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FEDIOL 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

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

2- and 3-MCPD<sup>1</sup> 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 present in vegetable oils.

More recently identified, 2- and 3- MCPD esters are formed in vegetable oils during the refining process. A number of different factors contribute to their formation, notably the temperature that is applied during the deodorisation step of the refining process (over 230°C) that is needed to reach quality and safety specifications. Research is still on-going to better understand the formation processes, notably regarding 2-MCPD and 2-MCPD esters, which are less known compounds.

According to EFSA findings<sup>2</sup>, 2- and 3-MCPD esters occur in vegetable oils and fats, with palm oil showing higher levels. The 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 ?

In 2001, European and national scientific authorities set the upper safe level (i.e. TDI of 2 µg per kg of body weight per day) of 3-MCPD that can be consumed on a daily basis over a lifespan. 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.

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<sup>1</sup> i.e. 2-monochloropropane-1,3-diol and 3-monochloropropane-1, 2-diol

<sup>2</sup> 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, page 33-35

In the recent EFSA Opinion (May 2016), 3-MCPD esters are considered to have the same toxicological profile as 3-MCPD.

After analysing available repeated dose studies, EFSA has established 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 May 2016. Based on this TDI, EFSA identified a potential health concern as it determined of potential for exposure above TDI in certain age groups. EFSA is currently reopening its opinion. See below under question 3 for more details.

Due to a lack of toxicological information, the health effects of 2-MCPD and 2-MCPD esters are less understood and therefore, despite available occurrence data, no TDI has been set.

### 3. What does the JECFA assessment regarding 3-MCPD ester imply?

In November 2016, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) also carried out a risk assessment on 3-MCPD esters based on the same research data as EFSA (Cho et al.) and using the same type of modelling approach for the determination of the upper safe dose (Benchmark Dose Modelling). JECFA, however, came to the conclusion that the TDI for 3-MCPD esters should be 4 µg per kg body weight per day and not 0.8 µg per kg body weight as concluded by EFSA<sup>3</sup>.

These divergent findings arose due to differences in the application of the benchmark dose modelling for the dose-response analysis by JECFA and by the EFSA CONTAM Panel. In its meeting in January 2017, the EFSA CONTAM Panel agreed<sup>4</sup> that it is appropriate to reopen its Scientific Opinion on the risks for human health related to the presence of 3- and 2-MCPD, and their fatty acid esters, and glycidyl fatty acid esters (EFSA-Q-2014-00535) to address the identified scientific divergence. The EFSA Scientific Committee meeting in February 2017<sup>5</sup> highlighted that "While there is a substantial alignment of the two scientific bodies (i.e. EFSA and JECFA) in the identification of the hazards for 3-MCPD and its fatty acid esters and glycidyl fatty acid esters, the divergence consists mainly in the dose-response analyses performed, due to methodological differences in the application of the benchmark dose (BMD) approach".

Work is currently ongoing in EFSA to address these divergences.

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

As highlighted by EFSA in its opinion, 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. 2-MCPD and 2-MCPD esters were not included in the recent JECFA assessment.

EFSA is recommending investigating further the metabolism and mode of actions of these substances in order to better characterize them in a near future.

### 5. What are glycidyl esters? In which foods are they present and why?

EFSA, in its May 2016 Opinion, states that glycidyl esters are formed during the

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<sup>3</sup> JECFA 83rd meeting summary, 8-17 November 2016. Full monograph not yet published.

<sup>4</sup> EFSA Scientific Panel on Contaminants in the Food Chain, Minutes of the 82nd plenary meeting, Held on 24-26 January 2017, Parma (Italy), Agreed on 20-02-2017  
[http://www.efsa.europa.eu/sites/default/files/event/170124-m\\_0.pdf](http://www.efsa.europa.eu/sites/default/files/event/170124-m_0.pdf)

<sup>5</sup> 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>

refining of vegetable oils and fats at high temperatures, particularly in the deodorisation step. The deodorisation aims to remove unwanted taste and odour and meet customer quality and safety specifications.

Glycidyl esters are only found in refined vegetable oils and fats and in foods that contain refined vegetable oils and fats, with a higher occurrence in palm oil. It is likely that they have been part of the human diet since man started to eat cooked food.

#### 6. What are the potential implications of glycidyl esters for human health?

According to EFSA's May 2016 Opinion, glycidyl esters (GE) are substances for which, due to their profile, no TDI can be set. For the glycidyl esters risk assessment, EFSA used the Margin of Exposure (MoE) approach to determine whether these substances are of concern. The MoE approach determines whether a value is of high concern, low concern or unlikely to be of safety concern. The magnitude of an MoE only indicates a level of concern and does not quantify the risk<sup>6</sup>.

