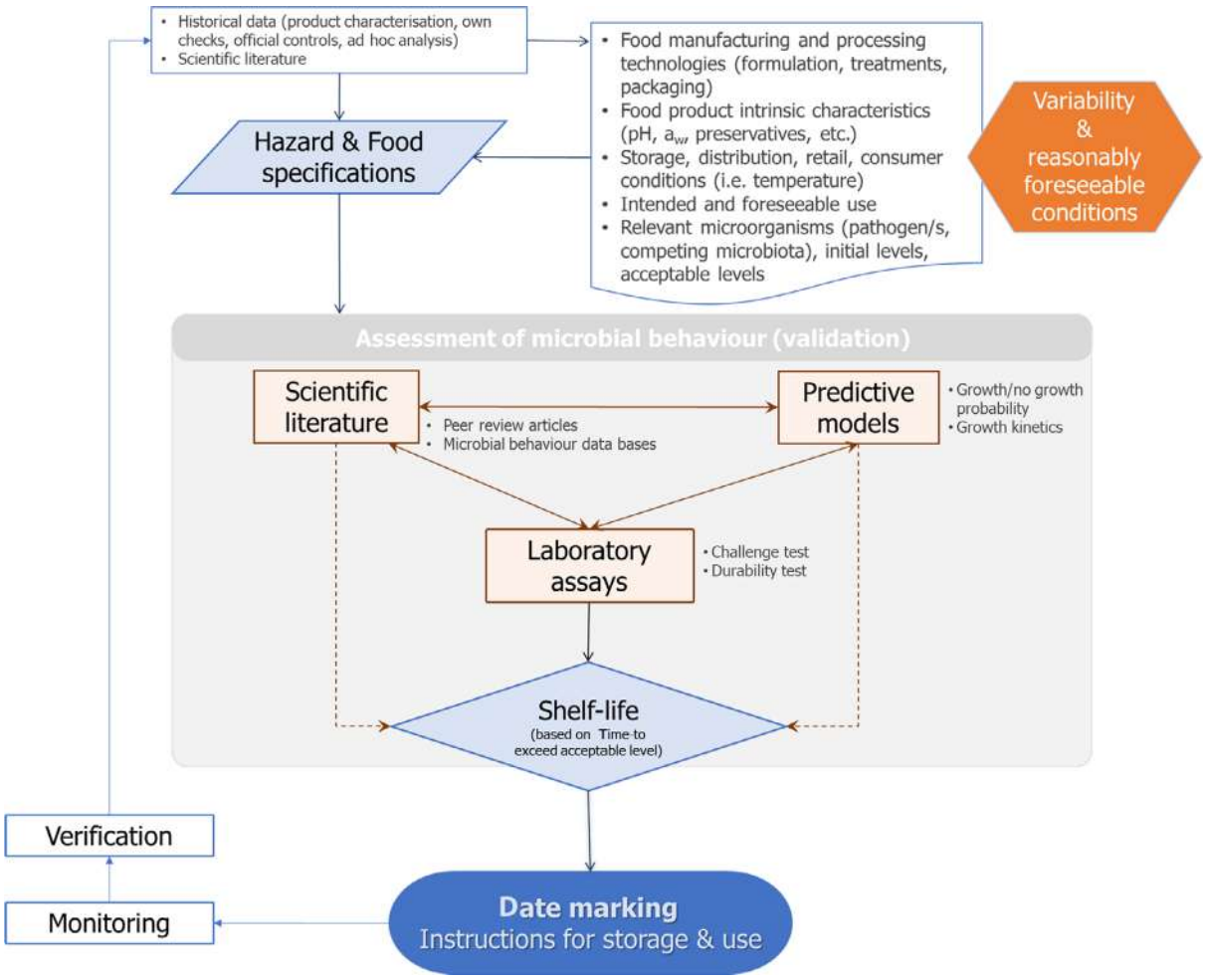


Figure 3: Flowchart summarising the step wise approach to set shelf-life date

i) Relevant microorganism/s and initial levels in the final food product

A shelf-life study should start by determining the relevant microorganism/s limiting the shelf-life in the final food product from foodstuff specifications regarding the factors affecting the probability of occurrence and levels of the relevant microorganism in the end product, e.g. product formulation (raw materials, ingredients, additives etc.) as well as the manufacturing and technological processes and operations (including processing and preservation technologies, hygiene, steps favouring exposure to contamination etc.) (see Section 3.2.1).

To determine the initial levels of the relevant microorganism/s different sources of information can be used. Published data from official control audits may provide some insights for some pathogenic microorganisms monitored/surveyed at country or EU level, which can be complemented by scientific literature covering the type of product and process of concern. An estimation of the initial levels can be made more specifically from historical data records (i.e. results from own-checks within the FSMS verification activities). In the particular case of pathogens, usually at levels below the detection of plate count, probabilistic approaches have been proposed to estimate the distribution of the concentration of the pathogenic microorganisms from presence/absence microbiological results (Crépet et al., 2007; Valero et al., 2014).

ii) The intrinsic, extrinsic and implicit characteristics of the end product determining the growth behaviour of the microorganisms in the product

The key factors governing the growth behaviour of the relevant microorganism/s described in Section 3.2.2, such as pH, a_w, preservatives, packing (gas composition and packing material), background microbiota etc. should preferably be characterised from product samples taken from commercial production processes rather than samples manufactured ad hoc specifically for the measurements. Importantly, the characterisation of pH and a_w in multicomponent foods should be done after equilibrium has been reached in physico-chemical properties between the food components (FDA/CFSAN 2010).

The inherent variability linked to the product and production process (i.e. intra- and inter- batch variability) has to be known and the reasonable worst-case values should be considered for subsequent steps. For some of these factors, the quantitative characterisation needs to be based on the measuring of conditions in the compartment/phase that is most relevant from the microbiological point of view. For instance, the amount of salt and organic acids in the water phase of the product, or the amount of CO_2 from the packing gas dissolved in the water phase, as this is the fraction relevant for the microbiological cells.

The reasonably foreseeable conditions (Section 3.4.1) to which the food will be exposed once it has left the immediate control of the FBO, including retail storage, handling and intended and expected use by the end user/consumer and the expected shelf-life should be also recorded.

The information collected within the preliminary activities described in (i) and (ii) should enable the relevant pathogenic microorganisms to be identified and the food specifications determining growth behaviour to be defined.

iii) Assessing the behaviour of the relevant microorganisms in the specified food (validation of shelf-life)

Several procedures and tools can be complementarily used to assess if the food product supports the growth of the relevant microorganisms and, if so, to quantify the growth during the expected shelf-life of the food. The final aim is to demonstrate that under a hypothetical contamination of the food with a relevant pathogenic or spoilage microorganism, levels will not exceed the acceptable level during the expected shelf-life, thus validating the shelf-life of the food concerned.

The procedures and tools have to be selected and implemented on a case-by-case basis, depending on their availability, and the purpose of the study. In principle, the more tools and sources of information, the more reliable will be the evidence supporting the conclusion about shelf-life duration. A description of the procedures to be used is presented below.

A) Data from scientific literature

Published reviews of studies dealing with the behaviour of the relevant pathogenic microorganisms in a foodstuff considering the intrinsic, extrinsic and implicit factors within the food specifications provided can be useful. Besides the scientific articles, the ComBase (www.combase.cc) and the Microbial Response Viewer (http://mrviewer.info/) portals offer databases with a great number of

microbial growth curves collected from scientific publications as well as directly donated by researchers/research institutions.

Scientific literature is particularly relevant when aiming to demonstrate that the food characteristics and the conditions of production, packing and storage do not support the growth of the relevant microorganism. In this respect, scientific information about the minimal pH, a_w and temperature for the growth of a variety of pathogenic microorganisms provide a valuable insight to understand whether a 'best before' date is appropriate or a 'use by' date data is required (see Sections 3.2.2.1 and 3.3.1).

