Guidance on date marking and food information - Part 1

Roland Lindqvist
EFSA BIOHAZ Panel member
FBOs should follow a risk-based approach when deciding on the type of date marking.

Clarity was needed on the differentiation between foods that at the end of shelf-life might become:
- ‘injurious to health’ due to growth of pathogenic microorganisms
- ‘unfit for human consumption’ due to growth of spoilage non-pathogenic microorganisms

To support FBO and national authorities in implementing correct and consistent practices, EFSA was asked to provide scientific advice.
Providing guidance on date marking and related food information (Part 1)

**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 food business operators when deciding whether a ‘use by’ date is required and setting the 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 food business operators when deciding whether a ‘best before’ date is appropriate and setting the shelf-life and the required storage conditions.
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:
- The characteristics of a food and the intrinsic/extrinsic factors which might change once the package is opened
- The factors to be considered in deciding to indicate the storage conditions and/or time limit for consumption after opening the package.

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 risk
The relevance of a pathogen for the shelf-life of a perishable food will depend on different factors 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.
### Relevant Pathogenic Microorganisms

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

- Fraction within total food microbiota that is responsible for spoilage of a given foodstuff in a given ‘spoilage domain’
- 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.

<table>
<thead>
<tr>
<th>Spoilage microorganisms</th>
<th>Relevant foods/comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aerobic or anaerobic spore-forming bacteria and/or spores; including genera <em>Bacillus</em>, <em>Clostridium</em>, <em>Alicyclobacillus</em></td>
<td>In heat-treated foods (e.g. mild pasteurization) 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 <em>Clostridia</em> (non-pathogenic)</td>
</tr>
<tr>
<td>Lactic acid bacteria, e.g. psychrotrophic genera such as <em>Leuconostoc</em>, <em>Weissella</em> and <em>Lactobacillus</em></td>
<td>In vacuum-packed foods and MAP foods (e.g. <em>Photobacterium phosphoreum</em> in MAP fish products (Dalgaard et al., 1997))</td>
</tr>
<tr>
<td>Yeasts e.g. <em>Candida</em> spp., <em>Saccharomyces</em> spp. and moulds e.g. <em>Penicillium</em> spp., <em>Botrytis</em> spp., <em>Alternaria</em> spp.</td>
<td>Yeasts and moulds mostly dominate the microbiota of a food when the conditions are less favorable for bacterial growth i.e. low pH, aw such as fruits and derived products (juices, marmalades and fresh-cut fruits), yoghurt, cheese or other fermented foods, etc.</td>
</tr>
</tbody>
</table>
Factors determining the type and the levels of microorganisms in the end product.

- Raw materials and intermediate ingredients
- Processing environment
- Manufacturing steps

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

- Intrinsic factors
- Extrinsic or environmental factors
- Implicit factors
Guidance on the decision to apply a ‘use by’ or ‘best before’ date

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?

Q2. Is the food product frozen?

Q3. Does the food product undergo a validated lethal treatment eliminating all spores of foodborne pathogenic bacteria?

Q4. Does the food product undergo a validated lethal treatment eliminating all vegetative cells of foodborne pathogenic bacteria?

Q5a. Is there a potential of recontamination of the food product before packing?

Q5b. Is there a potential of recontamination of the food product before packing?

Q6. Does the food product undergo a validated post-lethality treatment eliminating all vegetative cells of foodborne pathogenic bacteria?

Q7. Is the post-lethality treatment applied in packed products or followed by aseptic packing or hot filling?
Guidance on the decision to apply a ‘use by’ or ‘best before’ date

Q7. Is the post-lethality treatment applied in packed products or followed by aseptic packing or hot filling?

Q8. Does the food product support the growth of vegetative cells of pathogenic bacteria?
To answer check the following Table:

<table>
<thead>
<tr>
<th>pH</th>
<th>&lt;3.9</th>
<th>3.9-4.2</th>
<th>4.2-4.6</th>
<th>4.6-5.0</th>
<th>&gt;5.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;0.88</td>
<td>NG</td>
<td>NG</td>
<td>NG</td>
<td>NG</td>
<td>NG</td>
</tr>
<tr>
<td>0.88-0.90</td>
<td>NG</td>
<td>NG</td>
<td>NG</td>
<td>G</td>
<td>G</td>
</tr>
<tr>
<td>0.90-0.92</td>
<td>NG</td>
<td>NG</td>
<td>G</td>
<td>G</td>
<td>G</td>
</tr>
<tr>
<td>0.92-0.96</td>
<td>NG</td>
<td>G</td>
<td>G</td>
<td>G</td>
<td>G</td>
</tr>
<tr>
<td>&gt;0.96</td>
<td>NG</td>
<td>G</td>
<td>G</td>
<td>G</td>
<td>G</td>
</tr>
</tbody>
</table>

Q9. Does the food product support the germination, growth and toxin production of spores of pathogenic bacteria?
To answer check the following Table:

<table>
<thead>
<tr>
<th>pH</th>
<th>&lt;4.6</th>
<th>4.6-5.6</th>
<th>&gt;5.6</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;0.92</td>
<td>NT</td>
<td>NT</td>
<td>NT</td>
</tr>
<tr>
<td>0.92-0.95</td>
<td>NT</td>
<td>NT</td>
<td>T</td>
</tr>
<tr>
<td>&gt;0.95</td>
<td>NT</td>
<td>T</td>
<td>T</td>
</tr>
</tbody>
</table>

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 growth or toxin production of pathogenic bacteria during the shelf-life. The food product can be stored at ambient temperature unless quality reasons requires refrigeration.

'Best before' date

'Use by' date
Food characteristics and storage conditions support the growth of both pathogenic (hazard) and specific spoilage organisms (SSO) during storage.
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.

Potential factors to consider in the determination of ‘reasonably foreseeable conditions’ for the determination of shelf-life include:

- Consumer behaviour (unintended use of food)
- Storage temperatures at distribution, storage and retail level
- Storage temperature at consumer level
Guidance on approaches to determine shelf-life

- Relevant microorganisms and initial levels
- Intrinsic, extrinsic and implicit characteristics
- Behaviour of the relevant microorganisms in the specified food
- Monitoring and verification of shelf-life date
PreRequisite Program (nr. 16) describes preventive measures to be taken for best before date marked foods but also foods without a legally required shelf-life date.

Many EU MS have regional/national guidance documents on food donations.

Marketing of food past the ‘best before’ date is allowed in several countries provided it 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.
Data on pathogens 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 and a summary of 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, it is difficult to exclude any of the pathogens capable of growing at the currently used storage temperatures.
Raw materials, processing environment and manufacturing steps determine type and levels of microorganisms in the food product.

The intrinsic, extrinsic and implicit factors of the food product determine which microorganisms can grow 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.
The decision on the type of date marking needs to be taken on a product-by-product basis.

A decision-tree (DT) consisting of a sequential list of ten questions was developed, and supported with examples, to assist FBOs in deciding the type of date marking for a certain food product.

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.
Reasonably foreseeable conditions 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.

A case-by-case procedure to determine and validate the shelf-life of a food product should be applied.
Guidelines on food donations cover a wider range of foods and situations than those in opinion, and do not cover marketing of foods past the ‘best before’ date.

Food products eligible for donation are categorized based on their shelf-life with:
- characteristics of spoiled food
- storage temperatures and estimation of time frame
- Guidance on labelling and traceability of the donated food.

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.
To provide training activities and support (food characteristics and DT)

To collect time-temperature data during distribution, retail and domestic storage of foods, and to carry out consumer-based studies (characterise RFC)

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

To develop ALOP/FSO for most food-pathogen combinations
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