

3-,2-MCPD and their fatty acid esters and glycidyl fatty acid esters

1) EFSA opinion on 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 food¹

EFSA delivered a scientific opinion on free and esterified 3- and 2-monochloropropane-1,2-diol (MCPD) and glycidyl esters in food. Data on 2-MCPD toxicity were insufficient for dose–response assessments. Chronic treatment with glycidol increased the incidence of tumours in several tissues of rats and mice, likely via a genotoxic mode of action. The Panel selected a BMDL10 value for 3-MCPD of 0.077 mg/kg bw per day for induction of renal tubular hyperplasia in rats and derived a tolerable daily intake (TDI) of 0.8 µg/kg bw per day. The mean exposure to 3-MCPD was above the TDI for ‘Infants’, ‘Toddlers’ and ‘Other children’. For glycidol, the Panel selected a T25 value of 10.2 mg/kg bw per day for neoplastic effects in rats. The margins of exposure (MoEs) were 11,300–102,000 and 4,900–51,000 across surveys and age groups at mean and P95 exposures, respectively. An exposure scenario for infants receiving formula only resulted in MoEs of 5,500 (mean) and 2,100 (P95). MoEs of 25,000 or higher were considered of low health concern.

2) Regulatory follow up currently under discussion – does not necessarily reflect the views of the Commission services

The regulatory follow-up to the outcome of the EFSA opinion was discussed at the Expert Committee "Industrial and Environmental Contaminants" on 30 June 2016. **The outcome of this discussion, although not yet agreed, is hereby outlined for your input. In view of the discussions at the next meeting of the Expert Committee in September 2016, any comments, information, input of relevance for this discussion should be provided to Frans Verstraete (preferably by email – Frans.Verstraete@ec.europa.eu) by Monday 5 September at the latest.**

¹ EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2016. 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

a) Vegetable oils and fats

The setting of a maximum level of 3-MCPD-esters and glycidyl esters in vegetable oils and fats was found to be appropriate.

The establishment of a maximum level of glycidyl esters of 1.0 mg/kg to be applicable as from September 2017 was suggested. This maximum level is in line with the commitment made by the EU Oil and Protein meal Industry. The commitment was very much welcomed by the Committee and it was acknowledged that it is a strong commitment requiring substantial efforts from the industry.

The establishment of a maximum level of 3-MCPD esters of 2.0 mg/kg to be applicable as from September 2017 was suggested. This maximum level is in line with the commitment made by the competent authority of a main producing country of palm oil. The commitment was nuanced in further follow-up messages. The EU Oil and Protein meal Industry have expressed concerns as regards the achievability/feasibility of this maximum level without serious compromising other safety and quality parameters.

It was furthermore stressed in the Committee that in case further discussions would indicate the need to set a higher level for 3-MCPD-esters, then it should be considered to set the higher level only for palm oil/fat and a significant lower level for the other vegetable oils and fats.

It was considered that there was no need to set for the time being a maximum level for 2-MCPD esters given that EFSA could not conclude on the toxicity of 2-MCPD esters and furthermore there appears to be a good correlation between the presence of 3-MCPD (esters) and 2-MCPD (esters). Consequently any measure taken to reduce the presence of 3-MCPD esters should also result in a reduction of the presence of 2-MCPD esters in vegetable oils and fats.

b) Infant formula and follow-on formula

Given the health concerns expressed in the EFSA opinion for infants and young children, in particular infants receiving infant formula only, it is appropriate to establish strict measures for 3-MCPD esters and glycidyl esters to ensure a high level of human health protection.

The suggested maximum levels take into account the need to set strict maximum levels to address the public health concerns outlined in the EFSA opinion, the available occurrence data, the commitments made by the competent authority of a main producing country of palm oil as regards 3-MCPD esters in palm oil provided to infant formula producers, and by the EU Oil and Protein meal Industry as regards glycidyl esters and the information provided by Specialised Nutrition Europe.

c) Other foods containing vegetable oils and fats

The appropriate risk management measures for foods containing vegetable oils and fats (and also other foods) other than infant formula and follow-on formula shall be discussed in a second phase (from autumn 2016 onwards) and might include other risk management measures/approaches than/besides the setting of maximum levels and **this taking into consideration the input from European professional stakeholder organisations**

d) Suggested maximum levels

Food commodity	3-MCPD esters (mg/kg)	glycidyl esters (mg/kg)
Vegetable oils and fats for direct human consumption or use as an ingredient in food	2.0	1.0
Infant formula and follow-on formula (powder)	0.125	0.075
Infant formula and follow-on formula (liquid)	0.015	0.010

3) Comments and information from stakeholder organisations

In view of the discussions at the next meeting of the Expert Committee in September 2016, the European stakeholder organisations are invited to provide any comments, information, input of relevance for this discussion on the suggestions made in this paper to Frans Verstraete (preferably by email – Frans.Verstraete@ec.europa.eu) by Monday 5 September at the latest.