The information gathered from scientific literature and databases can be conclusive (e.g. the food characteristics and environmental conditions do not support the growth of the relevant microorganism/s). In other instances, the available information does not cover specific characteristics of the food or the desired storage conditions, and thus, the application of additional complementary approaches may be required before the shelf-life can be set. These additional approaches can be based on the application of predictive microbiology tools and/or laboratory studies (challenge test or durability studies).

B) Predictive microbiology

Predictive microbiology models are mathematical equations useful to quantify the growth behaviour of microorganisms as a function of specific intrinsic and extrinsic, and in some examples, implicit factors. The increased number of microbial models produced during the last 25 years has led to the development of user-friendly tools in order to transfer knowledge between academics/researchers and stakeholders of the food sector with a wide range of applications. Examples include product and process design, exposure assessment, HACCP system support, studies of shelf-life and compliance with microbiological criteria (Tenenhaus-Aziza and Ellouze, 2015; Koutsoumanis et al., 2016). The most important benefit for the users is that these tools can assist decision-making in a short time frame and allow practices to be actioned almost in real time. This is particularly interesting when developing new formulations, packing conditions, etc. In relation to shelf-life, several practical applications of predictive microbiology can be listed, including the prediction of the probability of growth of a microorganism under a given combination of conditions (intrinsic and extrinsic factors) considered by the model, to predict the growth rate and simulate the increase in the concentration of a microorganism during the shelf-life and test the impact of the variability of the input values, including different foreseeable storage temperature scenarios etc. An accurate selection of the tool should be done for the purpose of the study, taking into account its predictive domain and performance, as well as being aware of its limitations and uncertainties. Some models are based on laboratory (broth) media and usually overestimate the microbial growth, while food-based models may show better ability to predict the impact of the food and storage condition on the microbial growth (e.g. Coleman et al., 2003). Predictive models also differ on the approaches used to build the model, e.g. purely empirical (such as polynomials and response surface methodology) or more mechanistic based on the gamma concept or the cardinal parameters of growth (McKellar and Lu, 2003; Ross et al., 2014). In any case, for predictive purposes in the determination of the shelf-life of foods, models validated for the food and storage conditions under study must be used. In addition, the reliability of the outputs depends on the quality and relevance of the input data used (i.e. intrinsic and extrinsic characteristics as described in (ii)).

Trained and experienced personnel with an understanding of food microbiology and the limitations and the conditions of use of predictive models are required to properly interpret the results obtained (European Commission, 2013).

C) Laboratory studies

Experiments at laboratory scale can also be required within an overall shelf-life study in order to experimentally assess the growth of the relevant microorganism/s in the food using durability tests and/or challenge tests. For both types of test, an accurate experimental design and execution are key for the reliability of the results (NACMCF, 2010; EURL *Lm*, 2019).

C1) **Durability tests** consist of the evaluation of the behaviour of the relevant microorganism/s in naturally contaminated food. This type of assay can be considered more realistic than a challenge test, as the contamination reflects the reality regarding the strain/s, distribution and initial concentration etc. Durability tests are used to calculate the proportion (and the associated confidence interval) of commercial food units exceeding the acceptable level at the end of shelf-life. Durability tests are useful when the relevant microorganism occurs at quantifiable levels from the earliest stages of the assay. For pathogens, the relative low prevalence, heterogeneous distribution among food units within a

batch and the usually low concentration in the end-products limit the use of this type of laboratory assay (European Commission, 2013). A few studies have been reported, for instance one on naturally contaminated salmon (e.g. Skjerdal et al., 2014).

C2) **Challenge tests** consist of monitoring the behaviour of the relevant microorganism/s in deliberately contaminated (inoculated under controlled conditions) food, either to assess the growth potential (i.e. the $\log_{10}$ increase during the test period when the food is stored under defined reasonably foreseeable non-isothermal storage conditions) or to estimate the growth kinetic parameters (i.e. maximum specific growth rate) at a constant temperature. An accurate design of the experiment by experienced personnel needs to account for the variability of the food, the microorganism/s (strains) and the storage conditions. The level of contamination has to be sufficiently high to be able to quantify it from the beginning of the test. The usual heterogeneity of the contamination and the physiological state (with a relevant impact on the lag phase) is difficult to consider in a laboratory assay. Currently several guidelines are available, in particular on how to perform challenge tests and calculate the growth potential and/or the specific growth rate, specifically for *L. monocytogenes* (Health Canada, 2012; EURL *Lm*, 2019), non-proteolytic *C. botulinum* (Health Canada, 2010), or for any other microorganism (pathogen or spoilage microorganism) (IFT/FDA, 2003a,b; MAF, 2011; ISO 20976-1, 20196-1:2019).

It is worth mentioning the possibility of exploiting the results of a challenge test performed to estimate the specific growth rate of the relevant microorganism/s in a specific food product under another set of conditions through the application of the principles of predictive microbiology based on the 'gamma concept'.[17] This approach enables further simulations to be performed of the growth at different scenarios not explicitly tested, thus enabling the assessment of a wide range of reasonably foreseeable conditions of storage. In the EURL *Lm* 2019 guidelines and the ISO 20976-1, 20196-1:2019, this approach is described for temperature, requiring the knowledge of the T_{min} of the microorganism/s under study. The Sym'Previus portal (http://symprevius.eu/) offers a user-friendly tool to combine the results of the challenge test (exponential growth rate at a reference temperature) and predictive modelling to assess the behaviour of the microorganism at a constant or dynamic temperature profile not experimentally assessed. This approach could also be applied for other intrinsic and extrinsic factors than temperature, if the corresponding cardinal parameter (minimum value for growth) of the strain used for the challenge test is known.

The combination of the different tools enables the evaluation of the shelf-life either as a single case approach or a stochastic (risk) based approach (European Commission, 2013). In the single case approach, the different factors are fixed to a 'reasonably foreseeable conditions' scenario. With this approach, the combination of assumptions may lead to an excessively conservative scenario (highest contamination, fastest growing strain, no lag time, highest pH, a_w and temperature etc.). In some cases, it may show that even under this worst-case scenario, the food will comply with the acceptable level of the pathogenic microorganisms at the end of the expected shelf-life. The stochastic approach is based on the combination of a distribution of input values and the application of probabilistic Monte-Carlo simulation, and therefore, it takes into account the variability of the factors governing microbial growth leading to a more realistic estimation of the behaviour of the microorganisms throughout the food supply chain (Koutsoumanis and Angelidis, 2007).

The stepwise approach is also applicable when determining the shelf-life due to the growth of spoilage microorganisms causing undesirable sensorial changes to the food product. During validation of the sensory shelf-life of perishable food products, besides the microbiological and physico-chemical analysis, samples should be followed for sensorial analysis (including odour, taste, texture etc.). Further, the variability of sensory ability/sensing spoilage and more general evaluation on how the stability of the food is evolving during the attributed shelf-life and storage conditions is conducted. It can be important to perform the validation study for several samples, produced at different days to include variability in the validation study outcomes.

Based on the outcome of the applied approaches, a decision has to be taken regarding the specific date (i.e. duration of shelf-life) to be labelled on the product (either for the 'use by' or the 'best before' date) and the associated storage conditions. A margin of safety for the final decision, depending on

[17] Gamma (γ) was developed by Zwietering et al. (1992) and further developed by Zwietering (1999) Zwietering et al. (1996) and Le Marc et al. (2002) and is based on the premise that factors affecting the microbial growth rate act in an independent and multiplicative manner and can be represented by a fraction of the maximum growth rate (when the factor is at the optimum value). Thus, the γ is a dimensionless value that can range from 0 (the factor totally inhibits the growth) to 1 (the factor does not have any inhibitory effect and the growth rate is equal to the growth rate at optimum conditions). The interaction between environmental factors can be described with an additional independent term (Le Marc et al., 2002).

the approach and how reasonably foreseeable conditions have been applied, is sometimes used. However, the approach of considering the inherent variability of the product and the production process (i.e. worst-case scenario of food specifications) and reasonably foreseeable conditions of storage and use, implicitly incorporates the safety margin from the earlier steps of the shelf-life study, excluding the need for adding it to the final output of the study.

