QUESTIONNAIRE ON YOUNG-CHILD FORMULAE

27 May 2014

Article 12 of Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control[1] requires the Commission to present a report to the European Parliament and to the Council, after consulting the European Food Safety Authority (EFSA), on the necessity, if any, of special provisions for milk-based drinks and similar products intended for young children (hereinafter "young-child formulae").

Upon request of the Commission, in the opinion of 9 October 2013 on nutrient requirements and dietary intakes of infants and young children in the European Union[2], EFSA concluded that formulae, including young-child formulae, are one of the means to increase n-3 PUFA, iron and vitamin D intakes of infants and young children (these were identified by EFSA as nutrients, together with iodine, at risk of inadequate intakes for some infants and young children in the EU). According to EFSA, however, other means, such as fortified cow's milk, fortified cereals and cereal-based foods, supplements or the early introduction of meat and fish into complementary feeding and their continued regular consumption, are other efficient alternatives to increase intakes of these nutrients. EFSA therefore concluded that no unique role of young-child formulae with respect to the provision of critical nutrients in the diet of infants and young children living in Europe can be identified, so they cannot be considered as necessary to satisfy the nutritional requirements of young children when compared with other foods that may be included in their normal diet. EFSA also noted that the content of ALA, DHA (if added), iron, vitamin D and iodine in currently marketed young-child formulae is within the range of permitted concentrations in follow-on formula and, except for iron, also in infant formulae.

In the draft opinion released for public consultation on 24 April 2014 on the essential composition of infant and follow-on formulae[3], after having recalled the conclusions of its opinion of October 2013, EFSA noted that formula consumed during the first year of life can continue to be used by young children and therefore did not consider it necessary to propose specific compositional criteria for formulae consumed after one year of age.

In preparation for the drafting of the report required by Article 12 of Regulation (EU) No 609/2013, the Commission services consider it necessary, at this stage, to collect data and information from national competent authorities and relevant stakeholders on young-child formulae through the questions contained in this document.

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1 OJ L 181, 29.6.2013, p. 35

2 EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. EFSA Journal 2013;11(10):3408, 103 pp. doi:10.2903/j.efsa.2013.3408, http://www.efsa.europa.eu/en/efsajournal/doc/3408.pdf

3 EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), xxxx. Draft Scientific Opinion on the essential composition of infant and follow-on formulae released for public consultation. EFSA Journal 20xx;xx(xx):NNNN, 104 pp. doi:10.2903/j.efsa.20xx.NNNN, http://www.efsa.europa.eu/en/consultations/call/140424.pdf. The EFSA opinion is expected to be finally adopted at the end of June, together with a technical report explaining whether and how EFSA took account of the comments received.

This document does not contain questions on scientific aspects related to young-child formulae since these were already covered by the EFSA opinion. In addition, the document does not contain questions on the composition of young-child formulae currently on the market in the EU or questions on the market volume/market share of these products, given that these aspects were covered in the data collection exercise requested by EFSA in preparation for its opinions and carried out by AINIA[4].

While we understand that you may not be able to reply to all questions, we would kindly request to provide as many answers as possible where relevant to your authority or association. In case of national competent authorities, we are interested in data specific to the respective Member States. In case of European associations, we are preferably interested in aggregated data at EU level. However, please also provide data related to specific Member States, when available.

Please be as specific as possible in your responses and provide information on the source of the information and on how the info was gathered (e.g. formal survey or other).

Please submit your answers to the questionnaire by **18 July 2014 at the latest**.

Please send your requests for guidance/clarification, answers, and any supporting evidence to:

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Dora Szentpaly dora.szentpaly-kleis@ec.europa.eu

[4] Report of "data collection with respect to the availability and nutritional composition of different types of milk-based drinks and similar products for young children with the denomination of "growing up milks" or "toddlers' milks" or with similar terminology currently on the market in EU Member States, EFSA-Q-2013-00292, http://www.efsa.europa.eu/en/supporting/doc/505e.pdf

A. Market data

1. Please provide any available information on the following elements with respect to young-child formulae:
    - Price of young-child formulae on the market in the EU. Is the price higher than that of infant and follow-on formulae / milk? Are there differences in the price of these products depending on the distribution channel (e.g. purchase via Internet)?
    - Import/export of young-child formulae to and from the EU market (value and main trading partners).

2. Please provide any available information on fortified milks. Are you aware of the existence of milks on the market in the EU that are fortified in nutrients of interest to young children (vitamin D, iron, n-3 PUFA, iodine) as highlighted by the EFSA opinion of October 2013? What is the composition of these products? Are they marketed targeting young children or other sub-groups of the general population or the general population in its entirety? What is their price, especially when compared to young-child formulae?

