Working Group of the Advisory Group on the Food Chain and Animal and Plant Health on the implementation of Article 11(1) of Regulation (EU) No 609/2013

17 February 2015

Summary Record

Participants:

DG SANTE, European Commission (Basil Mathioudakis, Alexandra Nikolakopoulou, Francesco Carlucci, Dora Szentpaly)

AESGP – Association of the European Self-Medication Industry
BEUC – The European Consumer Organisation
CELCAA – Comité europeéen de liaison des commerces agroalimentaires
ECPA – European Crop Protection Association
EDA – European Dairy Association
EHPM – European Federation of Associations of Health Products Manufacturers
Eurocommerce
PFP – Primary Food Processors
ELC- Federation of European Specialty Food ingredients Industry
Food Supplements Europe
IBFAN – International Baby Food Action Network
MNI – Medical Nutrition Industry
SNE – Specialised Nutrition Europe
WHO Regional Office for Europe / Division of Non-communicable Diseases and Life-course

1. OPENING OF THE MEETING AND ADOPTION OF THE AGENDA

COM welcomed the participants by explaining the objective of the meeting: to give the opportunity to interested parties to provide the Directorate General for Health and Food Safety (SANTE) with relevant comments on the content of three delegated acts that are currently being prepared on:

- infant formula and follow-on formula;
- food for special medical purposes and
- processed cereal-based food and baby food.

Adoption of these measures is required by Article 11(1) of Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control[1] (hereinafter, the Regulation on Food for Specific Groups, FSG). COM recalled the process for adoption of the measures and noted that the different texts could be subject to further changes after the meeting, following internal discussions within the COM services.

[1] OJ L 181, 29.6.2013, p. 35

It explained that the draft measures follow the structure of the existing legislation applicable to the different foods[2], given that they aim at transferring the existing rules under the new framework of the FSG Regulation and to update them where necessary. Updates are based on the most recent advice of the European Food Safety Authority for infant formula and follow-on formula (EFSA, *Scientific Opinion on the essential composition of infant and follow-on formulae*[3], 2014) and previous discussions with Member States, NGOs and other stakeholders. Proposed changes to the rules on labelling for the different products are mainly aimed at ensuring consistency with the new framework introduced by Regulation (EU) No 1169/2011 on the provision of food information to consumers, with adaptations where necessary taking into account the products' characteristics. Other changes are introduced to take into account the requests of the European Parliament and the Council during the negotiations on the FSG Regulation.

The COM presented the agenda and recalled that a discussion will take place under any other business on young-child formulae, on the basis of a Working Document that was circulated to participants. The agenda was adopted with this modification. The COM also recalled that additional written comments should be submitted by the end of February 2015.

2. DISCUSSION ON THE DRAFT DELEGATED REGULATION ON INFANT FORMULA AND FOLLOW-ON FORMULA

The discussion was structured so as to follow the order of the different Articles and Annexes being considered for inclusion in the Delegated Regulation.

Subject matter and scope

IBFAN noted that follow-on formula is not different from infant formula and should therefore be subject to the same provisions applicable to infant formula with respect to labelling, presentation, advertising and promotion in general, on the basis of the principles laid down in the WHO International Code of Marketing of Breast-milk Substitutes. According to IBFAN, the transfer of existing rules is being carried out without a proper analysis of how these are working today. In their view, this would therefore maintain problems that the existing rules have not solved. IBFAN also noted that the existing rules of Directive 2006/141/EC would allow Member States to further restrict marketing of follow-on formula, while the proposed Regulation would not allow that anymore. IBFAN finally asked to introduce in the text references to resolutions of the World Health Assembly on infant and young child feeding.

COM underlined that the European Parliament and Council gave a mandate to the COM to adopt delegated acts and it is the COM's responsibility to carefully respect this mandate and not to go beyond it. COM also noted that Directive 2006/141/EC, as well as the draft Delegated Regulation, provides for Member States to give effect to principles and aims of the International Code of Marketing of Breast-milk Substitutes. In this context, the rules laid down in the Directive (and the draft Delegated Regulation) should be in conformity with the principles and the aims of the Code, bearing in mind the particular legal and factual situations existing in the EU. It is a general rule of EU law that all new rules adopted by Member States

[2] Commission Directive 2006/141/EC on infant formulae and follow-on formulae, Commission Directive 1999/21/EC on foods for special medical purposes and Commission Directive 2006/125/EC on processed cereal-based foods and baby foods

[3] http://www.efsa.europa.eu/fr/efsajournal/doc/3760.pdf

at national level must be pre-notified to the Commission, which evaluates their compatibility with EU law. Nothing changes in this respect with the Delegated Regulation.

