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, 2 February 2015

Chairman: Mr Basil Mathioudakis

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

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 requires the Commission to adopt by 20 July 2015 delegated acts on the specific compositional and information requirements for the categories of food falling within the scope the Regulation, including infant formula and follow-on formula.

The Commission recalled the previous discussions held in the framework of the Expert Group on specific points related to infant formula and follow-on formula and asked Member States' experts to provide detailed feedback on all the aspects covered by the Working Document (Recitals, Articles, Annexes that could be included in the delegated Regulation). The Commission also noted that final rounds of consultations on three delegated acts to be adopted pursuant to Article 11 of Regulation (EU) No 609/2013 will be held in the month of February. More specifically, the draft delegated Regulations on infant formula and follow-on formula, processed cereal-based food and baby food and food for special medical purposes will be discussed with 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 same drafts will then be discussed on 18 February 2015 with the Expert Group.

On a general note, the Commission explained that the draft Delegated Regulation on infant formula and follow-on formula follows the structure of Commission Directive 2006/141/EC on infant formulae and follow-on formulae given that it aims at transferring the existing rules laid down by the Directive for these products under the new framework of Regulation (EU) No 609/2013 and to update them where necessary. Updates are based on the most recent advice of the European Food Safety Authority (EFSA, 2014, *Scientific Opinion on the essential composition of infant and follow-on formulae*), 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. The Commission finally noted that the approach on pesticides in foods for infants and young children is still being considered and for this reason, no provision is included in the Working Document.

One expert asked what would be the impact of the draft Delegated Regulation on rules adopted at national level to transpose the ***WHO International Code of Marketing of Breast-milk Substitutes***. The Commission explained 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 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.

A group of Member States' experts asked the Commission to introduce ***a centralised pre-authorisation procedure*** at EU level for all ingredients added on a voluntary basis to infant formula and follow-on formula. This procedure would be based on the scientific advice of EFSA and on a final decision by the Commission. Some of these experts stressed that such a centralised authorisation procedure would at least be necessary for formulae manufactured from protein hydrolysates. Other Member States' experts expressed support for the approach described in the Working Document. The Commission expressed its reservations on the introduction of a centralised authorisation procedure for all optional ingredients, given that such a procedure would have a strong negative impact on operators (in terms of administrative burden and possibility to develop innovative products) and on the Commission services (that would be overloaded with requests).

Discussions then moved on to ***labelling requirements*** for infant formulae and follow-on formulae. Apart from technical issues (e.g. the order of presentation of nutrients in the nutrition declaration, the possibility to repeat the nutrition declaration on the label), the most discussed point was related to ***the possibility for milk-based formulae to bear the "lactose free" statement***. The Commission explained that the existing legislation only allows soy-based formulae to bear such statement. All milk-based formulae that want to describe their lactose-free status are therefore currently marketed as food for special medical purposes (FSMPs) and this practice should not be encouraged (given that there are doubts that in all cases lactose-free formulae would comply with the definition of FSMP). For this reason, it is proposed to allow use of the "*lactose-free*" statement also on milk-based formulae, provided that the lactose content is lower than 0.01 g/100 kcal (in line with what EFSA noted in its opinion). According to some Member States, this proposal would lead to an increased number of such products on the market. According to another, this proposal should be further considered given that not all lactose-free formulae would be suitable for galactosaemic infants. The Commission noted that milk-based lactose-free products would remain on the market anyway as FSMPs, and that the status quo has contributed to an abuse of the definition of FSMPs. The Commission showed openness to further consider how to inform consumers through the label that some lactose-free formulae are not suitable for galactosaemic infants.

Member States' experts had different views on the length of the ***transitional period*** to be given to infant formula and follow-on formula manufacturers after the delegated act enters into force in order to adapt to the new rules. While some agreed with the proposal made by the Commission (three years), other asked for a longer transition period (five years).

Discussions then took place on ***technical aspects of the different Annexes***. Minor suggestions for redrafting were made by Member States' experts that the Commission agreed to further consider.

2. Any other business

Following the request of one Member State, the Expert Group held an exchange of views on the use of flavourings in foods for infants and young children. The expert from that Member State was in particular interested in knowing the state of play and future action on the subject.

The Commission explained that Commission implementing Regulation (EU) No 872/2012 was adopted on 1 October 2012 and establishes in Annex I of Regulation (EC) No 1334/2008 the list of permitted flavouring substances in the EU. The Regulation explains both in a recital and in an Article that the use of flavourings and source materials in infant formulae, follow-on formulae, processed cereal-based foods and baby foods and dietary foods for special medical purposes intended for infants and young children will be harmonised in the future in the framework of specific rules to be adopted on the composition of foodstuffs intended for infants and young children. Meanwhile, Member States are able to apply stricter national provisions than the ones provided for in the list of flavouring substances.

In order to better reflect on the next steps on the matter, the Commission would need to gather detailed information on the situation on the market. As a first step, the Commission could invite stakeholders in the sector to provide information on the flavourings currently used in foods for infants and young children.

The Expert Group requested the Commission to engage into further activities in this area, and expressed support for the proposed data collection exercise. The Commission explained that it will further engage in the matter after having finalised the adoption of the delegated acts required by Regulation (EU) No 609/2013 (by 20 July 2015).