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

on young-child formulae

19 September 2014

Summary Record

Participants:

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AESGP – Association of the European Self-Medication Industry
CELCAA - Comité Européen de liaison des commerces agroalimentaires
EDA – European Dairy Association
EHPM – European Federation of Associations of Health Product Manufacturers
PAN Europe – Pesticide Action Network Europe
ENSA - European Natural Soyfood Manufacturer Association
IBFAN – International Baby Food Action Network
SNE – Specialised Nutrition Europe

1. OPENING OF THE MEETING AND ADOPTION OF THE AGENDA

COM welcomed the participants by explaining that the objective of the meeting is to give the opportunity to interested parties to provide the Directorate General for Health and Consumers with relevant information, comments and recommendations in preparation for the report on the necessity, if any, of specific provisions for young-child formulae.

COM presented the agenda which was then adopted without comments.

2. DISCUSSION ON YOUNG-CHILD FORMULAE ON THE BASIS OF THE WORKING DOCUMENT PREPARED BY THE COMMISSION SERVICES

2.1. Introduction

COM recalled the context in which the meeting is taking place: Article 12 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] requires the Commission to present a report to the European Parliament and to the Council, after consulting the European Food Safety Authority (EFSA), on the necessity, if any, of special provisions for milk-based drinks and similar products intended for young children (hereinafter "young-child formulae").

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

COM referred to the opinions adopted by EFSA on the subject: the opinion of 9 October 2013 on nutrient requirements and dietary intakes of infants and young children in the European Union[2] and the opinion of 26 June 2014 on the essential composition of infant and follow-on formulae[3]. A short summary of the EFSA opinions was provided.

COM recalled that in preparation for the drafting of the report, it carried out a consultation with national competent authorities and relevant stakeholders between 3 June and 18 July 2014 on the basis of a questionnaire. The aim of the Working Group meeting is to further consult with stakeholders on the basis of a Working Document. The Working Document (attached), which has been shared with stakeholders ahead of the meeting, summarizes the results of the questionnaire (part A) and describes possible future options for action (part B).


Working Document

2.2. Summary of the replies

COM provided an account of part A of the Working Document, which summarizes the replies received to the questionnaire submitted to Member States and stakeholders in June 2014.

COM focused on the different aspects related to young-child formulae which were covered by the questionnaire:

- Market data (for young-child formulae and fortified milks);
- Marketing of young-child formulae;
- Consumer behaviour;
- Legal status and national rules for young-child formulae;
- Views on future regulatory options.

Stakeholders were asked to comment on whether they considered that the provided summary correctly represented their positions or certain aspects should be additionally included (or better represented) in the report.

IBFAN underlined that they would like the report to also focus on the inappropriate consumption of young-child formulae by infants and on the impact that promotion of young-child formulae has on breastfeeding rates for infants. The COM took note of the comment, but recalled that the report's scope will be young-child formulae and the necessity, if any, of specific provisions to regulate them.

[2] EFSA NDA Panel (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, http://www.efsa.europa.eu/en/efsajournal/doc/3408.pdf

[3] EFSA NDA Panel (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, http://www.efsa.europa.eu/fr/efsajournal/doc/3760.pdf

ENSA asked that a statement is included in the report that soy based young-child formulae can also be used in case of allergy to cow's milk protein. The Commission noted that adverse reactions to soy have been reported in milk protein-allergic patients fed with formulae containing soy protein and therefore it would not be appropriate to include such a statement.

No other comments were made on the summary of the replies.

2.3. Exchange of views on possible future options for action

COM explained that it has for the moment identified three different options for future action with respect to young-child formulae that should be further considered in view of the preparation of the report. These options are described in section B of the Working Document.

