



Brussels, 31.3.2016
SWD(2016) 99 final

COMMISSION STAFF WORKING DOCUMENT

Young-child formulae: background information

Accompanying the document

**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND
THE COUNCIL**

on young-child formulae

{COM(2016) 169 final}

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INTRODUCTION

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 ("the Regulation on Food for Specific Groups", or "FSG Regulation")¹ introduces compositional and information requirements for certain foods for specific groups of the population. The Regulation repeals Directive 2009/39/EC of the European Parliament and of the Council on foodstuffs intended for particular nutritional uses² (so called "dietetic foods"), abolishes the concept of "dietetic food" and revises the framework applicable to these products.

Article 12 of the Regulation provides that: *"By 20 July 2015, the Commission shall, after consulting the Authority, present to the European Parliament and to the Council a report on the necessity, if any, of special provisions for milk-based drinks and similar products intended for young children regarding compositional and labelling requirements and, if appropriate, other types of requirements. The Commission shall consider in the report, inter alia, the nutritional requirements of young children, the role of those products in the diet of young children and whether those products have any nutritional benefits when compared to a normal diet for a child who is being weaned. Such a report may, if necessary, be accompanied by an appropriate legislative proposal."*

As explained in recital 31 of the Regulation, the rationale for this request is the increasing number of milk-based drinks and similar products being placed on the Union market and promoted as particularly suitable for young children. Such products, which can be derived from protein of animal or vegetable origin such as cows' milk or soy, are often marketed as "growing up milks" or "toddlers' milks" or with similar terminology. No specific composition requirement for these products is set in EU legislation. Different views exist on whether these products are necessary to satisfy the nutritional needs of young children or have any nutritional benefits when compared to other foods that can constitute the normal diet of young children.

This Staff Working Document (SWD) accompanies the Commission report to the European Parliament and to the Council on young-child formulae that meets the obligation set for the Commission by Article 12 of the FSG Regulation. The SWD provides more detailed information on the findings of the Commission report and is structured as follows:

- it provides a description of the methodology and the sources used for drafting the report and an explanation of the relevant terminology;
- it provides a detailed picture of the market of young-child formulae in the EU;
- it provides a description of consumer's perception and behaviour regarding these products;
- it provides a description of the legal framework applicable to young-child formulae in the EU;

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 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).

- it recalls the main points of the European Food Safety Authority (EFSA)'s scientific assessment on these products;
- it summarizes the positions of Member States and interested parties in the consultation phase.

1. METHODOLOGY AND SOURCES

As required by the FSG Regulation, the Commission consulted EFSA in preparation for the report on young-child formulae. The report and this SWD build upon the two opinions adopted by EFSA on the subject:

- *"Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union"*³, adopted on 9 October 2013;
- *"Scientific Opinion on the essential composition of infant and follow-on formulae"*⁴, adopted on 26 June 2014.

The two opinions are summarised in Chapter 6 of this SWD.

The report and this SWD are also based on the study carried out by the Asociación de Investigación de la Industria Agroalimentaria (AINIA) upon request of EFSA in preparation for the two abovementioned opinions: *"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"*⁵. The AINIA study provides detailed information on the market of young-child formulae in the EU and has served as a basis for the description of this market sector in Chapter 3 of this SWD.

The report and this SWD take also into account the outcome of consultations with:

- national competent authorities in the context of the Expert Group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control⁶ and
- interested parties in the context of the Working Group of the Advisory Group on the Food Chain and Animal and Plant Health on young-child formulae⁷.

More specifically, a questionnaire on young-child formulae was sent on 27 May 2014 to all Member States, and on 3 June 2014 to Members of the Advisory Group on the Food Chain and Animal and Plant Health and selected interested parties. The targeted consultation was open until 18 July 2014 and replies received past the deadline were also considered.

On the basis of the replies received to the questionnaire, a Working Document was submitted to the attention of the Working Group of the Advisory Group on the Food Chain and Animal and Plant Health on young-child formulae and was discussed in a dedicated meeting on 19

³ 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.

⁴ 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.

⁵ 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.

⁶ Expert group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control, Reference E02893 in the Register of Commission Expert Groups and other similar entities,

http://ec.europa.eu/food/safety/labelling_nutrition/special_groups_food/expert_group/index_en.htm

⁷ Advisory Group on the Food Chain and Animal and Plant Health, Reference E00860 in the Register of Commission Expert Groups and other similar entities,

http://ec.europa.eu/dgs/health_food-safety/advisory_groups_action_platforms/advisory_group_en.htm

September 2014. That Working Document provided a summary of the contributions received to the questionnaire and described possible means for dealing with this subject at EU level, in order to obtain further feedback from interested parties.

That same Working Document was submitted to the attention of Member States together with a summary record of the discussion with interested parties⁸. The two documents were discussed in a dedicated meeting of the Expert Group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control on 10 October 2014.

An additional Working Document describing an alternative approach (non-legislative measures), which was not covered in the first round of consultations, was submitted to the attention of the Working Group of the Advisory Group on the Food Chain and Animal and Plant Health on young-child formulae and was discussed in a dedicated meeting on 17 February 2015. That same Working Document was submitted to the attention of Member States and discussed in a meeting of the Expert Group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control on 18 February 2015.

A summary of the comments of the Member States and interested parties is provided in Chapter 7 of this SWD.

Additional sources to the report and the SWD will be quoted in footnotes.

⁸ During the preparation of the report, position papers were also provided by interested parties that were not originally consulted by the Commission. These documents were also considered in the preparation of the report.

2. TERMINOLOGY

For the purposes of the report, the following terminology shall be used:

- *Infant*: a child under the age of 12 months (Article 2(2)(a) of the FSG Regulation).
- *Young child*: a child aged between one and three years (Article 2(2)(b) of the FSG Regulation).
- *Young-child formula*: this will be the denomination used to refer to the products subject of the report, namely milk-based drinks and similar protein-based products specifically processed/formulated and intended to satisfy the nutritional requirements of young children aged 1-3 years.

Different terminology is normally used to refer to these products (e.g. "*growing-up milk*" or "*toddlers' milks*"). It is, however, considered preferable not to use the denomination "*growing up milk*", as this would imply a particular beneficial effect on growth for young children. Similarly it is preferable not to use the term "*toddlers' milk*", as a "young child" is better defined by age in the legislation⁹.

- *Fortified milks*: 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.
- *Infant formula*: food intended for use by infants 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). Infant formula is currently regulated by Directive 2006/141/EC¹⁰, which also provides a very similar definition of infant formula.
- *Follow-on formula*: 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 (Article 2(2)(d) of the FSG Regulation). Follow-on formula is currently regulated by Directive 2006/141/EC, which also provides a very similar definition of follow-on formula.
- *Follow-up Formula*: food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children (Art. 2.1.1 - Codex Alimentarius Standard for Follow-Up Formula¹¹).
- *Baby food*: 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; (Article 2(2)(f) of the FSG Regulation). Baby food is currently

⁹ EFSA also referred to "*young-child formulae*" in its two opinions on the subject.

¹⁰ 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). 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). Directive 2006/141/EC will be repealed and replaced from 22 February 2020 by 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)

¹¹ Codex Alimentarius, Codex Standard for Follow-Up Formula - Codex Stan 156-1987.

regulated by Directive 2006/125/EC¹², which provides a very similar definition of baby food.

- *Nutrition claim*: any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to: (a) the energy (calorific value) it (i) provides; (ii) provides at a reduced or increased rate; or (iii) does not provide; and/or (b) the nutrients or other substances it (i) contains; (ii) contains in reduced or increased proportions; or (iii) does not contain (Article 2(2)(4) of Regulation (EC) No 1924/2006)¹³.
- *Health claim*: any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health (Article 2(2)(5) of Regulation (EC) No 1924/2006).
- *Interested parties*: all components of the society that showed the Commission services an interest in young-child formulae during the preparation of the report. The concept includes, by way of example: industry stakeholders, consumers' associations and other NGOs. It excludes institutional counterparts like Member States or EFSA. A full list of such interested parties is provided in Annex.

¹² Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (OJ L 339, 6.12.2006, p. 16).

¹³ 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).

3. THE MARKET OF YOUNG-CHILD FORMULAE IN THE EU

This Chapter provides a detailed picture of the market of young-child formulae in the EU. It first gives an account of the presence of the products in the different Member States and describes the products' composition and characteristics. It then provides an overview of the size of the market of young-child formulae, as well as information on the market's value and structure, including information on products' price. It finally describes how young-child formulae are marketed in the EU, providing information on a number of aspects, such as what sales denomination is used, what claims are made and what population groups are targeted.

This overview only covers young-child formulae and does not cover fortified milks¹⁴.

3.1. Products' presence in the different Member States

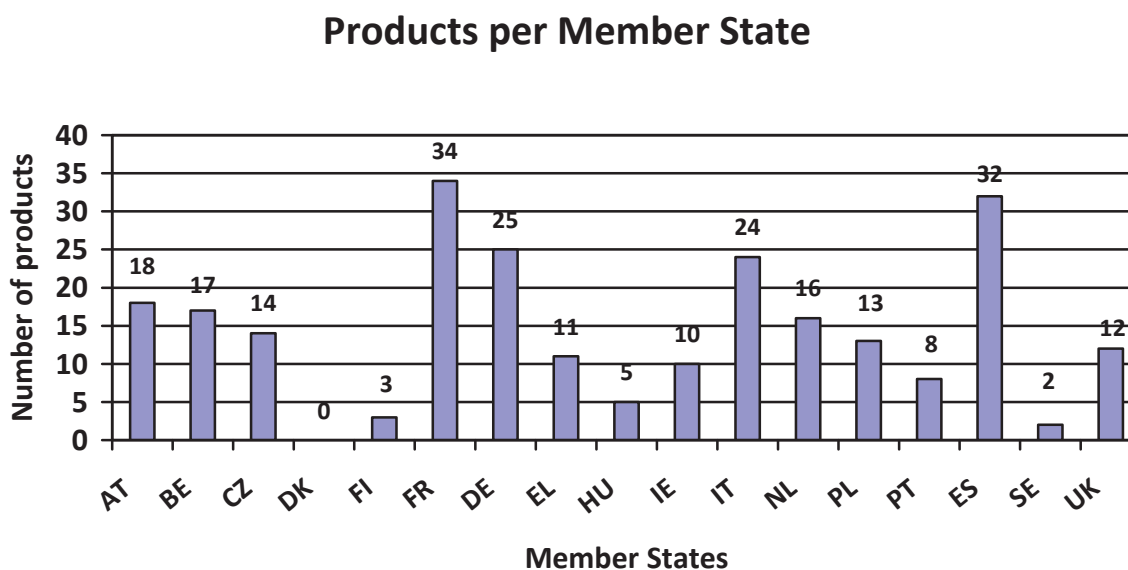
Hundreds of young-child formulae are present on the EU market. Available data¹⁵ from 17 Member States representing 90 % of the total EU28 population (calculated from Eurostat data), with significant geographic representation of the different areas of Europe, have listed 244 different young-child formulae from 62 food business operators currently available on the market (Austria (n = 18), Belgium (n = 17), Czech Republic (n = 14), Denmark (n = 0), Finland (n = 3), France (n = 34), Germany (n = 25), Greece (n = 11), Hungary (n = 5), Ireland (n = 10), Italy (n = 24), Netherlands (n = 16), Poland (n = 13), Portugal (n = 8), Spain (n = 32), Sweden (n = 2) and United Kingdom (n = 12)).

The abovementioned data are represented in Figure 1, showing that the countries with the greatest number of products collected were France and Spain, followed by Germany and Italy. In contrast, the countries with the smallest number of products collected were Finland, Sweden and Denmark.

¹⁴ During the consultation phase, Member States and interested parties were asked to provide any available information on fortified milks. On the basis of the replies received, it appears that a number of fortified milk products exist in almost all Member States. The products 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 polyunsaturated fatty acids. Their protein content is normally not modified. These products are marketed at a lower price than young-child formulae and target the general population or sub-groups thereof (e.g. children) with specific nutrition and health claims (e.g. fortified in vitamin D for bone health, or fortified in omega-3 for cardiovascular health). They however never target young children only. During the consultation phase, several Member States also underlined that these fortified milk products can contain fruit or flavours (e.g. vanilla or chocolate). Different national competent authorities, 2014, *Reply to the questionnaire on young-child formulae*.

¹⁵ AINIA (2013) p. 5-9; EFSA (2013), p. 13; Denmark 2014, *Reply to the questionnaire on young-child formulae*.

Figure 1 - Number of products per Member State (source: AINIA data)



3.2. Products' composition and characteristics

Almost half of the young-child formulae analysed by AINIA were in liquid form (44.7%, n = 109) and the remaining were marketed in the form of powder to be reconstituted. The great majority of the reviewed young-child formulae (96%, n = 234) is based on cow's milk as a source of protein. Goat milk and soy are the sources of protein used in three and seven formulae, respectively¹⁶.

The energy content of the analysed young-child formulae is varied, and so is their composition¹⁷. Tables 1-3 below provide an overview of the maximum, minimum and median values of the different nutrients present in the young-child formulae reviewed by AINIA.

Table 1 - Maximum, minimum and median content of different macronutrients (source: AINIA data)

Nutrient	Units	Max (/100 kcal)	Min (/100 kcal)	Median (/100 kcal)
Protein	g	6.7	2.0	2.6
Casein	g	2.4	0.1	1.7
Whey Protein	g	1.2	0.4	0.7
W/C (Whey/Casein) Ratio	g	6.3	0.5	1.5
Carbohydrates	g	15.4	7.3	12.6
Sugars	g	13.7	3.1	9.9
Lactose	g	13.5	0.1	9.0
Sucrose	g	10.4	0.6	2.1
Glucose	g	1.8	0.0	0.5
Maltose	g	5.0	0.1	0.2
Maltodextrin	g	11.2	1.4	4.1
Fat	g	5.7	3.0	4.3
Saturated Fat	g	4.3	0.2	1.4

¹⁶ EFSA (2013), p. 13; AINIA (2013) p. 9.

¹⁷ AINIA (2013); EFSA (2013).