EFSA concluded that exposure gives rise to health concerns for infants, toddlers and other children, and in particular for infants receiving "formula-only" diet; there are similar concerns for high-quantity consumers.

In line with the profile described in existing assessments of these substances, FEDIOL members already regarded glycidyl esters as substances that potentially could pose health concerns. Hence, FEDIOL members already took measures to reduce the levels of these substances and can already demonstrate significant achievement in this respect. Over the period 2010 to 2015, a 50% reduction of glycidyl esters has been achieved, as highlighted in the EFSA opinion. FEDIOL members have committed to achieve further reduction.

#### 7. What does the JECFA assessment for glycidyl esters imply ?

The approach followed by JECFA in November 2016 for glycidyl ester is the same as the approach used by EFSA i.e. Margin of Exposure approach. The outcomes of the JECFA and the EFSA assessments can be regarded as similar. EFSA also concluded in February 2017 that it will not reopen its opinion on glycidyl esters<sup>7</sup>.

#### 8. Why is higher occurrence found in palm oil and what are the implications?

Palm oil contains higher levels of glycidyl esters and 3-MCPD esters. This is the result of several different factors such as: the higher natural occurrence of some substances present in palm fruit (so-called "precursors") that are converted into 3-MCPD esters in further processing; the maturity of palm bunches at harvest; the time delay between harvesting and processing; transport.

As highlighted by EFSA, levels of glycidyl esters in palm oil show that mitigation techniques have delivered results, namely a 50% reduction in glycidyl esters over a 5-year period (2010-2015).

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<sup>6</sup> EFSA MoE approach: <http://www.efsa.europa.eu/en/efsajournal/pub/2578>

<sup>7</sup> Ibidem footnote 5.

9. Should products containing these substances be removed from the market?

The concerns expressed by EFSA relate to long-term exposure, as is the case for other undesirable substances that occur in the food chain either naturally or during food production.

At no point have European Commission services indicated that operators should withdraw products from the market or change their product formulations. Calling for the removal or ban of products and/or ingredients from the market would in our views be disproportionate.

We understand that the European Commission has already engaged without delay with Member States to define possible legislative measures such as setting maximum levels for 3-MCPD esters and glycidyl esters. These discussions are ongoing.

At the same time, the vegetable oil and fat industry continues implementing its mitigation program to reduce glycidyl esters. Before the EFSA report had been elaborated, industry had designed and started implementing mitigation measures, which led to achieving substantial reductions in the levels of glycidyl esters. Our industry is also stepping up its work on 3-MCPD esters and will duly keep the authorities informed of progress made.

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

10. 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. EFSA applies three validated American Oil Chemist's Society (AOCS) methods of analysis that provide directly comparable results (developed by SGS, DGF and Unilever) to test 2- and 3-MCPD esters and glycidyl esters in vegetable oils and fats<sup>8</sup>. FEDIOL has been using the above methods for its data collection.

Methods for more complex food products have only been available since March 2015; and these were only validated later that 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 matrices<sup>9</sup>.

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<sup>8</sup> AOCS Official Method Cd 29a-13 Approved 2013: 2- and 3-MCPD Fatty Acid Esters and Glycidol Fatty Acid Esters in Edible Oils and Fats by Acid Transesterification; AOCS Official Method Cd 29b-13 Approved 2013: Determination of Bound Monochloropropanediol- (MCPD-) and Bound 2,3-epoxy-1-propanol (glycidol-) by Gas Chromatography/Mass Spectrometry (GC/MS); AOCS Official Method Cd 29c-13 Approved 2013: Fatty-acid-bound 3-chloropropane-1,2-diol (3-MCPD) and 2,3-epoxy-propane-1-ol (glycidol), Determination in Oils and Fats by GC/MS (Differential Measurement). (It should be mentioned that 2 out of the 3 methods listed hereinbefore enable to test 2-MCPD esters).

<sup>9</sup> 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.

