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, 15 October 2020

Chair: Ms Fruzsina Nyemecz

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 control[1] requires the Commission to adopt delegated acts on the specific compositional and information requirements for the categories of food falling within the scope of the Regulation, including baby foods (BF) and processed cereal-based foods (PCBF). The COM explained that the main objective of the meeting was to exchange views on a draft delegated act amending delegated Regulation EU 2016/127 as regards the date of application of its provisions on infant formula and follow-on formula manufactured from protein hydrolysates.

2. FORMULAE MANUFACTURED FROM PROTEIN HYDROLYSATES

2.1 Draft delegated act amending delegated Regulation EU 2016/127 as regards the date of application of certain of its provisions

The COM presented its proposal to defer the application of the requirements laid down in Regulation 2016/127 for infant and follow-on formulae manufactured from protein hydrolysates by one year due to the unexpected delays caused by the COVID-19 outbreak in the ongoing scientific assessments.

While all Members States who took the floor agreed with the initiative to extend the transition period, some of them questioned the proposed timeframe arguing in particular that the adoption by the European Food Safety Authority (EFSA) of the Explanatory note to the Scientific and Technical guidance for the preparation and presentation of an application for authorisation of an infant and/or follow-on formula manufactured from protein hydrolysates[2] might also have caused difficulties for food business operators and delays in the scientific assessments.

The COM explained in detail the reasons why an extension of one year was proposed, highlighting in particular that it would prevent unjustified market disruptions by allowing the completion of the assessment of those submissions, which were submitted in compliance with the scientific criteria on time, as well as the subsequent amendment of the annexes of Regulation EU 2016/127[3]. It also clarified that the risk assessment of a submitted file and the subsequent risk management decisions are taking place according to the scientific standards

[1] OJ L 181, 29.6.2013, p. 35
[2] https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2020.EN-1858
[3] OJ L 25, 2.2.2016, p. 1–29

and the legislative framework in force at the time of application. For that reason, each protein hydrolysate is assessed according to the EFSA guidance applicable at the time of the submission of the file. The submissions (filed in 2019) are therefore subject to the scientific criteria applicable at the time, that is EFSA`s 2017 Scientific and Technical Guidance[4], hence the explanatory note adopted in 2020 is not applicable to these submissions.

Following the above explanation none of the Member States raised concerns over the proposal during the meeting. The COM invited Member States` experts to send their comments and official position on the proposal in writing following the meeting.

3. AOB

Upon request of a Member State, the COM explained that in accordance with article 6(1)d of Regulation 2016/128 information on the source and nature of the protein shall be labelled in the nutrition declaration. The purpose of the listed additional mandatory particulars of the nutritional declaration is to ensure the appropriate use of food for special medical purposes (FSMPs) for healthcare professionals (HCPs) and for patients by providing more complete information to them. Therefore, all the nutrients whose indication is useful/needed for HCPs and patients for the appropriate use of the products need to be included in the nutrition declaration.

Following a question of another Member State concerning the legal status of plant (rice) protein hydrolysates, the COM recalled that according to Regulation 2016/127, infant and follow-on formulae manufactured from protein hydrolysates should only be allowed to be placed on the market, if their composition corresponds to the requirements laid down in the Regulation. Those requirements might be updated in the future by the COM in order to allow the placing on the market of formulae with a composition different from the one already positively assessed, following a case-by-case evaluation of their safety and suitability by EFSA. Hence, as of the date of application of the new rules, formulae containing protein hydrolysates, including rice protein hydrolysates, can only be placed on the market if their safety and suitability have been established by EFSA. In the context of Commission Directive 2006/141/EC, all the Member States that intervened were of the view that rice protein hydrolysates do not meet the requirements of the Directive, hence cannot be legally placed on the market under the current rules.

Following the request of a Member State, the COM clarified that a statement different from the warning as provided for in Article 5(h) of Regulation 2016/128 might be used on FSMPs, provided that the same level of information and consumer protection is ensured.

[4] https://www.efsa.europa.eu/en/efsajournal/pub/4779