

COMMISSION STAFF WORKING DOCUMENT

on young-child formulae

[Supporting document for the meeting of the Working Group of the Advisory Group on the Food Chain and Animal and Plant Health of 19 September 2014]

Introduction

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 control¹ 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 Union², 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 its opinion of 26 June 2014 on the essential composition of infant and follow-on formulae³, 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.

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), 2014. Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014;12(7):3760, 106 pp. doi:10.2903/j.efsa.2014.3760 <http://www.efsa.europa.eu/fr/efsajournal/doc/3760.pdf>

In preparation for the drafting of the report required by Article 12 of Regulation (EU) No 609/2013, and in order to collect useful data and information, the Commission services carried out a consultation with national competent authorities and relevant stakeholders on young-child formulae on the basis of a questionnaire. The consultation, that lasted from 3 June to 18 July 2014 was addressed to all EU Member States, all the members of the Advisory Group on the Food Chain and Animal and Plant Health and selected stakeholders in the field⁴.

In order to further consult with stakeholders on the basis of the received replies to the abovementioned questionnaire, a Working Group meeting of the Advisory Group on young-child formulae will take place on 19 September 2014. All the stakeholders that were originally consulted through the questionnaire have been invited to the meeting of 19 September.

This Working Document is prepared to facilitate the discussions in the Working Group of 19 September. More specifically, this Working Document:

- provides a summary of the contributions received to the questionnaire and
- describes possible future options for action in order to obtain further feedback from stakeholders.

Information included in this Working Document does not represent the final Commission's thinking on young-child formulae as this will be included in the report requested by Article 12 of Regulation (EU) No 609/2013.

A. Summary of replies received to the questionnaire

24 Member States + Norway replied to the questionnaire⁵. Among the consulted stakeholders, replies were received from Specialised Nutrition Europe (SNE), IBFAN/Baby Feeding Law Group and the European Natural Soy and Plant Based Manufacturers Organisation (ENSA). Replies were also received from the associations First Steps Nutrition and Secteur Français des Aliments de l'Enfance (SFAE).

A summary of the replies received is provided below.

⁴ The consultation did not cover scientific aspects related to young-child formulae since these were already covered by the EFSA opinion. In addition, the consultation did not cover 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 (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>).

⁵ Replies received after the deadline of 18 July 2014 were also taken into account.

A.1 Market data

A.1.1. Young-child formulae

According to the information received, the price of young-child formulae varies slightly depending on the Member State and on the distribution channel. Member States generally agreed that the price is very similar or slightly lower than that of infant formulae or follow-on formulae. As in the case of infant formulae and follow-on formulae, products in powdered form tend to be more expensive than those in liquid form. It has been reported by one stakeholder that "organic" young-child formulae, or young-child formulae made from goat's milk protein are sold with a price premium.

Young-child formulae are distributed through different channels: retailers, e-commerce websites and, in a limited number of cases, pharmacies. It has been reported that the price of young-child formulae sold on the Internet is in general similar to that of formulae sold in super-markets. When formulae are sold through the pharmacies, prices tend to be slightly higher than in supermarkets.

Young-child formulae are manufactured in a few Member States and Switzerland and exported to the rest of the EU and to third countries.

A.1.2. Fortified milks

Fortified milks are present in almost all Member States. These milks are fortified with a series of micronutrients (e.g. very often with vitamin D, which is also mandatorily added to milk in some Member States) and in a limited number of cases and Member States with n-3 PUFA. It was underlined by many Member States that no product exists that is fortified in all the critical nutrients identified by EFSA in its opinion of 2013.

Member States also commented that the price of fortified milks is generally cheaper than that of young-child formulae and that fortified milks are marketed targeting the general population or children in general (never targeting young children only as this would qualify the product as dietetic food). Several Member States also underlined that these fortified milk products can contain fruit or are flavoured with chocolate/vanilla/strawberry...

A.2 Marketing of young-child formulae

The sale denomination commonly used for the product is "growing up milks". "Toddlers' milk" is also used, as well as "milk based drink for young children" or "milk drink for toddlers". In case of soy-based products, the denomination used is "growing up drinks" or "Soy drinks for children between 1-3 years with added minerals and vitamins".

Member States and stakeholders reported that a variety of nutrition claims on the substances present in young-child formulae making these interesting for young children are used for the marketing of the products (e.g. "contains micronutrients/n-3 PUFA/FOS/GOS/probiotics", "reduced protein content"). Specific health claims on the role of the substance are also made, as well as generic claims on the role of the product in contributing to healthy growth of young children. Particular emphasis is sometimes put on certain critical nutrients present in the product (e.g. iron, vitamin D), on the contribution that consumption of young-child formula makes to the requirements of young children and on the difficulty to otherwise achieve these requirements.

The products are sometimes marketed as specifically tailored to young children's needs, as a "nutritional safety net" for parents, and nutritional superiority to cow's milk is often used as a marketing argument. Certain brands focus on the "organic" nature of the product.

