

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Deputy Director-General for the Food Chain

22. 02. 2013
SANCO/E4/FC/iv
ANAS (2013) 238583

Dear Ms Geslain-Lanéelle,

Subject: Commission request for a scientific opinion on milk based-drinks and similar products intended for infants and young children

The Commission's proposal for a Regulation of the European Parliament and the Council on foods intended for infants and young children and on food for special medical purposes¹ aims at revising the legal framework applicable to food for particular nutritional uses as set out today in Directive 2009/39/EC². Negotiations on the proposal are reaching their conclusion and it is expected that such Regulation will be adopted in the next months.

Once the new Regulation is adopted, the Commission will need to adopt delegated acts setting specific rules for the categories of food covered by the Regulation, including infant formulae and follow-on formulae, which are today covered by Directive 2006/141/EC³. This Directive sets essential requirements for infant formula and follow-on formula, which are based on a number of opinions of the Scientific Committee on Food, the latest one being the "Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae", adopted on 4 April 2003⁴. In the last ten years, scientific and technological developments on the essential composition of these products have progressed and there are increasing calls for a review of the legislation to reflect such developments.

Ms Catherine Geslain-Lanéelle
Executive Director
European Food Safety Authority
Via Carlo Magno 1/A
I-43100 Parma

¹ COM (2011) 353

² Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses, OJ L 124, 20.5.2009, p. 21

³ Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses, OJ L 124, 20.5.2009, p. 21

⁴ Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae, adopted on 4 April 2003, SCF/CS/NUT/IF/65 Final, 18 May 2003

In addition, in the context of the abovementioned revision of the legal framework, it is expected that the Commission will be requested to consult the EFSA and to draft a report on the necessity, if any, of special provisions for milk-based drinks and similar products intended for young children. Indeed, in the last years, increasing numbers of milk-based drinks and similar products are marketed in different Member States with the denomination of 'growing-up milks' or 'toddlers' milks' or with similar terminology (hereinafter 'growing-up milks'). They are promoted as being particularly suitable for young children and, as such, under the current rules, may be considered as foodstuffs for particular nutritional uses. However, no composition requirements for these products are set in EU legislation.

Different views exist in the scientific community and among stakeholders on whether these products are necessary to satisfy the nutritional requirements of young children or have any nutritional benefits when compared to other foods that can constitute the normal diet of young children. In this context, some would argue that, given the potential variability of weaning diets that may result in different nutrient intakes for this group of the population, these products are convenient, as a liquid element in the diet of young children, in contributing to meeting their nutritional requirements. Taking all these elements into account, the European Parliament and the Council agreed that these products should be subject of a specific reflection.

In the meantime, at international level, the Codex Committee on Nutrition and Food for Special Dietary Uses (CCNFSDU) agreed at its 34th session in December 2012 to revise the existing standard for follow-up formulae⁵, which dates back to 1987 and applies to food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children up to three years of age. The first discussion on this subject will take place at the next session of the CCNFSDU to be held on 4-8 November 2013.

Taking into account the developments described above, it is considered necessary to request the EFSA to provide a scientific opinion on all milk-based drinks and similar products intended for infants and young children.

Such opinion should review the existing scientific data and provide advice to the Commission on the nutritional requirements of infants and young children. It should also provide scientific advice on the essential composition requirements of infant formulae and follow-on formulae. At the same time, the opinion should inform the Commission on the importance of the role that 'growing-up milks' may have as a liquid element in the diet of young children. On that basis, the opinion should advise the Commission on the necessity of 'growing-up milks' to satisfy the nutritional requirements of young children and, if considered appropriate, advise the Commission with respect to the appropriate age range and the essential composition of 'growing-up milks'.

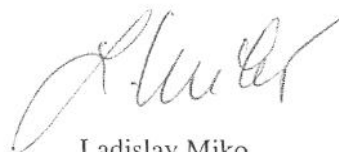
⁵ CODEX STAN 156-1987

This opinion will constitute the updated scientific basis for preparing the new delegated act on infant formulae and follow-on formulae and will inform the Commission when drafting the report on milk-based drinks and similar products intended for young children. At the same time, this advice will be useful in the context of the on-going process of the Codex Alimentarius to revise the existing Codex standard on follow-up formulae and will allow the EU to play an active role, based on up to date scientific advice.

The Authority is asked to provide a Scientific Opinion by 31 October 2013.

My services remain at your disposal for further information. On this matter, you can contact Mr Francesco Carlucci who is responsible for this dossier in Unit E4 Nutrition, Food Composition and Information and Ms Sabine Osaer, who is the relevant contact point in Unit 03 in charge of Relations with Agencies and Advisory Groups. Their respective phones and e-mail addresses are indicated below.

Yours sincerely,



Ladislav Miko

Encl.: Request for a scientific opinion on milk based-drinks and similar products intended for infants and young children

Cc: Mr B. Mathioudakis, Mr R. Vanhoorde, Mr F. Carlucci, Ms S. Osaer,
Health and Consumers Directorate General

Mr V. Curtui – **European Food Safety Authority (by e-mail)**

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EUROPEAN COMMISSION REQUEST TO THE
EUROPEAN FOOD SAFETY AUTHORITY
FOR A SCIENTIFIC OPINION ON:

Milk based-drinks and similar products intended for infants and young children

Background

Directive 2009/39/EC on foodstuffs intended for particular nutritional uses lays down general rules⁶ on the composition of such foods that are specially designed to meet the particular nutritional requirements of the persons to whom they are intended, including infants and young children in good health.

