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AUTHORITY OF IRELAND

Report of the Scientific Committee
of the Food Safety Authority of Ireland

2018

Enterobacteriaceae limits for ice cream (containing milk ingredients) and frozen dairy desserts sampled when placed on the market

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BACKGROUND

Enterobacteriaceae are a group of bacteria that are used to assess the general hygiene status of a food product. This group includes species that originate from the intestinal tract of animals and humans, as well as from plants and the environment. Enterobacteriaceae should be readily removed from equipment and surfaces by appropriate cleaning procedures and are generally inactivated by heating treatments (pasteurisation, etc.) used in food production. Enterobacteriaceae are used as indicators of poor hygiene, inadequate processing or post-process contamination of foods.

Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs lays down microbiological criteria for certain microorganisms and the implementation rules to be complied with by food business operators when implementing the general and specific hygiene measures referred to in Article 4 of Regulation (EC) No 852/2004. Within this, 'process hygiene criterion' is defined as "a criterion indicating the acceptable functioning of the production process. Such a criterion is not applicable to products placed on the market. It sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law." This regulation sets a process hygiene criterion for ice cream (at the end of manufacturing) in relation to Enterobacteriaceae where n=5 (number of sample units), with limits m=10 CFU/g and M=100 CFU/g and c=2. This means that the result is:

- **Satisfactory** if all sample units are less than or equal to 10 CFU/g
- **Acceptable** if no more than two sample units are between 10 CFU/g and 100 CFU/g, and the rest of the sample units are less than or equal to 10 CFU/g
- **Unsatisfactory** if one or more of the sample units are greater than 100 CFU/g or more than two sample units are between 10 CFU/g and 100 CFU/g.

In practice, ice cream may be served as whipped ice cream from an ice cream machine at retail level or served as a scoop ice cream (containing milk ingredients) or a frozen dairy dessert at retail level. These products are dependent on adequate temperature control and good hygiene to prevent cross-contamination and ensure food safety. As such, these ice cream products may be sampled and tested for Enterobacteriaceae at the retail stage as a useful way to assess hygiene and temperature control measures at retail level. However, currently in Food Safety Authority of Ireland (FSAI) Guidance Note No. 3, *Guidelines for the Interpretation of Results of Microbiological Testing of Ready-to-Eat Foods Placed on the Market (Revision 2)*, there are no limits for Enterobacteriaceae in ice cream (containing milk ingredients) or in whipped, scoop, or frozen dairy desserts (for more details, see Appendix 1). The legal process hygiene criterion limits for Enterobacteriaceae at the end of manufacturing (described above) are not appropriate, as it may be reasonable to expect that numbers would increase in the distribution chain post-manufacture. In addition, the process hygiene criterion is based on a sampling plan of five sample units being taken from the same batch. Sampling at retail level, however, generally involves taking single samples, because multiple samples from the same batch of food may not be available.

The Scientific Committee has been asked to assess whether an Enterobacteriaceae limit is appropriate for these products, and if so, what such a limit should be, using the three categories in FSAI Guidance Note No. 3, where:

- **Satisfactory** means that the test result indicates the food sample is of a satisfactory microbiological quality
- **Borderline** means that the test result indicates the food sample may be approaching an unsatisfactory microbiological quality
- **Unsatisfactory** means that the test result indicates the food sample is of an unsatisfactory microbiological quality.

ANSWER TO REQUEST FOR ADVICE

1. Should there be a guideline limit for Enterobacteriaceae in whipped ice cream sampled as it is poured from an ice cream machine at retail level?

Whipped/soft serve ice cream comes as three main types of prepared products which are added to the ice cream machine at retail level and subsequently stored at refrigeration temperatures.

Product types

1. Whipped/soft serve ice cream made from fresh liquid

- Stored at refrigeration temperatures for five to seven days until added to the ice cream machine.

2. Whipped/soft serve ice cream made from powdered mix

- This is a dried version of the liquid mix and can be stored for longer periods of time at room temperature.
- Water is added to the powder prior to being added to the ice cream machine; the water should be pre-chilled.

3. Whipped/soft serve ice cream made from ultra-heat-treated (UHT) liquid

- This is a liquid that has been sterilized and packed in sealed, sterile bags and can be stored for a very long time (several weeks or months) without refrigeration.
- UHT liquid can be poured into the ice cream machine immediately upon opening.

