Commission Implementing Regulation (EU) No 562/2012 of 27 June 2012 amending Commission Regulation (EU) No 234/2011 with regard to specific data required for risk assessment of food enzymes (Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings[(1)], and in particular Article 9(1) thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) Pursuant to Article 5(2) of Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings[(2)], the application dossier shall include all the available data relevant for the purpose of the risk assessment.

(2) Pursuant to Article 8(1) of Regulation (EU) No 234/2011 concerning specific data required for risk assessment of food enzymes, information shall be provided on the biological and toxicological data.

(3) A number of food enzymes currently placed on the Union market have been evaluated and authorised under national provisions in France and Denmark in accordance with the guidelines for the presentation of data on food enzymes of the Scientific Committee on Food ("the SCF") set out in opinion expressed on 11 April 1991 (published in 1992)[(3)]. A few food enzymes (e.g. chymosin, invertase and urease) have also been evaluated by the SCF[(4)].

(4) With regard to the toxicological properties of enzyme preparations, the SCF guidelines indicated that food enzymes which are derived from edible parts of (non genetically modified) plants and animals are generally considered as posing no health problems. According to the guidelines no special documentation for safety needs to be supplied provided that the potential consumption under normal use does not lead to an intake of any components which is larger than can be expected from normal consumption of the source as such, and provided that satisfactory chemical and microbiological specifications can be established.

(5) The European Food Safety Authority ("the Authority") has also indicated in its guidance on data requirements for the evaluation of food enzyme applications[(5)] that the justification for not supplying toxicological data for food enzymes from edible parts of animals and non genetically modified plants may include a documented history on the safety of the source of the food enzymes, the composition and the properties of the food enzyme as well as its use in food which demonstrates no adverse effects on human health when consumed in a comparable way, supported by any existing toxicological studies. Therefore, the enzyme application for food enzymes from such edible sources should not be required to include toxicological data.

(6) The concept of Qualified Presumption of Safety (hereinafter referred to as "QPS")[(6)] was established by the Authority as a tool for the assessment of the safety of micro-organisms that are introduced into the food chain either directly or as a source of additives or food enzymes. This concept means that, where a strain of micro-organism is assigned to a QPS group and satisfies the qualifications specified, the Authority does not need to carry out any further safety assessment of the production strain. Therefore, if the micro-organism used in the production of a food enzyme has a status of QPS according to the most recent list of QPS recommended biological agents adopted by the Authority, the enzyme application should not be required to include toxicological data. However, if residues, impurities, degradation products linked to the total enzyme production process (production, recovery and purification) could give rise for concern the Authority, pursuant to Article 6(1) of Regulation (EC) No 1331/2008, may request additional data for risk assessment, including toxicological data.

(7) Pursuant to Article 6(a) of Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes[(7)] a food enzyme may be included in the Union list only if it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed. The reduction of data required for risk assessment in relation to food enzymes obtained from edible parts of non genetically modified animals and plants, and from micro-organisms that have a status of QPS does not have a negative impact on the quality of the risk assessment based on the SCF and the Authority’s guidance.

(8) With regard to grouping of specified food enzymes in one application, the Authority has already indicated in its guidance on data requirements for the evaluation of food enzyme applications that specified food enzymes with the same catalytic activity, produced by the same micro-organism strain and by the substantially same manufacturing process may be grouped in one application, even if as a rule each individual food enzyme must be assessed.

(9) It is appropriate that food enzymes obtained from edible parts of plants or animals which have the same catalytic activity and which are processed from the same source (e.g. at species level) and with a substantially same production process may be grouped under one application.

(10) It is also appropriate that food enzymes obtained from micro-organisms which have a status of QPS or from micro-organisms which have been used in the production of food enzymes that have been evaluated and authorised by the competent authorities in

France or Denmark in accordance with the SCF guidelines of 1992 may be grouped under one application under the same conditions.

(11) Pursuant to Article 6(1) of Regulation (EC) No 1331/2008, during the risk assessment the Authority may request additional information in duly justified cases.

(12) The establishment of the Union list of food enzymes should take place smoothly and should not disturb the existing food enzyme market. The derogation from submitting toxicological data and the possibility of grouping dossiers will reduce the burden on applicants and in particular on small and medium size enterprises.

(13) The derogation from submitting toxicological data and the possibility of grouping dossiers should not apply to food enzymes which are produced from genetically modified plants or animals as defined in point 5 of Article 2 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[8] nor to food enzymes which are produced from or produced with genetically modified micro-organisms as defined in Article 2(b) of Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms[9]. However, as regards food enzymes obtained from genetically modified micro-organisms through the use of techniques listed in Annex II, Part A, point 4 of Directive 2009/41/EC, the derogation from submitting toxicological data should apply if the parent strains of the micro-organisms have a status of QPS[10].

(14) Regulation (EU) No 234/2011 should therefore be amended accordingly.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

(**1**) OJ 354, 31.12.2008, p. 1.

(**2**) OJ L 64, 11.3.2011, p. 15.

(**3**) http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_27.pdf

(**4**) http://ec.europa.eu/food/fs/sc/scf/reports_en.html

(**5**) http://www.efsa.europa.eu/en/efsajournal/pub/1305.htm

(**6**) http://www.efsa.europa.eu/en/efsajournal/doc/587.pdf

(**7**) OJ L 354, 31.12.2008, p. 7.

(**8**) OJ L 268, 18.10.2003, p. 1

(**9**) OJ L 125, 21.5.2009, p. 75.

(**10**) http://www.efsa.europa.eu/en/efsajournal/doc/587.pdf. See page 13

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 562/2012, Introductory Text.