Monounsaturated	g	3.0	0.7	1.9
Polyunsaturated	g	3.4	0.4	0.9
Linoleic Acid n-6	g	2.4	0.1	0.8
Arachidonic Acid (ARA)	g	0.2	0.0	0.0
Alpha Linolenic Acid n-3	mg	589.2	0.0	103.0
Eicosapentaenoic acid (EPA)	mg	81.8	11.8	19.0
Docosahexaenoic acid (DHA)	mg	42.6	0.4	6.4
Fibre	g	2.4	0.0	0.8

Table 2 - Maximum, minimum and median content of different minerals (source: AINIA data)

Nutrient	Units	Max (/100 kcal)	Min (/100 kcal)	Median (/100 kcal)
Sodium	mg	85.7	15.9	40.4
Potassium	mg	322.9	85.9	126.8
Chloride	mg	166.2	14.1	75.0
Calcium	mg	270.8	77.1	126.9
Phosphorus	mg	185.7	46.4	77.6
Magnesium	mg	49.0	6.6	10.4
Iron	mg	2.9	1.0	1.8
Zinc	mg	3.0	0.1	1.1
Copper	mg	0.1	0.0	0.1
Manganese	mg	1.0	0.0	0.0
Fluoride	mg	0.1	0.0	0.0
Selenium	µg	6.7	1.0	2.4
Iodine	µg	54.0	0.0	20.0
Chromium	µg	1.5	1.4	1.4
Molybdenum	µg	4.4	4.1	4.2

Table 3 - Maximum, minimum and median content of vitamins and some other nutrients (source: AINIA data)

Nutrient	Units	Max (/100 kcal)	Min (/100 kcal)	Median (/100 kcal)
Vitamin A	µg	176.3	9.6	101.6
Vitamin D	µg	6.0	0.9	2.1
Vitamin E	mg	7.0	0.0	1.6
Vitamin K	µg	16.3	0.0	7.5
Vitamin C	mg	34.8	2.2	15.4
Thiamin	mg	1.2	0.0	0.1
Riboflavin	mg	1.2	0.0	0.2
Niacin	mg	4.1	0.0	0.9
Vitamin B ₆	mg	0.7	0.0	0.1
Folic Acid	µg	42.2	0.0	22.4
Vitamin B ₁₂	µg	0.9	0.0	0.3
Biotin	µg	7.5	0.0	3.1
Pantothenic acid	mg	6.8	0.0	0.7
Choline	mg	123.2	0.8	14.9
Inositol	mg	14.9	1.7	6.4
Taurine	mg	19.4	0.3	8.1
Carnitine	mg	3.7	1.1	2.1

The amounts of nutrients reported by AINIA were generally in the ranges reported by Specialised Nutrition Europe (SNE)¹⁸ and in the review by Crawley and Westland¹⁹.

Table 4 below provides a comparison carried out by EFSA of the nutrient composition and energy content of the cow's milk based young-child formulae reviewed by AINIA with the essential composition of cow's milk based infant formulae and follow-on formulae according to Directive 2006/141/EC and the nutrient composition and energy content of full fat cow's milk²⁰.

The protein content of the reviewed young-child formulae is normally lower than the mean protein content of cow's milk and is, in most cases, within the permitted range for infant formulae and follow-on formulae, as laid down in Directive 2006/141/EC. The carbohydrate content of the reviewed young-child formulae is normally higher than the mean carbohydrate content of cow's milk and, in most cases, within the permitted range for infant formulae and follow-on formulae. In addition, while lactose is the primary sugar present in cow's milk, different sugars can be present in young-child formulae (lactose, sucrose, glucose, maltose). These sugars are also used in infant formulae and follow-on formulae, in line with the conditions laid down in Directive 2006/141/EC. Sometimes honey is added to young-child formulae²¹. The fat content of the reviewed young-child formulae is normally lower than the mean fat content of full fat cow's milk and, in most cases, within the permitted range for follow-on formulae.

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. As underlined by EFSA²², in comparison with cow's milk, currently marketed young-child formulae contain more ALA, docosahexaenoic acid (DHA) (if added), iron and vitamin D but similar amounts of iodine. The median content of these nutrients in the reviewed young-child formulae is within the range of permitted concentrations in follow-on formulae and, except for iron, also in infant formulae. These nutrients have been identified as critical nutrients by EFSA, as will be further described in Chapter 6.

Table 4 - Nutrient composition and energy content of cow's milk based young-child formulae currently on the EU market, of infant and follow-on formulae (cow's milk based) as per Directive 2006/141/EC and of full-fat cow's milk (source: EFSA, based on AINIA data)

	Young-child formula (cow's milk based) ²³			Follow-on formula (cow's milk based)		Infant formula (cow's milk based)		Cow's milk, full fat
	P5	Median	P95	Min	Max	Min	Max	Mean
Energy (kJ/100 g)	209.0	281.0	339.0	251.0	293.0	251.0	293.0	289.0
Energy (kcal/100 g)	50.0	67.0	81.0	60.0	70.0	60.0	70.0	69.0
Nutrient per	P5²⁴	Median	P95	Min	Max	Min	Max	Mean

¹⁸ Specialised Nutrition Europe (SNE), 2013, data shared with the European Commission and representing predominantly EU countries where SNE is present through one of its members associations.

¹⁹ Crawley H and Westland S, 2013, *Fortified milks for children - A worldwide review of fortified milks marketed for children over 1 year of age*, First Steps Nutrition Trust.

²⁰ EFSA (2013), p. 99-100.

²¹ Belgium, 2014, *Reply to the questionnaire on young-child formulae*.

²² EFSA (2013), p. 74.

²³ Based on 234 products.

²⁴ Percentiles are based on formulae containing the nutrient.

	Young-child formula (cow's milk based) ²³			Follow-on formula (cow's milk based)		Infant formula (cow's milk based)		Cow's milk, full fat
	P5	Median	P95	Min	Max	Min	Max	Mean
100 kcal								
Protein (g/100 kcal)	2.1	2.6	3.6	1.8	3.5	1.8	3.0	4.8
Taurine ²⁵ (mg/100 kcal)	7.0	8.1	15	–	< 12	–	< 12	–
Carbohydrates (g/100 kcal)	11.1	12.6	14.3	9.0	14.0	9.0	14.0	6.8
Fat (g/100 kcal)	3.5	4.3	4.8	4.0	6.0	4.4	6.0	6.1
SFA (g/100 kcal)	0.4	1.4	2.1	–	–	–	–	–
ARA ²⁶ (mg/100 kcal)	1.1	4.1	14.3	–	–	–	–	0.0
DHA ²⁷ (mg/100 kcal)	2.2	6.4	22.3	–	–	–	–	0.0
ALA ²⁸ (mg/100 kcal)	57.6	103.0	169.0	> 50	240	>50	240	0
LA ²⁹ (mg/100 kcal)	500.0	758.0	1 043.0	300.0	1 200.0	300.0	1 200.0	70.0
Sodium (mg/100 kcal)	27.6	40.3	57.1	20.0	60.0	20.0	60.0	64.3
Chloride (mg/100 kcal)	61.2	75.0	114.0	50.0	160.0	50.0	160.0	146.5
Potassium (mg/100 kcal)	101.0	127.0	199.0	60.0	160.0	60.0	160.0	215.1
Calcium (mg/100 kcal)	94.4	127.0	220.0	50.0	140.0	50.0	140.0	176.7
Phosphorus (mg/100 kcal)	58.4	77.3	134.0	25.0	90.0	25.0	90.0	138.3
Copper (µg/100 kcal)	35.0	61.5	118.0	35.0	100.0	35.0	100.0	0.0
Iodine (µg/100 kcal)	12.2	20.2	34.8	10.0	50.0	10.0	50.0	23.0
Iron (mg/100 kcal)	1.3	1.8	2.4	0.6	2.0	0.3	1.3	< 0.1
Magnesium (mg/100 kcal)	8.1	10.4	20.0	5.0	15.0	5.0	15.0	16.8
Manganese (µg/100 kcal)	5.9	14.6	106.0	1.0	100.0	1.0	100.0	0.0
Selenium (µg/100 kcal)	1.4	1.6	5.5	1.0	9.0	1.0	9.0	1.9
Zinc (mg/100 kcal)	0.7	1.2	2.0	0.5	1.5	0.5	1.5	0.6
Vitamin A (µg RE/100 kcal)	77.8	102.0	141.0	60.0	180.0	60.0	180.0	57.5
Vitamin D (µg/100 kcal)	1.4	2.1	3.3	1.0	3.0	1.0	2.5	0.1
Vitamin E (mg TE/100 kcal)	0.9	1.6	3.1	0.5/g PUFA, not < 0.5 mg/ 100 kcal	5.0	0.5/g PUFA, not < 0.5 mg/ 100 kcal	5.0	0.1
Vitamin K (µg/100 kcal)	4.5	7.5	11.8	4.0	25.0	4.0	25.0	0.0

²⁵ In 31% of all young-child formulae.

²⁶ In 12% of all young-child formulae.

²⁷ In 13% of all young-child formulae.

²⁸ In 78% of all young-child formulae.

²⁹ In 80% of all young-child formulae.

	Young-child formula (cow's milk based) ²³			Follow-on formula (cow's milk based)		Infant formula (cow's milk based)		Cow's milk, full fat
	P5	Median	P95	Min	Max	Min	Max	Mean
Thiamine (mg/100 kcal)	0.07	0.12	0.27	0.06	0.3	0.06	0.3	0.0
Riboflavin (mg/100 kcal)	0.14	0.20	0.35	0.08	0.4	0.08	0.4	0.3
Pyridoxine (mg/100 kcal)	0.06	0.10	0.30	0.035	0.175	0.035	0.175	0.0
Cobalamin (mg/100 kcal)	0.18	0.27	0.59	0.1	0.5	0.1	0.5	0.7
Biotin (µg/100 kcal)	2.2	3.1	6.6	1.5	7.5	1.5	7.5	4.3
Folate (µg/100 kcal)	7.3	22.4	38.6	10.0	50.0	10.0	50.0	9.1
Niacin (mg/100 kcal)	0.57	0.90	3.1	0.3	1.5	0.3	1.5	1.0
Pantothenic acid (mg/100 kcal)	0.42	0.71	1.3	0.4	2.0	0.4	2.0	0.6
Vitamin C (mg/100 kcal)	8.7	15.9	23.4	10.0	30.0	10.0	30.0	1.9
Choline ³⁰ (mg/100 kcal)	10.0	14.9	23.0	–	–	7	12	
Inositol ³¹ (mg/100 kcal)	4.0	6.3	13.5	–	–	4	40	

The review from AINIA does not cover the presence of flavouring substances in young-child formulae, as this was not requested by EFSA for the purposes of its work. It has however been reported that at least certain young-child formulae in the market in the EU contain flavourings (e.g. vanilla)³².

3.3. Market size and value, prices and structure of the market

This section focuses on a number of different aspects related to the market of young-child formulae: market size and value, products' price and market structure.

3.3.1. Size of the market of young-child formulae

On the basis of available data³³ from 11 EU Member States (Austria, Belgium, Finland, France, Germany, Italy, Netherlands, Portugal, Spain, Sweden, and the UK), representing around 74% of the total EU28 population + Switzerland, the combined retail market size for young-child formulae in terms of volume for these countries can be estimated to more than 42 000 tonnes in 2012 (including formulae in liquid and powder form). As it is shown in Figure 2 below, the biggest markets in terms of volume in 2012 were France and Spain, followed by Italy, UK and Germany. The smallest reviewed markets were Finland and Sweden.

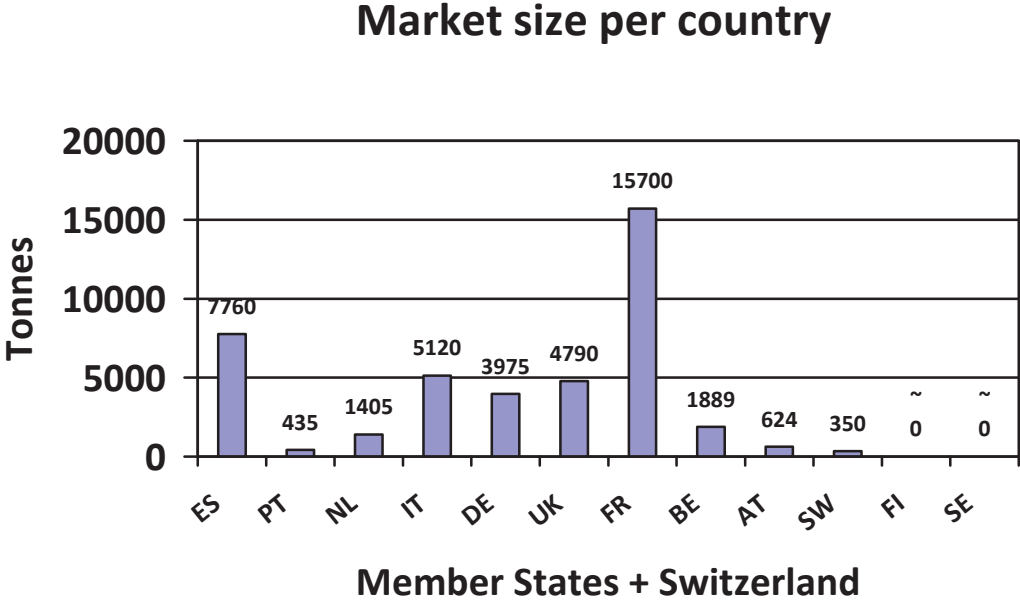
³⁰ In 34% of all young-child formulae.

³¹ In 11% of all young-child formulae.

³² Crawley H and Westland S, (2013), p. 53-58; First Steps Nutrition Trust, 2014, *Reply to the questionnaire on young-child formulae*.

³³ AINIA (2013), p. 12-34. This market share represents the top players accounting for 80% of the market in those countries.

Figure 2 – Market size (volume as tonnes) per country – 2012 (source: AINIA data)

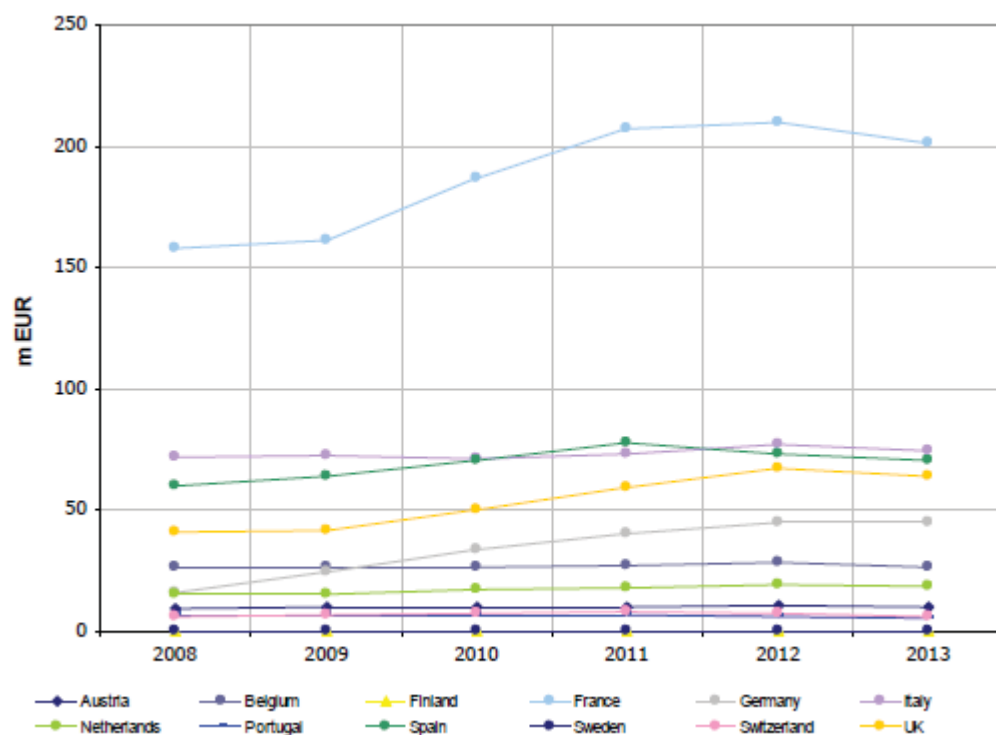


In the period 2008-2012, the market experienced growth in all the abovementioned countries with the exception of Portugal (where it decreased by 10.3% with a compound annual growth rate of -2.7%) and ranged from a 2.9% growth in Switzerland (compound annual growth of 0.7%) to a 265.7% growth in Germany (compound annual growth of 38.3%). Notable growths were also reported in Spain (45.6% growth, with a compound annual growth of 9.8%), Italy (44.6% growth with a compound annual growth of 9.7%) and the Netherlands (40.2% growth with a compound annual growth of 8.8%).

