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COMMISSION

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**COMMISSION REGULATION (EU) …/…**

**of XXX**

**amending Regulation (EC) 1881/2006 as regards maximum levels of glycidyl fatty acid esters in vegetable oils and fats, infant formula, follow-on formula and foods for special medical purposes intended for infants and young children**

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**amending Regulation (EC) 1881/2006 as regards maximum levels of glycidyl fatty acid esters in vegetable oils and fats, infant formula, follow-on formula and foods for special medical purposes intended for infants and young children**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food[1], and in particular Article 2(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 1881/2006[2] sets maximum levels for certain contaminants in foodstuffs.

(2) In May of 2016, the Scientific Panel on Contaminants in the Food Chain (CONTAM) of the European Food Safety Authority ('the Authority') adopted a scientific opinion on the Risks for human health related to the presence of 3-and 2-monochloropropanediol (MCPD), and their fatty acid esters, and glycidyl fatty acid esters in food[3].

(3) In view of the updated guidance of its Scientific Committee on the use of the benchmark dose approach in risk assessment[4], the Authority has decided to re-open the assessment of 3-MCPD and its fatty acid esters, following a detailed analysis of the divergences in opinions, concerning that contaminant, between the Joint FAO/WHO Expert Committee on Food Additives[5] and the Authority. Therefore it is appropriate to wait for the outcome of the assessment of 3-MCPD and its acid esters before taking appropriate regulatory measures.

(4) Glycidyl fatty acid esters are food contaminants found at highest levels in refined vegetable oils and fats. Glycidyl fatty acid esters are hydrolysed in glycidol in the gastrointestinal tract.

(5) The Authority concluded that glycidol is a genotoxic and carcinogenic compound. In view of the genotoxic and carcinogenic potential of glycidol, the Authority applied a margin of exposure ('MoE') approach. Scenarios of exposure for infants, toddlers and other children ranging from 12800 to 4900 and in infants receiving only formula diet resulted in a MoE of about 5500 to 2100. The Authority considered that a MoE lower

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1 OJ L 37, 13.2.1993, p. 1.

2 Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

3 Scientific opinion on the risks for human health related to the presence of 3- and 2-monochloropropanediol (MCPD), and their fatty acid esters, and glycidyl fatty acid esters in food. EFSA Journal 2016;14(5): 4426, 159 pp. doi:10.2903/j.efsa.2016.4426

4 Minutes of the 82nd Plenary meeting of the Scientific Committee held on 13-14 February 2017. Available at https://www.efsa.europa.eu/sites/default/files/event/170213-m.pdf

5 Joint FAO/WHO Expert Committee on Food Additives, Eighty-third meeting, Rome, 8–17 November 2016, Summary and Conclusions. Available at http://www.fao.org/3/a-bq821e.pdf

than 25000 is of health concern. It is therefore appropriate to establish a maximum level for the presence of glycidyl fatty acid esters in vegetable oils and fats placed on the market for the final consumer or for use as an ingredient in food. Because of the health concern for infants, toddlers and young children it is appropriate to establish a stricter maximum level for vegetable oils and fats destined for the production of baby food and processed cereal-based food for infants and young children.

(6) In order to exclude any possible health concerns as regards infants, toddlers and young children, in particular, taking into account the possible exposure to glycidyl esters of infants solely fed on infant formula, it is appropriate to establish a specific strict maximum level for infant formula, follow-on formula and food for special medical purposes intended for infants and young children. However there is a need to further reduce the presence of glycidyl fatty acid esters in infant formula, follow-on formula and food for special medical purposes intended for infants and young children and therefore it is necessary to review the maximum levels once a reliable method of analysis is available to analyse stricter levels in view of ensuring an effective enforcement of these levels.

(7) Food business operators should be granted enough time to adapt their production processes.

(8) Regulation (EC) No 1881/2006 should therefore be amended accordingly.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

The Annex to Regulation (EC) No 1881/2006 is amended in accordance with the Annex to this Regulation.

*Article 1*

Foodstuffs listed in the Annex to this Regulation that were lawfully placed on the market before the entry into force of this Regulation may remain on the market until *[OPOCE please insert precise date – this is 6 months after the date of entry into force of this Regulation]*

*Article 2*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*
*The President*
*Jean-Claude JUNCKER*