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\(^1\) 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 soya. 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 (over 230°C) that is needed to reach quality and safety specifications. Research has taken place to better understand the formation processes and is still on-going, notably regarding 2-MCPD and 2-MCPD esters, which are less known compounds.

According to EFSA findings\(^2\), 2- and 3-MCPD esters occur in 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?

In 2001 European and national scientific authorities set a limit (i.e. TDI of 2 µg per kg of body weight per day) on the maximum amount of 3-MCPD that should be consumed on a daily basis. Regulatory limits for 3-MCPD are defined in EU law for soya sauce and for hydrolysed vegetable protein.

\(^1\)i.e. 2-monochloropropane-1,3-diol and 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, page 33-35
In the recent EFSA Opinion (May 2016), 3-MCPD esters are considered to have the same toxicological profile as 3-MCPD and are therefore a potential health concern.

After analysing a small number of long-term exposure studies, EFSA has established a tolerable daily intake (TDI). Thus a TDI of 0.8 μg per kg of body weight per day has been set as group TDI for both 3-MCPD and 3-MCPD esters.

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 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.

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

4. 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 refining of vegetable oils at high temperatures, i.e. 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.

5. 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.

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 pose health concerns. Hence, FEDIOL members have already taken 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.

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6. 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 as a result of several different factors such as: the higher natural occurrence of some substances present in palm fruit (so-called "precursors"); the maturity of palm bunches at harvest; the 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).

7. 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 3MCPD esters and glycidyl esters.

At the same time the oils and fats 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 and achieved substantial reductions in the levels of glycidyl esters. Our industry is also stepping up its work on 3MCPD esters and will duly keep the authorities informed of progress made.

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Analytics of MCPDE and GE

8. 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. 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

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4 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).
(JRC) developed methods for the analysis of MCPD (both in free and ester form) and glycidyl esters in various food matrices\(^5\).

### Industry Actions and Mitigation Measures

9. 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 that prevent, remove or reduce the occurrence of these substances. Implementing mitigation measures takes time as they need to take into account the specific process, plant design 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 oils to 1ppm (or 1mg/kg) because of the 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.

10. 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 with the potential to prevent, reduce or remove 2- and 3-MCPD esters and glycidyl esters\(^6\). For these substances it is critical to reduce the temperature and duration of the refining process. 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; and indeed EFSA acknowledges a substantial reduction

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\(^6\) FEDIOL published a Review of mitigation measures for 3MCPD esters and Glycidyl esters, June 2015, which is available on the [FEDIOL web-site](https://www.fediol.eu).
has been achieved (50% over a five-year period in the case of palm oil). Mitigation on 3MCPD esters has proven to require more time to implement, but with the TDI set by EFSA, FEDIOL members will accelerate their development and implementation plans.

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 reduction on 2-MCPD esters.

11. What will be the industry’s next steps?

On glycidyl esters, FEDIOL companies are continuing the implementation of their roadmaps.

As regards 3-MCPD esters, work is currently focusing on developing internal company roadmaps. Given the outcome of EFSA opinion establishing the low TDI of 0.8µg/kg bw/d, which was unexpected for 3-MCPD esters, FEDIOL members are currently assessing thoroughly all feasible mitigation options that may provide substantial reduction of 3-MCPD esters exposure and their implications.

According to current feedback by companies on their ongoing work, we expect receiving intermediate conclusions as of the third quarter of 2016 and implementation roadmaps between the third and fourth quarter of 2016. Specific focus is also given to address the health concerns raised on infant foods.

At this point in time, we do not know what may be achievable or feasible for the reduction of 3-MCPD esters without serious compromises to other safety and quality parameters and without undesired side effects, i.e. on environment. Capital expenditure that might be required and operating costs are at this point undetermined.

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

If feasible, our members are also assessing by which date potential mitigation options could possibly be implemented in every relevant site allowing 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.

12. 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. For industry, the EFSA opinion provides direction and impetus for the continued efforts that still need to be and will be made.

For our part FEDIOL members had already decided in 2015 – prior to the publication of the EFSA Opinion - to work towards applying a maximum level of 1 ppm of glycidyl ester by September 2017. This decision – which was highly ambitious, given the implementation of mitigation measures required - will achieve a significant improvement. The EFSA Opinion is an invitation for our sector to set ambitious targets for 3-MCPDE as well. We are addressing this new challenge with full and due diligence.