3.3.2. Value of the market of young-child formulae

In terms of market value, the same data from AINIA³⁴ allow to estimate a combined retail market value for young-child formulae of more than €500 million for the 12 countries in 2012. As it is shown in Figure 3 below, the biggest markets in terms of value in 2012 were France and Italy, followed by Spain, UK and Germany.

Figure 3 – Market value (million €) per country (source: AINIA data)³⁵



3.3.3. Price of young-child formulae

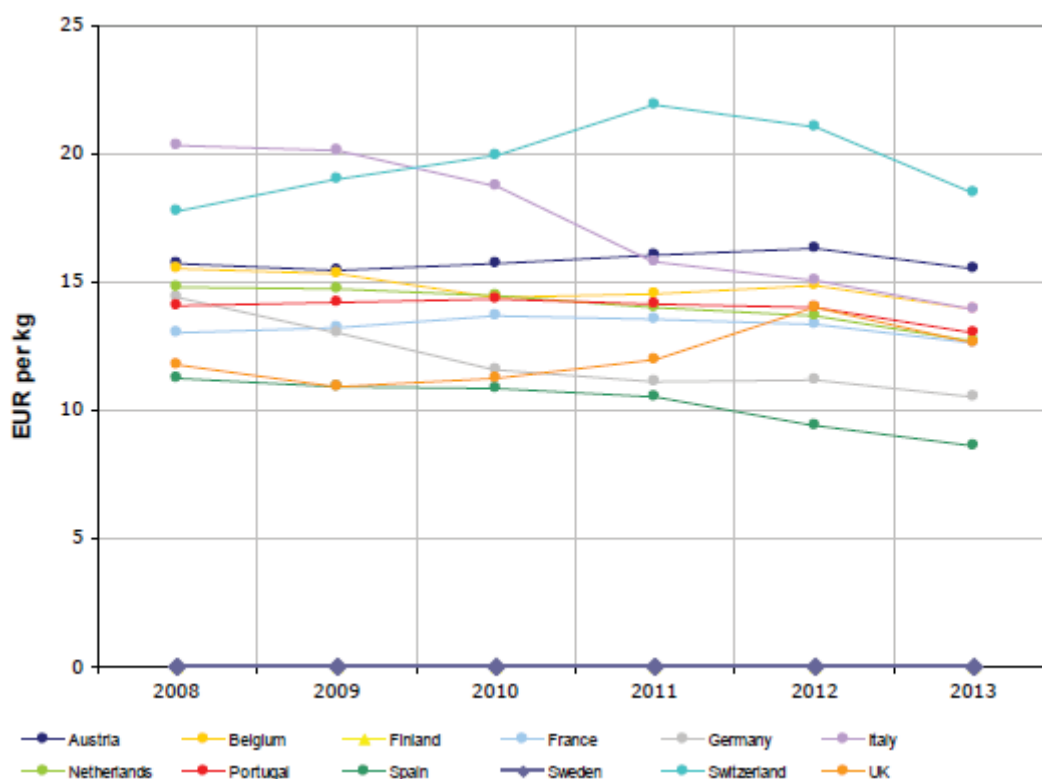
Figure 4 below shows the differences in retail market unit price for young-child formulae as reported by AINIA³⁶. Among EU Member States, in 2012, prices were highest in Austria (€15-17.5 per kg) and lowest in Spain (€7.5-10 per kg).

³⁴ AINIA (2013), p. 32. Data are only available in a chart. The value of €500 million should be considered an approximation based on rounded values.

³⁵ AINIA (2013), p. 32.

³⁶ AINIA (2013), p. 34. Data are only available in a chart and, therefore, referred to in ranges for presentational purposes. The price per kg reported by AINIA does not allow distinguishing between products sold in powder and liquid form.

Figure 4 – Retail market unit price (€ per kg) (source: AINIA data)³⁷



Stakeholders confirmed³⁸ that the price of young-child formulae can vary. They noted that a number of market parameters, such as the influence of retailers in setting the final price, food taxes, VAT etc. play a role in the final price paid by the consumer.

Information received from national competent authorities³⁹ also confirmed that prices differ depending on Member State, brand, product presentation (liquid vs powder) and distribution channel. More specifically, information received from national competent authorities shows that the price of young-child formulae is very similar or slightly lower than that of infant formulae or follow-on formulae (it was underlined that in France the price tends to decrease with age, namely that infant formulae are slightly more expensive than follow-on formulae, that are slightly more expensive than young-child formulae). Young-child formulae are also more expensive than cow's milk. By way of comparison, 1 litre of whole cow's milk in Spain (based on Eurostat data⁴⁰) cost in 2012 on average €0.77. Considering that around 140 g of powdered product are needed to reconstitute 1 litre of young-child formulae⁴¹, and using the

³⁷ AINIA (2013), p. 34.

³⁸ European Natural Soyfoods Manufacturers Association (ENSA), 2014, *Reply to the questionnaire on young-child formulae*; Secteur Français des Aliments de l'Enfance (SFAE), 2014, *Reply to the questionnaire on young-child formulae*.

³⁹ Different national competent authorities, 2014, *Reply to the questionnaire on young-child formulae*.

⁴⁰ Eurostat, 2013, *Detailed average prices report (2012)*, http://ec.europa.eu/eurostat/documents/272892/272992/Consumer_Prices_Research_2013.pdf/0effc4ed-134c-4af4-a401-1a72fc74db8c

⁴¹ Based on amounts generally recommended by manufacturers.

reported price per kg by AINIA⁴², this would mean that an equivalent amount of reconstituted young-child formula cost at least €1.05 (36.4% more expensive than cow's milk). Similarly, 1 litre of whole cow's milk in the Netherlands (based on Eurostat data) cost in 2012 on average €0.88. Based on the same assumptions, 1 litre of reconstituted young-child formulae would cost at least €1.75 (98.9% more expensive than cow's milk)⁴³.

Young-child formulae are distributed through different channels: retailers, specialised stores, websites and, in a more limited number of cases, pharmacies. Member States tend to agree that when formulae are sold in pharmacies, prices tend to be slightly higher than in supermarkets. It has also been reported by many Member States that the price of young-child formulae sold on the Internet is, in general, similar to that of formulae sold in super-markets (and in certain cases slightly lower)⁴⁴. "Organic" young-child formulae or young-child formulae made from goat's milk protein are reported by some NGOs to be sold with a price premium⁴⁵. The price of soy-based young-child formulae is reported to be similar to other young-child formulae⁴⁶.

3.3.4. Structure of the market of young-child formulae

The market of young-child formulae is divided among a small number of players, with limited space for other actors. By way of example, in the UK, in 2012, the two companies with the largest share of the market occupied 96.5% of the retail market share by volume. Similarly, in France in the same year, the four companies with the largest share of the market occupied 82.8% of the market and in Germany the three companies with the largest share occupied 98.6% of the market⁴⁷. These companies are, in most cases, multinational companies selling their products in different Member States. Figures 5, 6 and 7 below provide a more detailed account of the situation in these three Member States.

⁴² On the basis of AINIA data, the price per kg of young-child formulae in Spain is reported to be in the range €7.5-10 per kg. The lowest value in the range (€7.5) is used here for calculation purposes. This value is an estimation as it is based on prices reported by AINIA that represent the totality of the sector and do not distinguish between liquid and powder form.

⁴³ On the basis of AINIA data, the price per kg of young-child formulae in the Netherlands is reported to be in the range €12.5-15 per kg. The lowest value in the range (€12.5) is used here for calculation purposes. This value is an estimation as it is based on prices reported by AINIA that represent the totality of the sector and do not distinguish between liquid and powder form.

⁴⁴ Different national competent authorities (2014).

⁴⁵ The International Baby Food Action Network (IBFAN), 2014, *Reply to the questionnaire on young-child formulae* (IBFAN's contribution also represents the position of the Baby Feeding Law Group); First Steps Nutrition Trust (2014).

⁴⁶ ENSA (2014).

⁴⁷ AINIA (2013).

Figure 5 – Market share by company in the UK – 2012 (source: AINIA data)

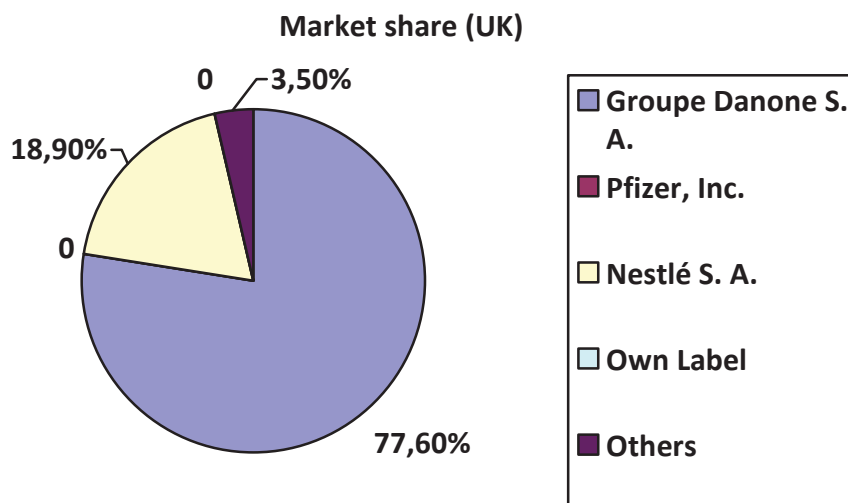


Figure 6 – Market share by company in FR- 2012 (source: AINIA data)

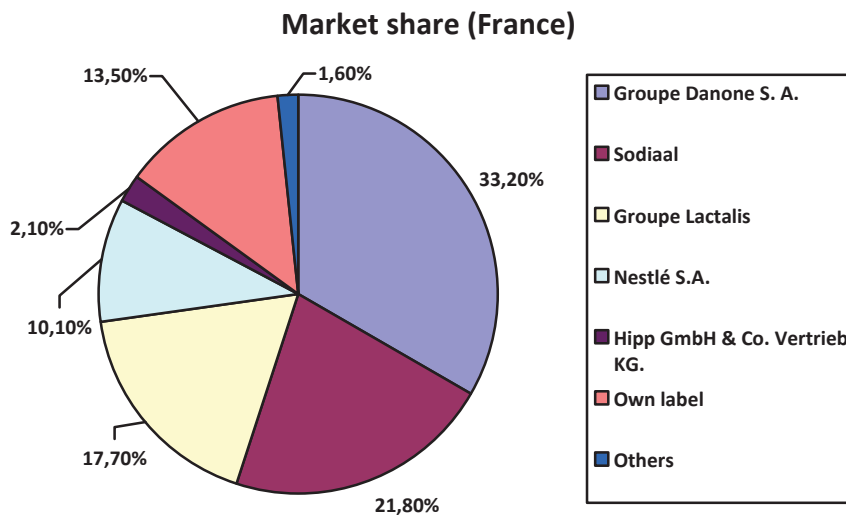
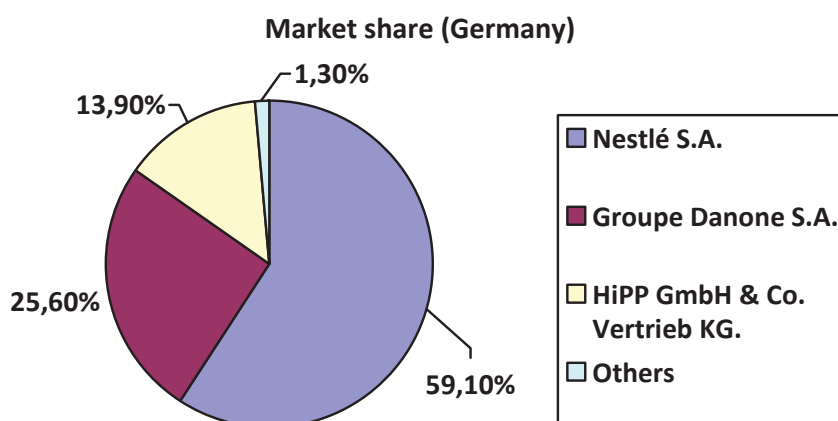


Figure 7 – Market share by company in Germany – 2012 (source: AINIA data)



It has been reported⁴⁸ that young-child formulae are manufactured in a limited number of Member States (e.g. ES, BE, DE, NL, FR) and Switzerland and then traded to the rest of the EU and outside the EU. Data from France show that around two thirds of volumes are produced for export (out of this, one third is exported to other EU Member States and two thirds to third countries). France exports three times more than the volume of imports.

3.4. The marketing of young-child formulae

As explained in Chapter 1 of this SWD, the Commission has carried out extensive consultation with Member States and interested parties in preparation for the report on young-child formulae. The results of this consultation have made it possible to identify a series of different aspects related to the marketing of young-child formulae in the EU.

Sales denomination: the denomination most commonly used to market young-child formulae in the different EU Member States is "*growing-up milk*". "*Toddlers' milk*" is also commonly used, as well as "*junior milk*" / "*junior drink*", "*milk based drink for young children*"⁴⁹ or "*milk drink for toddlers*". It has been reported that the product is sometimes called "*follow-on formula from 12 months*"⁵⁰. 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*"⁵¹. In the case of young-child formulae made from goat's milk protein, the denomination used is sometimes "*milk based food based on powder goat milk for young child above 1 year*"⁵².

Use of claims / other statements: the marketing of young-child formulae is based on the product's specific formulation. Operators market young-child formulae as products with a specific formulation for the nutritional needs of young children. In this context, a variety of nutrition claims are often used that describe the products' particular nutritional properties. These nutrition claims are, for example, related to ingredients that are added to the product and that are considered beneficial for young children (e.g. "*contains vitamin D*" or "*with iron*", "*added omega-3*"), or to nutrients that the products contain in reduced proportion, so

⁴⁸ Different national competent authorities (2014); SFAE (2014).

⁴⁹ This is also the sales denomination in French law for the product.

⁵⁰ Sweden, 2014, *Reply to the questionnaire on young-child formulae*.

⁵¹ ENSA (2014); Belgium (2014).

⁵² Belgium (2014).

that it is more suitable for young children (e.g. "*contains less saturated fats than cow's milk*", "*reduced protein*", "*protein content adapted to the needs of young children*").

Specific health claims on the role of the different ingredients are also made (e.g. "*calcium and vitamin D are needed for normal growth and development of bone in children*" or "*iron contributes to normal cognitive development of children*"), as well as generic statements on the role/suitability of the products in contributing to healthy growth of young children. Special emphasis is, in particular, put on certain nutrients present in the products (e.g. iron, vitamin D) that are considered critical for young children (because intake through the diet is commonly reported as inadequate or nutrient status is low). 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. Two NGOs reported that young-child formulae are shown as a "nutritional safety net" for parents⁵³, and nutritional superiority to cow's milk is often used as a marketing argument (e.g. "*nutritionally superior to cow's milk*", "*contains 40 times more iron than cow's milk*"). Certain brands focus on the "organic" nature of the product.

