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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on young child formulae

{SWD(2016) 99 final}

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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on young-child formulae

1. INTRODUCTION

This report meets the obligation set for the Commission by Article 12 of Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control ("Regulation on Food for Specific Groups", or "FSG Regulation")[1].

Article 12 requires the Commission to present to the European Parliament and to the Council, after consulting the European Food Safety Authority (EFSA), a report on the necessity, if any, of special provisions for milk-based drinks and similar products intended for young children.

This report builds upon two Scientific Opinions of EFSA[2], a market study carried out for EFSA[3] and extensive consultation with national competent authorities and interested parties. It is accompanied by a Staff Working Document (SWD) with more detailed information on its findings.

2. THE MARKET OF YOUNG-CHILD FORMULAE[4] IN THE EU

2.1 Products' presence and composition

Young-child formulae are not defined in EU legislation. They can be described as specifically processed/formulated protein-based drinks intended to satisfy the nutritional requirements of young children aged 1-3 years[5]. While the number of

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1 Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

2 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; 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.

3 AINIA, Centro Tecnológico, 2013, *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 supporting publication 2013:EN-505.

4 The denomination "*young-child formulae*" will be hereinafter used to refer to the products subject of the report (in line with the way EFSA referred to these products in its Scientific Opinions on the matter).

5 For the purposes of this report, the concept of "*young-child formulae*" does not include "*fortified milks*", namely milks fortified in different nutrients (e.g. vitamins or minerals) and marketed to the general population or sub-groups thereof (e.g. children in general), but not exclusively to young children aged 1-3 years.

manufacturers is small, there are hundreds of young-child formulae present on the EU market. The number of products per Member State can vary significantly.

The energy content and composition of young-child formulae is varied[6]. In most cases, cow's milk is used as a source of protein[7] but the product's protein content is normally lower than in cow's milk and, in most cases, within the range permitted by the legislation for infant formulae and follow-on formulae[8]. Young-child formulae are fortified in a number of micronutrients (e.g. iron, vitamin D), polyunsaturated fatty acids (e.g. alpha-linolenic acid (ALA)) and other substances (e.g. taurine) that are commonly present in infant formulae and follow-on formulae and, in many cases, are not present (or present in lower amounts) in cow's milk. Young-child formulae can contain different sugars (e.g. lactose, sucrose, glucose, maltose), sometimes honey and, in certain cases, flavourings (e.g. vanilla).

2.2 Market size and value, prices and structure of the market

The market of young-child formulae experienced growth in almost all the reviewed countries in the period 2008-2012. In 2012, retail market size can be estimated to more than 42 000 tonnes and retail market value to more than €500 million[9].

The price of young-child formulae varies among Member States depending on a number of parameters, such as the role of distributors and taxes. Their price is similar to (or slightly lower than) that of infant formulae or follow-on formulae and higher than that of cow's milk or fortified milk[10]. Young-child formulae are distributed through different channels (retailers, specialised stores, websites and pharmacies) and prices in pharmacies tend to be slightly higher than in supermarkets.

The market of young-child formulae is divided among a small number of manufacturers. Products are manufactured in a few Member States and Switzerland

6 AINIA (2013); EFSA (2013).

7 Proteins from goat milk and soy are used in a limited number of products on the market.

8 "*Infant formula*" is a "*food intended for use by infants* [i.e. children under the age of 12 months] *during the first months of life and satisfying by itself the nutritional requirements of such infants until the introduction of appropriate complementary feeding*" (Article 2(2)(c) of the FSG Regulation). "*Follow-on formula*" is a "*food intended for use by infants* [i.e. children under the age of 12 months] *when appropriate complementary feeding is introduced and which constitutes the principal liquid element in a progressively diversified diet of such infants*" (Article 2(2)(d) of the FSG Regulation). Infant formula and follow-on formula are currently regulated by 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), which also provides very similar definitions of these products. The FSG Regulation requires the Commission to adopt rules for infant formula and follow-on formula, by the means of delegated acts, taking into account the existing requirements of Directive 2006/141/EC (Article 11(1) and recital 27 of the FSG Regulation). The new Commission delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (OJ L 25, 2.2.2016, p. 1) will repeal and replace Directive 2006/141/EC as of 22 February 2020.