In this respect, the time to consumption (TTC) approach (Daelman et al., 2013), which characterises the consumer stage of the reasonably foreseeable conditions, has been suggested as one approach to define safety margins covering potential consumer abuse. The TTC is based upon a consumer survey, different situations are identified, such as the frequency of purchase of the food, if consumers respect the use by date or not and how long the foods are stored in their refrigerator. From the survey results, the time-to-consumption distribution can be derived and the shelf-life date adjusted to the date with a very low probability of being exceeded.

(iv) Monitoring and verification of shelf-life date

As a control measure, in addition to the validation, the shelf-life needs to be monitored and verified. The monitoring procedures consist of checking that labelling and printing of the shelf-life date on a package is part of the production process and is correctly done. Correct labelling and printing are control measures to avoid later problems and need to be addressed in hazard analysis of the FBO. In some cases, this step needs to be controlled as a CCP (critical control point) indicating that the allocated shelf-life on the batch is monitored carefully with registration (i.e. in case of short shelf-life dates with multiple foods packed on same line and small batches with high turnover so the probability of errors in date labelling is high). In other cases, this step will be controlled as a PRP (prerequisite program) 'work methodology' (Commission Notice 2016/C278/01). The daily monitoring of the production as CCP or PRP needs to be well organised by the FBO so that mistakes can be reduced or excluded.

Verification of the shelf-life should be performed periodically. In the verification study, samples of the end product can be followed during the shelf-life and in the prescribed conditions or taken at different points within the distribution/supply chain. It is important to perform verification studies based on several packages to include the effects of variability. The same parameters as for the shelf-life validation can be reassessed (i.e. microbial and sensorial analysis) and the outcome of the verification should confirm the earlier validation outcomes. The higher the number of batches verified at the end of the shelf-life, the higher the confidence level will be. Records of customer and consumer complaints can also be used in the verification procedures.

3.4.3. Concluding remarks

- In the case of use-by date, the shelf-life of a product should never be longer than whichever is the shortest between the 'sensory shelf-life' or the 'safe shelf-life'. The first relates to quality changes, in this opinion due to microbial growth, and the latter relates to the safety of foods.
- The term reasonably foreseeable conditions of distribution, storage and use of foods (Regulation (EC) No 2073/2005) refers to the conditions that the food is exposed to after it has left the immediate control of the FBO who has produced it. These conditions should reflect the expected variability that the food is exposed to, and since not all consumers and other actors in the food chain can be expected to follow the instructions provided by the FBO, include some degree of deviation from these instructions. The 'reasonably foreseeable conditions' should be considered by the FBO when setting the shelf-life.
- Several factors contribute to a large variability in consumer storage temperatures, and consumer handling and preparation conditions, making it difficult to define what should be considered a reasonably foreseeable condition.
- Except for guidelines to laboratories and FBOs on how to carry out shelf-life studies with regard to the *L. monocytogenes* microbiological criteria for RTE food established by Regulation (EC) No 2073/2005, and the ISO 20976-1, 20196-1:2009 to conduct challenge tests, general guidelines with a wider scope on which factors to consider and how to define the reasonably foreseeable conditions have not been found.
- Several guidelines for conducting 'safe' shelf-life studies of perishable foods, developed by public and private organisations, describe stepwise approaches addressing several key aspects with variable levels of comprehensiveness.

- A case-by-case procedure to determine and validate the 'safe' shelf-life of a food should be applied and key steps are, (i) to identify the relevant pathogenic microorganism(s) and estimate its initial concentrations in the food product, (ii) to characterise the intrinsic, extrinsic and implicit factors of the food affecting the growth behaviour of the pathogen and (iii) to assess the growth behaviour of the pathogen in the food product under reasonably foreseeable conditions during storage, from retail to consumption to determine the time at which the pathogen will reach maximum acceptable levels. The same stepwise approaches should apply to determine the 'sensory' shelf-life.
- To accurately assess the growth behaviour of the relevant pathogenic microorganisms, the intrinsic variability of the product and production process as well as the reasonably foreseeable conditions to which the food product will be exposed need to be known. Complementary methodological tools including scientific literature, predictive microbiology models and/or laboratory assays (particularly challenge tests) can be used on a case-by-case basis. Personnel trained and experienced in the use of such tools and with an understanding of food microbiology are required to perform shelf-life studies.

3.5. Guidance on indicative time limits for marketing or donation of foods past the 'best before' date (ToR 2c)

In the EU, food donations guidelines are available for both fresh and frozen foods, as well as non-prepacked, prepacked foods which do not need a 'best before' date, and prepacked foods which carry date marking (EFSA BIOHAZ Panel, 2018a, 2020). In EFSA's Scientific Opinion on the hazard analysis approaches for certain small retail establishments and food donations: second scientific opinion (EFSA BIOHAZ Panel, 2018a, 2020) and the recently published Commission Notice,[16] a specific PreRequisite Program (nr. 16) regarding 'Evaluation for food donation and allocation of remaining shelf-life', including all these food categories, has been established for FBOs who want to donate foods. In this PRP, which needs to be included in the FSMS of an FBO in case of food donations, it is stated that the following preventive measures need to be taken (1) Evaluation if a 'best before' or 'use by' date is present on prepacked foods and decide which remaining shelf-life time still can be allocated. However, a strict interpretation is applied regarding the 'use by' date. Foods placed on the market (including those intended for food donation) must not exceed the 'use by' date, neither during distribution nor before intended consumption. (2) In case of prepacked foods without a legally required shelf-life date (e.g. packed fruits and vegetables, bakery wares, wine, etc.) a sensorial evaluation and decision if still fit for consumption. (3) In the case of food with a 'best before' date, foods exceeding this date may be considered for food donation but this food should be routinely checked to: (i) ensure integrity of packing material (no damage, no opening, no condensation etc.), (ii) ensure proper storage of the food according to required temperature and other conditions (e.g. deep freezing at −18°C or dried storage), (iii) in case of frozen food, control the freezing date, (iv) evaluate sensory property (still acceptable for consumption (absence of moulds, rancidity etc.)) and (v) ensure no exposure to any other significant food safety hazard or other health risk (EFSA BIOHAZ Panel, 2018a, 2020).

The food donation/acceptance chain is less structured and organised than the conventional food supply chain, often involving volunteer workers without much food safety training, and this has been identified as a bottleneck for handling perishable foods (De Boeck et al., 2017). Other concerns that can be raised are related to the consumers of the donated food and to what extent the proportion of vulnerable consumers in terms of susceptibility, restricted access to suitable cooking and storage facilities or lack of food safety knowledge is higher than in the general population (Vidgen and Gallegos, 2014; De Boeck et al., 2017). For FBOs, there can also be issues of liability and reputation (EFSA BIOHAZ Panel, 2018a, 2020). All these considerations underline the need for harmonised and correct date marking, as well as proper handling of foods, so that donations past the date marking are limited to 'best before' products. There is only partial overlap between EFSA BIOHAZ Panel (2018a), in which a simplified FSMS approach to food donations in general is described and the present ToR where the scope is limited to donation or marketing of foods past a 'best before' date, i.e. related to the last point (3) in the PRP described above.