Suitability of ingredients for infant formula and follow-on formula

IBFAN requested that the Delegated Regulation establishes a pre-authorisation procedure for all substances added on a voluntary basis to formulae and underlined the importance of independent scrutiny of the scientific studies used as evidence to support the addition of substances. IBFAN also asked for new provisions on post-market surveillance of the ingredients added to formula products.

COM noted that the existing system, based on a case-by-base assessment by national competent authorities of the safety and suitability of ingredients added to formulae, has been working well so far. For this reason it is proposed to maintain it while, at the same time, stricter rules are proposed on the promotion of ingredients with no proven beneficial effects in order to protect consumers. With respect to the request to add provisions on post-market surveillance, the COM noted that enforcement of EU law is carried out by national competent authorities.

SNE noted that the legislation should support investments in innovation and product development carried out by the industry.

WHO noted that the proposed legislation requires a systematic review of the available data relating to the expected benefits and to safety considerations in order to prove suitability of ingredients for infants. WHO commented that "systematic reviews" may have flaws and suggested redrafting referring to evidence-based sound science. COM noted that the proposed wording is coming from the existing legislation and is aimed at ensuring the highest level of scientific evidence. It added that the proposed text does not refer only to systematic reviews but also to "*appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies*".

Requirements on pesticides and pesticide residues

The COM explained that it intends to maintain, for the time being, the rules of Directive 2006/141/EC on pesticides and pesticide residues that have proven to be sufficiently protective so far. These rules date back to the late 90s. Because of the scientific uncertainty at that time as to the adequacy of existing acceptable daily intake (ADI) values of pesticides and pesticide residues for the protection of the health of infants and young children, it was considered appropriate to adopt, on the basis of the precautionary principle, a default MRL fixed at 0,01 mg/kg for all pesticides and more severe limitations for a small number of pesticides.

Exchanges between the Commission and EFSA have revealed that a thorough update of the rules on pesticides in foods for infants and young children would require a significant amount of time given that a comprehensive evaluation should be carried out on a number of aspects, including the appropriateness of the toxicological reference values for infants and young children as such. For this reason, and in order to respect the provisions of FSG Regulation that require adoption of delegated acts by 20 July 2015, it is proposed to maintain the requirements on pesticides as they are and, at the same time, to request EFSA to provide a full scientific assessment on the matter (and to update rules in the future).

ECPA noted that the default MRL limit of 0.01 mg/kg is not scientifically based, and the criteria for setting specific MRLs (below 0.01 mg/kg) for selected active substances are not sufficiently clearly defined.

Requirements on labelling, presentation and advertising, promotional and commercial practices

IBFAN reiterated its concerns that the existing rules of Directive 2006/141/EC are not working, in particular with respect to the provision requiring that infant formula and follow-on formula are clearly distinguishable, or the provision prohibiting point-of-sale promotion. Also BEUC flagged enforcement problems related to the existing rules. The Commission noted that enforcement of EU law is a responsibility of national competent authorities. Complaints can be made to the Commission if interested parties consider that Member States are not applying EU law correctly.

IBFAN and WHO called again for stricter restrictions on advertising for follow-on formula, including the prohibition to make claims, taking into account the growing size of the market of these products.

ELC and SNE asked that operators are allowed to indicate in the nutrition declaration all substances that are allowed for use in infant formula and follow-on formula. SNE also asked that the exact amounts of molybdenum present in formulae are not indicated in the nutrition declaration, taking into account the technical difficulties related to measurement of these amounts.