COM requested stakeholders to provide their advice on the different options (in terms of costs and benefits) taking into account the conclusions of EFSA in its opinions of October 2013 and June 2014 and focusing, if possible, on a series of aspects listed in the Working Document:

- Consumers' protection;
- Consumers' choice (variety of products being offered to consumers), information (e.g. level of information on the products) and behaviour (e.g. ability to understand information provided);
- Free circulation of young-child formulae in the internal market;
- Access to the EU market from third countries operators;
- Competitiveness of enterprises, operating costs, especially SMEs;
- Development of innovative products;
- Price of young-child formulae;
- Legal clarity, administrative burden for operators (especially SMEs) and national authorities;
- Enforcement by national authorities.

Discussions then moved on to the different options one by one and participants were asked to express their views.

Option 1 - No specific legislation for young-child formulae

COM presented the option on the basis of the Working Document and opened the floor for comments.

PAN EUROPE explained that it does not support option 1, as this would result in an insufficient level of protection for vulnerable consumers like young children, particularly with respect to requirements on pesticides residues. According to PAN EUROPE, if no legislation is adopted, young-child formulae would have to comply with the legislation on pesticide residues applicable to food for the adult population. This would result in young children being exposed to too high levels of pesticide residues. PAN EUROPE would support an approach based on the precautionary principle that would set lower residue levels for young-child formulae (as it is the case for infant formulae and follow-on formulae, on the basis of Directive 2006/141/EC, and for processed cereal-based foods and baby foods, on the basis of Directive 2006/125/EC).

COM took note of this comment, but commented that in addition to young-child formulae, young children aged 1-3 years consume a diversified diet which includes a series of foods for normal consumption. Therefore regulation of young-child formulae would only partially address the stakeholder's concern. COM also recalled that EU legislation on pesticide and pesticide residues is already very strict and already takes into account the most vulnerable groups of the population.

IBFAN explained that it does not support option 1. According to IBFAN, this option would result in an insufficient level of consumer protection, as it will be not possible to strictly control young-child formulae, in particular with respect to advertising and marketing practices. IBFAN asked the COM's views on whether, in the absence of specific rules of young-child formulae at EU level, Member States would be allowed to regulate the matter at national level. COM clarified that national measures in not harmonised areas of EU law would have to be notified by national authorities and assessed by the COM for compatibility with EU law on a case by case basis. COM added that if Option 1 were to be pursued, it would be because this is considered the adequate solution. National measures adopted afterwards would therefore need good arguments to prove that this is not the case.

SNE explained that it does not support option 1 since this would undermine effective consumer protection for young children in the EU. According to SNE the existing horizontal measures of EU food law are not sufficient with respect to young-child formulae. SNE also explained that in the absence of EU legislation on young-child formulae, the risk exists that Member States would adopt rules at national level. The establishment of a specific legal framework for young-child formulae at EU level would avoid this risk, it would guarantee that the same standards would apply to young-child formulae circulating in the entire Internal Market and would also ensure high level of standards when exporting products to third countries.

ENSA expressed support for option 1 as, in their view, current horizontal rules of EU food law, and in particular the legislation on nutrition and health claims, are sufficient to regulate young-child formulae. ENSA called on the COM to ensure that, regardless of the option chosen, soy-based formulae are treated in the same way as cow's milk-based formulae and no discrimination exists in the legislation.

EDA stated that their position on the subject is not finalised yet. They did not take a position in favour or against the option but noted that the category of young-child formulae would take advantage from a specific legal framework.

Option 2: Adoption of specific rules for young-child formulae

COM presented the option on the basis of the Working Document and opened the floor for comments.

IBFAN positioned itself against this option as, in their view, it would give too much prominence to this category of products which are not needed. IBFAN also noted that decisions taken at EU level on the subject will have an impact in the global scene at CODEX level, where the standard for formula drinks for infants aged 6-12 months and young children aged 12-36 is being revised.

SNE explained that it does not consider this option as the preferred one because it goes against the Better Regulation agenda. It added however that the industry needs legal clarity that can be ensured only through clear legislation.

Option 3: Extension of existing requirements to cover young-child formulae

COM presented the option on the basis of the Working Document and opened the floor for comments. COM asked stakeholders to first focus on option 3a) and then option 3b).