Use of images: images of young children or, most often, imaginary characters or animals (e.g. teddy bears, giraffes, rabbits and elephants) are present on the label/advertising of the products. When images of young children are used, the young children are represented as standing on their own feet in order to represent children older than one year of age (in cases of products targeted for young children older than two years the young child is sometimes represented as more active/walking). In the case of young-child formulae made from goat's milk protein, pictures of goats are often used. Finally images of families are sometimes used.

Statements on the superiority of breastfeeding/recommendations on a balanced diet: statements on the superiority of breastfeeding are reported to be used, in certain cases, on a voluntary basis, and appear on the labelling/advertising of products (e.g. on Internet websites). More often, products bear statements recommending that young-child formulae are consumed as part of a varied, balanced diet. 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.

Targeted age range and differences in composition: young-child formulae are developed and marketed for young children aged 1-3 years or, in certain cases, for narrower sub-groups, the most common being 1-2 years and 2-3 years. It has been reported that the products are sometimes marketed as suitable from 10 months on or from 15 months on⁵⁴.

When an operator develops different products for different age-related sub-groups, the composition varies. The main differences have been reported to be in the amount of energy and macro-nutrients. Products for the age range 2-3 years normally contain a lower level of energy, fat, protein and carbohydrates than those for the age range 1-2 years. With respect to micronutrients, some Member States reported that lower levels of micronutrients are present in products for older young children, although the difference is sometimes only minor⁵⁵. Another Member State⁵⁶ reported that higher levels of micronutrients can be present in

⁵³ First Steps Nutrition Trust (2014); IBFAN (2014).

⁵⁴ It is reported that sometimes the product is marketed for children older than 3 years. This is however out of the scope of the report that covers only milk-based drink intended for young children.

⁵⁵ Czech Republic, 2014, *Reply to the questionnaire on young-child formulae*; United Kingdom, 2014, *Reply to the questionnaire on young-child formulae*. This was confirmed by First Steps Nutrition Trust and IBFAN in their contribution to the questionnaire on young-child formulae (2014).

⁵⁶ Ireland, 2014, *Reply to the questionnaire on young-child formulae*.

products for older young children. In this context, the association representing French producers (Syndicat Français des Aliments de l'Enfance, SFAE) explained that the composition of formulae targeting young children 2-3 years old tends to fit to the local dietary habits, taking into account the reduction in milk consumption in older young children. As a result, the formulae might be more concentrated in certain nutrients⁵⁷.

Distinction from infant and follow-on formulae: the distinction between young-child formulae and infant formulae and follow-on formulae is ensured by the product denomination (e.g. "growing-up milk", "toddlers' milk"), by an indication on the label of the age range for which the product is intended (e.g. "+1"), by the use of a numbering system based on the concept of staging (1 for infant formulae, 2 for follow-on formulae, 3 and 4 for young-child formulae⁵⁸) and/or by the use of different colours/design on the labels.

Some Member States and NGOs, however, underlined that the distinction between young-child formulae and infant formulae and follow-on formulae is, in certain cases, difficult, due to the strong similarities in the packaging between products of the same brand, and requires a careful reading of the product label⁵⁹. It was also noted by one Member State that the similarities in the branding between infant and follow-on formulae on one side and young-child formulae on the other, coupled with the fact that the products are presented next to each other, in the same area of shops, can give the message to consumers that young-child formulae are a logical consequence/necessity after one year of age⁶⁰. During the meeting of the Working Group of the Advisory Group on the Food Chain and Animal and Plant Health of 19 September 2014, the representative of IBFAN (also on behalf of the Baby Feeding Law Group) underlined that similarities in the branding of young-child formulae and formulae for infants have an impact on breastfeeding rates for infants and on wrong consumption of young-child formulae before one year of age.

Specific sub-groups of the population with particular conditions: as it was confirmed by one stakeholder⁶¹, young-child formulae are developed for young children in good health but who may have inadequate dietary intakes or be at risk of inadequate nutritional status. As such, young-child formulae are not developed for specific sub-groups of the young-children population with particular conditions. However, it has been reported that young-child formulae targeting lactose intolerant consumers are on the market in different EU Member States. These products are lactose-free (either because they have been processed to remove the lactose content or because they are naturally lactose-free) and are normally targeting the age range 1-3 years.

⁵⁷ SFAE (2014).

⁵⁸ From the information received, it appears, however, that the numbers 3 and 4 are not used consistently. In certain cases, number 3 stands for products intended for infants after 10 months, and number 4 for products intended for young children after 15 months; in other cases, number 3 stands for products intended for young children after 12 months, and number 4 for products intended for young children after 24 months.

⁵⁹ Slovakia, 2014, *Reply to the questionnaire on young-child formulae*; Austria, 2014, *Reply to the questionnaire on young-child formulae*; UK (2014); IBFAN (2014); First Steps Nutrition Trust (2014).

⁶⁰ Croatia, 2014, *Reply to the questionnaire on young-child formulae*.

⁶¹ SNE (2014).

4. CONSUMER'S PERCEPTION AND BEHAVIOUR

This Chapter describes different aspects related to the behaviour of consumers of young-child formulae⁶². It focuses on consumption patterns of young children, analysing intakes of young-child formulae, as well as of other protein-rich liquid drinks that can form part of young children's diet (e.g. breast milk, cow's milk). It describes parents' and other caregivers' perception of young-child formulae, trying to address the question of why are these products consumed (or not consumed) by young children. It also focuses on the role of recommendations of health care professionals and national authorities, as these are powerful factors influencing parents' and caregivers' behaviour when it comes to young-child formulae.

In this context, it should be noted that young children's feeding practices vary significantly throughout the EU, taking into account social, economic and cultural differences, differences in the recommendations from health care professionals and national authorities and product availability. For this reason, no study exists reporting on intakes of breast milk, cow's milk, milk-based drinks and similar products in the diet of young children throughout the EU. Similarly no single study reports on parents and other caregivers' perception, behaviour, interest, understanding and preference with respect to young-child formulae throughout the EU.

For the purposes of the report, three Member States will be analysed in depth in the following sections. These Member States have been identified as sufficiently representative of the EU in terms of market size, differences in feeding practices and recommendations from health care professionals and national authorities. A conclusive paragraph summarizes the situation for the overall EU, based on the submissions of Member States and interested parties.

4.1. United Kingdom

4.1.1. Consumption data

Relevant consumption data for young children in the UK can be obtained from the Diet and Nutrition Survey of Infants and Young Children (2011) and the National Diet and Nutrition Survey (2008/09 – 2011/12).

The Diet and Nutrition Survey of Infants and Young children was commissioned by the Department of Health and the Food Standards Agency to provide detailed information on the food consumption, nutrient intakes and nutritional status of infants and young children aged 4 up to 18 months living in private households in the UK. The survey was carried out in 2011 in all four countries of the UK, and was designed to be representative of the UK population. The survey report was published in March 2013⁶³.

Data from the survey⁶⁴, represented in Table 5 below, show that the proportion of young children aged 12 to 18 months being still breastfed amounted to 8% with an estimated mean volume of 290 g/day. 1% were still given "first milk" formula, 1% "hungrier baby milk" formula, 16% "follow-on milk" formula and 3% "other milk products". 18% of children in the age range were given "growing-up milk" formulae, with a mean intake of 342 g/day. 79% of the respondents were given whole milk with a mean intake of 329 g/day (amounts similar to

⁶² Depending on the context, the word "consumer" can refer either to young children or to parents and caregivers and their role in young children's nutrition.

⁶³ Lennox A, Sommerville J, Ong K., Henderson H. and Allen R. (Eds), 2013, *Diet and Nutrition Survey of Infants and Young Children, 2011*.

⁶⁴ Lennox A, Sommerville J, Ong K., Henderson H. and Allen R (2013), Table 6.2. The terminology used is that of the survey.

those of "growing up milks"). According to the survey, young-child formulae were also used by 3% of families with children aged 10-11 months with a mean intake of 397 g/day⁶⁵.

Table 5 - Total quantities of food consumed (grams) per day: consumers⁶⁶ only, 12-18 months (source: Diet and Nutrition Survey of Infants and Young Children 2011)

Food group	Mean	Median	% consumers ⁶⁷
Whole milk (3.8% fat)	329	341	79
Semi skimmed milk (1.8% fat)	169	52	13
Other milk and cream ⁶⁸	75	15	10
Water	143	109	76
'First milk'	389	394	1
'Hungrier babies milk'	350	336	1
Follow-on milk	323	311	16
'Growing up milk'	342	343	18
Soy milk	373	308	0
Other milk products ⁶⁹	387	405	3
Breast milk	290	230	8

The National Diet and Nutrition Survey was designed to assess the diet, nutrient intake and nutritional status of the general population aged 1.5 years and over, living in private households in the UK. Jointly funded by Public Health England (PHE), an executive agency of the Department of Health, and the UK Food Standards Agency, the survey has been carried out in all four countries of the United Kingdom and is designed to be representative of the UK population. Results covering the first four years of the rolling programme from 2008/09 to 2011/12 were published in May 2014⁷⁰.

Data from the survey⁷¹, represented in Table 6 below, show intakes and intake rates for milk and milk products and commercial foods for young children in the age range 18-36 months. The data are presented in a similar format to that of the Diet and Nutrition Survey of Infants and Young Children, so that comparisons can be made. As it appears, whole cow's milk is consumed by a smaller percentage of respondents (64%) than in the age range 12-18 months. Amounts consumed are also reported to be lower (mean of 280 g). Consumption of semi skimmed milk picks up (43% of respondents, mean intakes of 192 g), while consumption of commercial toddler foods decreases significantly to 17% of respondents (mean consumption of 57 g).

⁶⁵ Lennox A, Sommerville J, Ong K., Henderson H. and Allen R (2013), Table 6.2.

⁶⁶ Per cent consumers is over four days although the gram intake is per day.

⁶⁷ Small numbers of consumers are rounded down to zero.

⁶⁸ Includes 1% fat and skimmed milk.

⁶⁹ Includes hypoallergenic, goats and 'goodnight' milks.

⁷⁰ Bates B, Lennox A, Prentice A, Bates C, Page P, Nicholson S and Swan G (Eds), 2014, *National Diet and Nutrition Survey: Results from Years 1, 2, 3 and 4 (combined) of the Rolling Programme (2008/2009 – 2011/2012)*.

⁷¹ Bates B, Lennox A, Prentice A, Bates C, Page P, Nicholson S and Swan G (2014), Table 5.2c.

Table 6 - Total quantities of food consumed (grams) per day: consumers⁷² only, 18-36 months (source: National Diet and Nutrition

Food group	Mean	Median	% consum
Whole milk (3.8% fat)	280	238	64
Semi skimmed milk (1.8% fat)	192	144	43
1% fat milk	214	218	0
Skimmed milk (0.5% fat)	335	200	4
Other milk and cream	205	100	22
Commercial toddler foods	57	25	17
Tea, coffee and water	228	194	81

In brief, data from the surveys carried out in the UK show that breastfeeding rates are very low after one year of age. Cow's milk is generally consumed for the entire period 12-36 months, but semi-skimmed milk is increasingly consumed with age. Consumption of formula products (part of the food group "commercial toddler food") decreases after 18 months.

4.1.2. Parents' and other caregivers' perception of young-child formulae

An insight on parents' and other caregivers' perception of young-child formulae in the UK can be obtained from an online survey carried out by the consumer organisation *Which?* between 8 November and 6 December 2012. The survey included 727 mothers with children under three years old (478 of these had children between one and three).

The survey showed that: *“mothers absorb marketing claims about the benefits of added ingredients in milks they see in advertisements and marketing material, citing these as reasons why they use toddler milk. Top reasons for using these milks include:*

- *It was the next stage of formula so moved on automatically (46%)*
- *It has nutrients appropriate to development for this age (40%)*
- *Has more nutrients than cow’s milk (32%)*
- *Concerned that baby is not getting enough nutrients from food (27%).*

Which? also reported that: *“parents will stick with the same brand when using follow-on and toddler milks, even if prices rise. When originally choosing infant formula, parents told us trust and familiarity of the brand are two of the top three factors when choosing a formula milk, only surpassed by recommendation from a friend/family”*⁷³.

4.1.3. Recommendations of health care professionals and national authorities

Survey information on health care professionals’ perception of formulae in the diet of young children in the UK is not available. Similarly, no information is available on specific recommendations given by health care professionals in the UK on the intake of milk and/or formulae for young children.

⁷² Per cent consumers is over the four days although the gram intake is per day.

⁷³ Which?, 2013, *Toddler milks – a winning formula?*, <http://www.staticwhich.co.uk/documents/pdf/toddler-milks-a-winning-formula---which-report-331142.pdf>

Useful information on the recommendations given by national authorities in the UK can be obtained from the website *NHS Choice*⁷⁴, which provides quick to read advice from the government on health related issues.

With respect to cow's milk and formula drinks in the diet of young children the website states: "*from 12 months full-fat cows' milk is fine as [young children's] main drink. Infant formula, follow-on formula or growing-up milk is not needed once your baby is 12 months old.*"⁷⁵ It also adds: "*Cows' milk doesn't contain enough iron and other nutrients to meet young babies' needs. That's why it shouldn't be given as a drink to babies until they are 12 months old. Whole milk should be given to children until they are two years old, as they need the extra energy and vitamins it contains. Semi-skimmed milk can be introduced once your child is two years old, as long as they're a good eater and they have a varied diet. Skimmed and 1% milk are not suitable for children under five, as they don't contain enough calories. Lower-fat milks can be used in cooking from the age of one though*"⁷⁶.

4.2. Germany

4.2.1. Consumption data

No up-to-date representative data are available on eating habits of young children in Germany.

A partial estimate about breastfeeding rates in young children can be derived from a nationwide breastfeeding survey, which included 1 717 mother-child-pairs, but was conducted more than 15 years ago, in 1997/98⁷⁷. This survey showed that the rate of breastfeeding mothers (breastfeeding combined with complementary feeding and, in certain cases, formulae) at 12 months of age amounted to 13%. No data on frequency and volumes of intake of formula products were collected in this study.

Data on volumes of breast milk, formula products and cow's milk consumed can be drawn from a nationwide survey on food consumption of infants and young children, which was conducted in 2001/02 in order to estimate the long and short-term dietary intake of pesticide residues (VELS Study)⁷⁸. Data from the VELS study are shown below in Table 7⁷⁹.

Estimates of intakes of breast milk, formula products and cow's milk consumed by young children in Germany can also be drawn from data collected in the German Dortmund Nutritional and Anthropometric Longitudinally Designed (DONALD) study. The DONALD study, launched in 1985 by the Research Institute of Child Nutrition in Dortmund, is a longitudinal (open cohort) study collecting detailed data on diet, growth, development and

⁷⁴ <http://www.nhs.uk/Pages/HomePage.aspx>

⁷⁵ <http://www.nhs.uk/Conditions/pregnancy-and-baby/Pages/help-baby-enjoy-foods.aspx?tabname=Getting%20pregnant>

⁷⁶ <http://www.nhs.uk/conditions/pregnancy-and-baby/pages/drinks-and-cups-children.aspx?tabname=Labour%20and%20birth>

⁷⁷ Kersting M, Dulong M, 2002, *Assessment of breast-feeding promotion in hospitals and follow-up survey of mother-infant pairs in Germany: the SuSe Study*. Public health nutrition, Aug;5(4):547–552.