Images of young children or, most often, imaginary characters are present on the label/advertising of the products. Statements on the superiority of breastfeeding and, more often, statements on the importance of a balanced diet are used by operators on a voluntary basis. The products are also marketed with statements on the suitable age for consumption and, sometimes, with statements indicating that they are not suitable for infants under 6 or 12 months.

On the basis of the information received, it appears that the distinction between young-child formulae and infant and follow-on formulae is ensured by the product denomination, by an indication on the label of the age range for which the product is intended or by the use of a numbering system (1 and 2 for infant and follow-on formulae, 3 and 4 for young-child formulae) and by the use of different colours on the labels. Some Member States and stakeholders, however, underlined that the distinction between young-child formulae and infant and follow-on formula can in certain cases be more difficult due to the strong similarities in the packaging between products of the same brand. One Member State noted that similarities in the branding coupled with the presentation of the products in the same area in supermarkets, can give the message to consumers that young-child formulae are a logical consequence / necessity after one year of age.

According to the respondents to the questionnaire, young-child formulae on the market target the entire age-range 1-3 years or narrower sub-groups, the most common being 1-2 years and 2-3 years. In certain cases, products are marketed as suitable from 10 months on, from 15 months on, or from three years on. Within the same product line, the composition can vary depending on the age range. However contribution from respondents show that in certain cases amounts are higher in products for older ages while in other cases such amounts are lower.

From the information received it appears that there are no young-child formulae placed on the market in the EU targeting specific sub-groups of the young-child population with the exception of a lactose-free range for lactose intolerant consumers.

A.3 Consumer behaviour

Detailed answers were provided by many Member States and stakeholders which in some cases referred to specific studies carried out in different Member States.

In general, on the basis of the received data, it can be reported that breastfeeding rates decrease significantly after the age of one year in the Member States. Consumption of formula products decreases with age while a corresponding increase in the consumption of cow's milk can be determined. Data also shows that formulae tend to be consumed as alternatives to cow's milk after one year of age. Young-child formula consumption is at its highest in the age range 12-18 months and decreases afterwards.

One stakeholder underlined how parents' and other caregivers' perception, behaviour, interest, understanding and preference with respect to young-child formulae vary depending on a number of factors, including health care professional's advice, national authority guidance, availability, familiarity with the category and sociocultural elements.

Three different studies mentioned by Member States and stakeholders show that parents and other caregivers tend to absorb information about the benefits of young-child formula they hear from health care professionals, other experienced sources but also in advertisements and marketing material, citing these as reasons why they use young-child formulae (e.g. "it has nutrients appropriate to development for this age", "it is better than cows' milk").

Only a few Member States and stakeholders replied on the health care professionals' perception of formulae in the diet of young children and on the existence of relevant national dietary recommendations. It was however noted that health care professionals' advice can vary depending on the Member State. In certain Member States consumption of young-child formulae is recommended for practical reasons (i.e. difficulty to reach adequate intakes for all nutrients in the diet). In other Member States, health care professionals prefer to recommend milk consumption and do not recommend young-child formulae. Similarly, while certain national authorities recommend consumption of young-child formulae on the basis of practical considerations, others advocate for the consumption of cow's milk from one year on, and underline that formula products are not needed if a normal diet is followed (in certain cases supplementation is recommended). One stakeholder noted that soy drinks are recommended as part of a healthy varied daily diet after one year of age.

A.4 Legal status and national rules for young-child formulae

According to the information received, young-child formulae are notified as dietetic foods pursuant to Article 11 of Directive 2009/39/EC on foodstuffs intended for particular nutritional uses in at least 14 Member States. Many other Member States consider these products as fortified foods (some require a notification for these products, while others do not).

Young-child formulae are not present in at least two Member States' markets. According to the information received, only one Member State has adopted specific rules on young-child formulae. In this Member State it is foreseen that if the young-child formula complies with the requirements of follow-on formula it only needs to be notified. If the composition is different, a dossier must show its safety and suitability. Several other Member States check the composition of young-child formulae on the basis of the labelling reference values laid down in Directive 2006/141/EC for infants and young children.

A.5 Views on future regulatory options

Member States' answers to the questionnaire showed different positions on whether specific rules should be adopted for young-child formulae.

Some Member States underlined that specific rules should not be adopted as the products are not necessary and horizontal rules of EU food law would sufficiently ensure consumer protection and the free circulation of young-child formulae in the EU.

Other Member States flagged that specific rules should be adopted in order to regulate the composition as well as the labelling/marketing of these products. Finally, another group of Member States clarified that their position is not finalised yet or showed flexibility on the point.

Most stakeholders that provided replies supported the adoption of specific rules for young-child formulae. Different regulatory solutions were proposed by those who supported adoption of specific rules.