9 AINIA (2013), p. 12-34. Data from 11 EU Member States, representing around 74% of the total EU 28 population + Switzerland.

10 Data provided by Member States and interested parties in the consultation phase (2014).

and traded to the rest of the EU and to third countries. EU manufacturers are leaders in the global scene[11].

2.3 The marketing of young-child formulae[12]

The denomination most commonly used to market young-child formulae in the EU is "*growing-up milk*". Other denominations used are, for example, "*toddlers' milk*" or "*milk-based drink for young children*"[13].

Young-child formulae are marketed as products specifically formulated for the nutritional needs of young children. Generic statements on the role/suitability of the products in contributing to healthy growth of young children are used and the products are often presented as playing a key role in contributing to achieve the nutritional requirements of young children and on the difficulty to otherwise achieve these requirements through the normal diet. Nutritional superiority to cows' milk is often used as a marketing argument (e.g. "*contains 40 times more iron than cows' milk*").

In this context, a variety of nutrition claims are used to describe ingredients that are added to the product and that are considered beneficial for young children (e.g. "*contains vitamin D*" or "*added omega-3*"), or nutrients that the product contains in reduced proportion, for improved suitability for young children (e.g. "*reduced protein*"). Authorised health claims on specific ingredients and referring to children's development and health are also used and emphasis is put on those nutrients considered critical for young children (e.g. "*iron contributes to normal cognitive development of children*).

Young-child formulae are marketed for young children aged 1-3 years or, in certain cases, for narrower sub-groups (1-2 and 2-3 years). The distinction with infant formulae and follow-on formulae is ensured by the product denomination (e.g. "*toddlers' milk*"), by an indication on the label of the age range (e.g. "+1") or of corresponding numbers (1 for infant formulae, 2 for follow-on formulae, 3 and 4 for young-child formulae) and/or by the use of different colours/design on the label.

3. CONSUMERS' PERCEPTION AND BEHAVIOUR

Young children's feeding practices vary significantly throughout the EU, taking into account socioeconomic and cultural differences, differences in the recommendations from health care professionals and national authorities and product availability.

In general terms, it can be reported[14] that breastfeeding decreases significantly after the age of one year in the Member States, both in terms of rates and intakes. Formula products are competing with cows' milk in the diet of young children, and differences

11 Around two thirds of volumes of young-child formulae manufactured in France are produced for export (out of this, one third is exported to other EU Member States and two thirds to third countries) and France exports three times more than the volume of imports, Secteur Français des Aliments de l'Enfance (SFAE), 2014, *Reply to the questionnaire on young-child formulae.*

12 Data provided by Member States and interested parties in the consultation phase (2014).

13 In case of soy-based products, the denomination normally used is "*growing up drink*".

14 Data provided by Member States and interested parties in the consultation phase (2014). The SWD analyses in detail practices in UK, Germany and France.

in preferences exist depending on the Member State. Consumption of young-child formula is generally at its highest in the age range 12-18 months and decreases afterwards. At the same time, a corresponding increase in the consumption of cow's milk can be noted.

Different sources of information influence parents' and caregivers' decisions on young-child formulae, including not only the products' labelling and advertising, but also advice from health care professionals, and exchanges with family and friends with previous experience. The most common arguments put forward by parents and caregivers for using young-child formulae are the suitability to the nutritional needs of young children and the superiority to cows' milk.

In certain Member States, consumption of young-child formulae is recommended by national authorities/health care professionals for practical reasons (i.e. difficulty to reach adequate intakes for all nutrients through a diversified diet). In other Member States, health care professionals and national authorities prefer to recommend cow's milk consumption, in the context of a balanced diet (sometimes together with supplementation).