⁷⁸ Verzehrsstudie zur Ermittlung der Lebensmittelaufnahme von Säuglingen und Kleinkindern für die Abschätzung eines akuten Toxizitätsrisikos durch Rückstände von Pflanzenschutzmitteln.

⁷⁹ Forschungsinstitut für Kinderernährung Dortmund (FKE), 2003, *Ernährungsphysiologische Auswertung einer repräsentativen Verzehrsstudie bei Säuglingen und Kleinkindern VELS mit dem Instrumentarium der DONALD Studie, Schlussbericht*.

metabolism between infancy and adulthood. Data from the DONALD study are shown below in Table 8⁸⁰.

Both the VELS and the DONALD study show that young children beyond the age of 1 year consume very low amounts of breast milk and rather small amounts of formula products⁸¹. Also, both studies show that these intakes decrease with age. Both studies also show that intakes of milk and milk products remain high in the age range 1-3 years with minor fluctuations in intakes.

Table 7 – Mean intakes of different foods (gram per day) at different ages and divided by sex (source: VELS study)

Food	Mean intakes (at different age and per sex)					
	1 year		2 years		3 years	
	Male	Female	Male	Female	Male	Female
Breast milk (g/d)	15.7	18.6	0	0	0	0
Formula products (g/d)	43.6	81.5	19.5	13.4	16.2	0.1
Milk and milk products (g/d)	289.9	228.1	303.0	274.3	274.9	259.5

Table 8 – Mean intakes of different foods (gram per day) at different ages (source: Hilbig)

Food	Mean intakes (at different ages)			
	12 months	18 months	24 months	36 months
Breast milk (g/d)	12.9	0.9	0.4	0
Formula products (g/d)	146.1	41.2	19.9	13.4
Milk and milk products (g/d)	244.1	340.2	326.8	316.8

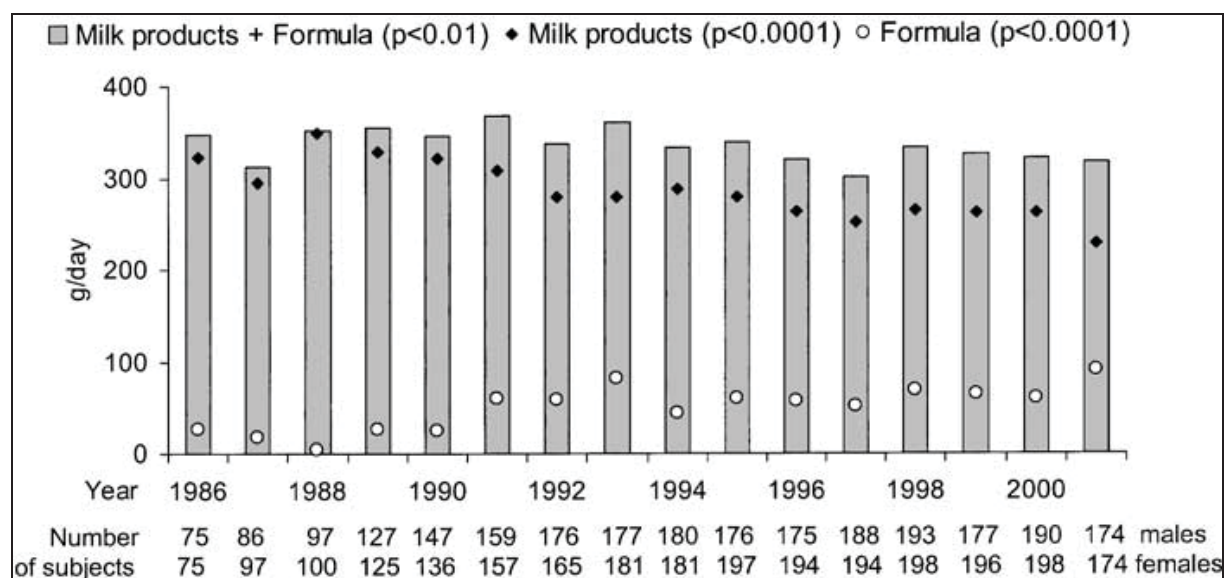
Other relevant data can be obtained from an analysis of dietary records from the DONALD study for the period 1986-2001⁸². The data, shown in Figure 8 below, reveal that young children aged 1 to 3 years have been consuming similar total amounts of milk and formula over the years (approximately 300 g per day). However, the proportion coming from formula compared to milk has started to shift, with a larger proportion of the gram intake coming from formula, which can suggest that formula products are replacing cows' milk in the diets of young children in Germany.

⁸⁰ Hilbig A, 2005 *Längerfristige Trends bei der Ernährung von Säuglingen und Kleinkindern der DONALD Studie im Zeitraum 1989 – 1999*.

⁸¹ It should however be taken into account that when the data for these two analyses were collected, young-child formulae in the form as they exist today were not on the market in Germany.

⁸² Alexy U, Kersting M, 2003, *Time trends in the consumption of dairy foods in German children and adolescents*, *European Journal of Clinical Nutrition*, 57, 1331-1337.

Figure 8 - Time trends of 'milk products' and 'formula' intake in 1–3-y-old participants of the DONALD Study 1986–2001 (source: Alexy and Kersting on the basis of data from the DONALD study)



These conclusions are also supported by a more recent analysis of the dietary records from the DONALD study for the period 2005-2008 which revealed that an increasing number of young children consumed formula products as an alternative to cows' milk⁸³. When looking more carefully into the data, this recent analysis also shows that the proportion of young children consuming formula products with an adapted protein content decreases rapidly from 90% at the age of 9 months to just 3% at the age of 36 months. As a comparison, the percentage of those children consuming cows' milk and cows' milk products significantly increases.

In brief, data from surveys carried out in Germany show that breast milk consumption is very low after one year (both in term of rates and intakes). Intakes of formula products in young children in Germany are relatively low, and decrease with age. Consumption of cow's milk remains on the contrary predominant. Recent data show however that an increasing number of young children are consuming formula products (as an alternative to cow milk).

4.2.2. Parents' and other caregivers' perception of young-child formulae

The German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR) carried out a survey in 2011 on consumers' perception of young-child formulae⁸⁴, interviewing 853 caregivers of young children and dividing them into two groups depending on whether they were used to purchase young-child formulae or cow's milk.

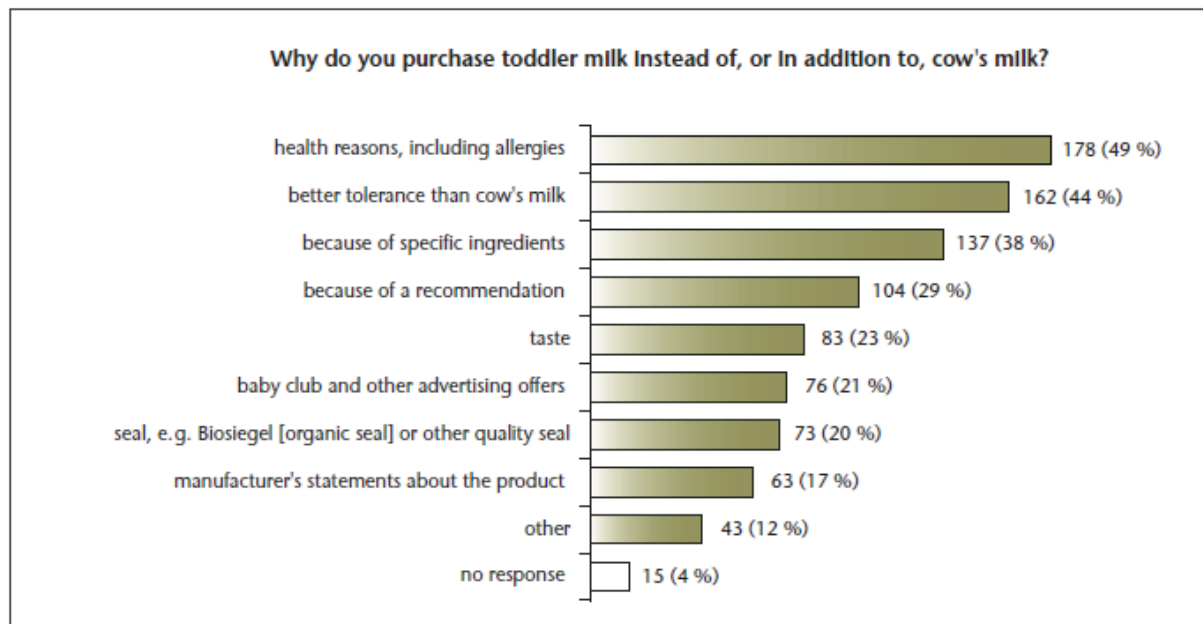
Figure 9 below⁸⁵ shows the main reasons given by respondents to the question "why are you buying young-child formula?".

⁸³ Alexy U, Kersting M, 2010, *DONALD News Kindermilch oder Kuhmilch in der Kleinkindernahrung*, Ernährungs Umschau, 8: 405.

⁸⁴ Tilgner A, Ehlers A, Röder B, Martin A, Weißenborn A, 2013, *What drives parents to buy toddler milk?*, Ernährungs Umschau international, 60(7): 116–123. For more details refer to the final report from BfR on young-child formulae: Bundesinstitut für Risikobewertung, 2014, *Kindermilch – Abschlussbericht*.

⁸⁵ Tilgner A, Ehlers A, Röder B, Martin A, Weißenborn A, (2013).

Figure 9 – Main reasons for purchasing young-child formulae (source: Tilgner et al.)



The most common answers selected by respondents were health reasons, including allergy avoidance, the better tolerance in comparison to cow's milk, as well as the product's specific composition. Other answers provided referred to recommendations, taste, advertising offers, special quality seals and claims made by the manufacturers.

Participants who could remember specific claims made on the products mostly recalled claims related to the vitamin and mineral content, the good tolerance of the products and claims related to the superiority of young-child formula when compared to cow's milk. About two thirds of the purchasers of young-child formulae preferred the products in powder form and regarded the longer shelf-life of the powder as an important advantage relative to cow's milk. 16% of the purchasers also saw disadvantages for toddler milk when compared to cow's milk, the most important being the higher price⁸⁶.

When asked how they became aware of young-child formulae for the first time, 30.4% of respondents indicated that information was obtained in retailers/supermarket. 20.5% indicated family members and acquaintances and 13.7% a midwife. 13.2% referred to advertising in the media, 11.5% to a doctor⁸⁷.

In brief, the survey shows that caregivers receive information on young-child formulae from different sources, including operators. Only a limited number of respondents became aware of the product following health care professionals' advice.

4.2.3. Recommendations of health care professionals and national authorities

The BfR adopted in 2014 a report on young-child formulae. The report concludes that after the age of 1 year, in general, there is no nutritional necessity for specific foods and it is desirable that young children adapt to a diversified diet with fresh ingredients consumed by the family. The BfR also notes that young-child formulae can increase the supply of micronutrients in young children, but are not better suitable for these purposes than other fortified foods or the early introduction of meat or fish in the diet of young children. The report concludes that families should receive information explaining the importance of

⁸⁶ Tilgner A, Ehlers A, Röder B, Martin A, Weißenborn A, (2013).

⁸⁷ BfR (2014), p. 12.

ensuring that young children taking part in the family diet receive a diversified diet, that young-child formulae are unnecessary from a nutritional point of view and that their extensive consumption might lead to excess intakes of certain nutrients⁸⁸.

Considerations on young-child formulae are also provided in the recommendations on nutrition and physical activity for children 1–3 years old from the network "*Healthy start – Young child family network*". This is a project of the Federal Government with the support of leading institutions, professional societies and associations, which aims to develop harmonised recommendations for actions in the field of nutrition and physical activity⁸⁹. In the document it is explained that cows' milk is useful food for young children and that "special milk drinks" are in principle not necessary for a balanced diet of young children. The recommendations go beyond this statement and underline that if young-child formulae are to be used, preference should be given to those products that comply with the recommendations of the German Society of Paediatrics and Adolescent Medicine (DGKJ).

The DGKJ adopted updated guidance⁹⁰ on young child-formulae in 2011. In this document, DGKJ recalls that young-child formulae are in principle not necessary and that young children should consume 1/3 litre of cow's milk (preferably with a fat content of 1.5%) and milk products per day as part of a balanced diet (vitamin D fortification of milk is recommendable). It then recommends specific compositional requirements for young-child formulae if they are used in place of cow's milk: it is recommended that the nutritional composition of young-child formulae is similar to whole cow's milk regarding nutrients such as calcium, vitamins A and riboflavin and similar to low-fat cow's milk regarding energy content. The content of critical nutrients such as iodine and vitamin D should be in line with that laid down in Directive 2006/141/EC on infant formulae and follow-on formulae. Flavouring and sweetening agents should not be added.

⁸⁸ BfR (2014) p.45.

⁸⁹ Koletzko B, Armbruster M, Bauer C-P et al., 2013, *Ernährung und Bewegung im Kleinkindalter Handlungsempfehlungen des Netzwerks „Gesund ins Leben – Netzwerk Junge Familie“*, ein Projekt von IN FORM, Monatsschrift Kinderheilkunde, 12.

⁹⁰ Ernährungskommission der Deutschen Gesellschaft für Kinder- und Jugendmedizin e.V. (DGKJ) (Böhles HJ, Fusch C, Genzel-Boroviczén O, Jochum F, Kauth T, Kersting M, Koletzko B, Lentze MJ, Mihatsch WA, Przyrembel H, Wabitsch M), 2011, *Zusammensetzung und Gebrauch von Milchgetränken für Kleinkinder Aktualisierte Empfehlungen der Ernährungskommission der Deutschen Gesellschaft für Kinder- und Jugendmedizin (DGKJ)*, Monatsschrift Kinderheilkunde, 10, 159:981–984.

4.3. France

4.3.1. Consumption data

Relevant consumption data for France can be obtained from the NutriBébé Survey, carried out in 2013 by TNS Sofres on behalf of the French formulae manufacturers' association (SFAE). SFAE has been requesting every eight years since 1981 a national survey on feeding behaviour and consumption in children under 3 years old. The 2013 survey was carried out on 1 188 mothers of infants and young children representative of the French population⁹¹ and was divided in two parts: the first one describing caregivers' behaviour and the second one the nutritional intakes.

Table 9 below summarizes the outcome of the 2013 survey with respect to consumption of breast milk, formula products and cow's milk in young children, taking into account different age ranges. As it appears, rates of consumption of breast milk are very low after one year of age. Consumption of young-child formula is at its peak in the age range 12-17 months and tends to decrease afterwards, while consumption of cow's milk increases and reaches its peak in the age range 30-35 months.