Many EU MS have written national and regional guidance documents on food donations, because the nature of and the way in which donated foods are collected, stored and distributed by FBOs and charity organisations may be different (BIO by Deloitte, 2014; EFSA BIOHAZ Panel, 2018a, 2020). Most of these documents include tables with a list of food categories or specific food products that are eligible to be donated. These lists are positive lists, i.e. include foods that are suitable for

redistribution. These tables show foods that can be used by food banks or charities categorised based on their shelf-life, e.g. 'very long shelf-life', 'long shelf-life', 'limited shelf-life', 'short shelf-life' or 'very short shelf-life' and include details on the characteristics of spoiled food for each of the listed food categories (Ayuntamiento de Madrid, 2017; FASFC, 2017; Caritas Italiana, Fondazione Banco Alimentare O.N.L.U.S., 2015; Dutch Food Banks Association, 2015). The Czech guidance on principles of compulsory food donation divides foods safe for donation into two groups according to the degree of risk associated with their handling and subsequent consumption: 'low risk' and 'medium risk'. Foods classified as 'high risk' (e.g. ready meals) are not considered suitable for donation. Typical examples of food products are also given for each of these categories associated with specific mandatory parameters for delivery and collection for the donated food as well as possible reasons for refusal (Czech Confederation of Commerce and Tourism and the Czech Food Bank Federation, online). The Italian guidance divides foods according to the level of attention which must be observed by operators ('high', 'moderate' and 'low') in relation to the nature of each food, to ensure the correct application of good working practices ensuring the safety of food for human consumption. Examples of food are also provided for each category combined with indications about the transport and storage temperatures (Caritas Italiana - Fondazione Banco Alimentare O.N.L.U.S., 2015). In some cases, indications are also given regarding certain food products or food categories for which food donation is not recommended (e.g. buffet food, sushi, non-pasteurised fresh cheeses, fresh fish and seafood) (Ayuntamiento de Madrid, 2017).

The time period within which the foodstuff remains fit for distribution by food banks and charities once it has exceeded its 'best before' date is estimated in some guidance documents. However, this time window is purely indicative, and a case-by-case assessment is always required. If there is any reason to suspect that a foodstuff may have become unfit for consumption, under no circumstances can it be distributed (FASFC, 2017). In some documents, storage recommendations for the donated food are provided including generic maximum periods of time after 'best before' date during which these foods can still be donated as well as the storage temperatures (Ayuntamiento de Madrid, 2017; FASFC, 2017). Guidance on the information that should be included in the donating FBOs traceability system is included in the Irish and Italian guidance (Caritas Italiana - Fondazione Banco Alimentare O.N.L.U.S., 2015; FSAI, 2017). In some cases, it is mentioned that to avoid a shortage in supplies for food banks and charities as a result of administrative constraints, a decision can be taken to relax the applicable traceability regulations, without compromising food safety. Given that this concerns the final part of the food chain and that the foodstuffs in question have already been fully identified and labelled for the purposes of consumption, the goods can quickly be withdrawn from the market or recalled if needed (FASFC, 2017).

Labelling guidelines are given in some guidance documents, indicating e.g. that if prepacked foodstuffs are delivered to food banks or charities without the required labelling, the right labelling must be provided before the foodstuffs are distributed to the consumer. The minimum information that must appear on each package intended for the consumer and distributed by a food bank or charity is detailed in the Belgian and Dutch guidance documents (FASFC, 2017; Dutch Food Banks Association, 2018). The Italian guidance states that suppliers are permitted to donate un-labelled or inadequately labelled food not fully compliant with legislative and commercial regulations. In these circumstances, donors/suppliers may send such food to charitable organisations by providing them with a separate document, in the appropriate national language, reporting all the information required by Regulation (EU) No 1169/2011 so that it may be available to the recipients. The charitable organisations must ensure that such mandatory information is made available to the beneficiaries (Caritas Italiana - Fondazione Banco Alimentare O.N.L.U.S., 2015).

Most guidance documents are intended specifically for food banks and charities, i.e. non-profit purposes aiming to provide maximum protection for consumers and to reduce food wastage (Evira, 2017; FASFC, 2017; Caritas Italiana - Fondazione Banco Alimentare O.N.L.U.S., 2015; FSA, 2016; Dutch Food Banks Association, 2018; Czech Confederation of Commerce and Tourism and the Czech Food Bank Federation; DILA, 2011). Some documents are dedicated specifically to provide guidance on the donation of meals (DRAAF Rhône-Alpes, 2013; ASAE and DGAV, online).

Some guidance documents also include sections describing other requirements for charitable organisations distributing food aid, such as own-check plans, sanitisation, waste management, personnel hygiene, correct hygiene and transport practices (Caritas Italiana - Fondazione Banco Alimentare O.N.L.U.S., 2015; Evira, 2017; Dutch Food Banks Association, 2018).

An important issue for food donations is the product liability of the FBO when the food is donated past indicated shelf-life (described in section 4 of the Commission Notice 2017/C 361/01).[18] In De Boeck et al. (2017) it is stated that for all operators in the agro-food chain also EU Council Directive 374/1985[19] concerning product liability applies. Donors (FBOs which are providing donated foods) are responsible for product hygiene and food safety until the moment charity organisations or food banks accept the donated products. In practice, a form can be signed in which the transfer of responsibility is described (De Boeck et al., 2017).

Marketing of foods past the 'best before' date is not covered by most of the donating guidelines. Marketing of food past the 'best before' date is allowed in several countries (e.g. Greece, Norway, Sweden). For instance, in Norway food with what is described as 'short best before date' is sold by special shops over the internet at a reduced price (Norwegian Food Safety Authority, 2019). In Sweden, marketing of foods past their 'best before' date is allowed at retail under the responsibility of the seller (Swedish Food Agency, 2020). The seller should evaluate if the food is fit for consumption after the best before date. Under certain conditions, e.g. that the national regulations for frozen foods are fulfilled, and with specific labelling instructions, it may also be appropriate to freeze foods and sell them past their 'best before' date. Information in support of these regulations, directed at consumers, highlights that best before foods are fit for consumption as long as they look, smell and taste normal, and highlights specific information for risk groups. In Greece, marketing of foods past their 'best before' date is also allowed at retail (Government Gazette, No 2983/B, 30.8.2017, Article 13[20]) provided that they are clearly separated from other foods and they are labelled with capital letters as 'PAST BEST BEFORE DATE'. The Greek legislation provides maximum times for consumption of foods after the best before date as follows:

A) One week for products with best before indicated by day and month.
B) One month for products with best before date indicated by month and year
C) Three months for products with best before date indicated by year only

It needs to be noted, however, that the Greek legislation does not include or refer to any scientific basis for the above maximum time limits.

In summary, the review of the approaches and published guidelines on food donations show that the following topics are highlighted and addressed at various levels of detail:

- The guidelines commonly cover a wider range of foods (not only 'best before'-marked foods) and situations (e.g. donation of meals) than the scope of the present ToR.
- Food products eligible for donation are categorised based on their shelf-life with
    - The most common characteristics of spoiled food for each shelf-life category indicated;
    - The recommended storage temperatures and an estimation of the time window within which the food remains fit for distribution by food banks and charities once it has exceeded its date of minimum durability;
    - Guidance on labelling and traceability of the donated food.
- General requirements for charitable organisations distributing food aid, such as own-check plans, sanitisation and waste management.
- Guidance on correct hygiene requirements for personnel and transport practices.

Based on the information in the opinion on the variability between food products due to different raw materials, production processes, storage and packing conditions and consumer habits, which emphasises that shelf-life need to be considered on a case-by-case basis, as well on the review of the donation guidelines it is not considered realistic to give indicative time limits of different food products, with a best before date. However, the general principles as explained in the EFSA BIOHAZ Panel (2018a) and recent Commission Notice 2020/C 199/01 and here above, can be applied across EU.

3.5.1. Concluding remarks

- A specific PreRequisite Program (nr. 16) applicable to the donation or marketing of foods past the 'best before' date was presented in the EFSA 'Second scientific opinion on hazard analysis

[18] Commission notice — EU guidelines on food donation C/2017/6872 OJ C 361, 25.10.2017, p. 1–29.
[19] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. OJ L 210, 7.8.1985, p. 29–33.
[20] Government Gazette, No 2983/B, 30.8.2017. Available online: http://www.et.gr/index.php/anazitisi-fek

approaches for small retail establishments' (EFSA BIOHAZ Panel, 2018a, 2020) and in the Commission Notice 2020/C 199/01. This PRP describes preventive measures to be taken for best before date marked foods but also foods without a legally required shelf-life date (e.g. packed fruits and vegetables, bakery wares, wine etc.). Food with a 'best before' date exceeding this date may be considered for food donation but should be routinely checked to: (i) ensure integrity of packing material, (ii) proper storage of the food, (iii) in case of frozen food, control the freezing date, (iv) evaluating sensory properties (still acceptable for consumption (absence of moulds, rancidity etc.) and (v) ensure no exposure to any other significant food safety hazard or other health risk.