One of the measures adopted under that framework legislation is Commission Directive 2006/141/EC on infant formulae and follow-on formulae⁷. That Directive was adopted originally in 1991 and revised globally in 2006.

The Directive defines 'infants' as "children under the age of 12 months" and 'young children' as "children aged between one and three years".

The Directive also defines 'infant formulae' as "foodstuffs 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" and 'follow-on formulae' as "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".

The Directive sets essential requirements for the composition of infant formula and follow-on formula, which are based on a number of opinions of the Scientific Committee on Food, the latest one being the "Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae", adopted on 4 April 2003⁸. In the last ten years, scientific and technological developments on the essential composition of these products have progressed and there are increasing calls for a review of the legislation to reflect such developments.

The Commission's proposal for a Regulation of the European Parliament and the Council on foods intended for infants and young children and on food for special medical purposes⁹ aims at revising the legal framework applicable to food for particular nutritional uses and, among others, at repealing Directive 2009/39/EC. Negotiations on the proposal are reaching their conclusion and it is expected that such Regulation will be adopted in the next months.

⁶ Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses, OJ L 124, 20.5.2009, p. 21

⁷ Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC, OJ L 401, 30.12.2006, p. 1

⁸ Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae, adopted on 4 April 2003, SCF/CS/NUT/IF/65 Final, 18 May 2003

⁹ COM (2011) 353

Once the new Regulation is adopted, the Commission will need to adopt delegated acts setting specific rules for the categories of food covered by the Regulation, including infant formulae and follow-on formulae.

In the last years, increasing numbers of milk-based drinks and similar products are marketed in different Member States with the denomination of 'growing-up milks' or 'toddlers' milks' or with similar terminology. The composition of these products varies with respect to the protein origin (they can be derived from protein of animal or vegetable origin such as cows' milk, goats' milk, soy or rice) and other ingredients. They are promoted as being particularly suitable for young children and, as such, under the current rules, may be considered as foodstuffs for particular nutritional uses. However, no composition requirements for these products are set in EU legislation.

Different views exist in the scientific community and among stakeholders on whether these products are necessary to satisfy the nutritional requirements of young children or have any nutritional benefits when compared to other foods that can constitute the normal diet of young children. In this context, some would argue that, given the potential variability of weaning diets that may result in different nutrient intakes for this group of the population, these products are convenient, as a liquid element in the diet of young children, in contributing to meeting their nutritional requirements. Taking all these elements into account, the European Parliament and the Council agreed that these products should be subject of a specific reflection. Therefore, in the abovementioned revision of the legal framework, the Commission will be requested, after consulting the European Food Safety Authority, to draft a report on the necessity, if any, of special provisions for milk-based drinks and similar products intended for young children (hereinafter 'growing-up milks').

In the meantime, at international level, the Codex Committee on Nutrition and Food for Special Dietary Uses (CCNFSDU) agreed at its 34th session in December 2012 to revise their existing standard for follow-up formulae¹⁰, which dates back to 1987 and applies to food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children up to three years of age. Such review will cover all aspects of the existing standard and will include consideration of issues such as technological and scientific developments in follow-up formula production and composition over the past 25 years, the age range of the intended population, product definition and the role of such products in the diet of infants and young children. Furthermore, following comments by WHO and some Codex Member Countries and observers, the review may also consider whether this standard is still necessary at all. The first discussion on this subject will take place at the next session of the CCNFSDU to be held on 4-8 November 2013.

Taking into account the developments described above, it is considered necessary to request the EFSA to provide a scientific opinion on all milk-based drinks and similar products intended for infants and young children.

¹⁰ CODEX STAN 156-1987

Terms of reference

In accordance with Article 29(1) (a) of Regulation (EC) No 178/2002¹¹, the European Commission asks EFSA to:

- Provide advice on the nutritional requirements of infants and young children and, in particular, on those requirements that may be satisfied by breast milk, milk-based drinks and similar products. In this context it will also be important to provide advice to the Commission on how these nutritional requirements evolve during the age period 0-3 years.
- Provide advice on the essential composition requirements of infant formulae and follow-on formulae by updating the relevant opinions of SCF on the matter.
- Provide advice on the importance of the role that 'growing-up milks' may have as a liquid element in the diet of young children, with respect to elements such as the pattern of consumption, the nutritional intake and any other relevant aspect related to exposure to substances that may be present in their diet. In this context it would be useful to take into account that different products are on the market which may have a considerably varied composition.
- Provide advice on whether 'growing-up milks' are necessary to satisfy the nutritional requirements of young children or have any nutritional benefits when compared to other foods that may be included in the normal diet of young children (such as breast milk, infant formulae, follow-on formulae, cows' milk and other similar products).
- If considered appropriate, advise the Commission with respect to the appropriate age range and the essential composition of 'growing-up milks'.

¹¹ OJ. L 31, 01.02.2002. p. 1