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**FEDIOL general Q&A
on
2- and 3-MCPD and Their Esters and Glycidyl Esters**

**Occurrence in Vegetable Oils and Fats and in Food
Potential Implications for Human Health and EU actions**

1. What are 3-MCPD and 2- and 3-MCPD Esters? In which foods are they present and why?

3-MCPD¹ are substances formed during food production and food preparations when they are exposed to high temperatures. They were identified in the late 1970s in the composition of hydrolysed vegetable protein (HVP) such as in soya sauces. They are not naturally present in vegetable oils.

2- and 3- MCPD esters were identified more recently and are formed in vegetables oils during the refining process. A number of different factors contribute to their formation, notably the presence of precursors and the temperature applied during the refining process that is needed to reach quality and safety specifications.

According to EFSA findings², 2- and 3-MCPD esters occur in refined vegetable oils and fats. These substances also occur in other product groups, which contain fats and oils. It is likely that they have been part of the human diet since man started to eat cooked food.

2. What are the potential implications, for human health, of 3-MCPD and 3-MCPD esters according to EFSA? Which actions have been taken at EU level?

In 2001, European and national scientific authorities set the upper safe level (i.e. TDI) of 3-MCPD that can be consumed on a daily basis over a lifespan at 2 µg per kg body weight per day. Regulatory limits for 3-MCPD were defined in EU law for soya sauce and for hydrolysed vegetable protein that are low enough to protect consumer's health.

According to EFSA, 3-MCPD esters are considered to have the same toxicological profile as 3-MCPD.

¹ i.e. 3-monochloropropane-1,2-diol

² EFSA scientific opinion, "Risks for human health related to the presence of 3- and 2-MCPD and their fatty acid esters, and glycidyl fatty acid esters in food", 2016.

In May 2016, EFSA set a tolerable daily intake (TDI) of 0.8 µg per kg of body weight per day for both 3-MCPD and 3-MCPD esters. In November 2016, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) also carried out a risk assessment on 3-MCPD esters³, setting a TDI of 4 µg per kg body weight per day. As EFSA identified in February 2017⁴, the difference between EFSA and JECFA was mainly due to methodological differences in the application of the benchmark dose (BMD) approach.

Following an update to the EFSA guidance on the benchmark dose modelling approach (BMDL), EFSA re-evaluated its opinion on 3-MCPDE and published an update in January 2018⁵ in which a revised TDI of 2 µg per kg of body weight per day was set for both 3-MCPD and 3-MCPD esters.

EU risk management discussions led to the setting of maximum levels (MLs) in Regulation (EU) No 2020/1322 of 23 September 2020, amending Regulation (EC) No 1881/2006 as regards maximum levels of 3-monochloropropane diol (3-MCPD), 3-MCPD fatty acid esters and glycidyl fatty acid esters in certain foods⁶: 1.25 mg/kg in vegetable oils and fats from coconut, maize, rapeseed, sunflower, soybean, palm kernel and olive oils (composed of refined olive oil and virgin olive oil) and mixtures of oils and fats with oils and fats only from this category and 2.5 mg/kg for other vegetable oils (including pomace olive oils), fish oils and oils from other marine organisms and mixtures of oils and fats with oils and fats only from this category and mixtures of oils and fats from the two above mentioned categories. Such EU MLs for 3-MCPD and 3-MCPD esters enter into force on 1st January 2020.

4. What are glycidyl esters?

Glycidyl esters (GE) are also formed during the refining of vegetable oils and fats at high temperatures, particularly in the deodorisation step. Deodorisation aims to remove unwanted taste and odour and produce oils and fats with required quality and safety specifications.

Glycidyl esters are also found therefore in refined vegetable oils and fats and in foods containing them, and they are also likely to have been part of the human diet since man started to eat cooked food.

5. What are the potential implications, for human health, of GE? Which actions have been taken at EU level?

Based on a Margin or Exposure (MoE) approach, EFSA concluded that exposure to GE gives rise to health concerns for infants, toddlers and other children, and in particular for infants receiving “formula-only” diet. Concerns were also expressed for other groups consuming large amounts of refined vegetable oils and fats.

EFSA also recognized at the same time a 50% reduction in the levels of GE over the period 2010 to 2015.

³ JECFA 83rd meeting summary, 8-17 November 2016.