- Many EU MS have regional/national guidance documents on food donations, which may reflect the variability across Europe in the nature of and the way in which donated foods are collected, stored and distributed by FBOs and charity organisations. The guidelines commonly cover a wider range of foods (not only 'best before' date marked foods) and situations (e.g. donation of meals) than those within the scope of the present opinion.
- The approaches and published guidelines highlight for 'best before' foods:
    - Food products eligible for donation are categorised based on their shelf-life with
        - The most common characteristics of spoiled food for each shelf-life category indicated;
        - The recommended storage temperatures and an estimation of the time window within which the food remains fit for distribution by food banks and charities once it has exceeded its date of minimum durability;
        - Guidance on labelling and traceability of the donated food.
    - General requirements for charitable organisations distributing food aid.
    - Guidance on correct hygiene requirements for personnel and transport practices.
- Marketing of food past the 'best before' date is allowed in several countries under the responsibility of the seller that the food is fit for human consumption. Indicative time limits were either not provided other than by highlighting the sensory properties of the food or when time limits were indicated without providing their scientific basis.
- Due to the variability, among MS, between food products and consumer habits, it was not considered appropriate to present indicative time limits for food donated or marketed past the 'best before' date. However, the general principles as outlined in EFSA BIOHAZ Panel (2018a) and Commission Notice 2020/C 199/01 can be applied across the EU.
- The food donation/acceptance chain is less structured and organised than the conventional food supply chain, which underlines the need for harmonised and correct date marking, as well as proper handling of foods, so that donation past the date marking is limited to 'best before' products. Especially since potential consumers may be more likely to be members of a more vulnerable population in terms of susceptibility, food safety knowledge and access to suitable cooking and storage facilities.

4. Conclusions

The opinions should develop a risk-based approach to be followed by food business operators when deciding on the type of date marking (i.e. 'use by' date versus 'best before' date), setting of shelf-life and the related food information that should be provided on the labelling in order to ensure food safety.

***ToR 1a)** Give guidance on the relevant microbiological hazards that should be taken into account by FBO in determining whether a food, from a microbiological point of view, is likely to constitute an immediate danger to human health; and on **ToR 1b)** the types of foods where it is more likely to find those pathogenic microorganisms:*

- To assist in the identification of relevant microbiological hazards (understood as pathogenic microorganisms) for the shelf-life of perishable foods, data on pathogens of concern in different types of food categories and their ecological determinants for growth were reviewed, and information sources of food-borne outbreak data indicating the association between different food commodities and implicated pathogens were provided.
- Guidance is presented in the form of useful sources of information and a non-exhaustive summary of relevant bacterial pathogens capable of growing in prepacked temperature-controlled foods under reasonably foreseeable conditions.

- The identification of relevant pathogenic microorganisms is food product-specific. Considering the huge variability existing in the food chain in terms of ingredients, product types, modes of processing and packaging, it is difficult to *a priori* exclude any of the pathogens capable of growing at the currently used storage temperatures.

ToR 1c) *Give guidance on the intrinsic/extrinsic factors that might influence the growth of those pathogenic microorganisms and consequently have an impact on: (1) the decision whether a 'use by' is required, (2) the shelf-life (the period up until when a food is not likely to constitute an immediate danger to human health), either linked to the composition of a food (e.g. pH, a_w, presence of food additives) or to the production process and/or the way a food is marketed (e.g. production processes like pasteurisation, type of packaging), and (3) storage conditions throughout the food chain and the intended use of the food; and* ***ToR 2a)*** *Guidance on the intrinsic/extrinsic factors that might influence the growth of spoilage non-pathogenic microorganisms and consequently have an impact on: (1) the shelf-life; either linked to the composition of a food or linked to the production process and/or the way a food is marketed, and (2) the storage conditions throughout the food chain and the intended use of the food);*

- The raw materials, the processing environment and the manufacturing steps determine the type and the levels of microorganisms in the food product when released to the market.
- The intrinsic (especially pH and a_w), extrinsic (especially temperature and atmosphere) and implicit factors (such as interactions with competing background microorganisms) of the food product determine which microorganisms can grow and their growth potential during subsequent storage until consumption. Information on growth limiting factors is provided as a basis for guidance on the decision of the types of appropriate date marking and shelf-life.
- It is important for the FBO to understand the purpose and effect of the processes applied in the steps during manufacture, and examples are given on the potential impact of manufacturing processes on the prevalence and levels of microorganisms in the food product.

ToR 1d) *Give guidance on how the factors identified above influence the decision whether a 'use by' date is required.*

- The decision on the type of date marking (i.e. whether a 'use by' date is required or a 'best before' date is appropriate) needs to be taken on a product-by-product basis, considering the product characteristics (intrinsic, extrinsic and implicit factors), and the processing and storage conditions.
- A decision tree (DT) consisting of a sequential list of 10 questions was developed, and supported with examples, to assist FBOs in deciding the type of date marking for a certain food product.
- In the case of food products processed in a way that eliminates pathogenic microorganisms and avoids recontamination, or which does not support their growth, the risk to consumer health would not increase during shelf-life, and a 'best before' date is appropriate. In contrast, if there is no pathogen elimination step, or there is the possibility of recontamination after such a treatment, and the food product supports the growth of the contaminating pathogen, the risk to the consumer is expected to increase during shelf-life and a 'use by' date is required.
- Overall, it is considered that the DT will result in appropriate and consistent outcomes on the type of date marking within the interpretation of regulations and the assumptions made in its development, e.g. using growth or no growth as basis for decisions.
- The identified uncertainties are considered to result in a DT that may overestimate the risk (a 'best before' food will end up with a 'use by' date) for some food products, unless the FBOs make appropriate use of the opportunity in the DT (Question 10) to demonstrate that their product does not support the growth of pathogens under reasonably foreseeable temperature conditions of distribution and storage, irrespectively of the time frame. The potential overestimation is partly a consequence of the lack of risk assessments and acceptable levels of hazards at the time of consumption.

ToR 1d) *Give guidance on the setting of shelf-life and the required storage conditions and on* ***ToR 2b)*** *how the factors identified above influence the setting of shelf-life and the required storage conditions.*

- Reasonably foreseeable conditions, as described in Regulation (EC) No 2073/2005, refer to the conditions of distribution, storage and use that the food product is exposed to when it has left

the immediate control of the FBO, and need to be considered by the FBO when setting the shelf-life.

- In the case of 'use by' date, the shelf-life of a product should never be longer than whichever is the shortest between the 'sensory shelf-life' or the 'safe shelf-life'. The first relates to quality changes, in this opinion due to microbial growth, and the latter relates to the safety of foods.
- Except for guidelines to laboratories and FBOs on how to carry out shelf-life studies with regard to the *L. monocytogenes* microbiological criteria for RTE food established by Regulation (EC) No 2073/2005, and the ISO 20976-1, 20196-1:2009 to conduct challenge tests, general guidelines with a wider scope on which factors to consider and how to define the reasonably foreseeable conditions have not been found.
- A case-by-case procedure to determine and validate the shelf-life of a food product should be applied and key steps are:

  i) to identify the relevant pathogenic/spoilage microorganisms and estimate its initial levels,
  ii) to characterise the intrinsic, extrinsic and implicit factors of the food product affecting the growth behaviour of the pathogenic/spoilage microorganism and,
  iii) to assess the growth behaviour of the pathogenic/spoilage microorganism in the food product (based on literature, predictive models, challenge tests or durability studies) during storage, from retail to consumption, to determine the time at which the pathogenic/spoilage microorganism will reach maximum acceptable levels under the appropriate reasonably foreseeable conditions.

