

RECOMMENDATIONS

COMMISSION RECOMMENDATION

of 10 September 2014

on the monitoring of the presence of 2 and 3-monochloropropane-1,2-diol (2 and 3-MCPD), 2- and 3-MCPD fatty acid esters and glycidyl fatty acid esters in food

(Text with EEA relevance)

(2014/661/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) 3-Monochloropropane-1,2-diol (3-MCPD) is a food processing contaminant classified as a possible human carcinogen for which a tolerable daily intake (TDI) of 2 µg/kg b.w. has been established ⁽¹⁾. A maximum level of 20 µg/kg for hydrolysed vegetable protein (HVP) and soy sauce has been established by Commission Regulation (EC) No 1881/2006 ⁽²⁾ for liquid products containing 40 % dry matter, corresponding to a maximum of 50 µg/kg in the dry matter.
- (2) Esters of 2- and 3-monochloropropane-1,2-diol (MCPD) and glycidyl esters are important contaminants of processed edible oils used as foods or food ingredients. The European Food Safety Authority (EFSA) Panel on Contaminants in the Food Chain (CONTAM) agreed with the estimate of 100 % release of 3-MCPD from its esters in humans ⁽³⁾.
- (3) Glycidyl fatty acid esters (GE) are process contaminants generated during the deodorisation step of edible oil refining. The toxicological relevance of glycidyl fatty acid esters has not yet been fully elucidated. Glycidol itself is categorised as probably carcinogenic to humans. Latest scientific studies indicate an (almost) entire release of glycidol from fatty acid esters within the human digestive tract.
- (4) On 20 September 2013, EFSA has published a scientific report on the analysis of occurrence of 3-monochloropropane-1,2-diol (3-MCPD) in food in Europe in the years 2009-2011 and preliminary exposure assessment ⁽⁴⁾.
- (5) More occurrence data on the presence of the MCPD fatty acid esters and glycidyl fatty acid esters are necessary to enable a more accurate exposure assessment.
- (6) Therefore it is appropriate to recommend the monitoring of the presence of MCPD, MCPD-esters and glycidyl esters in vegetable oils and fats, derived foods and foods containing vegetable oils and fats.

⁽¹⁾ Opinion of the Scientific Committee on Food on 3-monochloropropane-1,2-diol (3-MCPD) updating the SCF opinion of 1994 (adopted on 30 May 2001) http://ec.europa.eu/food/fs/sc/scf/out91_en.pdf

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

⁽³⁾ Statement of the Scientific Panel on Contaminants in the Food chain (CONTAM) on a request from the European Commission related to 3-MCPD esters <http://www.efsa.europa.eu/en/efsajournal/doc/1048.pdf>

⁽⁴⁾ European Food Safety Authority, 2013 Analysis of occurrence of 3-monochloropropane-1,2-diol (3-MCPD) in food in Europe in the years 2009-2011 and preliminary exposure assessment. EFSA Journal 2013;11(9):3381, 45 pp. doi:10.2903/j.efsa.2013.3381 Available online: www.efsa.europa.eu/efsajournal

HAS ADOPTED THIS RECOMMENDATION:

1. Member States should, with the active involvement of feed and food business operators, perform monitoring for the presence of 2 and 3-MCPD, 2 and 3-MCPD fatty acid esters and glycidyl fatty acid esters in food, and particularly in:
 - (a) vegetable oils and fats and derived products such as margarine and similar products,
 - (b) foods for particular nutritional uses as defined in Directive 2009/39/EC of the European Parliament and of the Council ⁽¹⁾ and intended for infants and young children, including infant- and follow on formulae as defined in Commission Directive 2006/141/EC ⁽²⁾ and dietary foods for special medical purposes as defined in Commission Directive 1999/21/EC ⁽³⁾ intended for use by infants,
 - (c) fine bakery wares, bread and rolls,
 - (d) canned meat (smoked) and canned fish (smoked),
 - (e) potato- or cereal-based snacks, other fried potato-based products,
 - (f) vegetable oil containing foods and foods prepared/produced with vegetable oils.

It is recognised that the analysis of 2 and 3-MCPD, 2 and 3-MCPD fatty acid esters and glycidyl fatty acid esters in foods mentioned in points (b) to (f) is very challenging and no methods of analysis, which have been validated by a collaborative study, are yet available. Therefore particular attention has to be paid when analysing foods mentioned in points (b) to (f) in order to ensure that the generated data are reliable.

Therefore, Member States which intend to analyse the presence of 2 and 3-MCPD, 2 and 3-MCPD fatty acid esters and glycidyl fatty acid esters in foods mentioned in points (b) to (f) may request, if appropriate and needed, the technical assistance of the Commission's Joint Research Centre, Institute for Reference Materials and Measurements (IRMM), Unit Standards for Food Bioscience.

2. In order to ensure that the samples are representative for the sampled lot, Member States should follow the sampling procedures laid down in Part B of the Annex to the Commission Regulation (EC) No 333/2007 ⁽⁴⁾.
3. In order to determine ester bound MCPD and glycidol, it is recommended to use the American Oil Chemists' Society standard methods. These methods are Gas-Chromatography Mass Spectrometry methods (GC-MS) which have been validated by a collaborative study for vegetable oils and fats and are available at www.aocs.org.

The Limit of Quantification (LOQ) should not be higher than 100 µg/kg for the analysis of MCPD and glycidol bound to fatty acid esters in edible oils and fats. For other foods containing more than 10 % fat, the LOQ should preferably be not higher when related to the fat content of the food, i.e. the LOQ for the analysis of fatty acid esters of MCPD and glycidol in food containing 20 % fat should not be higher than 20 µg/kg on whole weight basis. For foods containing less than 10 % fat, the LOQ should be not higher than 10 µg/kg on whole weight basis.

4. Laboratories should have quality control procedures in place to avoid the transformation of glycidyl esters into MCPD esters and vice versa during the analysis. Furthermore unambiguous specification of the measurand and separate reporting is necessary of the free 2- and 3- MCPD present in the analysed matrix from the 2- and 3-MCPD fatty acid esters, as both are measured as 3-MCPD. Following measurands should be reported separately:

- 2-MCPD
- 3-MCPD
- 2-MCPD esters
- 3-MCPD esters
- glycidyl esters.

⁽¹⁾ Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (OJ L 124, 20.5.2009, p. 21).

⁽²⁾ 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).

⁽³⁾ Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29).

⁽⁴⁾ Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and polycyclic aromatic hydrocarbons in foodstuffs (OJ L 88, 29.3.2007, p. 29).

There is no evidence for the time being of the presence of free glycidol in foods referred to in Point (1). However in case where free glycidol would be analysed, this should be reported separately.

5. Member States should ensure that the analytical results are provided on a regular basis (every six months) to EFSA in the EFSA data submission format in line with the requirements of EFSA's Guidance on Standard Sample Description (SSD) for Food and Feed ⁽¹⁾ and the additional EFSA's specific reporting requirements.

A simplified format, with fewer mandatory fields to be completed, will be made available to ensure maximum submission of useful available monitoring data.

6. A guidance note will be elaborated to ensure uniform application of this Recommendation and to ensure comparable reporting of results.

Done at Brussels, 10 September 2014.

For the Commission
Tonio BORG
Member of the Commission

⁽¹⁾ <http://www.efsa.europa.eu/en/datex/datexsubmitdata.htm>