4. THE LEGAL FRAMEWORK APPLICABLE TO YOUNG-CHILD FORMULAE

Until 19 July 2016 Directive 2009/39/EC of the European Parliament and of the Council[15] (which largely reproduces legislation adopted in 1989) lays down rules on foodstuffs intended for particular nutritional uses (so-called "dietetic foods"). This Directive defines dietetic foods as "*foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability*" (Article 1(2) of the Directive). The Directive does not contain an exhaustive list of product categories that are to be considered dietetic foods and, today, 17 Member States and Norway classify young-child formulae as dietetic foods[16], on the basis of the definition given above. These products must comply, as a consequence, with the rules of Directive 2009/39/EC, in particular, the general rule whereby the nature or composition of these products "*shall be such that the products are appropriate for the particular nutritional use intended*" (Article 3(1) of the Directive). They must also comply with mandatory labelling requirements, for example to indicate their suitability for the intended purpose (Article 9 of the Directive), and must be notified to the competent authorities of the Member States where they are placed on the market (Article 11 of the Directive). 10 Member States do not classify young-child formulae as dietetic foods[17].

In 2011, the Commission adopted a legislative proposal to simplify the legal framework applicable to dietetic foods[18]. The proposal aimed at abolishing the

15 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).

16 Data provided by Member States (2014).

17 Data provided by Member States (2014). Young-child formulae are not on the market in Denmark.

18 European Commission, 2011, *Proposal for a Regulation of the European Parliament and of the Council on food intended for infants and young children and on food for special medical purposes*, COM (2011) 353.

obsolete concept of "dietetic food", at repealing Directive 2009/39/EC and replacing it with a new framework covering foods for certain vulnerable groups of the population, for which specific rules were needed.

The European Parliament and the Council adopted the proposal in an amended form (the FSG Regulation), kept young-child formulae out of the scope of the Regulation but decided to require the Commission to further analyse in a report if specific provisions for these products are necessary.

The FSG Regulation will enter into application on 20 July 2016. On that date, Directive 2009/39/EC will be repealed and young-child formulae placed on the market today as "dietetic foods" will be classified as normal foods, fortified in certain nutrients and targeting a specific sub-group of the population (i.e. young children), as it is the case already in the 10 Member States that do not classify young-child formulae as dietetic foods.

Under the new legal framework, young-child formulae fall under the scope of Regulation (EC) No 1925/2006 of the European Parliament and of the Council[19] and have to comply with the rules of this Regulation (e.g. on the addition of vitamins and minerals and on labelling, presentation and advertising). Article 15 of the Regulation allows Member States to establish notification obligations for manufacturers in order to monitor the market.

Young-child formulae need also to comply with the other relevant rules of EU law that apply to all foods. For example, young-child formulae must be safe in line with the rules of Regulation (EC) No 178/2002 of the European Parliament and of the Council[20]. Food additives, pesticide residues and novel substances in young-child formulae must comply, respectively, with the rules of Regulations of the European Parliament and of the Council (EC) No 1333/2008[21], (EC) No 396/2005[22] and (EC) No 258/97[23]. Young-child formulae must provide food information, including the nutrition declaration, in line with the rules of Regulation (EU) No 1169/2011 of the European Parliament and of the Council[24] and can only bear specific nutrition and

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19 Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).

20 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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 (OJ L 31, 1.2.2002, p. 1).

21 Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

22 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

23 Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1). Regulation (EC) No 258/97 shall be repealed on 1 January 2018 by Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

24 Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive

health claims authorised at EU level pursuant to Regulation (EC) No 1924/2006 of the European Parliament and of the Council[25]. The use of such claims must be in compliance with specific conditions of use as well as with the general principles and requirements of Regulation (EC) No 1924/2006. In particular, Article 3 of the Regulation forbids use of misleading claims as well as of claims giving rise to doubt about the safety and/or the nutritional adequacy of other foods. Article 4(1) foresees that: "*food or certain categories of food must comply with [nutrient profiles] in order to bear nutrition or health claims* (…)"[26]. Article 10(3) foresees that references to general benefits of foods for overall good health may only be made if accompanied by more specific health claims.