ToR 2c) *Give guidance on the indicative time limits to be applied at EU level to facilitate marketing or donation of foods past the 'best before' date, provided that before the end of that period those foods shall not become unfit for human consumption.*

- The available guidelines on food donations commonly cover a wider range of foods (not only 'best before' marked foods) and situations (e.g. donation of meals) than those within the scope of the present opinion, and do not cover marketing of foods past the 'best before' date.
- Food products eligible for donation are categorised based on their shelf-life with:
  - The most common characteristics of spoiled food for each shelf-life category indicated;
  - The recommended storage temperatures and an estimation of the time frame within which the food remains fit for distribution by food banks and charities once it has exceeded its date of minimum durability;
  - Guidance on labelling and traceability of the donated food.
- Marketing of food past the 'best before' date is allowed in several countries under the responsibility of the seller provided that the food is fit for human consumption. Indicative time limits are either not provided, other than by highlighting the sensory properties of the food, or, when time limits are indicated, without providing their scientific basis.
- Due to the variability among MS, between food products and consumer habits, it was not considered appropriate to present indicative time limits for food donated or marketed past the best before date. However, the general principles as outlined in EFSA BIOHAZ Panel (2018a) and Commission Notice 2020/C 199/01 can be applied across the EU.

5. Recommendations

- To provide training activities and support, particularly for small food businesses and laboratories, aiming at contributing to a better understanding of microbial ecology of food and on the procedures to characterise the relevant factors determining shelf-life of perishable food. Increasing skills and capabilities will facilitate making harmonised and appropriate decisions on the type of date marking and will make procedures for setting the shelf-life date more achievable. Similar training and support on the DT and approaches described in the opinion may also be useful for competent authorities.
- To collect time–temperature data during distribution, retail and domestic storage of foods, and to carry out consumer-based studies to better understand the beliefs and behaviours that influence the storage conditions used in households for foods that have a 'use by' date and those with a 'best before' date, in order to have better data to characterise the reasonably foreseeable storage conditions of foods in EU MS.

- To clarify and provide guidelines on how to use reasonably foreseeable conditions in date marking decisions, i.e. what ranges of the existing variation to include, for instance about storage temperatures, storage times and consumer behaviour/intended use, and the protocols to apply when evaluating how pathogens will behave under these conditions. Guidance should also be provided for FBOs on how the outcome of consumer and other studies may be applied when estimating shelf-life. Guidance about the use of reasonably foreseeable conditions in different countries will improve harmonisation and be relevant for FBOs and competent authorities. A clarification of the use of reasonably foreseeable conditions will also be a help for risk assessors to define the scope of their risk assessments and for risk communicators in their development of advice to consumers and FBOs.
- To develop ALOP/FSO for most food–pathogen combinations since the lack of such data is an obstacle for setting shelf-life of foods in relation to food safety ('use by' date). The decision on the acceptable risk through the establishment of an FSO could facilitate a more efficient risk-based approach for date marking by the FBOs as is the case now for *L. monocytogenes* in RTE foods.

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Glossary

Acceptable level The term acceptable level has been used throughout the opinion to describe any microorganism level relevant for decisions on date marking taken by FBO for their food product considering the food characteristics and reasonably foreseeable use. The term may refer to m or M in a microbiological criterion, e.g. *Listeria monocytogenes* in RTE foods, to general threshold levels considered safe, e.g. levels of toxin producing *S. aureus*, or of a pathogen target level, or to spoilage microorganism levels not leading to a spoiled food. The term is synonymous to expressions such as level of relevance, level of concern, limit level, threshold level, microbial limit or level for shelf-life.

Aseptic packaging refers to filling 'sterile' product into 'sterile' containers under 'sterile' conditions (CAC/RCP 40, 1993). When this operation is implemented correctly, the end product is shelf-stable and bacteriologically safe for human consumption. In such a case, 'commercial sterility' is achieved (Pujol et al., 2015).

'Best before' date According to Article 2(2)(r) of the Regulation (EU) No 1169/2011, the 'date of minimum durability of a food' means the date until which the food retains its specific properties when properly stored. According to Annex X(1)(a) of the Regulation the 'date of minimum durability' shall be indicated by the words 'best before'. For the purpose of this opinion, the Regulation relates the 'best before' date to the retaining of the specific properties of the food, hereunder called food quality properties. Food quality properties differ widely between food categories as different specifications, characteristics or criteria are taken into consideration when determining the acceptability of the food for human consumption. For certain food categories, the EU legislation sets out specific minimum quality criteria, e.g. related to the acidity or nutrient content, which shall be respected for the production of those foods, for giving them a specific legal name or a specific quality classification, which should also be respected when placing them on the market and at the time of sale to the final consumers.

Defrosting or defreezing See thawing

Challenge test laboratory assay appropriately designed to study the behaviour of a microorganism(s) when deliberately inoculated in a food. Challenge testing is particularly useful to study the behaviour (e.g. growth and/or inactivation) of pathogens in food under reasonably foreseeable storage conditions as mentioned in Regulation (EC) No 2073/2005 (Annex II) in order to have an homogeneously distributed and quantifiable concentration in all test units, minimising the uncertainty associated with the usually low prevalence, low and heterogeneous concentrations of the food-borne pathogens in food.

Control measure actions and activities within HACCP-based Food Safety Management System that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level (CAC/GL 69, 2008). Many preventive control measures are

	part of prerequisite programmes (PRPs) and are intended to avoid contamination from the production environment. Control measures aiming at reduction or elimination of hazards are more specifically linked to particular production process e.g. pasteurisation, fermentation and may result in the establishment of critical control points (CCPs) or operational PRPs (Commission notice C278/2016).[15] Control measures should be validated, monitored and verified with detailed procedures and specifications to ensure their effective implementation (CAC, 2008).
Durability test	studies to evaluate the behaviour of a microorganism that may be naturally present in the product during the shelf-life under reasonably foreseeable conditions. Durability studies may be considered more realistic than a challenge test, as the contamination is naturally occurring. But the implementation of durability studies is limited value for evaluating the behaviour of pathogens, which are usually present at low prevalence and low and heterogeneous concentration (EURL *Lm*, 2019).
Food Safety Objective (FSO)	a statement of the maximum prevalence and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of protection **(accumulated) Lethality (F_0, P values)** The total accumulated lethality (L) of a given thermal treatment represents the time (minutes) equivalent to exposing the product to a reference temperature (T_{ref}), assuming instantaneous and isothermal heating and cooling. The L value is the basis for comparing the heat intensity between different thermal treatments. The L value is calculated from the time–temperature data measured on the coldest point of the food product located in the coldest point of the equipment during the entire thermal treatment and it depends on the thermal resistance constant (z) of the target microorganism (see methods for calculation in Myrseth, 1985). For sterilisation processes, the lethality is expressed as F_0, being T_{ref} = 121.1°C and z = 10°C. For thermal pasteurisation treatments, the lethality is described by P_{Tref}^{Z}, being T_{ref} and z variable depending on the hazard and product/process (Holdsworth, 2009)
Monitoring	The act of conducting in real time a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control (CAC, 2008). As regards the examples, this is the regular (or continuous if automatic) measuring of the temperatures and the observation of contamination and damages (EU Commission Notice, C278/2016).
Performance criteria	The required outcome of a step, or a combination of steps, that contribute to assuring a Food Safety Objective (FSO) is met. It is the change in hazard level required at a specific step in order to reduce the hazard level at the start of the step to a level at the end of the step that complies with the performance objective or the FSO (Gorris, 2004).
Prerequisites	Prerequisite programme(s) (PRP(s): Preventive practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety. The PRPs needed depend on the segment of the food chain in which the sector operates and the type of sector. Examples of equivalent terms are Good Agriculture Practice (GAP), Good Veterinarian Practice (GVP), Good Manufacturing Practice (GMP), Good Hygiene Practice (GHP), Good Production Practice (GPP), Good Distribution Practice (GDP) and Good Trading Practice (GTP). Sometimes, procedures to ensure traceability of food and recall in case of non-compliance are considered part of the PRPs. In Codex Alimentarius standards, PRPs are referred to as 'Codes of Good Practice' (EU Commission Notice, C278/2016).
'shelf-life'	The term 'shelf-life' is defined in Article 2(2)(f) of Regulation (EC) No 2073/2005 and means either the period corresponding to the period preceding the 'use by' or the minimum durability date, as defined, respectively, in Articles 9