Refrigeration temperatures

In Ireland, the recommended temperatures for refrigerated storage at retail and catering level are between 0 °C to 5 °C (National Standards Authority of Ireland (NSAI), 2007a, 2007b). Whipped ice cream is a product which may be stored at refrigeration or frozen temperatures and should therefore be stored at ≤5 °C (FSAI, 2017). A survey of whipped ice cream in 2008 (FSAI, 2008) found that 10% (31/326) of samples were taken from machines where the temperature display reading was recorded as >5 °C (with a range of 5.1 °C to 15 °C).

ENTEROBACTERIACEAE LIMITS FOR WHIPPED/SOFT SERVE ICE CREAM PRODUCT TYPE 1 (FRESH LIQUID)

For product type 1 (fresh liquid), it would be reasonable to assume that some slow growth of Enterobacteriaceae will occur at expected refrigerated temperatures over a storage period of five to seven days. Psychrotrophic strains of Enterobacteriaceae (*Citrobacter, Enterobacter, Erwinia, Escherichia, Hafnia, Klebsiella, Proteus* and *Serratia* species and some strains of *Yersinia enterocolitica*) are capable of growing slowly at temperatures as low as 0 °C (International Commission on Microbiological Specifications for Foods (ICMSF), 1978), while thermotolerant Enterobacteriaceae (*E. coli* and *Klebsiella oxytoca*) have a minimum temperature for growth of >7–8 °C (International Life Sciences Institute (ILSI) Europe, 2011). ComBase predictive models indicate that at 4 °C, *Yersinia* spp. will increase from 10^2 to 10^4 CFU/g in 8.5 days. The time needed for this growth decreases to 5.3 days at 7 °C, and to 3.4 days at 10 °C – all well within the five to seven days' storage of the 'fresh liquid' ice cream product type. Thus, even under correct chilling/ mild temperature abuse (7 °C), 10^4 CFU/g can be reached within the storage period without cross-contamination.

The following limits are considered suitable at retail level for these products based on single sampling:

Satisfactory ≤10^2 CFU/g

Borderline >10^2–≤10^4 CFU/g

Unsatisfactory >10^4 CFU/g

ENTEROBACTERIACEAE LIMITS FOR WHIPPED/SOFT SERVE ICE CREAM PRODUCT TYPES 2 (POWDERED MIX) AND 3 (UHT LIQUID)

In product type 2 (powdered mix), in general the water activity (a_w) will be low (<0.6) and most Enterobacteriaceae have a minimum a_w limit for growth close to 0.94. While some thermotolerant Enterobacteriaceae may be present in the powder, there should be no growth or increase in numbers of Enterobacteriaceae from end of manufacture to retail unless it is introduced by cross-contamination from the ice cream machine, or by water used to rehydrate the powdered mix or by staff handling the product.

For product type 3 (UHT liquid), there should be no growth or increase in numbers of Enterobacteriaceae from end of manufacture to retail unless it is introduced by cross-contamination from the ice cream machine or staff handling the product.

In all cases, if appropriate cleaning procedures have been applied to the ice cream machine there should not be Enterobacteriaceae present as a source of cross-contamination. However, with the widespread nature of this group of microorganisms in the environment, there is likely to be some increase in levels present post-cleaning.

For product types 2 and 3, where no Enterobacteriaceae growth is envisioned during storage, the following limits are considered suitable at retail level based on single sampling:

Satisfactory ≤10^2 CFU/g

Borderline >10^2–≤10^3 CFU/g

Unsatisfactory >10^3 CFU/g

2. Should there be a guideline limit for Enterobacteriaceae in scoop ice cream (containing milk ingredients) and frozen dairy desserts sampled at retail level?

Scoop ice cream and frozen dairy desserts are stored frozen at below −18 °C and in display freezers for serving at −10 °C to −15 °C. Growth of microorganisms, including Enterobacteriaceae, ceases at temperatures below −8 °C (ILSI Europe, 2011) along with most Gram-negative bacteria. Enterobacteriaceae are particularly susceptible to damage by freezing, which causes sub-lethal injury along with a further gradual inactivation during prolonged storage. Therefore, there should be no growth or increase in numbers of Enterobacteriaceae from end of manufacture to retail unless it is introduced by cross-contamination from the storage display equipment or serving tools.

If appropriate cleaning procedures have been applied, there should be no Enterobacteriaceae present as a result of cross-contamination. However, due to the widespread nature of this group of microorganisms in the environment, there is likely to be an increase in levels present post-cleaning.