National rules on young-child formulae only exist in France and were adopted in the context of the legislation on dietetic foods[27].

5. EFSA'S SCIENTIFIC ADVICE ON YOUNG-CHILD FORMULAE

In preparation for this report, the European Commission asked for EFSA's scientific advice. In its opinion of 9 October 2013[28], EFSA concluded that young-child formulae are one of the means to increase n-3 polyunsaturated fatty acids, iron and vitamin D intakes of infants and young children (these were identified by EFSA as nutrients, together with iodine, at risk of inadequacy for some infants and young children in the EU).

According to EFSA, however, other means, such as fortified cows' 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 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.

In its opinion of 26 June 2014[29], EFSA noted, in addition, that formulae 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 young-child formulae.

87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18). The rules on the nutrition declaration of Regulation (EU) No 1169/2011 shall fully apply from 13 December 2016.

25 Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9).

26 Nutrient profiles, to be established by the Commission, are not set yet and this condition is therefore not applicable for the moment.

27 Arrêté du 30 mars 1978 fixant les dispositions relatives aux aliments lactés diététiques, JO 24-05-1978 p. NC 4070-4075.

28 EFSA (2013).

29 EFSA (2014).

6. SUMMARY OF THE ISSUES RELATED TO YOUNG-CHILD FORMULAE

As described in the previous sections, young-child formulae are widespread in the EU. The EU market for these products is growing and their free circulation in the Internal Market has been efficient so far. EU manufacturers are leaders in the global scene and, in this context, it should be noted that Codex Alimentarius is currently carrying out a revision of STAN 156-1987[30] that will also include revised rules for young-child formulae.

From a nutritional point of view, young-child formulae are not necessary but are one of the means to increase intakes of certain nutrients at risk of inadequacy for some young children in the EU. There is no reported safety issue with respect to young-child formulae in the EU and the content of different nutrients in these products is generally within the ranges of permitted concentrations in follow-on formulae. However, some young-child formulae may contain substances (e.g. sugars, flavours) at amounts that are generally not recommended for young children (bearing in mind the role of sugars consumption in obesity development, or the impact of sugars or flavours on the development of young-children's taste). Others may lack the nutrients identified by EFSA as being at risk of inadequate intake for young children, or contain nutrients for which there is no such risk.

These issues can be addressed by the regulatory framework for food in the EU. For example, these products must provide a nutrition declaration in line with the conditions laid down in Regulation (EU) No 1169/2011. In addition, a product may bear claims only in line with the rules of Regulation (EC) No 1924/2006. In this case, Article 10(3) of Regulation (EC) No 1924/2006 establishes that generic statements referring to non-specific health benefits of the product (these could include statements on the product's suitability for young children) can only be used if accompanied by a specific authorised claim (e.g. "*calcium and vitamin D are needed for normal growth and development of bone in children*"). Furthermore, Article 4 of Regulation (EC) No 1924/2006 could be used to lay down conditions on the nutrient profiles that young-child formulae should respect in order to bear claims (thus ensuring the adequate composition of formulae bearing claims). Article 4 of Regulation (EC) No 1924/2006 has however not been applied yet.

The marketing of young-child formulae may in certain cases be considered misleading because it raises unjustified doubts on the nutritional adequacy of ordinary foods (e.g. to state "*contains 40 times more iron than cow's milk*" when cow's milk is not supposed to contain iron). From a legal point of view, however, this would constitute a misapplication of relevant provisions in EU legislation (e.g. Article 3 of Regulation (EC) No 1924/2006 which forbids claims that raise doubts on the nutritional adequacy of other foods).

As of 20 July 2016 all young-child formulae in the market in the EU will be classified in the same way (normal foods fortified in certain nutrients) and will have to comply with the relevant existing horizontal rules of EU food law.

While no change is expected in those Member States that already classify young-child formulae as food for normal consumption, some developments in the other 17

[30] Codex Alimentarius, Codex Standard for Follow-Up Formula - Codex Stan 156-1987.