⁴ EFSA Scientific Committee, Minutes of the 82nd Plenary meeting, Held on 13-14 February 2017, Agreed on 6 March 2017 <http://www.efsa.europa.eu/sites/default/files/event/170213-m.pdf>

⁵ EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), Knutsen, HK, Alexander, J, Barregård, L, Bignami, M, Brüschweiler, B, Ceccatelli, S, Cottrill, B, Dinovi, M, Edler, L, Grasl-Kraupp, B, Hoogenboom, LR, Nebbia, CS, Oswald, IP, Petersen, A, Rose, M, Roudot, A-C, Schwerdtle, T, Vleminckx, C, Vollmer, G, Wallace, H, Lampen, A, Morris, I, Piersma, A, Schrenk, D, Binaglia, M, Levorato, S and Hogstrand, C, 2018. Scientific Opinion on the update of the risk assessment on 3-monochloropropane diol and its fatty acid esters. EFSA Journal 2018;16(1): 5083, 48 pp. <https://doi.org/10.2903/j.efsa.2018.5083>

EU risk management discussions led to the setting of maximum levels (MLs) in Regulation (EC) No 1881/2006: 1mg/kg in vegetable oils and fats. Such EU MLs for GE entered into force in 2018, although FEDIOL members were already achieving a maximum level of 1mg/kg in vegetable oils and fats by September 2017, as the result of an industry commitment taken in mid-2015.

6. What are the potential implications, for human health of 2-MCPD and 2-MCPD esters?

Due to insufficient toxicological information, EFSA could not undertake a risk characterization and could not set a TDI for 2-MCPD and 2-MCPD esters in 2016.

EFSA has therefore recommended further research into the metabolism and mode of actions of these substances.

It is expected that the implementation of strategies by FEDIOL members to mitigate 3-MCPD esters will lead as well to a reduction in levels of 2-MCPD esters.

Analytics of 2- and 3-MCPD esters and glycidyl esters

7. What are the methods applicable to test 2- and 3-MCPD esters and glycidyl esters in vegetable oils and fats? What about processed foods?

In recent years, huge efforts have been made to develop and evaluate analytical methodologies for 2- and 3-MCPD esters and glycidyl esters in vegetable oils and fats, in order to find appropriate and reliable methods. There are a number of direct and indirect methods of analysis available.

FEDIOL prepared an overview of available analytical methods, which can be found [here](#) (updated March 2019). FEDIOL will continue monitoring analytical developments very closely and update its overview on a regular basis.

Methods for more complex food products have been available since March 2015 and were validated later in the same year. The European Joint Research Center (JRC) developed methods for the analysis of MCPD (both in free and ester form) and glycidyl esters in various food matrices⁶.

Industry Actions and Mitigation Measures

8. What steps are undertaken to reduce 2- and 3-MCPD esters and glycidyl esters?

⁶ Thomas Wenzl, Vasilios Samaras, Anupam Giri, Gerhard Buttinger, Lubomir Karasek, Zuzana Zelinkova, 2015. Development and validation of analytical methods for the analysis of 3-MCPD (both in free and ester form) and glycidyl esters in various food matrices and performance of an ad-hoc survey on specific food groups in support to a scientific opinion on comprehensive risk assessment on the presence of 3-MCPD and glycidyl esters in food. EFSA supporting publication 2015: EN-779, 78 pp.

There are a variety of measures that can contribute to prevent, reduce or remove 2- and 3-MCPD esters and glycidyl esters⁷.

FEDIOL members first focused on GE, due to the risk profile of this substance. GE mitigation methods are now in place in each factory, whilst maintaining all other processing conditions required to ensure the quality and safety of vegetable oils and fats. FEDIOL members comply with EU maximum levels (MLs) set by Regulation (EC) No 1881/2006.

Achieving lower 3-MCPD esters is more complex. Hence, specific techniques to prevent and reduce their occurrence had to be developed independently of the methods used to mitigate GE. The 3-MCPDE mitigation techniques are now being implemented by companies at each of their processing facilities to ensure that EU maximum levels required by the new Regulation will be met.

It is expected that the implementation of strategies to mitigate 3-MCPD esters will lead as well to a reduction in levels of 2-MCPD esters.

To get a fuller picture on mitigation practices, the Codex Alimentarius initiated work on a Code of Practice for the reduction of 3-MCPDE and GE in refined oils and fats and food products made with refined oils and fats. As an observer to the Codex Alimentarius, FEDIOL provided input throughout the process. The Code of Practice was adopted in 2019 and can be found [here](#).

9. What will be FEDIOL industry's next steps?

As regards to 3-MCPD esters, FEDIOL apply mitigation measures across their different facilities to fully comply with Regulation (EU) No 2020/1322.

GE mitigation methods are already fully in place, and companies will continue to apply them to ensure compliance with EU maximum levels.

FEDIOL will continue providing occurrence data on 2- and 3-MCPDE and GE to EFSA.

⁷ FEDIOL published a *Review of mitigation measures for 3-MCPD esters and Glycidyl esters*, June 2015, which is available on the [FEDIOL web-site](#)