Table 9 – Consumption rates of breast milk, formula products and cow's milk as a percentage of the sample (source: NutriBébé survey 2013)

Food	Rate of consumption (at different ages)			
	12-17 months	18-23 months	24-29 months	30-35 months
Breast milk (%)	6	9	2	0
Infant Formula (%)	0	0	0	0
Follow-on formula (%)	2	4	0	0
Young child formula (%)	53	47	31	24
Cow's milk (%)	33	35	64	73

Table 10 below summarizes the outcome of the 2013 survey with respect to intakes of formula products and cow's milk in young children, taking into account different age ranges. As it appears, intakes of formula products decrease with age, while intakes of cows' milk increase (taking the largest part at 24 months).

Table 10 – Intakes of formula products and cow's milk (grams) (source: NutriBébé survey 2013)

Food	Intakes (at different ages)			
	12-17 months	18-23 months	24-29 months	30-35 months
Infant Formula (g)	4.2	2.5	0	0
Follow-on formula (g)	23.3	20.5	2.6	0
Young child formula (g)	233.3	221.9	119.4	68.0
Cow's milk (g)	164.6	152.4	213.0	209.8

⁹¹ Detailed analysis of the results of the NutriBébé survey are starting to be published (see in particular Tavoularis G, 2015, *Enquête Nutri-Bébé 2013 Partie 1. Présentation et considérations méthodologiques*, Archives de Pédiatrie, 22 (10), Supplement 1, 10S1–10S6 and Bocquet A, Vidailhet M, 2015, *Enquête Nutri-Bébé 2013 Partie 2. Comment les mères nourrissent-elles leur enfant?* Archives de Pédiatrie, 22 (10), Supplement 1, 10S7–10S19). Data covered in this Chapter have been taken from the publications above and integrated by: SFAE, 2014, "Que révèle l'enquête NutriBébé 2013?", le Pédiatre, 262, XLX; the press package accessible on the website of SFAE at: <http://www.secteurfrancaisdesalimentsdelenfance.com/comment-sont-nourris-nos-bebes-en-2013/>; the replies from France and SFAE to the questionnaire on young-child formulae (2014) and additional data that SFAE shared with the Commission on the results of the NutriBébé survey.

Other data from the survey show that the percentage of mothers giving young-child formulae to their children is higher among mothers who are still breastfeeding or used to breastfeed (32%) than among mothers who did not breastfeed (25%). On the contrary, consumption of cow's milk is higher among non-breastfeeding mothers (48%) than among mothers who breastfed their babies at some point (31%). The preferred type of cow's milk is semi-skimmed milk (88% of caregivers in 2013) which is by far more consumed than whole cow's milk (12% in 2013). 76% of caregivers have a preference for normal cow's milk while 21% are interested in milk fortified with different vitamins (main one being vitamin D).

Table 11 below summarizes the outcome of the previous survey, carried out for SFAE in 2005 on 713 infants and young children⁹². As it appears, similar trends were already present, in particular with respect to the decrease in rates of consumption of young-child formulae and increase in consumption of cow's milk. Full comparability between the studies of 2005 and 2013 cannot however be ensured because of the minor differences in the age range, and the fact that the 2005 survey was carried out on non-breastfeeding mothers only, so that no data exist on intakes of breast milk.

Table 11 – Consumption rates of formula products and cow's milk as a percentage of the sample (source: NutriBébé survey 2005)

Food	Rate of consumption (at different ages)			
	13-18 months	19-24 months	25-30 months	30-36 months
Infant Formula (%)	0	0	0	0
Follow-on formula (%)	9	0	0	0
Young child formula (%)	52	27	26	8
Cow's milk (%)	34	69	73	87

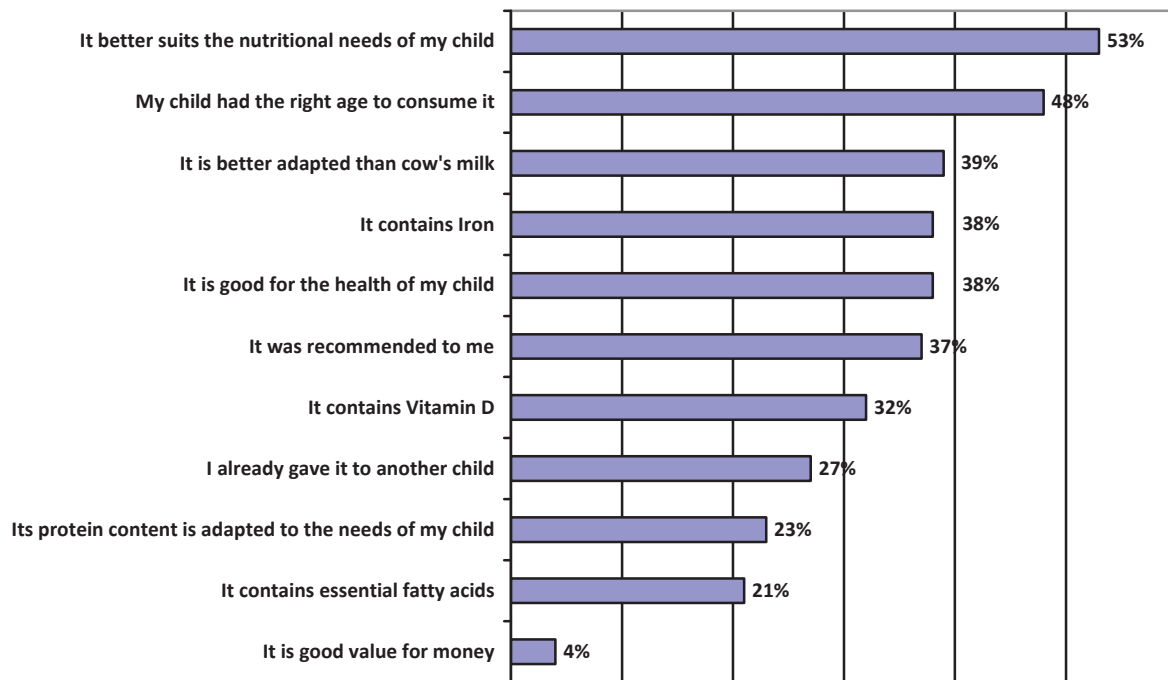
In brief, data from France confirm trends identified in Germany and the UK, whereby breastfeeding is low after one year. Young-child formulae consumption is at its peak in the period 12-18 months and decreases afterwards, replaced by consumption of cow's milk. These trends have been stable in the last 8 years.

4.3.2. Parents' and other caregivers' perception of young-child formulae

The survey carried out for SFAE in 2013 also provides useful information on the perception of caregivers with respect to young-child formulae. Figure 10 below summarises the main reasons given by respondents to the question "why are you passing on to young-child formula?".

⁹² Turberg-Romain C, Lelievre B, Le Heuzey M-F, 2007, *Evolution of feeding behaviours in mothers of infants and young children from 1 to 36 months old in France*, Archives de Pédiatrie, 14(10), 1250–1258.

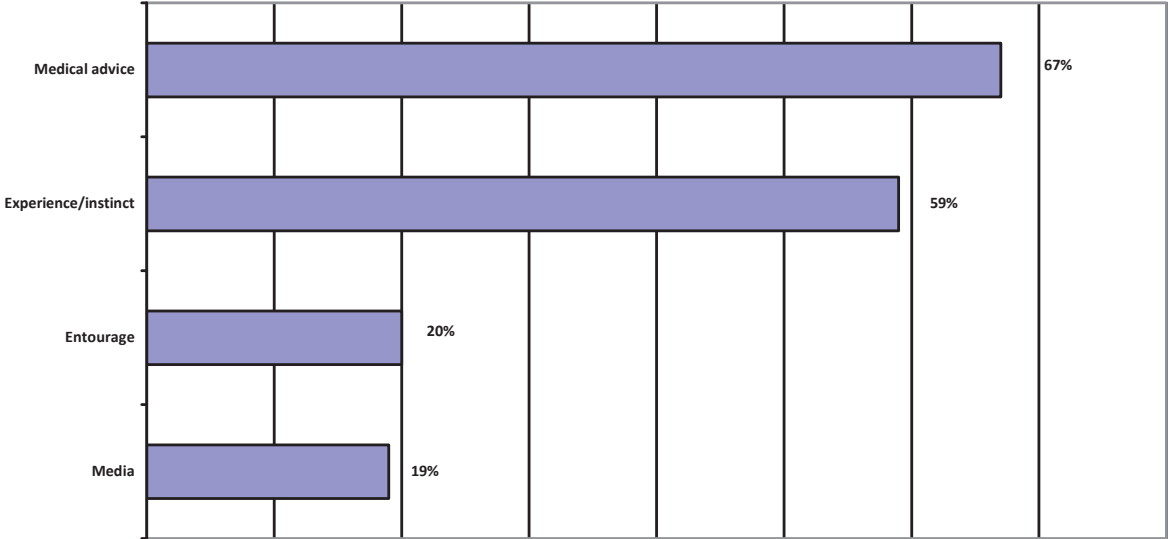
Figure 10 – Answers given to the question "why are you passing on to young-child formula?" (as a percentage of the sample (multiple answers were possible)) (source: NutriBébé survey)



As it appears, the most frequent answers relate to the better suitability of young-child formulae to the nutritional needs of young children, to the fact that the young child had the right age to consume the product, to the superiority of the product when compared to cow's milk, to its iron content, to its positive impact on the health of young children and to the fact that the product was recommended by someone. Only 4% of respondents found the product to be good value for money.

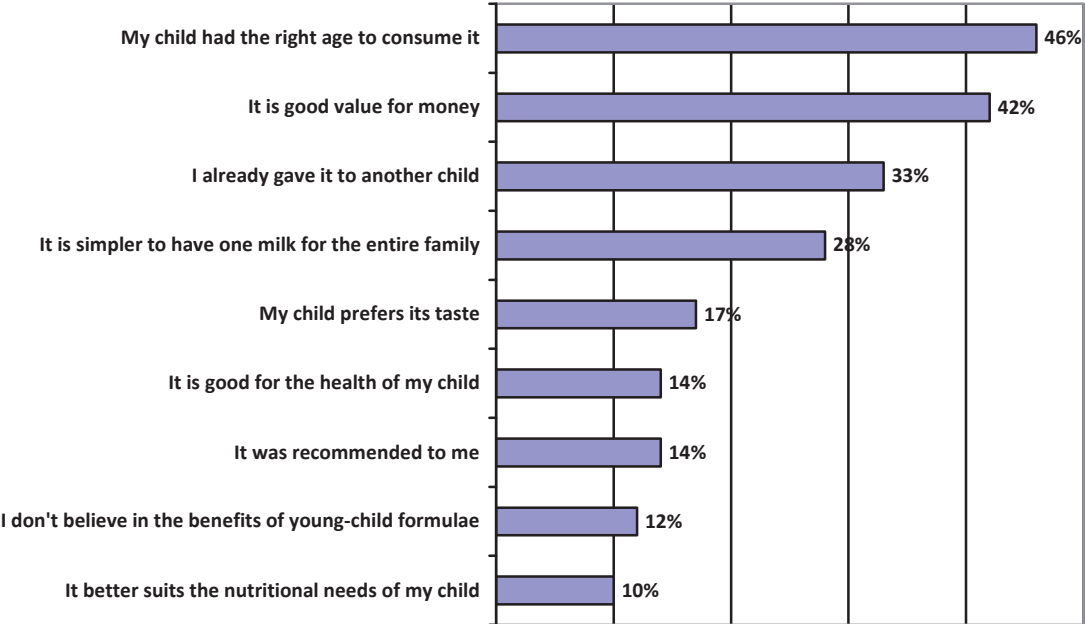
As in the case of the UK and Germany, it appears that parents and caregivers absorb information they receive from different sources about young-child formulae. Figure 11 below summarises the most frequent answers given by respondents to the question "what influenced your decision to give young-child formulae?". In the case of France, medical advice is reported as the strongest factor influencing the decision, followed by experience, entourage and media.

Figure 11 – Answers given to the question "what influenced your decision to give young-child formulae?" (as a percentage of the sample (multiple answers were possible)) (source: NutriBébé survey)



By way of comparison figures 12 and 13 below show the reasons given by respondents to the questions "why are you passing on to cow's milk?" and "what influenced your decision to give cow's milk?". The most common answers are focused on the right age of the young child to consume the product, the value for money aspect, experience, and practical implications. Only 12% reported that their decision to pass on to cow's milk was linked to distrust in the benefits of young-child formulae.

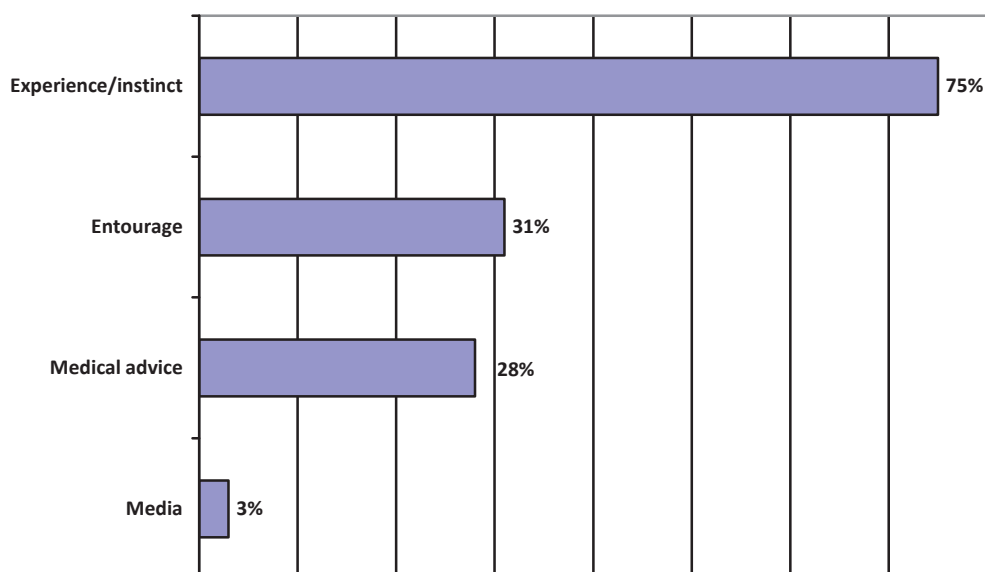
Figure 12 – Answers given to the question "why are you passing on to cow's milk?" (as a percentage of the sample (multiple answers were possible)) (source: NutriBébé survey)



Experience/instinct is cited as the most common influencing factor (the influence of experience appears higher in the decision to give cow's milk than to give young-child formulae, 75% vs. 59%). Medical advice is mentioned only by 28% of respondents (while

67% of respondents mentioned medical advice as an influencing factor for the decision to use young-child formulae).

Figure 13 – Answers given to the question "what influenced your decision to give cow's milk?" (as a percentage of the sample (multiple answers were possible)) (source: NutriBébé survey)



4.3.3. Recommendations of health care professionals and national authorities

The medical community in France, and more specifically paediatricians, support the consumption of young-child formulae for the period 12-36 months. Different articles have been written on the subject by paediatricians, and the consumption of young-child formulae is recommended at amounts of 500 ml per day (it is recommended not to exceed the total daily amount of 800 ml/day of all milk products in order to avoid excess protein intake)⁹³. It is argued that the daily consumption of cow's milk after one year risks contributing to inadequate intakes of a number of nutrients in young children. Consumption of young-child formulae contributes to avoiding the risk of inadequate intakes for all these nutrients (with the exception of vitamin D) without any risk for excess intakes (if recommended consumption is followed)⁹⁴.