B. The marketing of young-child formulae

1. Please provide any available information on the sales denomination used to market young-child formulae in the EU (e.g. "growing up milk", "toddler milk", or other) and on any particulars provided on a voluntary basis in the labelling and advertising that might be relevant to their promotion.

2. Please provide any available information on the following elements:
    - Whether pictures of babies or imaginary characters (e.g. bears or other) are used in the marketing of young-child formulae in the EU;
    - Whether statements indicating the superiority of breastfeeding are used in the marketing of young-child formulae in the EU;
    - Whether the marketing of young-child formulae in the EU makes it possible to make a clear distinction between these products and infant and follow-on formulae.

3. Please provide any available information on whether there are young-child formulae placed on the market in the EU which target sub-groups within the range 1-3 years (e.g. products for the age range 1-2, 2-3)? If yes, what are the differences in composition?

4. Please provide any available information on whether there are young-child formulae placed on the market in the EU which target specific sub-groups of the young-child population with particular conditions (e.g. lactose intolerant young children or other)?

C. Consumer behaviour

1. Please provide any available information on intakes of breast milk, animal milk (e.g. cows', goats'), vegetable "milk" (e.g. soy), fortified milks and formulae in the diets of young children. In answering this question please identify the type of product, the age range of the population, the frequency and volume of consumption and whether fortified milks or formulae are consumed in addition to breast milk or other milks.

2. Please provide any available information on parents and other caregivers' perception, behaviour, interest, understanding and preference with respect to young-child formulae and on how formulae are used in feeding young children. In answering this question, particular attention should be paid to the willingness of parents and other caregivers to pay a price premium for these products and to considerations related to the "convenience" of consuming these products.

3. Please provide any available information on health care professionals' perception of formulae in the diet of young children and on specific recommendations they give regarding the dietary intake of milk and/or formulae for young children.

4. Please provide any available information on dietary recommendations from national authorities, when they exist, regarding the dietary intake of milk and/or formulae for young children.

D. Legal status and national rules for young-child formulae

1. Please provide information on whether young-child formulae currently marketed in the EU Member States are notified to national competent authorities as "dietetic foods" pursuant to Article 11 of Directive 2009/39/EC on foodstuffs intended for particular nutritional uses[5]. If this is not the case, please provide information on the legal status of these products and on whether they are notified to national competent authorities in the context of other legislation (e.g. fortified foods, notified pursuant to Article 15 of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods[6]).

2. Please provide information on whether national rules exist for young-child formulae at Member States' level. Please describe the rules and provide your evidence-based assessment of how these rules are performing with respect to the following aspects:

- Consumers' protection;
- Consumers' choice (variety of products being offered to consumers), information (e.g. level of information on the products) and behaviour (e.g. ability to understand information provided);
- Free circulation of young-child formulae in the internal market;
- Access to the EU market from third countries' operators;
- Competitiveness of enterprises and operating costs, especially SMEs;
- Development of innovative products;
- Price of young-child formulae;

[5] OJ L 124, 20.5.2009, p. 21.
[6] OJ L 404, 30.12.2006, p. 26.

- Legal clarity, administrative burden for operators (especially SMEs) and national authorities;
- Enforcement by national authorities.

E. Views on future regulatory action

On 20 July 2016 Regulation (EU) No 609/2013 will enter into application. Directive 2009/39/EC will be repealed and the concept of "dietetic food" will disappear.

In the absence of specific legislation, young-child formulae notified today as "dietetic foods" would be considered as foods for normal consumption targeting a specific sub-group of the population (i.e. young children) and would have to comply with the existing relevant rules of EU food law, and in particular with the legislation on fortified foods, nutrition and health claims and food information to consumers.

1. Your evidence-based views on whether young-child formulae should be the subject of specific regulatory measures or not in the EU after 20 July 2016 would be appreciated. In providing arguments in favour or against the introduction of specific regulatory measures, please focus on the following aspects:

- Consumers' protection;
- Consumers' choice (variety of products being offered to consumers), information (e.g. level of information on the products) and behaviour (e.g. ability to understand information provided);
- Free circulation of young-child formulae in the internal market. Can it be expected that other Member States will adopt specific legislation in areas not harmonised at EU level yet (e.g. compositional requirements, mandatory information)?
- Access to the EU market from third countries operators;
- Competitiveness of enterprises, operating costs, especially SMEs;
- Development of innovative products;
- Price of young-child formulae;
- Legal clarity, administrative burden for operators (especially SMEs) and national authorities;
- Enforcement by national authorities.

2. If you are of the view that young-child formulae should be the subject of specific regulatory measures after 20 July 2016, please provide your evidence-based views on the regulatory option that you consider would perform best with respect to the aspects identified in question E.1. In providing your views, account should be taken of the conclusions of EFSA in its opinion of October 2013 and its draft opinion of 2014 with particular attention to the fact that EFSA is currently not proposing compositional requirements for young-child formulae.