The following limits are considered suitable at retail level for these products based on single sampling:

Satisfactory $\leq 10^2$ CFU/g

Borderline $>10^2$–$\leq 10^3$ CFU/g

Unsatisfactory $>10^3$ CFU/g

RECOMMENDATION

Where hygiene problems are repeatedly identified (i.e. through breaches of these recommended Enterobacteriaceae limits) in a business selling soft serve/whipped ice cream, the business may wish to consider changing to use of: (i) a self-pasteurising machine, as this will make it easier to maintain a high level of hygiene; and/or (ii) UHT liquid, as this product has the least risk for Enterobacteriaceae contamination and growth.

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APPENDIX 1: FSAI REQUEST FOR ADVICE FROM THE SCIENTIFIC COMMITTEE

Topic title: Enterobacteriaceae limits for ice cream (containing milk ingredients) and frozen dairy desserts sampled when placed on the market

Date requested: 30 September 2016

Date accepted: 2 December 2016

Target deadline for advice: Draft to Scientific Committee by June 2017

Form of advice required: A brief report which addresses the questions posed

Background/Context

In 2011, the FSAI requested advice from the Scientific Committee regarding potential discrepancies between national guideline microbiological limits applicable to ready-to-eat foods sampled at point of sale (FSAI Guidance Note No. 3 (GN3)) and legal process hygiene limits applicable for certain foods sampled during or at the end of the manufacturing process (Commission Regulation (EC) No. 2073/2005).

The national guideline limit set in GN3 for an unsatisfactory level of Enterobacteriaceae in a ready-to-eat food was $\geq 10^4$ CFU/g. This limit was considered lenient compared to the unsatisfactory process hygiene criterion limit of >100 cfu/g laid down in Regulation 2073/2005 for food category 2.2.8 'Ice cream (containing milk ingredients) and frozen dairy desserts' sampled at the end of the manufacturing process. The Scientific Committee concluded that it was not appropriate to set guideline limits for Enterobacteriaceae in 'Ice cream (containing milk ingredients) and frozen dairy desserts' sampled at retail level. It found that Enterobacteriaceae are a broad group which can be used to assess the general hygiene status of a food product. Unlike *E. coli*, Enterobacteriaceae are not a clear indication of faecal contamination and there is no level of Enterobacteriaceae which can be classified as hazardous (see Appendix 2, page 37 of FSAI Guidance Note No. 3 Revision 2 (GN3 (Rev 2)). Consequently, there are currently no limits for Enterobacteriaceae in ice cream (containing milk ingredients), whether whipped or scoop, or frozen dairy desserts in GN 3 (Rev 2).

In 2016, the FSAI became aware that the Official Food Microbiology Laboratories (OFML) group was applying the process hygiene criterion for food category 2.2.8 to whipped ice cream sampled after the liquid ice cream mix had been added to the ice cream dispensing machine at retail level, interpreting that to be the end of the manufacturing process. The FSAI had not interpreted this criterion to apply at retail level. In addition, during the discussion with the FSAI, the OFML group noted that testing for Enterobacteriaceae in ice cream at the point of sale under GN3 had been useful to assess hygiene and temperature control in retail shops for both whipped and scoop ice cream.

A 2008 FSAI/Health Service Executive (HSE) national survey assessing the microbiological quality of whipped and scoop ice cream found that whipped ice cream for which the liquid mix was held at ≤5 °C in the machine had a significantly lower aerobic colony count (ACC) and Enterobacteriaceae results than whipped ice cream for which the liquid mix was held at >5 °C. The type of machine had a strong statistically significant effect on both the ACC and the Enterobacteriaceae results. Better results were reported for whipped ice cream obtained from self-pasteurising machines than from non-pasteurising machines. In the case of scoop ice cream, samples were found to be of a better microbiological quality (ACC and Enterobacteriaceae) when the serving utensils were cleaned both before and during serving.

Questions for the Scientific Committee

1. Should there be a guideline limit for Enterobacteriaceae in **whipped** ice cream sampled as it is dispensed from an ice cream machine at retail level?
2. If yes to Q1, what guideline limit should apply?
3. Should there be a guideline limit for Enterobacteriaceae in **scoop** ice cream (containing milk ingredients) and **frozen dairy desserts** sampled at retail level?
4. If yes to Q3, what guideline limit(s) should apply?

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