The paediatricians' recommendations on consumption of young-child formulae are in line with those of the Programme National Nutrition Santé (PNNS), a public health plan launched in 2001 with the aim to improve health through nutrition⁹⁵. The PNNS proposes a series of nutrition recommendations based on scientific advice, with the aim to help the population and the professionals understand the information received on nutrition.

⁹³ Bocquet A, Bresson JL, Briend A, Chouraqui JP, Darmaun D, Dupont C, Frelut ML, Ghisolfi J, Goulet O, Putet G, Rieu D, Turck D, Vidailhet M, Merlin JP, Rives JJ, 2003, *Alimentation du nourrisson et de l'enfant en bas âge - Réalisation pratique*, Archives de pédiatrie, 10(1), 76-81.

⁹⁴ Comité de nutrition de la Société française de pédiatrie (Ghisolfi J, Vidailhet M, Fantino M, Bocquet A, Bresson JL, Briend A, Chouraqui JP, Darmaun D, Dupont C, Frelut ML, Girardet JP, Goulet O, Hankard R, Rieu D, Turck D), 2011, *Lait de vache ou lait de croissance : quel lait recommander pour les enfants en bas âge (1-3 ans) ?* Archives de pédiatrie, 18(4), 355-358.

⁹⁵ <http://www.mangerbouger.fr/pnns/>

With respect to young-child formulae, the PNNS recommends⁹⁶ their consumption until three years of age at amounts of 500 ml/day because of their adapted composition to the needs of young children. Alternatively, whole milk should be preferred to skimmed milk. The PNNS' recommendation also recognises the possibility to occasionally substitute formula consumption with dairy products fortified in iron, vitamins and essential fatty acids, and to introduce cheese in the diet.

4.4. Summary for Chapter 4

The data described in sections 4.1. to 4.3. show a series of common trends with respect to different aspects related to the behaviour of consumers of young-child formulae that are confirmed, with some variations, by the information provided by Member States and interested parties in the consultation phase.

As regards consumption data, it can be reported that breastfeeding decreases significantly after the age of one year in the different Member States, both in terms of rates and intakes. Formula products are competing with cows' milk in the diet of young children, and differences in the preference exist depending on the Member State. However, it can generally be reported that consumption of young-child formula is at its highest in the age range 12-18 months. After this period, consumption of formula products decreases with age. At the same time, a corresponding increase in the consumption of cow's milk can be noted.

As regards parents' and other caregivers' perception, it can be reported that in the different Member States, different sources influence parents' and caregivers' decisions on young-child formulae, including manufacturers through labelling and advertising, health care professionals and other persons in their entourage with previous experience (e.g. family, friends). The most common arguments put forward by parents and caregivers to justify preference for young-child formulae are the suitability to the nutritional needs of young children, the superiority to cows' milk, its adapted composition, and the fact that the products correspond to the age of the young children.

As regards recommendations of health care professionals and national authorities, significant differences can be reported among Member States. In certain Member States consumption of young-child formulae is recommended 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) instead of young-child formulae. In certain Member States, while young-child formulae are not recommended, health care professionals suggest the consumption of products with a specific composition, in order to better target the nutritional needs of young children.

⁹⁶ <http://www.mangerbouger.fr/pour-qui-242/enfants/la-phase-de-diversification-6-mois-3-ans/bien-manger-57/la-3eme-etape-de-diversification-apres-1-an.html>

5. EXISTING LEGAL FRAMEWORK APPLICABLE TO YOUNG-CHILD FORMULAE

Young-child formulae are currently not covered by specific legislative measures under EU law. Nevertheless, like all foods, they have to comply with the different provisions of EU law that are relevant for them.

Pursuant to Article 17(1) of Regulation (EC) No 178/2002⁹⁷ (the "General Food Law" Regulation), food business operators have the responsibility to ensure that the food they place on the market complies with the relevant provisions of EU law.

National competent authorities are responsible for the enforcement of EU food law (Article 17(2) of the General Food Law Regulation). In this context, they are competent for the classification of products and for deciding which legislation specific products have to comply with. This can result, in certain cases, in the same product having to comply with different EU legal acts depending on the Member States in which it is placed on the market.

According to the information received from Member States' competent authorities⁹⁸, young-child formulae are currently classified as foodstuffs intended for particular nutritional uses (so-called "dietetic foods") in 17 Member States⁹⁹ and Norway. This legislation, however, has been repealed in 2013 with effect from 20 July 2016 (see Chapter 5.5).

According to the same sources, young-child formulae are classified as foods for normal consumption fortified in certain nutrients pursuant to Regulation (EC) No 1925/2006¹⁰⁰ in 10 Member States¹⁰¹.

This Chapter describes the rules applicable today to young-child formulae when they are classified as dietetic foods and when they are classified as foods for normal consumption fortified in certain nutrients. It then describes some of the other horizontal rules of EU food law young-child formulae have to comply with, regardless of young-child formulae's classification status, and existing rules applicable to these products at national level. It finally summarizes how young-child formulae were considered in the revision of the legislation applicable to dietetic foods that led to the adoption of the FSG Regulation.

5.1. EU rules applicable to young-child formulae when classified as dietetic foods

Directive 2009/39/EC (recast version of older legislation, first adopted in 1977) defines foodstuffs for particular nutritional uses 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). Article 1(3) of the Directive explains that "*a particular nutritional use shall fulfil the particular nutritional requirements: (a) of certain categories of persons whose digestive processes or metabolism are disturbed; or (b) of certain categories of persons who are in a special*

⁹⁷ 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).

⁹⁸ Different national competent authorities (2014).

⁹⁹ Bulgaria, Cyprus, Czech Republic, Croatia, Finland, France, Germany, Hungary, Ireland, Italy, Lithuania, Netherlands, Poland, Portugal, Romania, Slovenia (although the products only recently entered the market) and Sweden.

¹⁰⁰ 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).

¹⁰¹ Austria, Belgium, Estonia, Greece, Latvia, Luxembourg, Malta, Slovakia, Spain, United Kingdom.

physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs; or (c) of infants or young children in good health".

Directive 2009/39/EC does not contain an exhaustive list of product categories that are to be considered dietetic foods. As already explained in the previous paragraph, on the basis of the definition given above, today, 17 Member States + Norway classify young-child formulae as dietetic foods. These products need therefore to comply with the rules of Directive 2009/39/EC.

Directive 2009/39/EC sets a series of general principles and requirements for dietetic foods. By way of example, it foresees that *"the nature or composition of [dietetic foods] shall be such that the products are appropriate for the particular nutritional use intended"* (Article 3(1) of the Directive). It requires dietetic foods to *"comply with any mandatory provisions applicable to foodstuffs for normal consumption, save as regards changes made to them to ensure their conformity with the definitions (...)"* (Article 3(2) of the Directive). It lays down a series of mandatory labelling requirements for these products (Article 9 of the Directive) to make sure that dietetic foods provide the nutrition declaration (Article 9(3)(b)), as well as indication of their particular nutritional characteristics (Article 9(2) and 9(3)(a)). In the case of products intended for infants and young children in good health, that indication shall be replaced by a reference to the purpose for which they are intended. According to Article 2(2)(b) of the Directive, food for normal consumption cannot be labelled, presented or advertised in a way that is likely to give the impression that dietetic foods are involved. Article 10(1) of the Directive then foresees that *"the products shall only be allowed on the retail market in pre-packaged form, and the packaging shall completely cover the products"*.

Article 4 of Directive 2009/39/EC foresees the adoption of specific provisions for a number of categories of dietetic foods listed in Annex to the Directive. With respect to foods for infants or young children in good health, the Annex does not list young-child formulae, but lists infant formulae and follow-on formulae (specifically regulated today by Commission Directive 2006/141/EC) and processed cereal-based foods and baby foods (specifically regulated today by Commission Directive 2006/125/EC).

Young-child formulae clearly do not fall under the scope of these two Commission Directives. Indeed, infant formulae and follow-on formulae are defined as foods intended for particular nutritional use by infants (i.e. children under the age of 12 months) (Article 2 (c) and (d) of Directive 2006/141/EC), unlike young-child formulae, which are foods intended for use by young children (i.e. children aged between one and three years). Directive 2006/125/EC clearly excludes milks intended for young children from its scope (Article 1(3) of Directive 2006/125/EC). Since young-child formulae do not belong to any of the categories of dietetic foods for which specific rules were to be adopted, young-child formulae classified as dietetic food need to comply only with the general requirements of Directive 2009/39/EC.

In accordance with Article 11 of Directive 2009/39/EC, in order to permit efficient official monitoring of dietetic foods which do not belong to one of the groups listed in Annex, manufacturers or importers of dietetic food shall notify the competent authorities of the Member States where the product is placed on the market, by forwarding it a model of the label used for the product. The competent authority is empowered, where necessary, to require the manufacturer or, where appropriate, the importer, to produce the scientific work and the data establishing the product's compliance with Directive 2009/39/EC.

If young-child formulae are classified as dietetic foods they will also have to comply with the rules of Regulation (EC) No 953/2009¹⁰².

5.2. EU rules applicable to young-child formulae when classified as food for normal consumption fortified in certain nutrients

Regulation (EC) No 1925/2006 "harmonises the provisions laid down by law, regulation or administrative action in Member States which relate to the addition of vitamins and minerals and of certain other substances to foods, with the purpose of ensuring the effective functioning of the internal market, whilst providing a high level of consumer protection" (Article 1(1)).

If a Member State does not classify young-child formulae as dietetic foods, it will consider these products as foods for normal consumption, fortified in certain nutrients, and therefore falling under the scope of Regulation (EC) No 1925/2006. In this case, young-child formulae have to comply with the rules of this Regulation¹⁰³.

The Regulation foresees that only vitamins and minerals listed in Annex to the Regulation in the form described therein can be added to foods (Article 3(1)). It lays down general principles for the addition of vitamins and minerals to foods (Article 3(2)), a series of restrictions on the addition of vitamins and minerals (Article 4), rules on purity criteria (Article 5) and specific conditions for the addition of vitamins and minerals (Article 6). Article 6(1), in particular, foresees that "when a vitamin or a mineral is added to foods, the total amount of the vitamin or mineral present, for whatever purpose, in the food as sold shall not exceed maximum amounts". These amounts, to be established by the Commission, are not set yet and this condition is therefore not applicable for the moment. Article 6(6) establishes that "the addition of a vitamin or a mineral to a food shall result in the presence of that vitamin or mineral in the food in at least a significant amount where this is defined according to [Annex XIII of Regulation (EU) No 1169/2011 on the provision of food information to consumers¹⁰⁴](...)". In the case of beverages, significant amounts are to be calculated as 7,5 % of the nutrient reference values for vitamins and minerals (for the adult population) specified in Annex XIII of Regulation (EU) No 1169/2011. These values are to be supplied by 100 ml of the product. Article 6(6) also foresees the possibility for the Commission to adopt "measures determining the minimum amounts, including any lower amounts, by derogation from the significant amounts mentioned above, for specific foods or categories of foods (...)".

Article 7 of the Regulation lays down requirements on the labelling, presentation and advertising of foods to which vitamins and minerals have been added and foresees that such labelling, presentation and advertising:

¹⁰² Commission Regulation (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses (OJ L 269, 14.10.2009, p. 9).

¹⁰³ Regulation (EC) No 1925/2006 applies without prejudice to the provisions concerning "foods for particular nutritional uses and, in the absence of specific provisions, compositional requirements of such products rendered necessary by the particular nutritional requirements of the persons for whom they are intended" (Article 1(3)(a) of Regulation (EC) No 1925/2006).

¹⁰⁴ 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 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).

- a) "(...) shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients (...)" (Article 7(1));
- b) "(...) shall not mislead or deceive the consumer as to the nutritional merit of a food that may result from the addition of these nutrients" (Article 7(2)).

Article 7 of the Regulation also requires mandatory nutrition labelling of products to which vitamins and minerals have been added.

In order to facilitate efficient monitoring of foods to which vitamins and minerals have been added, Article 15 of the Regulation allows Member States (but does not require them) to require the manufacturer or the person placing foods containing such substances on the market in their territory to notify the competent authority of that placing on the market by providing a model of the label used for the product.

5.3. Other horizontal EU rules applicable to young-child formulae

Regardless of whether young-child formulae are classified as dietetic foods pursuant to Directive 2009/39/EC or foods for normal consumption fortified in certain nutrients pursuant to Regulation (EC) No 1925/2006, they need to comply with all the other relevant horizontal rules of EU food law that apply to them.

By way of example, young-child formulae need to comply with the requirements of Regulation (EC) No 178/2002, in particular with Article 14(1) and 14(2) whereby "*1. Food shall not be placed on the market if it is unsafe. 2. Food shall be deemed to be unsafe if it is considered to be: (a) injurious to health; (b) unfit for human consumption.*"

Young-child formulae also need to comply with rules on labelling laid down by Regulation (EU) No 1169/2011 on the provision of food information to consumers. In this context, the labelling of young-child formulae must provide a series of mandatory particulars, must comply with provisions laying down specific conditions for the provision of information on labelling and must respect some general principles (that also apply to the presentation and advertising of young-child formulae). In particular, pursuant to Article 7(1) of Regulation (EU) No 1169/2011, the labelling, presentation and advertising of young-child formulae "*shall not be misleading, particularly:*

- (a) as to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production;*
- (b) by attributing to the food effects or properties which it does not possess;*
- (c) by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients;*
- (d) by suggesting, by means of the appearance, the description or pictorial representations, the presence of a particular food or an ingredient, while in reality a component naturally present or an ingredient normally used in that food has been substituted with a different component or a different ingredient".*

In addition, food information on young-child formulae "*shall be accurate, clear and easy to understand for the consumer*" (Article 7(2) of the Regulation).

Young-child formulae then need to comply with the rules of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. In accordance with this Regulation, nutrition and health claims made in commercial communications, whether in the labelling, presentation

or advertising of young-child formulae, must be based on and substantiated by generally accepted scientific evidence (Article 1(2) and 6(1) of the Regulation). Only permitted claims that are included in lists established at EU level on the basis of EFSA's assessment can be used on young-child formulae, and provided that they comply with the general principles and requirements laid down in the Regulation as well as with the specific conditions existing for them.

By way of example, Article 3 of the Regulation foresees that "*(...) the use of nutrition and health claims shall not:*

- a) be false, ambiguous or misleading;*
- b) give rise to doubt about the safety and/or the nutritional adequacy of other foods;*
- c) encourage or condone excess consumption of a food;*
- d) state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general. (...)*
- e) refer to changes in bodily functions which could give rise to or exploit fear in the consumer, either textually or through pictorial, graphic or symbolic representations".*

Article 4(1) foresees that: "*food or certain categories of food must comply with [nutrient profiles] in order to bear nutrition or health claims (...)*". Nutrient profiles, to be established by the Commission, are not set yet and this condition is therefore not applicable for the moment.