3a) Inclusion of young-child formulae in the definition of "baby foods"

PAN EUROPE did not support this option.

IBFAN was not in favour of this option because, in their view, young-child formulae are a liquid part of the diet of young children and would therefore not fit in the concept of 'baby foods' as defined in Directive 2006/125/EC.

SNE did not support this option.

3b) Inclusion of young-child formulae in the definition of follow-on formulae

IBFAN noted that young-child formulae are on the market in most EU Member States. Given the inadequacy of the other proposed options IBFAN acknowledged that option 3b) is the one that could allow to establish an appropriate regulatory framework for young-child formulae and an adequate level of consumer protection. It however underlined that if this option is pursued, the relevant specific provisions for these products will be crucial. In this context IBFAN stated that it will be necessary to consider carefully, among others, the addition of optional ingredients to young-child formulae (which IBFAN opposes for all formula products), the sugar levels in the products and the restrictions on the products' labelling, advertising and marketing (IBFAN would support application of the rules of the WHO International Code of Marketing of Breast Milk Substitutes to all formula products). COM took note of the comment but underlined that discussion in the Working Group is focused on the options, in preparation for the report. Consideration of the specific rules will come at a later stage, if the decision is taken to regulate young-child formulae.

ENSA expressed their concern regarding option 3b). According to the association, this option would not amount to better regulation as it would force manufacturers of soy-based young-child formulae to reformulate their products with respect to certain nutrients levels and would have an impact on existing products on the market. ENSA called on again for equal treatment of all young-child formulae. COM asked ENSA to provide more info on the matter in writing in order to better understand the reasons and extent of the potential negative impact of the option on soy-based young-child formulae. It then reiterated that the topic of the Working

Group is to discuss the different options and not the detailed composition requirements applicable to the products if it is ultimately decided to regulate young-child formulae.

SNE expressed support for option 3b) which would have a positive effect on consumer protection, free circulation of goods in the internal market, legal clarity and competitiveness for the concerned category of products, without imposing additional burden for operators. According to SNE the option would also have the advantage of clarifying EU rules outside the EU and would have a positive impact on the global scene.

PAN EUROPE expressed support for this option but also stated that if this option is pursued, detailed discussions will be needed on a series of requirements applying to young-child formulae.

EDA recalled that their position on the subject is not finalised but expressed appreciation for option 3b). In their view, however, if this option is pursued, specific rules will be needed to ensure that the term 'dairy' is protected, in line with the rules on the Common Organisation of agricultural markets. Also, according to EDA, specific rules will need to make sure that the marketing of young-child formulae does not result in direct comparison with milk and with statements denigrating the quality of milk when compared to young-child formulae. COM took note of the comment but added that existing legislation should already avoid these abuses. Member States are responsible for the enforcement of the rules and if EDA believes that this is not the case, a complaint should be made to national authorities or the European Commission.

3. CONCLUSION OF THE MEETING

COM concluded the meeting by noting that the majority of the stakeholders were in favour of option 3b). It also noted that, although the subject of the meeting was a conceptual reflection on the different possible options to deal with young-child formulae, different stakeholders attached great importance to the detailed rules that would apply to young-child formulae if option 3b) is pursued. COM also recalled that one stakeholder supported option 1 and raised concerns on the impact of option 3b) for a specific type of young-child formulae. Those stakeholders who did not explicitly express an opinion did not object to the conclusions of the COM.

COM informed stakeholders with respect to the next steps related to the report on young-child formulae: the Working Document discussed with stakeholders, together with the views gathered during the meeting, will be discussed with Member States in the framework of the Expert Group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control. After the consultation with Member States, and on the basis of all the collected feedback, the COM will proceed with finalising the report. The adopted report will be presented to the European Parliament and the Council in order to generate a discussion on this topic.

COM reminded stakeholders who want to submit written comments to do so by 30 September 2014 at the latest.

END OF THE MEETING