

COMMISSION STAFF WORKING DOCUMENT

on FSMPs for infants

[Supporting Document for the Expert Group meeting of 7 February 2014]

Introduction

During the Expert Group meeting of 15 November 2013, discussions took place with Member States' experts on the provision of Art. 11(1)(g) of the FSG Regulation which requires that specific rules are set for FSMPs for infants in addition to compositional requirements, on pesticides, labelling, presentation, advertising, and promotional and commercial practices, as appropriate.

In that occasion, the Commission and the Expert Group agreed that a collection exercise of data on products notified as FSMPs for infants in different Member States would help in the reflection concerning the establishment of rules for these products.

Member States' experts were asked by the Commission to provide information on the products notified as FSMPs for infants in their territory, on the category of FSMPs the products belong to, on the product composition, on the age range that the products target, on their intended function, and finally on any other 'claim-like' statement used on the products (on functions other than the one for which the products are intended).

This document provides an analysis of the data submitted by Member States and raises a number of questions deriving from this data.

A. Results of the data collection exercise

Twenty Member States and Norway replied to the request of information. While the lists of products submitted by Member States were in most cases not exhaustive, still they were representative enough of the market of these products to contribute to the debate.

Below some key aspects of the market of FSMPs for infants in the EU are summarized on the basis of the data communicated by Member States.

FSMPs category: both nutritionally complete (with a standard or adapted nutrient formulation) and incomplete FSMPs for infants are present on the EU market.

Age range: FSMPs for infants target different age ranges. However, a simple distinction can be made between FSMPs for infants that can be consumed from birth and FSMPs for infants that can be consumed from later on in the life of the infant.

- In the first category, different age ranges exist. These are for example from birth onwards (no upper age limit defined), 0-6 months, 0-12 months, 0-36 months.
- Also in the second category different age ranges exist and products are mostly destined to infants older than 6 months. Ranges includes from 6 months onwards (no upper age limit defined), 6-12 months or higher. It is often the case that one product targets a very broad age range (e.g. from 6 months to 10 years) , and different amounts are recommended for consumption depending on the age (e.g. for the dietary management of renal failure or of maple syrup urine disease).

Intended function: Pursuant to Article (2)(2)(g) of the FSG Regulation food for special medical purposes means "*food specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or distributed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone*".

Given the abovementioned definition, FSMPs for infants should be intended for the dietary management of a number of diseases, disorders or medical conditions. From the data submitted, it appears that common diseases/disorders/conditions are allergies and intolerances, disturbance in amino acid or fatty acid metabolism, digestive disorders such as diarrhoea, constipation, intestinal gas, colics, dyspepsia, and regurgitation. Other common diseases/disorders/conditions for which FSMPs for infants are manufactured are the following: fat malabsorption, malnutrition, cystic fibrosis, epilepsy, galactosaemia, liver failure, and kidney failure.¹ In addition there are FSMPs for infants intended for the dietary management of infants born prematurely.

When analysing the notified FSMPs for infants on the basis of their intended functions, three broad categories could be considered:

1. An important number of FSMPs for infants are more likely than others to comply with the definition of food for special medical purposes given in Directive 1999/21/EC and in the FSG Regulation. Examples include products intended for the dietary management of impaired amino acid or fatty acid metabolism (e.g. diseases like PKU, Maple Syrup Urine Disease and acyl dehydrogenase deficiency).
2. Many notified products raise doubts with respect to their classification. The most eloquent examples are in the nutritionally incomplete category (e.g. products intended for the dietary management of vitamin D or vitamin K deficiency in infants).
3. An important part of the market of FSMPs for infants is composed of products that, depending on a case-by-case analysis, could comply or not with the definition of

¹ In addition, certain FSMPs for infants appear to be intended for the dietary management of different conditions at the same time (e.g. products intended for the dietary management of one or more digestive problem and/or related condition such as diarrhoea, constipation, regurgitation, colics, intestinal gas, allergies, intolerances, and dehydration).

FSMPs for infants. This category includes for example formulae for infants with cow's milk allergy or colics, formulae for premature infants or anti-regurgitation.

Claims: An important part of the FSMPs for infants covered by Member States' submissions bears nutrition or health claims not directly linked to the specific intended function of the product. The substances most often subject of these claims are vitamins and minerals, omega-3 fatty acids, so-called 'prebiotics' and 'probiotics'. Some claims are also reported on substances like nucleotides, or taurine. Very often the claim refers to the presence of the substance subject of the claim in breastmilk.