	and 10 of Directive 2000/13/EC (corresponding now to Article 24(1) and Article 2(2)(r) of Regulation (EU) No 1169/2011)
`Spoilage domain`	Refers to the range of conditions regarding intrinsic, extrinsic and implicit factors (food product characteristics, storage conditions and microorganisms in the food) within which the SSO grow faster than other microbial groups and/or generate sufficient amounts of metabolites causing the off-flavours and undesirable changes to the food matrix
TCS food	A food that requires time and temperature controls to limit the growth of pathogens or the formation of toxins. From 2013 onwards, the TCS (Time/Temperature Control for Safety) term replaces the previously used term 'potentially hazardous foods' (PHF) in the US Food Code (US FDA, 2013)
Thawing	Used here as a synonym to defrosting which was used in the ToRs. It describes the process of changing food from a solid frozen state to a soft or liquid state by increasing the temperature to above its freezing point. A food item may be partially thawed in that the surface temperature is above 0°C while the core is still frozen.
'use by' date	According to the first sentence of Article 24(1) of the Regulation (EU) No 1169/2011, it is a legal obligation to replace the generally required 'best before' date by the 'use by' date on foods which, from a microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health. The second sentence of Article 24(1) of the Regulation specifies that after the 'use by' date a food shall be deemed to be unsafe in accordance with Article 14(2) to (5) of Regulation (EC) No 178/2002. For the purpose of this opinion, the Regulation clearly relates the 'use by' date to food safety requirements related to the likeliness of immediate danger to human health, i.e. whether the food as a consequence of the growth of food-borne pathogenic microorganisms and/or microbiological activities such as the production of toxins and/or enzymes is likely after a short period to constitute an immediate danger to human health. Consequently, food bearing a 'use by' date shall not be placed on the market past that date
Validation	Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome. Revalidation may be required in case of changes. Detailed examples can be found in CAC/GL 69-2008. (EU Commission Notice, C278/2016)
Verification	The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP-based procedures (1). Verification is conducted periodically to demonstrate that the HACCP system is working as planned. Detailed examples can be found in CAC/GL 69-2008. (EU Commission Notice, C278/2016)

Abbreviations

AMA/P	Antimicrobial Agent or Process
ALOP	Appropriate Level of Protection
CCP	Critical Control Points
CFU	Colony-forming units
DT	Decision tree
FBO	Food Business Operator
FSMS	Food Safety Management System
FSO	Food Safety Objective
G	Growth
HACCP	Hazard Analysis and Critical Control Points
HPP	High-Pressure Processing
HTST	High Temperature Short Time
LAB	Lactic Acid Bacteria
MAP	Modified Atmosphere Packaging
MS	Member State

NG	No Growth
PRPs	Prerequisite Programmes
RePFED	Refrigerated Processed Foods with an Extended Durability
RFC	Reasonably Foreseeable Conditions
RTE	Ready-to-eat
SSO	Specific Spoilage Organisms
TCS	Time/Temperature Control for Safety
UHT	Ultra-High temperature

Appendix A – EU regulations relevant for date marking, shelf-life and related food information

Regulation (EC) No 178/2002 laying down the general principles and requirements of food law

- Article 14 Food safety requirements

1) Food shall not be placed on the market if it is unsafe.
2) Food shall be deemed to be unsafe if it is considered to be:

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

3) In determining whether any food is unsafe, regard shall be had:

   a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and
   b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

4) In determining whether any food is injurious to health, regard shall be had:

   a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
   b) to the probable cumulative toxic effects;
   c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

5) In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.

Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

- Article 2(f) provides the definition of 'shelf-life' which 'means either the period corresponding to the period preceding the 'use by' or the minimum durability date, as defined respectively in Articles 9 and 10 of Directive 2000/13/EC' (repealed and replaced by Regulation (EU) No 1169/2011).

Regulation (EU) No 1169/2011 on the provision of food information to consumers

- Article 9(1)(f) states that 'In accordance with Articles 10 to 35 and subject to the exceptions contained in this Chapter, indication of the following particulars shall be mandatory:... f) the date of minimum durability or the 'use by' date;...'
- Article 2(2)(r) provides the definition of the 'date of minimum durability of a food' which 'means the date until which the food retains its specific properties when properly stored'.
- Article 24(1) states that '1. In the case of foods which, from a microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health, the date of minimum durability shall be replaced by the 'use by' date. After the 'use by' date a food shall be deemed to be unsafe in accordance with Article 14(2) to (5) of Regulation (EC) No 178/2002'.
- Article 24(2) states that 'the appropriate date shall be expressed in accordance with Annex X'. This covers both the date of minimum durability and the 'use by' date. Annex X 1(a), (b), (c) and 2 specify how the dates shall be indicated.
- Annex X 1(d) states that 'subject to Union provisions imposing other types of date indication, an indication of the date of minimum durability shall not be required for:

  - 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,

- 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,
- beverages containing 10% or more by volume of alcohol,
- bakers' or pastry cooks' wares which, given the nature of their content, are normally consumed within 24 h of their manufacture,
- vinegar,
- cooking salt,
- solid sugar,
- confectionery products consisting almost solely of flavoured and/or coloured sugars,
- chewing gums and similar chewing products'.

Table eggs

Regulation (EC) No 589/2008 laying down detailed rules for implementing Council Regulation (EC) No 1234/2007 as regards marketing standards for eggs

- Article 12(1) states that 'Packs containing Class A eggs shall bear on the outer surface in easily visible and clearly legible type: … (d) the date of minimum durability in accordance with Article 13 of this Regulation; … (f) as a special storage condition in accordance with Article 3(1)(6) of Directive 2000/13/EC, an indication advising consumers to keep eggs chilled after purchase'.
- Article 13 states that 'The date of minimum durability referred to in Article 3(1)(5) of Directive 2000/13/EC shall be fixed at not more than 28 days after laying. Where the period of laying is indicated, the date of minimum durability shall be determined from the first day of that period'.
- Article 16 states that 'For loose egg sales, the following information shall be given in such a manner as to be easily visible and clearly legible to the consumer: … (e) the date of minimum durability'.

Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin

- Annex III, Section X, Chapter I, point 3 states that 'Eggs must be delivered to the consumer within a maximum time limit of 21 days of laying'.

Fresh poultry meat

Regulation (EC) No 543/2008 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 as regards the marketing of poultry meat

- Article 5(3) states that 'In the case of fresh poultry meat, the date of minimum durability shall be replaced by the 'use by' date in accordance with Article 10 of Directive 2000/13/EC'.

Live bivalve molluscs

Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin

- Annex III, Section VII, Chapter VII, point 2 states that 'In addition to the general requirements for identification marks contained in Annex II, Section I, the following information must be present on the label: (a) the species of bivalve mollusc (common name and scientific name); (b) the date of packaging, comprising at least the day and the month. By way of derogation from Directive 2000/13/EC, the date of minimum durability may be replaced by the entry "these animals must be alive when sold"'.

Pectinidae, marine gastropods and echinoderms which are not filter feeders harvested outside classified production areas

Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin

- Annex III, Section VII, Chapter IX, point 4 states that 'Food business operators handling pectinidae, live marine gastropods and live echinoderms which are not filter feeders, must comply with the following requirements: … (b) with the requirements of Chapter VI, point 2 concerning the closing of all packages of live pectinidae, live marine gastropods and live echinoderms dispatched for retail sale and Chapter VII concerning identification marking and labelling'.

