Commission Regulation (EU) 2020/1322 of 23 September 2020 amending Regulation (EC) No 1881/2006 as regards maximum levels of 3# monochloropropanediol (3-MCPD), 3-MCPD fatty acid esters and glycidyl fatty acid esters in certain foods (Text with EEA relevance)

COMMISSION REGULATION (EU) 2020/1322

of 23 September 2020

amending Regulation (EC) No 1881/2006 as regards maximum levels of 3#monochloropropanediol (3-MCPD), 3-MCPD fatty acid esters and glycidyl fatty acid esters in certain foods

(Text with EEA relevance)

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. In the Annex to this Regulation maximum levels are established for 3-monochloropropanediol (3-MCPD) and glycidyl fatty acid esters.

(2) On 21 November 2017, the Scientific Panel on Contaminants in the Food Chain ('the CONTAM Panel') of the European Food Safety Authority adopted a scientific opinion[(3)] on an update of the its assessment of the risks for human health related to the presence of 3-monochloropropanediol ('3-MCPD') and its fatty acid esters in food published in 2016[(4)], in view of the scientific divergence identified concerning the establishment of the tolerable daily intake (TDI) in the Joint FAO/WHO Expert Committee on Food Additives and Contaminants report[(5)].

(3) The CONTAM Panel established an updated group TDI of 2 μg/kg body weight per day for 3-MCPD and its fatty acid esters. It noted that this TDI is not exceeded in the adult population. However, a slight exceedance of the TDI was observed in case of the high consumers of the younger age groups and in particular in case of infants receiving formula only.

(4) 3-MCPD and its fatty acid esters are processing contaminants formed during the refinement process of vegetable oils. It is therefore appropriate to establish maximum levels for the presence of 3-MCPD and its fatty acid esters in vegetable oils and fats placed on the market for the final consumer or for use as an ingredient in food. As virgin olive oils do not contain glycidyl fatty acid esters, 3-MCPD and its fatty acid esters, it is appropriate that neither these new maximum levels for 3-MCPD and its fatty acid esters or the existing maximum level for glycidyl fatty acid esters apply to virgin oils

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2020/1322. (See end of Document for details)*

(5) However, given the possible health concern for infants 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 of processed cereal-based food for infants and young children.

(6) In order to exclude any possible health concerns as regards infants and young children, in particular taking into account the possible exposure to 3-MCPD and its fatty acid esters of infants solely fed on infant formula, it is appropriate to establish specific strict maximum levels, depending on whether they are sold in powder or liquid form, for infant formula, follow-on formula and food for special medical purposes intended for infants and young children.

(7) Given that the slight exceedance of the TDI was observed in high consumers of the younger age groups and not only in infants receiving formula only, it is appropriate to apply the same strict level to young child formula given that these formula are also consumed by the children younger than 3 years. In addition, it is appropriate to establish the existing maximum level for glycidyl fatty acid esters for infant formula and follow on formula also for young child formula.

(8) Furthermore, it has recently become evident by scientific publications and occurrence data received, that also fish oil and oils from other marine organisms can contain high levels of glycidyl fatty acid esters and 3-MCPD and its fatty acid esters. In order to ensure a high level of human health protection, it is appropriate to establish a maximum level for glycidyl fatty acid esters and 3-MCPD and its fatty acid esters in fish oil and oils from other marine organisms.

(9) Food business operators should be granted enough time to adapt their production processes and therefore it is appropriate that the maximum levels for 3-MCPD and its fatty acid esters and the new maximum levels of glycidyl esters in young child formula and fish oil and oils from other marine organisms only apply from 1 January 2021. Furthermore, it is appropriate to allow products not complying with the maximum levels for 3-MCPD and its fatty acid esters and placed on the market before that date to remain on the market until their date of minimum durability or use-by-date. However, given that glycidyl fatty acid esters are genotoxic carcinogens, and consequently their presence is a higher risk for public health, products not complying with the new maximum levels for glycidyl fatty acid esters and placed on the market before 1 January 2021 should only be allowed to remain on the market for a limited period of time.

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

(11) 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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2020/1322. (See end of Document for details)*

Article 2

Fish oils and oils from other marine organisms referred to in point 4.2.1 and 4.2.2 of the Annex to Regulation (EC) No 1881/2006 and young child formula referred to in point 4.2.3 and 4.2.4 of that Annex that were lawfully placed on the market before 1 January 2021 may continue to be marketed until 30 June 2021.

Foodstuffs listed under point 4.3 of the Annex to Regulation (EC) No 1881/2006 that were lawfully placed on the market before 1 January 2021 may continue to be marketed until their date of minimum durability or use-by date.

Article 3

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, 23 September 2020.

For the Commission

The President

Ursula VON DER LEYEN

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2020/1322. (See end of Document for details)*

ANNEX

In the Annex to Regulation (EC) No 1881/2006, Section 4 '3-monochloropropanediol (3# MCPD) and glycidyl fatty acid esters' is replaced by the following:

SECTION 4: 3-MONOCHLOROPROPANEDIOL (3-MCPD), 3-MCPD FATTY ACID ESTERS AND GLYCIDYL FATTY ACID ESTERS

Foodstuffs ([1])		**Maximum level (µg/kg)**
4.1	**3-monochloropropanediol (3-MCPD)**	
4.1.1	Hydrolysed vegetable protein ([30])	20
4.1.2	Soy sauce ([30])	20
4.2	**Glycidyl fatty acid esters, expressed as glycidol**	
4.2.1.	Vegetable oils and fats, fish oils and oils from other marine organisms placed on the market for the final consumer or for use as an ingredient in food, with the exception of the foods referred to in 4.2.2 and of virgin olive oils [a]	1 000[c]
4.2.2.	Vegetable oils and fats, fish oils and oils from other marine organisms destined for the production of baby food and processed cereal-based food for infants and young children ([3])	500[cf]
4.2.3	Infant formula, follow-on formula and foods for special medical purposes intended for infants and young children ([3]) ([29]) and young-child formula ([29]) [b] (powder)	50 [c]
4.2.4	Infant formula, follow-on formula and foods for special medical purposes intended for infants and young children ([3]) ([29]) and young-child formula ([29])[b] (liquid)	6,0[c]