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, 18 February 2015

Chairman: Mr Basil Mathioudakis

The Commission welcomed the experts by recalling the context of the meeting: Article 11 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 (the Regulation on Food for Specific Groups, FSG) requires the Commission to adopt by 20 July 2015 delegated acts on the specific compositional and information requirements for the different categories of food falling within the scope the Regulation.

The Commission explained that, after extensive consultations with Member States experts in the framework of this Expert Group, the purpose of the meeting was to have a final discussion on the texts (Recitals, Articles, Annexes, described in different Working Documents) that are being considered for inclusion in the draft Delegated Regulations on:

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

The Commission also noted that the texts could be subject to further changes following internal discussions within the Commission services and that the same texts were presented to NGOs and other stakeholders in a meeting of the Working Group of the Advisory Group on the Food Chain and Animal and Plant Health on 17 February 2015. The Commission asked for additional written comments to be submitted by the end of February 2015.

1. Exchange of views on the draft delegated Regulation on infant formula and follow-on formula

The Commission recalled that the draft Delegated Regulation was discussed in detail on 2 February 2015 in the previous meeting of the Expert Group and presented the changes compared to the previous document. It first focused on the new proposal to require a case-by-case assessment by the European Food Safety Authority (EFSA) on the safety and suitability of ***formulae manufactured from protein hydrolysates*** before the products can be placed on the market.

The Commission then presented its proposal to maintain, for the time being, the rules on ***pesticides and pesticides residues*** of Directive 2006/141/EC 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). Member States supported this approach.

Discussions then moved on to the rules on the ***nutrition declaration***. There was general support to allow indication in the nutrition declaration of all substances that are allowed for use in infant formulae and follow-on formulae and to clarify how the nutrition declaration should be presented.

Some Member States' experts reiterated their objections to ***the possibility for milk-based formulae to bear the "lactose free" statement*** (already discussed on 2 February). The majority of the experts supported the introduction of this possibility. One expert requested to give adequate prominence on the label to the indication that certain lactose-free formulae are not suitable for infants with galactosaemia. The Commission took note of the different comments.

One expert asked the Expert Group to further discuss whether additional restrictions should be introduced in the delegated act on ***advertising of follow-on formula*** and another expert supported this request. The Commission took note of these comments, but underlined that the European Parliament and Council gave a mandate to the Commission to adopt delegated acts and it is the Commission's responsibility to carefully respect this mandate and not to go beyond it. The Commission does not have a mandate to further restrict advertising of follow-on formula, given that a specific amendment along these lines was discussed during the negotiations on the FSG Regulation and was rejected by the European Parliament.

One expert asked to introduce ***notification requirements for follow-on formula*** to which new ingredients are added. Another one asked whether it could be clarified that, in the context of the notification procedure, national competent authorities are entitled to request data proving compliance with the legislation. The Commission explained that it is the responsibility of national competent authorities to enforce EU law, and in this context, they may request at any time the food business operator placing infant formula and follow-on formula on the market to produce all relevant elements and data establishing compliance with the legislation. The Commission will however further consider these requests.

Several experts showed sympathy for a longer ***transition period*** (e.g. five years) before the rules enter into application, in order to allow the industry to have sufficient time for testing and trials of the reformulated products. The Commission took note of these comments, but underlined that five years is an excessive request.

Discussions then took place on ***technical aspects of the different Annexes*** (e.g. possibility to continue to use certain glucose syrups with low levels of glucose, as a base for premixes or as

a source of maltose, oligo- and polysaccharides in the manufacturing of infant formula and follow-on formula). The Commission agreed to further consider these points.

2. Exchange of views on the draft delegated Regulation on Food for Special Medical Purposes (FSMPs)

The Commission presented the Working Document. It explained that the draft Delegated Regulation follows the structure of Commission Directive 1999/21/EC on dietary foods for special medical purposes, given that it aims at transferring the existing rules laid down by that Directive under the new framework of the FSG Regulation and to update them where necessary. Updates are based on previous discussions with Member States, NGOs and other stakeholders. Proposed changes to the rules on labelling 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 (e.g. rules on pesticides in FSMPs for infants and young children, rules on the labelling, presentation, advertising and promotional and commercial practices for FSMPs for infants).

Several Member States' experts asked that ***advertising restrictions*** are introduced in the Delegated Regulation for FSMPs. The Commission explained that such restrictions are proposed for FSMPs for infants (in line with the rules laid down in Directive 2006/141/EC for infant formula). However, advertising of FSMPs for the adult population is not widespread at the moment, and such restrictions at EU level do not seem justified. One expert asked whether a recital could clarify that the proposed ban on nutrition and health claims would not prevent operators to indicate on the label the ***characteristics of the products that make them useful for their intended use***. The Commission explained that it will reflect on a recital to clarify 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 Expert Group agreed that operators should not have to indicate ***sodium amounts*** twice on the label (together with other minerals, and next to the salt amount). One expert asked for a longer ***transition period*** for FSMPs for infants, if this is granted to infant formula and follow-on formula. Some Member States' experts raised the point that the ***maximum values*** for all vitamins and minerals in FSMPs for infants should be brought in line with those foreseen in the delegated act on infant formula and follow-on formula. The Commission recalled the importance of ensuring adequate flexibility in the compositional requirements for FSMPs and noted that no adverse effect was reported under the existing rules. The Commission took note of the comments and proposed to reconsider the issue in the coming years.

3. Exchange of views on the draft delegated Regulation on processed cereal-based food and baby food

The Commission presented the Working Document. It explained that the draft Delegated Regulation follows the structure of Commission Directive 2006/125/EC on processed cereal-based food and baby food, given that it aims at transferring the existing rules laid down by that Directive under the new framework of the FSG Regulation. The Commission explained that the changes introduced are minor, and focus on labelling aspects, mainly to ensure

consistency with the new framework introduced by Regulation (EU) No 1169/2011, with adaptations where necessary.

The Commission 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 Commission 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.

The Expert Group supported this commitment, and underlined the importance of such revision. One expert asked that, in this context, EFSA is required to analyse the issue of the appropriate age of introduction of complementary feeding. The Commission took note of this request and will consider it when preparing its mandate. It noted, however, that EFSA's Scientific Opinion on the appropriate age for introduction of complementary feeding was adopted very recently (in 2009).

4. AOB

The Commission 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 Commission presented to the Expert Group 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 Commission explained that this option was also presented during the Working Group of the Advisory Group on the Food Chain and Animal and Plant Health on 17 February 2015.

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