Member States can already be anticipated based on the information available at this stage.

For example, the repeal of Directive 2009/39/EC is expected to open up access to the market by abolishing the "special status" of dietetic foods and repealing the general compositional requirements and the existing notification procedure applicable to dietetic foods. This could theoretically increase competition and offer of products, and positively affect prices. While increased competition could make it more difficult for young-child formulae manufacturers to be rewarded for their investments, the opening up of the market would increase competitiveness in the general food sector and reduce market distortions. Legal certainty would increase (all products would be classified in the same way in the entire EU), the legal framework would be simplified and administrative burden would be reduced for business (e.g. abolition of the notification procedure for dietetic foods, provided that Member States do not require a notification for fortified foods).

Some reformulation and relabelling costs should be expected (e.g. compliance of products today classified as dietetic foods with the requirements on vitamins and minerals in Regulation (EC) No 1925/2006, adjustments of these products' labels to remove references to "dietetic foods" or to comply with the rules on the nutrition declaration of Regulation (EU) No 1169/2011 on the provision of food information to consumers as from 13 December 2016).

One could argue that, with the abolition of Directive 2009/39/EC and its general requirement whereby the nature or composition of the products "*shall be such that the products are appropriate for the particular nutritional use intended*", manufacturers today marketing young-child formulae as dietetic foods would be left with broader flexibility in deciding the composition of their products, which may lead to unsatisfactory composition of these foods.

Developments in the market after 2016 cannot entirely be foreseen at this stage and this description can therefore not fully take into account all potentially relevant factors. One big element of uncertainty that could strongly influence future developments in the field is how Member States will react after Directive 2009/39/EC is repealed. In any case, all draft national rules will be assessed by the Commission in order to verify compliance with EU law.

7. SUMMARY OF MEMBER STATES' AND INTERESTED PARTIES' POSITIONS

When consulted on whether specific action at EU level is needed for young-child formulae, the majority of Member States' experts expressed support for new action. Other Member States' experts expressed the different view that no specific action is needed for young-child formulae, raising in particular concerns that additional action would enhance their status without justification and, ultimately, mislead consumers. These national authorities also underlined that horizontal rules of EU food law can efficiently regulate these products (as it is already the case in ten Member States).

Additional action was supported by most interested parties (both industry and non-industry related).

8. CONCLUSIONS

In accordance with Article 12 of the FSG Regulation, this report addresses the necessity, if any, of special provisions for milk-based drinks and similar products intended for young children (i.e. young-child formulae) regarding compositional and labelling requirements.

The following can be concluded:

- The European Food Safety Authority (EFSA) issued scientific advice on young-child formulae in 2013 whereby these products are one of the means to increase intakes of certain nutrients at risk of inadequacy for some young children in the EU. However, according to EFSA, these products have "*no unique role*" and "*cannot be considered as a necessity to satisfy the nutritional requirements of young children*" when compared to other foods that may be included in their normal diet;

- The composition of young-child formulae is varied. However, the content of different nutrients in these products is generally within the ranges of permitted concentrations in follow-on formulae. There is no reported safety issue with respect to these products;

- The correct and complete application of the general framework of EU food law seems sufficient to adequately regulate the composition of young-child formulae (e.g. food additives, addition of vitamins and minerals or use of novel substances) and the communication on the characteristics of the products (e.g. food information, nutrition and health claims).

- After 20 July 2016, the situation will evolve in those Member States that today classify young-child formulae as dietetic foods as a consequence of the repeal of Directive 2009/39/EC and its general requirement whereby the nature or composition of the products "*shall be such that the products are appropriate for the particular nutritional use intended*". Many developments after 2016 cannot be foreseen at this stage given that no concrete information exists on how operators or consumers will adapt to the new legal framework or on how Member States will react at national level to the impossibility to continue using the aforementioned provision of Directive 2009/39/EC. In any case, all draft national rules will be assessed by the Commission in order to verify compliance with EU law.