IBFAN expressed concerns on the possibility to use the "lactose-free" statement on formulae, given that this statement is becoming increasingly trendy. The COM noted that the existing legislation allows use of this statement on soy-based formulae. At the same time, many lactose-free formulae are currently marketed as foods for special medical purposes (FSMPs), even if there are doubts that such products would in all cases really comply with the definition of FSMP. The proposal is therefore aimed at avoiding a misuse of the FSMP definition.

Entry into application

The COM explained that the draft Delegated Regulation would give a three-year transition period to operators to adapt to the new rules and noted that the same period was given when Commission Directive 2006/141/EC was adopted.

SNE asked for a longer transition period (five years) in order to have sufficient time for testing and trials of the reformulated products, taking into account the number of technical changes proposed. IBFAN on the contrary asked for a shorter transition period.

Annexes with detailed compositional requirements

The COM presented the different provisions laying down specific compositional requirements, based on the advice of EFSA of 2014. IBFAN asked for clarification on why specifications are laid down for nucleotides (that EFSA considered as unnecessary ingredients). IBFAN also asked for clarification on why maximum amounts for vitamins and minerals are set (taking into account that EFSA only proposed minimum amounts that should cover the nutritional needs of the majority of infants born at term). The COM explained that, in order to follow EFSA's advice, nutrition claims on nucleotides have been removed from the list of permitted claims for infant formula. At the same time, EFSA noted that there are no reports of adverse effects occurring with nucleotides complying with the current

specifications laid down in the legislation. For this reason, while nucleotides are not required to be added to formulae, in order to ensure consumers' protection, it is useful to mention the specifications they should comply with, if they are added. The COM also explained that maximum amounts for micronutrients are proposed (as it is the case today) in order to avoid indiscriminate addition of micronutrients and to ensure a uniform enforcement by the different national competent authorities. Maximum amounts also take into account variations of the natural nutrient content of food constituents used in the production phase and technological considerations, such as nutrient stability during shelf life and analytical variability.

SNE asked for technical adjustments in order to ensure that glucose syrups with low levels of glucose, used as a base for premixes or as a source of maltose, oligo- and polysaccharides, can continue to be used. SNE also asked for higher maximum amounts of certain micronutrients and for explanation in the legislation on how to calculate the available phosphorus in infant formulae and follow-on formulae. The COM took note of these requests.

3. DISCUSSION ON THE DRAFT DELEGATED REGULATION ON FOOD FOR SPECIAL MEDICAL PURPOSES (FSMPs)

The discussion was structured so as to follow the order of the different Articles and Annexes being considered for inclusion in the Delegated Regulation.

Compositional requirements for FSMPs

IBFAN requested that the Delegated Regulation establishes a pre-authorisation procedure for all FSMPs for infants. The COM explained that it would be impossible to foresee a pre-authorisation procedure for FSMPs, taking into account that flexibility is needed to develop innovative products intended for the dietary management of different diagnosed diseases, disorders and conditions. The COM noted that the rules of the Delegated Regulation should be drafted having in mind real FSMPs, and not products that are wrongly marketed as such. The COM also recalled that Article 3 of the FSG Regulation will allow the Commission to adopt implementing decisions to clarify specific borderline cases, and this should avoid the misclassification of products in the future.

Requirements on pesticides and pesticide residues

The COM presented the provisions on pesticides and pesticide residues that would apply to FSMPs for infants and young children and explained that these mirror those proposed for infant formula and follow-on formula. ECPA reiterated comments already made on the draft Delegated Regulation on infant formula and follow-on formula.

Specific requirements on labelling, presentation and advertising

The COM presented the different particulars that the draft Delegated Regulation requires to be included on the label on a mandatory basis, and focused on the one which requires the label to include a "*description of the properties and/or characteristics that make the product useful in relation to the disease, disorder or medical condition for the dietary management of which the product is intended, in particular, as the case may be, relating to the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product*".

SNE proposed amendments to ensure that, when providing this type of information, operators can refer to the specific dietary management of a patient, to the clinical use of the product,

and to the product's special processing and formulation. According to SNE, this information on the intended use of the product is important for those FSMPs that have a standard composition and are intended for the dietary management of different diseases. The COM took note of this request, and underlined that all information related to the intended use of the product should be communicated on the label, including the information mentioned by SNE. While the COM did not consider it necessary to refer in the legislation to the specific dietary management of a patient or to clinical use, it noted that it would further reflect on the need to specifically refer to the product's special processing and formulation.

