

**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, 11 June 2018

Chair: Mr Jacques Humières

1. Welcome

The Commission (COM) 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 control¹ requires the Commission to adopt delegated acts on the specific compositional and information requirements for the categories of food falling within the scope the Regulation, including baby foods (BF) and processed cereal-based foods (PCBF). The objective of the meeting was to provide an update on the state of play of the ongoing preparatory work in view of a new delegated act laying down specific composition and information requirements for BF and PCBF.

2. Joint section with the Joint Research Centre

The JRC presented to the experts the final report of the study on BF and PCBF.

Following the presentation Member States` experts were asked to share their views on the final report. One Member State asked for clarification as to whether fruit purees contained in commercial baby foods were included in the definition of added and free sugars. Another Member State asked the JRC to clarify how products concerned in the report had been categorised into the different product categories while another one questioned the JRC about the scope of the final report. The JRC clarified that only products intended for infants and young children were considered in the report. To obtain a detailed overview of the composition of such products that are sold in EU markets, the commercial database "Mintel - Global New Products Database" was used. It contains seven sub-categories under the category "baby food", which can be clearly matched to the PCBF and BF categories described in Directive 2006/125/EC². It was acknowledged that those categories, however, might not fully correspond to the legal sub-categories found in the Directive. The JRC further explained that the scope of the study was limited to the nutrient content of the products concerned and did therefore not cover other aspects such as the use of pesticides in BF and PCBF. Member States were asked to send their further comments on the report in writing by the end of June 2018 so that they could be taken into account in the final version to be published during the summer.

¹ OJ L 181, 29.6.2013, p. 35

² Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children, OJ L 339, 6.12.2006, p. 16

The COM explained the next steps and the timeframe for the future work on the delegated act. As regards the compositional aspects of the delegated act, on the basis of the final report and Member States' comments a first preliminary working paper on the possible structure of the delegated act is envisaged to be prepared and subsequently be discussed with Member States in the next Expert Group meeting (foreseen in October). A second working paper might then be prepared on the compositional requirements and discussed with Member States, which will serve as a basis for the future EFSA mandate on the compositional aspects (EFSA will be asked to comment on the appropriateness of the proposed compositional requirements).

As regards the labelling part of the delegated act, the COM recalled that EFSA had accepted (in September 2016) a mandate for an update of the scientific opinion on the appropriate age for introduction of complementary feeding of infants with a deadline of 30 September 2018. Due to the unexpected workload and high public interest in the topic an extension of the deadline for the mandate is envisaged until 31 July 2019. Once the scientific opinion will be adopted appropriate labelling requirements could be discussed with Member States that - together with the compositional requirements approved by EFSA - will serve as a basis for the drafting of the future delegated act.

Finally, the COM concluded that the work undertaken in the context of a comprehensive review of the rules laid down for BF and PCBF was challenging, considering the huge variety of food based dietary guidelines issued by Member States in the context of infant and young child feeding and the diversity of products marketed for that age group. The future delegated act in any case has to ensure that BF and PCBF placed on the market are safe and are compatible with a balanced diet of healthy infants and young children.

3. Update from the Commission on relevant EFSA's work

The COM informed the Expert Group of the draft scientific opinion on the update of the tolerable upper intake level (UL) for vitamin D in infants.

The COM recalled that EFSA had been requested to issue an opinion revising, if necessary, the UL for vitamin D for infants and to assess whether consumption of formula containing 3 µg/100 kcal of vitamin D, assuming additional vitamin D intakes through supplementation, is safe for infants. The COM presented to the experts the draft scientific opinion and asked the Member States experts' to share their preliminary views on it. Some Member States raised concerns about the methodology used by EFSA in reaching its conclusions on the UL for vitamin D for infants. Some others were concerned that the scientific opinion had not taken into account in the assessment the possible vitamin D intake through food supplements that together with the vitamin D intake from the normal diet might lead some infants to consume vitamin D above the UL.

As regards the possible risk management follow up, the majority of Member States who took the floor were in favour of lowering the maximum vitamin D content in infant formula from 3 µg/100 kcal (maximum amount permitted as per Delegated Regulation (EU) 2016/127) to 2.5 µg/100 kcal (maximum amount permitted as per Directive 2006/141/EC). Some others recalled that the maximum vitamin D level of 3 µg in infant formula had been set by the delegated regulation taking into account, amongst other, technological considerations brought forward by the manufacturers. Some Member States also indicated that national vitamin D supplementation policies for infants might need to be changed in view of the possible risk management measure and that use of certain warnings on the label might also be necessary. Furthermore, it was noted that consideration should be given to whether the maximum vitamin D content in follow-on formula would also need to be lowered. The COM indicated

that lowering the maximum vitamin D content in follow-on formula seemed to be less justified based on the EFSA opinion and taking into account the history of safe use of follow-on formula with a vitamin D content of 3µg/100kcal. COM invited the Member States to send their views on the possible risk management follow up in writing following the meeting.

4. AOB

EFSA gave a presentation to the experts on the main conclusions and recommendations of the EFSA scientific opinion on pesticides in foods for infants and young children. The Commission informed that the follow up of this opinion would be discussed both in the Expert Group on foods for specific groups and in the Standing Committee on Plants, Animals, Food and Feed - section pesticides residues for technical aspects related to pesticides residues. The COM highlighted that it would be essential to establish good collaboration at Member State level between the respective experts of both groups. As regards the specific EFSA recommendations to lower the Maximum Residue Limits for infant formula and follow on formula for a group of substances with an Acceptable Daily Intake below 0.0026 mg/kg bodyweight, the COM will carefully assess the situation. Analytical feasibility and real exposure of infants and young children would need to be taken into account when reflecting about the follow-up. As regards the legislation on foods for infants and young children, Directive 2006/141/EC³ on infant formula and follow on formula is still applicable and will be replaced by a delegated act in 2020 and in the case of protein hydrolysates in 2021 due to transitional measures laid down in the framework Regulation 609/2013. Any potential change of the legislation can therefore become applicable only as from 2020 and 2021 respectively. A Member State commented that in its view that issue should in particular be discussed in the relevant working group on pesticides due to its highly technical nature. Another Member State asked for clarification as to whether chlorate concentration in foods intended for infants and young children had been assessed by EFSA. The COM explained that the issue of chlorate's presence in foods was not in the scope of the scientific opinion of EFSA.

³ Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC, OJ L 401, 30.12.2006, p. 1