Article 5 of the Regulation foresees that:

- 1. "The use of nutrition and health claims shall only be permitted if the following conditions are fulfilled:*
 - (a) the presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence;*
 - (b) the nutrient or other substance for which the claim is made:*
 - (i) is contained in the final product in a significant quantity as defined in Community legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence; or*
 - (ii) is not present or is present in a reduced quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence;*
 - (c) where applicable, the nutrient or other substance for which the claim is made is in a form that is available to be used by the body;*
 - (d) the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the nutrient or other substance to which the claim relates, as defined in Community legislation or, where such rules do not exist, a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence;*

(...)

2. *The use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim (...)*".

Article 9 of the Regulation lays down specific conditions on comparative nutrition claims:

1. *"(...) a comparison may only be made between foods of the same category, taking into consideration a range of foods of that category. The difference in the quantity of a nutrient and/or the energy value shall be stated and the comparison shall relate to the same quantity of food.*
2. *Comparative nutrition claims shall compare the composition of the food in question with a range of foods of the same category, which do not have a composition which allows them to bear a claim, including foods of other brands"*.

Article 10 of the Regulation lays down specific conditions for health claims. In particular, it is foreseen that:

2. *"(...) Health claims shall only be permitted if the following information is included in the labelling, or if no such labelling exists, in the presentation and advertising:*
 - (a) a statement indicating the importance of a varied and balanced diet and a healthy lifestyle;*
 - (b) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;*
 - (...)*
 - (d) an appropriate warning for products that are likely to present a health risk if consumed to excess.*
3. *Reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim (...)*".

As explained in the guidance on the implementation of the Regulation (EC) No 1924/2006 on claims¹⁰⁵, since young-child formulae are products intended exclusively to young children, health claims on these products should be considered as health claims referring to children's development and health (covered by Article 14(1)(b) of the Regulation). These claims are listed on the EU Register of nutrition and health claims made on foods¹⁰⁶.

¹⁰⁵ Directorate-General for Health and Consumers (SANCO) 2007, *Guidance on the implementation of Regulation N° 1924/2006 on nutrition and health claims made on foods, Conclusions of the Standing Committee on the food chain and animal health*

http://ec.europa.eu/food/safety/docs/labelling_nutrition_claim_reg-2006-124_guidance_en.pdf

¹⁰⁶ <http://ec.europa.eu/nuhclaims/>

Finally, young-child formulae must comply with a number of other rules of EU food law (e.g. rules on food additives¹⁰⁷, flavourings¹⁰⁸, pesticide residues¹⁰⁹, contaminants¹¹⁰, hygiene¹¹¹, novel foods¹¹²).

5.4. National rules applicable to young-child formulae

As of today, only France has adopted specific national rules on the composition of young-child formulae¹¹³. In addition, France has established a working practice for these products based on the advice of the Scientific Committee for Food (SCF) of 1993 on the "*essential composition of infant formulae and follow-on formulae*". In that opinion, the SCF concluded that "*if a formula is to be used by 1-3 year old children it should have the same composition as the follow-on formula made for infants*"¹¹⁴. On that basis, if the young-child formula put on the market in France complies with the requirements of follow-on formula laid down in Directive 2006/141/EC, it only needs to be notified to the French competent authorities. If the composition is different, a dossier must be prepared to show the product's safety and suitability as foreseen by Directive 2009/39/EC¹¹⁵.

In this context it should be noted that several other Member States have established working practices for assessing the composition of young-child formulae on the basis of the labelling reference values laid down in Annex VII of Directive 2006/141/EC for infants and young children¹¹⁶.

¹⁰⁷ 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).

¹⁰⁸ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).

¹⁰⁹ 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).

¹¹⁰ Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 37, 13.2.1993, p. 1).

¹¹¹ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004 p.1); Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p.55).

¹¹² 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).

¹¹³ Arrêté du 30 mars 1978 fixant les dispositions relatives aux aliments lactés diététiques, JO 24-05-1978 p. NC 4070-4075.

¹¹⁴ Scientific Committee for Food, 1993, *Report on the essential requirements for infant formulae and follow-on formulae*, 34th series, 9, http://ec.europa.eu/food/safety/docs/labelling_nutrition-special_groups_food-children-scf_reports_34_en.pdf

¹¹⁵ France (2014).

¹¹⁶ Different national competent authorities (2014).

5.5. Young-child formulae and the FSG Regulation

In 2011, the Commission adopted a proposal for a Regulation of the European Parliament and the Council to revise the legislation applicable to dietetic foods¹¹⁷. The Commission's proposal stemmed from the considerations that more and more food products exist on the market that target specific groups of the population and that the horizontal rules of EU food law adopted in the past 15 years (e.g. Regulation (EC) No 1924/2006 on nutrition and health claims, Regulation (EC) No 1925/2006 on fortified foods) adequately ensure, in most cases, protection of consumers and good functioning of the Internal Market.

The Commission's proposal aimed at simplifying the existing legal framework, at abolishing the obsolete concept of "dietetic food" which had proven not fit for today's market and legal context, at repealing Directive 2009/39/EC and replacing it with a new framework covering foods for certain vulnerable groups of the population (i.e. infants, young children and people with specific diseases/disorders/medical conditions) for which specific rules were needed. In the Commission's view, the new Framework would set general principles and requirements and would be followed by delegated acts to be adopted by the Commission to set specific rules for the products included in the scope of the new Regulation (infant formulae, follow-on formulae, processed cereal-based foods and baby foods for infants and young children and food for special medical purposes). In the Commission's view, food for other population groups would be sufficiently covered by other horizontal rules of EU food law.

The Commission's proposal did not include young-child formulae in its scope. The Impact Assessment that accompanied it¹¹⁸ did not specifically analyse the market of these products.

During the negotiations on the Commission's proposal, the European Parliament adopted amendments requiring the Commission to prepare a report on young-child formulae. According to the European Parliament, a report, based on the advice of EFSA, should assess the need for special provisions for these products. The Council agreed with the European Parliament in its common position and proposed to require the Commission to draft a report on these products within two years from the entry into force of the Regulation. The Council requested the Commission to consider in the report, among others, the nutritional requirements of young children, the role of these products in the diet of young children and whether these products have any nutritional benefits when compared to a normal diet for a child who is being weaned. The Commission agreed with the European Parliament and the Council on the usefulness of a report, especially taking into account that different views exist on whether these products are needed or not to satisfy the nutritional requirements of young children¹¹⁹.

The Commission's proposal was amended and adopted by the European Parliament and the Council on 12 June 2013 with reference (EU) No 609/2013 (the FSG Regulation). Young-child formulae remain out of the scope of the FSG Regulation. However, as explained in the

¹¹⁷ 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.

¹¹⁸ European Commission, 2011, *Staff Working Paper - Impact Assessment accompanying the document "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"*, SEC (2011) 762.

¹¹⁹ European Commission, 2013, *Communication from the Commission to the European Parliament pursuant to Article 294(6) of the Treaty on the Functioning of the European Union concerning the position of the Council at first reading with a view to the adoption of a Regulation 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*, COM (2013) 241, p. 4-5.

introduction of this SWD, Article 12 of the FSG Regulation required the Commission to adopt a report on young-child formulae by 20 July 2015.

The FSG Regulation will enter into application on 20 July 2016 and, on that date, Directive 2009/39/EC will be repealed and the concept of "dietetic food" will disappear. 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 ten Member States.

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

As required by the FSG Regulation, in preparation for its report, the Commission consulted EFSA and asked the Authority to provide advice on the following points with respect to young-child formulae¹²⁰:

- *"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 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'."*

EFSA provided its advice to the Commission in two different opinions:

- *Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union, adopted on 9 October 2013;*
- *Scientific Opinion on the essential composition of infant and follow-on formulae, adopted on 26 June 2014.*

In its first opinion, EFSA first analysed the nutritional requirements of infants and young children in the EU by identifying the levels of nutrients considered adequate to cover the needs of the majority of healthy, term, normal weight infants and young children. It then compared these levels to data on intakes as well as to data on nutrient status for infants and young children, in order to identify critical nutrients in the diet of infants and young children for which there are risks of insufficient intakes in the EU. EFSA analysed different ways of tackling intakes of these critical nutrients and, in that context, analysed the role of young-child formula in the diet of young children.

Below are identified the most important aspects of EFSA's opinion of 2013:

- *"Based on the information available, the Panel considers that dietary intakes of LA [linoleic acid], calcium, phosphorus, magnesium, copper, selenium, chromium,*

¹²⁰ European Commission, 2013, *Request for a scientific opinion on milk based drinks and similar products intended for infants and young children*, Ares (2013) 238583. In preparation for the adoption of delegated Regulation (EU) 2016/127 laying down specific rules for infant formulae and follow-on formulae pursuant to Article 11(1) of the FSG Regulation, EFSA was also asked to provide advice on the essential composition requirements of infant formulae and follow-on formulae, by updating the relevant opinions of the Scientific Committee for Food on the matter.

molybdenum, manganese, fluoride, vitamin A, vitamin E, vitamin K, thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, biotin, folate, cobalamin, vitamin C and choline in infants and young children living in Europe do not give rise to concern over the risk of inadequate intakes".

- *"Intakes of energy, protein, salt and potassium of infants and young children living in Europe are generally high and intakes of dietary fibre low. Intakes of protein, salt and potassium do not reach levels which are of concern. The Panel notes that energy intakes above requirements may lead to an unfavourable gain in body mass".*
- *"Intakes of n-3 PUFAs [omega-3 polyunsaturated fatty acids], iron, vitamin D and iodine in some infants and young children living in Europe are critical and (...) some sub-groups in this population may be at risk of inadequacy".*
- *"In the first year of life, formulae (infant and follow-on formulae) provide caregivers with a safe alternative to breast milk when breast milk is not available to the infant, and in replacement of cow's milk, the consumption of which in large amounts in the first year of life is generally discouraged in infant feeding recommendations and FBDG [food based dietary guidelines] of European countries".*
- *"After the first year of life, FBDG generally advise the use of cow's milk in moderate quantities (around 300 to 500 mL per day) as an important source of nutrients for young children".*
- *"When formulae are consumed after the first year of life, they continue to replace cow's milk in whole or in part in the diet of young children which contains little or no ALA, DHA and iron and small amounts of vitamin D (...). However, at this age cow's milk consumption is no longer discouraged and no recommendations for replacement of this food category by other alternatives exist from medical societies at European level".*
- *"Formulae, including young-child formulae, are one of the means to increase n-3 PUFA, iron and vitamin D intakes in infants and young children living in Europe with inadequate or at risk of inadequate status of these nutrients. 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".*
- *"In comparison with cow's milk, currently marketed young-child formulae contain more ALA, DHA (if added), iron and vitamin D but similar amounts of iodine. The median content of these nutrients in young-child formulae is within the range of permitted concentrations in follow-on formulae and, except for iron, also in infant formulae".*
- *"Therefore, 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 the normal diet of young children (such as breast milk, infant formulae, follow-on formulae and cow's milk)."¹²¹*

¹²¹ EFSA (2013) [format and order modified for the purposes of the document].

In its second opinion, after having proposed compositional requirements for infant formulae and follow-on formulae, EFSA covered the remaining question asked by the Commission, namely whether EFSA considered it appropriate to advise the Commission with respect to the appropriate age range and the essential composition of young-child formulae.

After having recalled its conclusions from the first opinion, EFSA noted that "*formulae consumed during the first year of life can continue to be used by young children. Therefore, the Panel does not consider it necessary to propose specific compositional criteria for formulae consumed after one year of age*".¹²²

EFSA's second opinion was released as a draft for public consultation. The final opinion took into account the comments received and a technical report¹²³ was published together with the opinion, in which EFSA commented on the different comments received (that were also published).

¹²² EFSA (2014).

¹²³ EFSA, 2014, *Outcome of a public consultation on the draft Scientific Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on the essential composition of infant and follow-on formulae*, EFSA supporting publication 2014:EN-633.

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

Member States' experts and interested parties shared with the Commission services their views on young-child formulae. Below is provided an overall summary of the different positions¹²⁴.

The majority of Member States' experts expressed support (although to different extents) for additional action at EU level¹²⁵. In this context, they often referred to: the increased level of consumer protection that this approach would ensure for vulnerable consumers (both with respect to composition and marketing of young-child formulae), the increased legal certainty on the status of and rules applicable to the products, and the elimination of the risk of Member States adopting legislation at national level to regulate young-child formulae.

Other Member States' experts expressed the different view that young-child formulae are not necessary for young children, as highlighted by EFSA, and raised the concern that additional action would enhance their status, make their consumption increase and, ultimately, possibly mislead consumers. These national authorities also referred to the experience in the Member States that currently consider young-child formulae as fortified foods. This experience shows, in their view, that horizontal rules of EU food law are sufficient to efficiently regulate these products.

BEUC (the European Consumer Organisation) argued that legislative action would allow regulating the composition of young-child formulae to make it suitable for young children and restricting marketing practices used for these products. NGOs (IBFAN, the International Baby Food Action Network, and BFLG, the Baby Feeding Law Group) acknowledged that this approach could theoretically allow to establish an appropriate regulatory framework for young-child formulae and an adequate level of consumer protection. They, however, warned that a full evaluation can only be carried out if the specific provisions that would apply to young-child formulae are known (in their view, such specific provisions have, for example, a key role to ensure that consumers are informed that the products are not necessary).

Young-child formulae manufacturers (SNE) called for additional action and argued that legislative action to have young-child formulae covered by the rules on follow-on formulae could have a positive effect on consumer protection and on ensuring fair competition between operators. In their view, this approach would also guarantee legal clarity, free circulation of goods (as it would avoid adoption of rules at national level), innovation and competitiveness of the specific sector. This approach was also supported by the associations representing ingredients' manufacturers (ELC, the Federation of European Specialty Food Ingredients Industries) and the dairy industry (EDA, the European Dairy Association, who underlined that specific rules on young-child formulae should ensure that dairy terms are protected and milk is not denigrated by comparisons with the composition of young-child formulae).

¹²⁴ This paragraph is based on the discussions in the different meetings of the Expert Group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control (minutes available on DG SANTE website) and on all the documents submitted to DG SANTE on the matter during the consultation phase and afterwards.

¹²⁵ To include young-child formulae in the concept of follow-on formula and make them comply with some requirements applicable to follow-on formula.

ENSA (the association representing natural soy products manufacturers), stated that horizontal rules of EU food law are sufficient to regulate young-child formulae and expressed concerns that legislative action to have young-child formulae covered by the rules on follow-on formulae would force manufacturers of soy-based young-child formulae to reformulate their products.

ANNEX I

LIST OF INTERESTED PARTIES

The interested parties listed below provided comments in writing to the Commission services on young-child formulae or participated to the meeting of the Working Group of the Advisory Group on the Food Chain and Animal and Plant Health of 19 September 2014 on the subject

Acronym	Full name
AESGP	Association of the European Self-Medication Industry
BEUC	The European Consumer Organisation
BFLG	Baby Feeding Law Group (in particular Baby Milk Action and First Steps Nutrition Trust)
CELCAA	Comité Européen de liaison des commerces agroalimentaires
EDA	European Dairy Association
EHPM	European Federation of Associations of Health Product Manufacturers
ELC	Federation of European Specialty Food Ingredients Industries
ENSA	European Natural Soyfoods Manufacturers Association
IBFAN	International Baby Food Action Network
PAN Europe	Pesticide Action Network Europe
SFAE	Secteur Français des Aliments de l'Enfance
SNE	Specialised Nutrition Europe

ANNEX II

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