## Industry Actions and Mitigation Measures

### 11. What have vegetable oil and fat refiners been doing about these substances?

The vegetable oil and fat processing industry is committed to food safety and has worked on many aspects related to this issue, of which the following are of particular importance:

- Vegetable oil and fat refiners have been actively working on effective mitigation technologies.  
Converting pilot projects into full-scale production-line processes is complex; it requires the deployment of techniques in each single factory to prevent, remove or reduce the occurrence of these substances.  
Implementing mitigation measures takes time as industry needs to take into account the specific process, plant design in each site and location, whilst at the same time maintaining existing processing conditions that are required to ensure the quality and safety of vegetable oils and fats.
- Vegetable oil and fat refiners have – within the FEDIOL remit - collected a substantial amount of data according to validated test methods.  
These data have been submitted to EFSA to be used in its exposure and risk assessment. Over 4,000 data points have hence been collected and fed into the EFSA data bank.
- Vegetable oil and fat refiners have, as a priority, committed to reduce the levels of glycidyl esters of all vegetable oils to a maximum 1ppm (or 1mg/kg) by September 2017, because of the risk profile of this substance. They have also committed to continue reducing levels of 3-MCPD esters. The work undertaken by FEDIOL was shared with EU authorities and has been openly acknowledged.

### 12. Is it possible to reduce 2- and 3-MCPD esters and glycidyl esters? Which mitigation measures are available? Are they effective?

There are a variety of measures that can contribute to prevent, reduce or remove 2- and 3-MCPD esters and glycidyl esters<sup>10</sup>. For these substances, it is critical to reduce the temperature and duration of the refining process, especially the deodorisation. However, the refining conditions are also crucial to assure other minor components are being removed in order to obtain end products that both taste good and are safe.

The difficulty faced by refiners is that there is no one-size-fits-all technique, nor any breakthrough technology. Instead, what needs to be implemented are process developments that combine various different techniques and take into account parameters such as: the type of oil; refining conditions; and the specificities of each factory.

FEDIOL members have so far focused their efforts on glycidyl ester reduction as it was felt this was the top priority. EFSA acknowledged that a substantial reduction has been achieved (50% over a five-year period in the case of palm oil). Mitigation on 3-MCPD esters has proven to require more time to implement, but with the TDI set by EFSA in May 2016, FEDIOL members have accelerated their development.

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<sup>10</sup> FEDIOL published a Review of mitigation measures for 3-MCPD esters and Glycidyl esters, June 2015, which is available on the [FEDIOL web-site](#)

While the health risks associated with the current level of exposure to 2-MCPD esters are not characterised, it is expected that the implementation of strategies to mitigate 3-MCPD esters will lead as well to a reduction of 2-MCPD esters levels.

### 13. What will be the industry's next steps?

On glycidyl esters, FEDIOL companies are continuing the implementation of their mitigation plans aiming at reducing the levels of glycidyl esters in all vegetable oils and fats for food to 1 mg/kg.

As regards 3-MCPD esters, work is currently focusing on developing internal company strategies. EFSA set an unexpectedly low TDI of 0.8µg/kg bw/d for 3-MCPD esters in May 2016.

FEDIOL members are currently assessing thoroughly all feasible mitigation options that may provide substantial reduction of 3-MCPD esters exposure. Following the JECFA different outcome, EFSA decided to reopen its opinion, the outcome of which will further guide in terms of needed mitigations. See under question 3 for further details.

Companies continue to implement their roadmaps on how to address the levels of 2- and 3-MCPD esters and glycidyl esters. Specific focus is also given to address the health concerns raised in infant foods.

At this point in time, work is ongoing to define what is achievable or feasible for the reduction of 3-MCPD esters without seriously compromising other safety and quality parameters in refined vegetable oils and fats. In this complex assessment, undesirable side effects, i.e. on the environment, as well as capital expenditure required for new process equipment and operating costs also need to be taken into account.

Vegetable oil refining is a matter of balancing several parameters for a high quality and safe food for consumers. This includes managing potential contaminants whilst maintaining required functionality, shelf-life, colour of these products at optimal costs and with the lowest possible environmental impact. As this is a very complex matter with many angles, this takes some time.

FEDIOL members are assessing by which date effective mitigation options for 3-MCPD esters can be implemented in every refining site, allowing, if feasible, the definition of a FEDIOL roadmap including timelines to achieve reduction goals.

FEDIOL will follow any risk-management decisions that may be taken by the European Commission.

### 14. How will EFSA risk assessment be translated into maximum values?

It is the role of the European Commission to translate the risk assessment outcome into maximum values, where appropriate. Hence, for industry, the EFSA opinion provides direction and impetus for the continued efforts that still need to be made.

Prior to the publication of the ESFA report, FEDIOL members had already decided in 2015 to work towards applying a maximum level of 1 ppm for glycidyl ester by September 2017. This decision – which was highly ambitious, given the complexity of the implementation of required mitigation measures - will achieve a significant improvement in the exposure of consumers. Once the final EFSA Opinion will be released, we will also know what sort of reduction target we should aim for regarding 3-MCPD esters. Our current assessment of available mitigation technologies will help identify the reduction potential and the timeline for reduction.