EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Expert Group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control

Summary report

Brussels, 12 June 2017

Chair: Mr Francesco Carlucci

1. Exchange of views on the draft guidelines on the classification of food for special medical purposes

Introduction

The Commission (COM) welcomed the experts by recalling the context and the objective of the meeting: food for special medical purposes (FSMP) is regulated in the EU under Regulation (EU) No 609/2013 of the European Parliament and the Council on food for specific groups. Over the past years, Member States' national competent authorities have reported increasing difficulties with the enforcement of the legislative framework applicable to FSMP. Member States' experts have in particular flagged that an increasing number of products are notified as FSMP in their territory, but that doubts often arise on whether these products really correspond to the definition of FSMP and therefore correctly fall within the scope of the FSMP legislation. The misclassification of FSMP can result in differences in the enforcement of EU law from one Member State to another and may negatively affect the protection of consumers' interest, the free circulation of goods in the EU and fair competition among food business operators.

In light of the above, the Commission services (DG SANTE) are currently preparing guidelines on the classification of FSMP to assist both national competent authorities in their enforcement tasks and stakeholders in marketing their products under the appropriate legal framework (subject to the consideration that only the Court of Justice of the European Union is entitled to interpret Union law with final binding authority).

The objective of the meeting is to exchange views on a revised draft version of the guidelines (Working Document circulated prior to the meeting) that builds upon and takes account of previous consultations carried out with Member States and stakeholders.

The COM reminded Member States' experts that the Working Document was prepared by SANTE services and has not been adopted or endorsed by the European Commission. It cannot therefore be regarded as stating an official position of the Commission and does not prejudge the Commission's final decision on the matter.

Discussion on the Working Document

The Working Document was generally welcomed by the experts. The discussion was structured so as to follow the order of the different sections of the document, highlighting the substantial changes made to the previous versions. For each section, after a general presentation by the COM, the floor was opened for Member States to provide comments.

An account of the discussion is provided below.

Section 1
No comments were made on this section of the Working Document, which described the different provisions of EU law that are relevant for FSMP, as laid down in Regulation (EU) No 609/2013 of the European Parliament and the Council on food for specific groups and Commission Delegated Regulation (EU) 2016/128 supplementing Regulation (EU) No 609/2013 as regards the specific compositional and information requirements for food for special medical purposes.

Section 2
No comments were made on this section of the Working Document, which described the rights and responsibilities of food business operators, national competent authorities and the European Commission with respect to the classification of products (and their placing on the market) as FSMP.

Section 3
No comments were made on this section of the Working Document, which included considerations on the relevance of the mutual recognition principle for the classification of products as FSMP.

Section 4
This section of the Working Document included considerations on the relation between a novel food authorisation concerning the use of a specific substance in FSMP and the classification of products containing that substance as FSMP.

The Expert Group agreed with the content of the section. Two delegations made comments related to the authorisation process under the novel food Regulation and the implications this might have on the FSMP market. The COM took note of the comments but recalled that novel food authorisations are granted provided that the substances comply with the requirements of the novel food legislation, something which is out of the scope of the FSMP guidelines.

Section 5
This section of the Working Document focused on the different aspects of the definition of FSMP laid down in Article 2(2)(g) of Regulation (EU) No 609/2013: "*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 disturbed 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*".

Some Member States asked to redraft certain parts of the section in order to increase clarity (e.g. to better explain the concepts of "use under medical supervision" and "medically-determined nutrient requirements", to change/add new examples of what is/is not an FSMP). The COM took note of the different requests and committed to look into whether further changes can be introduced to accommodate them. It however noted that, as far as examples are concerned, the guidelines should refer to cases on which all Member States agree, as the classification of FSMP remains a competence of national authorities.

Section 6
No comments were made on this section of the Working Document, which included considerations on the composition of FSMP and its classification in categories.

Section 7
This section of the Working Document included considerations on the data that might be needed to demonstrate that a product is correctly placed on the market as FSMP.

One Member State asked the COM to provide further info on this aspect, especially in relation to Article 9 of Delegated Regulation (EU) 2016/128 which states " *When food for special medical purposes is placed on the market, the food business operator shall notify the competent authority of each Member State where the product concerned is being marketed of the information appearing on the label, by sending to it a model of the label used for the product, and of any other information the competent authority may reasonably request to establish compliance with this Regulation, unless a Member State exempts the food business operator from that obligation under a national system that guarantees an efficient official monitoring of the product concerned*".

The COM explained that the matter remains under the discretion of national competent authorities, which are competent for the application of EU law on a product-specific basis. It however brought the experts' attention to EFSA's scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013 (http://www.efsa.europa.eu/en/efsajournal/pub/4300). This document, also quoted in the Working Document, can provide useful information on the kind of data that might be relevant for deciding whether a product falls within the definition of FSMP or not.

2. AOB

Following the request of Slovenia and Croatia, Member States' experts exchanged views on the classification of formulae marketed as suitable for premature infants or for infants with particular conditions (e.g. constipation). The Member States that intervened explained that they currently classify these products as FSMP, but that they will look into future similar notifications on a case-by-case basis in light of the advice provided in the Commission's guidelines. The COM recalled that Member States, in their role of enforcers of EU law, remain responsible for the classification of products and that in the framework of Regulation (EU) No 609/2013 these formulae can only be placed on the market as infant formula/follow-on formula for healthy infants, or as FSMP for infants suffering from a disease/disorder/condition. In both cases, the products must comply with the relevant definitions and requirements of the legislation. As to the formulae that are intended for use by premature infants, the COM invited the experts to examine recital 29 of Regulation (EU) No 609/2013.

Following the request of Belgium, Member States' experts exchanged views on whether food supplements for infants and young children (e.g. vitamin D drops) can fall under the definition of baby foods, provided in Article 2(2)(f) of Regulation (EU) No 609/2013. All the Member States that intervened agreed that this type of products cannot be classified as baby foods: the majority of the intervening experts noted that the products are indeed classified as food supplements for infants and young children in their territory, while others noted that the products are classified as medicinal products. The COM reiterated that Member States remain responsible for the classification of products in their role of enforcers of EU law.

Following the request of the Netherlands, which asked for an update on young-child formulae, the Commission recalled that these products are out of the scope of Regulation (EU) No 609/2013. This Expert Group is therefore not the appropriate platform for discussions on the subject.

Following another request of the Netherlands, Member States' experts exchanged views on tolerances for nutrient values declared on labels. The Member States that intervened asked the Commission to carry out work to develop a guidance document on tolerances for food for specific groups, as these products were excluded from the scope of the existing Commission's guidelines on tolerances (adopted in 2012). The COM took note of the request but explained that work must be prioritised taking into account the urgency of the different actions and the Commission's limited resources. It asked Member States' experts to confirm in writing what future work they consider as a priority.

3. Commission updates on relevant EFSA's work

The COM informed the Expert Group of two Scientific Opinions recently adopted by EFSA on foods covered by Regulation (EU) No 609/2013:

- the Scientific Opinion on the safety and suitability for use by infants of follow-on formulae with a protein content of at least 1.6 g/100 kcal (http://www.efsa.europa.eu/en/efsajournal/pub/4781) and
- the Scientific and Technical Guidance for the preparation and presentation of an application for authorisation of an infant and/or follow-on formula manufactured from protein hydrolysates (http://www.efsa.europa.eu/en/efsajournal/pub/4779).

The COM also informed the Expert Group that EFSA has recently started work on a Scientific Opinion on the Tolerable Upper Intake Level of vitamin D for infants. The scientific opinion is due to be provided by the end of June 2018.