MNI asked for amendments to the text to allow operators to repeat the nutrition declaration on the front of pack (in order to easily communicate with health care professionals). COM disagreed with this argument. It noted that the legislation requires the label of FSMPs to provide an important amount of information and added that the provision of information through labels is not the only way of communicating with health care professionals.

MNI also asked for redrafting so that operators would not have to indicate sodium amounts twice on the label (together with other minerals, and next to the salt amount). COM took note of the comment and will further discuss it with Member States.

SNE, AESGP and EHPM asked for reassurance that the proposed ban on nutrition and health claims for FSMPs would not prevent operators to indicate on the label the characteristics of the products that make them useful for their intended use. The COM explained that all information related to the intended use of the product is required on a mandatory basis, and therefore cannot be considered as claims (voluntary statements). The COM noted that it will consider how to further clarify this in a recital but warned operators that they should not try to qualify promotional statements on FSMPs as mandatory information on the intended use of the product.

Entry into application

The Commission explained that the draft Delegated Regulation would give a three-year transition period to operators to adapt to the new rules.

MNI asked for a longer transition period (five years) for FSMPs for infants as requested for infant formula and follow-on formula.

4. DISCUSSION ON THE DRAFT DELEGATED REGULATION ON PROCESSED CEREAL-BASED FOOD AND BABY FOOD

The discussion was structured so as to follow the order of the different Articles and Annexes being considered for inclusion in the Delegated Regulation.

COM made an introductory remark noting that the draft Delegated Regulation transfers the existing rules applicable to these products with only minor changes (to labelling requirements). The COM acknowledged that the compositional rules for processed cereal-based food and baby food need updating, on the basis of a new assessment by EFSA. Taking into account the short deadlines laid down by the FSG Regulation for adopting delegated acts and the limited resources of EFSA, it was not possible to receive such advice at this stage. For this reason, the COM committed to require EFSA to provide scientific advice on the matter as soon as the delegated acts are transferred, and to revise the transferred rules accordingly afterwards.

IBFAN underlined the importance to revise compositional requirements for processed cereal-based food and baby food and to reconsider the appropriate age for introduction of complementary feeding (covered by an opinion of EFSA of 2009). According to IBFAN, EFSA's conclusion that the introduction of complementary food into the diet of healthy term infants in the EU between the age of 4 and 6 months is safe has a negative impact on global public health recommendations (including the WHO recommendation for exclusive breastfeeding of infants up to 6 months).

SNE requested the inclusion of a provision in the Delegated Regulation clarifying that all products marketed as complementary foods for infants and young children must comply with the requirements of the Delegated Regulation. The COM took note of this request but underlined that this provision is not legally necessary: if a product falls within the scope of the Delegated Regulation, it automatically must comply with it.

SNE also requested technical adjustments to the Annexes laying down compositional requirements. The COM noted that changes to compositional requirements should be introduced only after having consulted EFSA.

5. AOB

The COM recalled that Article 12 of the FSG Regulation requires the Commission to present a report to the European Parliament and to the Council, after consulting EFSA, on the necessity, if any, of special provisions for milk-based drinks and similar products intended for young children ("young-child formulae"). In preparation for the drafting of the report and in order to collect useful data and information, the services of DG SANTE consulted national competent authorities, relevant stakeholders and NGOs by the means of a questionnaire in June-July 2014 and through dedicated meetings in September 2014. Views of all interested parties were sought on three different possible policy options.

The COM presented to participants a new option that was identified during discussions within the Commission services: this would consist of non-legislative measures on young-child formulae at EU level in cooperation with the Member States, NGOs and stakeholders. The Option is further described in the Working Document (attached).

WD on young child formulae Advisory Gr

The COM opened the floor to ask participants to provide their feedback on this option. Only EDA and IBFAN took the floor and expressed reservations. EDA considered this option as too soft in terms of enforcement. IBFAN underlined that products should be regulated through legislation and restrictions on composition, labelling, presentation, advertising and marketing should be introduced.

The COM asked for the submission of additional comments in writing by the end of February 2015.