Statement on the superiority of breastfeeding: it has been reported by several Member States that FSMPs for infants on their market (either on the own initiative of operators, or upon request of the national competent authorities) bear statements on the superiority of breastfeeding.

B. Elements for discussion

Misclassification of FSMPs

The data submitted by Member States confirm that there is, at least in certain cases, a problem of misclassification of FSMPs for infants. These examples should be kept in mind in the context of future discussions on a possible guidance by the Commission on FSMPs.

On other hand, it should be underlined that a certain degree of judgment is intrinsic to the concept of food for special medical purposes and cases of divergent judgments on the status of a product in different Member States cannot be excluded.

Technical adaptation of the legislation on infant formulae and follow-on formulae

One important category of FSMPs for infants is composed of "anti-regurgitation" formulae. According to some stakeholders, the products are marketed as FSMPs because the thickeners used in these products (e.g. locust bean gum) are not allowed in infant formulae.

Another category of FSMPs for infants is composed of not-soy-protein-based formula for lactose intolerant infants. According to some stakeholders, even in this case the products are marketed as FSMPs because only infant formula and follow-on formula manufactured from soya protein can be lactose free and inform consumers about it.

➔ A discussion with experts is necessary on whether these technical issues should be addressed (both in the context of the relevant delegated act on infant formulae and follow-on formulae and of other legislation such as the one on food additives). If these issues were solved, an argument justifying the classification of the relevant products as FSMPs for infants would be eliminated.

Nutrition and health claims

Irrespective of the outcome of the broader discussion on nutrition and health claims in FSMPs, it appears obvious that further consideration is needed on what claims should be allowed in FSMPs for infants.

When analysing the data reported by Member States, the most striking fact is that many of the claims used in FSMPs for infants are neither authorised by the legislation on claims (e.g.

DHA and brain development was not included in the list of permitted claims because of the impossibility to set appropriate conditions of use) nor by Directive 2006/141/EC on infant formulae and follow-on formulae (e.g. taurine and brain development, nucleotides and immune system are not claims included in Annex IV of the Directive). Therefore these claims should already not be used under the current rules. In this context the future adoption of specific rules for FSMPs for infants would not be an answer to these problems.

Clearly one of the justifications for this situation has to be found in the difficulty reported by some Member States' experts in distinguishing between what is a nutrition or health claim covered by Regulation (EC) No 1924/2006 and what amounts to the mandatory statement currently required by Article 4(4)(c) of Directive 1999/21/EC on "*a description of the properties and/or characteristics that make the product useful (...)*".

→ As discussed in the other Working Document prepared for the meeting of 7 February, the delegated act on FSMPs could clarify that the abovementioned mandatory statement for FSMPs can only relate to those properties and characteristics that make the product useful in relation to the diseases, disorders or medical conditions for the dietary management of which the product is intended.

In addition, consideration should be given to provisions whereby FSMPs for infants are subject to a regime similar to the one currently foreseen for infant formulae and follow-on formulae. In other words, FSMPs intended for infants from birth would be subject to stricter rules and would be allowed to bear only the list of nutrition and health claims allowed for infant formulae (list currently under review). FSMPs intended for infants not from birth would be subject to rules allowing them to make claims as it is the case for follow-on formulae.

Statement on the importance of breastfeeding

Discussions took place in the past on whether the legislation should require FSMPs for infants to bear statements on the importance of breastfeeding. While certain Member States expressed their support to rules foreseeing such statements, it was also highlighted that the presence of such statements on the label of products recommended by doctors in cases where breastfeeding is not advisable would not be appropriate (in such cases this information would be contradicting the medical advice).

Data reported by Member States now shows that this practice is already being followed in certain cases by operators.

At this stage, further reflection is necessary on what would be the advantages and the disadvantages of having such a provision in the legislation.

Other provisions

Reflection on other provisions that could be foreseen in the delegated act for FSMPs for infants, and in particular on what provisions applicable to infant formulae and follow-on formulae should be extended, is currently on-going. While some of these do not seem problematic (e.g. provisions restricting the use of pictures of infants, or pictures or text which may idealise the use of the product; provisions restricting promotional practices to induce sales directly to the consumer at the retail level), more detailed discussion is needed on the issue of samples via the health care system and communication to health care professionals.