Working Group of the
Advisory Group on the Food Chain and Animal and Plant Health
on the

GUIDELINES ON THE CLASSIFICATION OF FOOD FOR SPECIAL MEDICAL PURPOSES

12 April 2017

Summary Record

Participants

Members of the Advisory Group
AESGP - Association of the European Self-Medication Industry
EDA - European Dairy Association
EHPM - European Federation of Associations of Health Products Manufacturers

Non-Members of the Advisory Group
Baby Milk Action / IBFAN (International Baby Food Action Network) UK
EU specialty food ingredients - Federation of European Specialty Food Ingredients Industries
Food Supplements Europe
MNI - Medical Nutrition Industry
SNE - Specialised Nutrition Europe
VLCD Industry Group - Very Low Calorie Diet Industry Group

European Commission, DG SANTE
Jacques Humières, Francesco Carlucci (Unit E1)

Introduction

The Commission representatives (COM) welcomed the participants by describing 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 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 obtain stakeholders' feedback on a Working Document containing a draft version of the guidelines (circulated prior to the meeting) that builds upon previous consultations carried out with Member States and was also submitted to Member States' experts for comments.

The COM explained that the Working Document was prepared by the Commission 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 all participants. The discussion was structured so as to follow the order of the different sections of the document. For each section, after a general presentation by the COM, the floor was opened for stakeholders to provide comments.

An account of the most important points discussed is provided below.

Section 1
This section of the Working Document described the different provisions of EU law which 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.

SNE and MNI asked that the guidelines clearly explain what is the legal regime applicable to FSMP in the transitional period until 22 February 2019 (when delegated Regulation (EU) 2016/128 enters into application, thus repealing and replacing Commission Directive 1999/21/EC on food for special medical purposes) and clarify that food business operators can already comply with the provisions of the delegated Regulation.

The COM noted that the request of SNE and MNI is out of the scope of the guidelines, as these are aimed at providing support to food business operators and national competent authorities on the issue of classification of products as FSMP.

Section 2
This section of the Working Document 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.

SNE and MNI noted that the language used in the guidelines should be as clear as possible for reasons of legal certainty. In this context, it was proposed to avoid the use of the word "claim" when the intention is not to refer to "nutrition and health claims" as defined in Regulation (EC) No 1924/2006 of the European Parliament and the Council. The COM agreed with this remark.

IBFAN asked whether the guidelines will focus on the level of scientific evidence needed to demonstrate compliance of a product with the requirements of the FSMP legislation and on the issue of cross-branding of FSMP for infants with other products for healthy infants (e.g.

infant and follow-on formulae). The COM explained that the application of EU law remains a responsibility of Member States and noted that the issues flagged by IBFAN would be out of the scope of the guidelines.

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
No comments were made on this section of the Working Document, which 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.

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*".

SNE and MNI focused on the point in the definition whereby FSMP is "*specially processed or formulated*" food and noted that the guidelines should clearly explain that FSMP can contain ingredients considered to be of "natural composition".

SNE and MNI also focused on the point in the definition whereby FSMP is intended "*for the dietary management of patients*" and asked that the guidelines provide a more detailed explanation of the concepts of "*limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food*" and "*medically determined nutrient requirements*". SNE and MNI noted that the guidelines should acknowledge that diseases evolve/have different levels of severity and FSMP might be necessary only at certain stages of disease development. They flagged that FSMP plays an important role in ensuring compliance of patients with specific dietary requirements and asked that this is also reflected in the guidelines.

IBFAN focused on the point in the definition whereby FSMP is "*to be used under medical supervision*" and noted that this requirement is not exclusive of FSMP as it also applies to formulae for healthy infants. IBFAN also focused on the concept of "*modification of the normal diet*" and noted that, in most cases, infants suffering from specific diseases/disorder/medical conditions can still be breastfed and this should be taken into account when evaluating whether a product for infants should be classified as FSMP.

Section 6
This section of the Working Document included considerations on the data that might be relevant to demonstrate that a product is correctly classified as FSMP.

Different stakeholders noted that the guidelines should not use the word "prove" (e.g. to prove that a product is correctly placed on the market as FSMP), since, in their view, it is not possible to obtain the level of evidence required to provide "absolute proof" that something is the case. Proposed alternatives included the words "demonstrate" or "establish". The COM took note of these comments.

Section 7
This section of the Working Document provided some examples of types of products for which there is consensus among Member States with respect to their FSMP status.

SNE and MNI noted that there is a wide diversity of FSMP products on the market for many different diseases, disorders and medical conditions and new products will appear in the future, as a consequence of research in product development. For this reason, SNE and MNI stressed that, if examples are to be included in the guidelines, the text should be more illustrative (by including a description of the three FSMP categories listed in Article 2(1) of delegated Regulation (EU) 2016/128 and some examples for each category) while, at the same time, should make it clear that these are only examples and do not constitute an exhaustive list of products to be considered as FSMP.

EU specialty food ingredients agreed with SNE and MNI that the guidelines should specify that the examples provided are only illustrative and do not constitute a closed list of FSMP, in order not to stifle innovation.

IBFAN recalled that the competence and responsibility to verify whether a product placed on the market as FSMP is appropriately classified as such lies with national competent authorities. In this context, IBFAN suggested that the guidelines should only include a limited list of straightforward examples on which all Member States agree, in order to avoid imposing choices on national competent authorities and touching upon Member States' rights with respect to the enforcement of EU law.

The COM noted that examples could be very useful for controlling authorities and food business operators but acknowledged the difficulty of the exercise. It agreed that the guidelines could only include a non-exhaustive list of examples for illustrative purposes, and that in accordance with Article 17(2) of Regulation (EC) No 178/2002 of the European Parliament and the Council on general food law, it is the responsibility of Member States to "*enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food (...) business operators at all stages of production, processing and distribution*".

The COM closed the meeting by inviting participants to provide written comments, if any, by the end of April 2017.