

NON PAPER

Implementation of microbiological criteria to infant formulae, follow-on formulae and baby food

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

Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs harmonises at the Union level the microbiological criteria for foodstuffs. The Regulation contains two kinds of criteria: food safety and process hygiene criteria.

*Food safety criteria for *Enterobacter sakazakii* (*Cronobacter* spp.) in infant formulae*

For dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age there is a food safety criterion for *Enterobacter sakazakii* (absence in 10 g, n = 30, c = 0). For dried follow-on formulae meant for babies older than six months there is no such criterion. The reason for the difference is that *Enterobacter sakazakii* is not considered to cause health risk to children older than 6 months as stated in the EFSA reports (2004 and 2006) on the risks of *E. sakazakii* to babies. According to the reports the highest risk concerns the infants less than 2 months old and no cases of illness have been associated with follow-on formulae.

Process hygiene criteria for Enterobacteriaceae in infant formulae and dried follow-on formulae

A limit for Enterobacteriaceae in both dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age (absence in 10 g, n = 10, c = 0) and dried follow-on formulae (absence in 10 g, n = 5, c = 0) is set as process hygiene criteria in the regulation.

2. Definitions for infant formulae, follow-on formulae and baby food

Directive 2006/141/EC on infant formulae and follow-on formulae; article 2:

- (a) 'infants' means children under the age of 12 months;
- (b) 'young children' means children aged between one and three years;
- (c) 'infant formulae' means foodstuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants until the introduction of appropriate complementary feeding;
- (d) 'follow-on formulae' means foodstuffs intended for particular nutritional use by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants.

Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children; recital 2

Processed cereal-based foods and baby foods for infants and young children are used as part of a diversified diet and do not constitute the sole source of nourishment of infants and young children.

Directive 2006/125/EC; article 8 (a)

The stated age shall not be less than four months of any product.

Directive 2006/141/EC; Article 13 (b)

In case of follow-on formulae, the labelling shall bear "a statement to the effect that the product is suitable only for particular nutritional use by infants over the age of six months, that it should form only part of a diversified diet, that it is not to be used as a substitute for breast milk during the first six months of life."

3. Implementation of the criteria to infant formulae, follow-on formulae and baby food and RASFF notifications

There have been some RASFF notifications on *Enterobacter sakazakii* findings in infant formulae and in baby food during the last years. For the infant formulae products meant for babies less than 6 months of age the food safety criterion applies and the product has to be withdrawn/recalled from the market and corrective action at the production plant has to be taken. The RASFF alert is also justified in case of non-compliance with the food safety criterion and possible distribution to the other members of RASFF network.

Follow-on formulae are meant for children older than six months (see Article 13 (b) of Directive 2006/141/EC and there is no food safety criterion which could justify withdrawals or recalls.

Processed cereal baby foods and baby foods for infants can be given from 4 months of age (see Article 8 of Directive 2006/125/EC). However, the food safety criterion applies only to infant formulae (as category) and not to processed cereal based foods and baby foods (independently of the starting age of taking these foods, 4 or 6 months).

4. General food safety requirements (Article 14 of Regulation (EC) No 178/2002)

Article 14 on food safety requirements of Regulation (EC) No 178/2002 of the European Parliament and of the Council 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, states that unsafe food shall not be placed on the market. According to the article food that complies with specific Union provisions, like microbiological criteria set in Regulation 2073/2005, is deemed to be safe.

However, as prescribed in Article 14 (8) of the Regulation, the competent authorities of Member States may take appropriate measures to impose restrictions where there are reasons to suspect, on a case-by-case basis, that despite conformity with the Union legislation, the food in question is unsafe. Moreover, in case of emergency, or if official control analysis reveals that a foodstuff is likely to constitute a serious risk to human health, the procedure set out in Article 54 of Regulation 178/2002 could also apply and national measures could be adopted on an interim basis. The Commission and the Member States shall be immediately informed of these measures, the future of which the Scientific Committee of Food Chain and Animal Health ('SCoFAH') shall decide. Article 14 shall in any case not be used systematically as a hidden food safety criterion.