B. Further consultation on possible future options for action

On the basis of the collected feedback, the Commission services have identified different options for future action that should be further considered in view of the preparation of the report on young-child formulae. These different options are briefly described below. **Stakeholders are invited to provide their views on the different options during the Advisory Group meeting (or in writing by 30 September 2014 at the latest).**

When providing feedback, account should be taken of the conclusions of EFSA in its opinions of October 2013 and June 2014, with particular attention to the fact that EFSA is currently not proposing compositional requirements for young-child formulae.

In providing arguments in favour or against the different options, focus should be 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;
- 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.

Option 1: No specific legislation for young-child formulae

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. The status quo would remain for those young-child formulae considered today as fortified foods (as it is the case in many Member States).

Young-child formulae would remain on the market and, in the absence of specific compositional rules, flexibility would be left to operators to manufacture their products. Horizontal rules of EU food law would ensure that the products are safe (general obligation for all foods placed on the market in the EU, plus rules on additives, contaminants, pesticides...), adequately labelled (products would comply with the rules of Regulation (EU) No 1169/2011 on the provision of food information to consumers as well as with the rules of Regulation (EC) No 1925/2006 on fortified foods) and do not make misleading claims about their nutritional or health properties (products would comply with the rules of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods).

In the absence of specific rules, and if no specific claim is made on young-child formula falling under the scope of the Claims Regulation, all products could theoretically be marketed as "suitable for young children", or "specifically formulated for young children". National authorities would have to ensure that the marketing of products for young children complies with the horizontal requirement whereby food information cannot be misleading for consumers.

Option 2: Adoption of specific rules for young-child formulae

The adoption of specific rules on the composition, labelling, advertising and marketing of young-child formulae would allow to tackle all the specificities of the product category with a specific piece of legislation.

If the decision is taken to set specific rules on young-child formulae, different regulatory solutions are open. In all cases, an amendment of Regulation (EU) No 609/2013 would be needed to include young-child formulae within the scope, and to define the product category.

Following EFSA's opinion whereby these products are not necessary and the composition of products on the market is within the ranges foreseen by the legislation on follow-on formulae, the justification for the need for specific composition requirements for young-child formulae would be questioned.

Furthermore, in the absence of proposed composition requirements from EFSA, it would be very difficult for risk managers to set requirements in the legislation that would have any scientific basis.

Option 3: Extension of existing requirements to cover young-child formulae

This option would build on the existing requirements for certain categories of foods for infants and young children and would make some of those applicable to young-child formulae, as relevant to the product category. Even in this case, an amendment of Regulation (EU) No 609/2013 would be needed to include young-child formulae within the scope of the Regulation.

Different regulatory solutions are open:

- a) One possibility would be to include young-child formulae in the definition of "baby foods"⁶, by deleting the exclusion of milk-based drinks from the definition of baby foods. This however, would be difficult to justify, as young-child formulae would not conceptually fit with the definition of "baby foods" or with the requirements for this category of food.
- b) Another possibility would be to modify the definition of "follow-on formula"⁷ so that it is considered *"food intended for use by infants **and young children** when appropriate complementary feeding is introduced and which constitutes the principal liquid element in a progressively diversified diet of such infants **and young children, with the exclusion of water"***.

This possibility would build on the conceptual similarity between follow-on formulae and young-child formulae and the potential role of these products in the diet of older infants and young children. It would take into account the fact that follow-on formulae are on the market and legislation already exists to regulate them. It would be based on the advice of EFSA in its opinion of 2014 whereby *"The median 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 formulae and, except for iron, also in infant formulae. The Panel notes that formulae consumed during the first year of life can continue to be used by young children"*. Finally, it would also be in line with the existing approach in the Codex Standard for follow-up formula.

After the definition of follow-on formula is modified, the relevant delegated measure could be reviewed in a way whereby if and when follow-on formulae are presented/marketed for young children, then such products would be required to comply at least with some minimum composition requirements applicable to follow-on formulae for infants (e.g. requirements on the critical nutrients identified by EFSA, or on sugars). If other ingredients, from those permitted for follow-on formulae, are added voluntarily by manufacturers, the relevant range of requirements of follow-on formulae for infants would apply. Labelling, advertising and marketing requirements applicable to follow-on formulae for infants could also be made applicable, as appropriate, to follow-on formulae for young children and adaptations could be foreseen (e.g. mandatory requirements on the indication of the intended use/target population of the product). This option would also ensure that other requirements applicable to follow-on formulae would be automatically extended to follow-on formulae for young children (e.g. contaminants, additives, pesticides...) and could be adapted if necessary.

⁶ (Art. 2(2)(f) of Regulation (EU) No 609/2013): *"'baby food' means food intended to fulfil the particular requirements of infants in good health while they are being weaned, and of young children in good health as a supplement to their diet and/or for their progressive adaptation to ordinary food, excluding: (i) processed cereal-based food; and (ii) milk-based drinks and similar products intended for young children"*;

⁷ Article 2(2)(d) of Regulation (EU) No 609/2013: *"'follow-on formula' means food intended for use by infants when appropriate complementary feeding is introduced and which constitutes the principal liquid element in a progressively diversified diet of such infants"*