Appendix B – Limiting conditions for pathogen growth

Table B.1: Potential pathogens[a] of concern for growth studies based on interaction of product pH and a_w[b] (reproduced from NACMCF, 2010)

A_W values	**pH values:**					
	< 3.9	**3.9 to < 4.2**	**4.2–4.6**	**> 4.6–5.0**	**> 5.0–5.4**	**> 5.4**
< 0.88	NG[c]	NG	NG	NG	NG	NG
> 0.88–0.90	NG	NG	NG	NG	*Staphylococcus aureus*	*S. aureus*
> 0.90–0.92	NG	NG	NG	*S. aureus*	*S. aureus*	*L. monocytogenes* *S. aureus*
> 0.92–0.94	NG	NG	*L. monocytogenes*[d] *Salmonella*	*Bacillus cereus* *Clostridium botulinum* *L. monocytogenes* *Salmonella* *S. aureus*	*B. cereus* *C. botulinum* *L. monocytogenes* *Salmonella* *S. aureus*	*B. cereus* *C. botulinum* *L. monocytogenes* *Salmonella* *S. aureus*
> 0.94–0.96	NG	NG	*L. monocytogenes*[d] Pathogenic *E. coli* *Salmonella* *S. aureus*	*B. cereus* *C. botulinum* *L. monocytogenes* Pathogenic *E. coli* *Salmonella* *S. aureus* *Vibrio parahaemolyticus*	*B. cereus* *C. botulinum* *L. monocytogenes* Pathogenic *E. coli* *Salmonella* *S. aureus* *V. parahaemolyticus*	*B. cereus* *C. botulinum* *C. perfringens* *L. monocytogenes* Pathogenic *E. coli* *Salmonella* *S. aureus* *V. parahaemolyticus*
> 0.96	NG	*Salmonella*	Pathogenic *E. coli* *Salmonella* *S. aureus* *L. monocytogenes*[d]	*B. cereus* *C. botulinum* *L. monocytogenes* Pathogenic *E. coli* *Salmonella* *S. aureus* *V. parahaemolyticus*	*B. cereus* *C. botulinum* *L. monocytogenes* Pathogenic *E. coli* *Salmonella* *S. aureus* *V. parahaemolyticus* *V. vulnificus*	*B. cereus* *C. botulinum* *C. perfringens* *L. monocytogenes* Pathogenic *E. coli* *Salmonella* *S. aureus* *V. parahaemolyticus* *V. vulnificus*

(a): *Campylobacter* spp., *Shigella* and *Yersinia enterocolitica* do not appear here because they are typically controlled when the pathogens listed are addressed.
(b): Data are based on the PMP (106), ComBase predictor (50), ComBase database (49) or peer-reviewed publications (11, 17, 45) [for details on references marked 11, 17, 45, 49, 50 and 106 please consult NACMCF, 2010].
(c): NG, no growth; when no pathogen growth is expected, but formulation or process inactivation studies may still be needed.
(d): *L. monocytogenes* should not be used if the pH of the product is < 4.4.

Appendix C – Uncertainty analysis

Table C.1: Sources of uncertainty in the decision tree (DT) affecting the decision on the type of date marking

Uncertainties related to	Source or location of the uncertainty	Nature, or cause, of the uncertainty as described by the experts	Impact of the uncertainty on the decision on the type of date marking using the DT (direction(1) and magnitude(2))
Decision Tree	Assumption: Steps/questions included in the tree	An important step/question may be missing or an irrelevant one is included	Inconclusive/+
	Assumption: Growth potential based on few factors (pH and a_w) as the main determining factor	The potential to initiate growth may be less than that indicated in the tables in Q8 and Q9 that rely on only two factors (pH and a_w) at optimum conditions	Overestimation/++ (but can be overcome with the correct use of Q10)
	Assumption: Inactivation at consumer stage not considered	Inactivation of hazards can take place in (non-ready to eat) foods at the consumer level (e.g. when foods are heat treated)	Overestimation/+ (but only relevant for a few types of foods, e.g. cuts of fresh meat)
	Structure: The relation between questions	The sequence of the questions may not reflect the relevant events that may take place and influence the outcome of the DT	Inconclusive/+
	Structure: Question 10) if FBO can demonstrate that the products do not support growth	High impact on the decision outcome from this single question requiring evidence and understanding from the FBO (see application), and use of relevant reasonably foreseeable conditions	Under- or overestimation/+++ (Important since this can reverse the decision, more serious if from 'use by' date to 'best before' date, i.e. leading to underestimation)
Decision Tree	Data for limiting pH and a_w	The limits used in the data tables included in Q8 and Q9 may not be representative for all relevant biological hazards	Underestimation/+ (Not considered likely/important except in case of emergence of hyper-tolerant strains, since the limiting pH and a_w are based on the most tolerant vegetative cells or spores known) Overestimation/++

(1): Underestimation, i.e. 'use by'-date foods would classify as 'best before' food, Overestimation, i.e. 'best before' foods would classify as 'use by' foods, Inconclusive, i.e. could influence in either way.
(2): Assessment of the magnitude of the uncertainty using a three-level semi-quantitative scale from low to high importance (+, ++ or +++).

Table C.2: Sources of uncertainty relating to the application and use by the FBOs of the date marking decision tree

Uncertainties related to	Source or location of the uncertainty	Nature, or cause, of the uncertainty as described by the experts
FBOs understanding of the DT	Misunderstanding of the concepts and questions in the DT	The questions (concepts and terms) and the data needed can be misunderstood
Food related data informing responses in the DT	Magnitude of inactivation	May be incorrect if lethal treatments/technologies are not properly validated
	Characterisation of intrinsic factors	Incorrect or non-representative data, for instance not capturing batch variability, may be used to characterise the factors determining the microbial growth potential or inactivation
	Characterisation of foreseeable conditions of storage, transport and use	Assumptions and data used to characterise the factors determining the microbial growth potential in the food chain until consumption may be incorrect or non-representative
	Approaches used by FBO to demonstrate that the food product does not support growth of pathogens	Possibility of incorrect application of the methodological approaches (e.g. literature review, challenge testing, predictive microbiology tools) or mis-interpretation of their results

DT: decision tree.

Appendix D – Survey data of the temperature of domestic refrigerators in the EU

Table D.1: Temperature survey data on domestic refrigerators in the EU [a]

Year reported	Country	N	Minimum temperature	Mean temperature	Max temperature	% refrigerators running at temperature °C[b]							Reference
						> 4	> 5	> 6	> 7	> 8	> 9	> 10	
2010	Greece	100	–0.3	6.3[c]	13.0	84	72	56	36	24	13	7	Koutsoumanis et al. (2010)
2010	Spain	33	0.6	7.9	14.5	84.9		78.8		51.5		15.1	Garrido et al. (2010)
2010	UK	50		5.9			71			30	29		WRAP (2010)
2011	Austria	82	0.5	8.6	15	94	93	91	88	73	46	43	Buxbaum et al. (2011)
2013	Serbia	100	–1.9	8.9[f]	20.8	NA	NA	NA	NA	NA	NA	NA	Đurić et al. (2013)
2013	Serbia	100	0.1	8.6[g]	21.4	NA	NA	NA	NA	NA	NA	NA	Đurić et al. (2013)
2013	Serbia	100	2.4	10.43[h]	21.8	NA	NA	NA	NA	NA	NA	NA	Đurić et al. (2013)
2014	Italy	84	2.5	8.1	15.9	94			73.8			51.2	Vergara et al. (2014)
2014	France	83	1.1	6.3	10.7			47					Derens-Bertheau et al. (2015)
2015	Sweden			5.9[d]						16			Marklinder and Eriksson (2015)
2016	UK	43	–1.7	5.9[e]	16.9	79.1	62.8	39.5	14.0	4.7	4.7	0.0	Evans and Redmond (2016)
2016	Portugal	51	3.3	5.5	9.3	NA	NA	NA	NA	NA	NA	NA	Galvão et al. (2016)
2019	Spain	160	0.0	5.4	12.7	71.0		41.0		11.0			Jofré et al. (2019)

N: number of refrigerators sampled.
(a): Published 2010 or late.
(b): Cumulative frequency of temperature data based on data reported by the authors.
(c): Based on data from middle shelves.
(d): Based on data from middle shelves front.
(e): Central refrigerator temperature.
(f): Top shelf.
(g): Bottom shelf.
(h): Refrigerator door.
NA: not available.