ADMINISTRATIVE GUIDANCE ON THE SUBMISSION OF DOSSIERS ON INFANT AND/OR FOLLOW-ON FORMULA MANUFACTURED FROM PROTEIN HYDROLYSATES

1. BACKGROUND

Commission Directive 2006/141/EC[1] lays down harmonised rules applicable in the entire EU to infant formulae and follow-on formulae. The Directive allows the use of protein hydrolysates as source of protein in infant formulae and follow-on formulae under certain conditions (Articles 5–7; Annex I, point 2.2; Annex II, point 2.2 and Annex VI). The Directive also lays down conditions for infant formulae manufactured from protein hydrolysates to bear a health claim describing the role of such products in reducing the risk of developing allergy to milk proteins (Article 13(6) and Annex IV, point 2.1).

Commission delegated Regulation (EU) 2016/127[2] transfers the existing rules of Directive 2006/141/EC under the new framework of Regulation (EU) No 609/2013 of the European Parliament and of the Council[3] and updates them, based on the opinion of the European Food Safety Authority (EFSA) of 2014[4]. In that opinion, EFSA noted that '*the safety and suitability of each specific formula containing protein hydrolysates has to be established by clinical studies. Information on protein sources and the technological processes applied should also be provided. In this context, the Panel notes that one particular formula containing partially hydrolysed whey protein has been evaluated for its safety and suitability by the Panel (…) and has been authorised for use by Directive 2006/141/EC*'. EFSA also noted that '*the criteria given in Directive 2006/141/EC alone are not sufficient to predict the potential of a formula to reduce the risk of developing allergy to milk proteins. Clinical studies are necessary to demonstrate if and to what extent a particular formula reduces the risk of developing short- and long-term clinical manifestations of allergy in at-risk infants who are not exclusively breast fed*'.

Taking into account EFSA's opinion, the delegated Regulation establishes that infant formula and follow-on formula manufactured from protein hydrolysates should only be allowed to be placed on the market if their composition corresponds to the one positively assessed by EFSA so far and prohibits the use of health claims describing the role of infant formula in reducing the risk of developing allergy to milk proteins. The requirements of Commission delegated Regulation (EU) 2016/127 shall apply to infant formula and follow-on formula manufactured from protein hydrolysates from 2021.

As explained in the recitals of the Regulation, these requirements may be amended in the future in order to allow the placing on the market of formulae manufactured from protein hydrolysates with a composition different from the one already positively assessed, following

[1] 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

[2] OJ L 25, 2.2.2016, p. 1

[3] Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009, OJ L 181, 29.6.2013, p. 35

[4] 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

a case-by-case evaluation of their safety and suitability by EFSA. In addition, if, after the assessment by EFSA, it is demonstrated that a specific formula manufactured from protein hydrolysates reduces the risk of developing allergy to milk proteins, further consideration will be given to how to adequately inform parents and caregivers about that property of the product.

It can be expected that dossiers on formulae manufactured from protein hydrolysates will be presented by food business operators for assessment by EFSA with a view to request possible modifications to the conditions applicable to these products in the delegated Regulation.

In this context, following a request from the European Commission EFSA provided a Scientific and Technical Guidance[5] regarding the type of data that food business operators should make available to the Authority in the future, when submitting dossiers on formulae manufactured from protein hydrolysates. The EFSA guidance document is intended to assist applicants in the preparation and presentation of well-structured dossiers by providing technical guidance on the information and data to be submitted to the Authority for the assessment of the safety and suitability of the formula and the product's efficacy in reducing the risk of developing allergy to milk proteins.

This guidance document is intended to provide administrative information to operators on the procedure of submitting a dossier related to infant and/or follow-on formula manufactured from protein hydrolysates in the context of delegated Regulation (EU) 2016/127.

2. PROCEDURE TO FOLLOW

2.1. General Procedure

Dossiers on infant and/or follow-on formula manufactured from protein hydrolysates should be submitted to the European Commission, Health and Food Safety Directorate-General, Unit E1, Food information and composition, food waste.

Dossiers should consist of the following separate elements:

- a letter clearly specifying the request with regard to what the dossier relates to. In this context the party responsible for the dossier should clearly explain whether the dossier is intended to substantiate 1) the safety and suitability of a specific formula and/or 2) the product's efficacy in reducing the risk of developing allergy to milk proteins.
- a **technical dossier** compiled following the guidelines entitled *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.*[6] When preparing the dossier petitioners may wish to consult the EFSA Secretariat for guidance on the presentation of the dossier.

  Note - the dossier should contain a summary document that can be separated.

[5] EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2017. 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, EFSA Journal 2017;15(5):4779

[6] http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4779/epdf

The letter, a copy of the summary document in paper format and a copy of the full technical dossier in electronic format on standard physical media (CD-ROM or equivalent) should be sent by registered post to the following address:

European Commission
Health and Food Safety Directorate-General
Directorate E – Food and feed safety, innovation
Secretariat Unit E1 – Food information and composition, food waste
B-1049 Brussels

3. FOLLOW UP OF A PETITION

After the receipt of a dossier, the petitioner will be sent an acknowledgement of the receipt of the request. The reference number given in the letter and the name of the product that is the subject of the petition should be quoted in any future correspondence. The Commission services will review the submission and inform the petitioner whether it is administratively accepted.

Once the Commission services have confirmed the administrative acceptance of the dossier, the petitioner will be asked to send the full technical dossier in electronic format (e.g. CD-ROM), the table of contents, list of Annexes and the signed cover letter specifying the request in paper format to the European Food Safety Authority at the address given below by registered post:

European Food Safety Authority - APDESK unit - Ms Karine Lheureux
Via Carlo Magno 1A
43126 Parma
Italy

The EFSA Secretariat may ask the petitioner to send additional copies or sections of the dossier to additional addresses. The Commission services and the EFSA reserve the right to request additional information as necessary for complete assessment of the dossier. EFSA will contact the petitioner directly should they require additional information. If additional information is submitted directly to the EFSA, then the petitioner should send a copy of the covering letter and the additional information in an electronic format to the Commission services at the address indicated in section 2.1.

4. CONFIDENTIALITY

It is noted that there is no legal basis for a request for confidential treatment of certain parts of the technical dossiers in the relevant pieces of the EU legislation applicable to the placing on the market of infant formula and follow-on formula. Therefore, the general provisions concerning confidentiality laid down by Article 39 of Regulation (EC) No 178/2002[7] will be applied by EFSA. When preparing the dossier petitioners may wish to consult the EFSA

[7] OJ L 31, 1.2.2002, p. 1

Secretariat for further information on confidentiality treatment of the elements of the dossier which are considered as confidential by the applicant.

In this context, the application in itself cannot be confidential. A confidential submission cannot be accepted. Sections considered as confidential by the applicant should be clearly marked as such and kept to a minimum. Applicants are encouraged to make publicly available a maximum of the information submitted, for example by posting on the Internet the contents of the application.

5. EFSA EVALUATION

The scientific opinions adopted by the Scientific Panels of the European Food Safety Authority will be made publicly available on the European Food Safety Authority's website (http://www.efsa.europa.eu).

Prepared by the Food information and composition, food waste Unit
Health and Food Safety Directorate-General