



Directorate-General for Health & Food Safety

**Recent development of EU food
safety legislation on contaminants,
with a particular focus on 3-MCPD
esters and glycidyl esters**

Frans Verstraete

Disclaimer

The provisions in this presentation are under discussion and have not been adopted or endorsed by the European Commission.

Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

Principles for regulating contaminants in feed and food in the EU

General food law

- * a **high level of protection of human health and animal health** has to be pursued
- * **free movement** within the European Union of feed and food compliant with EU legislation
- * **international standards** to be taken into account.
- * **feed and food placed on the market shall be safe**
- * **contaminant levels shall be kept as low as can reasonably be achieved following good practices at all stages (ALARA)**

Principles for regulating contaminants in feed and food in the EU

- * In order to achieve the general objective of a high level of protection of human health and animal health, **EU feed and food legislation shall be based on risk analysis** (process consisting of three interconnected components: risk assessment-risk management-risk communication)
- * Risk assessment shall be based on the **available scientific evidence** and undertaken in an **independent, objective and transparent manner** → **EFSA**
- * **Risk management shall take into account the results of risk assessment, other factors legitimate** to the matter under consideration and the precautionary principle where appropriate

From risk assessment to risk management

- Scientific risk assessment:
 - **assessment of the risks related to the presence of a contaminant in foodstuffs for human health / establishment of a tolerable intake / health based guidance value**
 - **exposure assessment: human exposure (average and 95 percentile) Particular attention to vulnerable groups of population, high level consumers, ...**
 - **risk characterisation: human exposure assessed in relation to the health based guidance value**

--> is the basis for the management measures to be taken

From risk assessment to risk management

- Risk assessment : health based guidance value → new approaches (The Margin of Exposure (MOE) approach, threshold of toxicological concern (TTC)...))
- Risk assessment always the basis for taking risk management measures related to food safety

From risk assessment to risk management

- Determination of foods/food groups significantly contributing to the exposure
- Food groups with frequent findings of high level of contamination
- Occurrence data of the contaminant/mycotoxin in the various food/food groups
- Setting a maximum level following the ALARA principle (As Low As Reasonably Achievable). The degree of severity of the application of this principle depends on the relation exposure - tolerable intake

From risk assessment to risk management

Other legitimate factors: considered on a case by case basis

- * Cost – benefit considerations (impact assessment)
- * Balance risks of contaminants – benefits of consumption of certain foods (health risk – health benefit considerations)
- * Feasibility/achievability by applying good practices
- * Analytical achievability/feasibility

MCPD esters and glycidylesters

- Collection of occurrence data on 3-MCPD -esters in different foodstuffs → EFSA report on occurrence became available in September 2013
- EFSA has been requested by the Commission for a risk assessment (see next slides)
- Recommendation 2014/661/EU on monitoring adopted on 10 September 2014.
- The monitoring of the presence of 2 and 3-MCPD, 2 and 3-MCPD esters and glycidyl esters is recommended in a whole range of foodstuffs (LOQ of 100 µg/kg)

EFSA opinion – mandate and terms of reference

European Commission requested EFSA a Scientific Opinion **on the risks for human health** related to the presence of 3- and 2-monochloropropanediol (3- and 2-MCPD) and 3- and 2-MCPD fatty acid esters and glycidyl fatty acid esters in food. The scientific opinion should, *inter alia*, comprise

- * evaluation of the toxicity, considering all relevant toxicological endpoints;
- * evaluation of the exposure of the EU population to 3- and 2-MCPD fatty acid esters and glycidyl fatty acid esters in addition to the exposure to 3- and 2-MCPD, including the consumption patterns of specific (vulnerable) groups of the population (e.g. high consumers, children, people following a specific diet, etc).

EFSA opinion – May 2016 - risk characterisation

2-MCPD and fatty acid esters

- The CONTAM Panel concluded that no health based guidance value could be established for 2-MCPD due to insufficient toxicological information.
- As a consequence, **no risk characterisation was possible for 2-MCPD and its esters.**
- In the EFSA opinion, a correlation between total 3-MCPD and 2-MCPD levels was made and concluded that the expected level of 2-MCPD is at about (or slightly higher than) half of the 3-MCPD level



European
Commission

EFSA opinion – May 2016 - risk characterisation

3-MCPD and fatty acid esters

- A group TDI of 0,8 µg/kg bw per day has been established
- **The mean exposure to 3-MCPD was below the group TDI of 0.8 µg/kg** bw per day in adolescents and adult age groups. In the younger age groups half of the dietary surveys had mean exposure at or above the group TDI.
- **The high exposure levels were above the group TDI for the younger age groups.** For adolescents high exposure levels were at or above the group TDI in half of the dietary surveys. For adult age groups, only the maximum P95 of dietary exposure was around the group TDI.
- **The estimated exposure levels to 3-MCPD of infants receiving formula only were above the group TDI both considering mean or P95 of occurrence.**

EFSA opinion – May 2016 - risk characterisation

Glycidol and glycidyl esters

- **Margin of exposure (MoE) approach for genotoxic and carcinogenic substances was applied.**
- The CONTAM Panel considered the dose-response data inadequate for benchmark dose (BMD) modelling. The T25 of 10.2 mg/kg bw per day was used as the reference point.
- In view of the use of T25 as a Reference point, **The Panel considered a MoE of 25,000 or higher as of low health concern.**
- For 'Infants', 'Toddlers' and 'Other children' the MoE estimates for the mean exposure ranged from 34 000 to 11 300; the MoEs for high exposure ranged from 12 800 to 4 900.
- For 'Adolescents' and 'Adults', 'Elderly' and 'Very elderly' age groups the MoE for the mean exposure ranged from 102 000 to 20 400, whereas at high exposure the range was from 51 000 to 9 300.
- **Scenarios of exposure in infants receiving formula only resulted in a MoE of about 5 500 for the mean occurrence and 2 100 for the P95 of occurrence.**

JECFA assessment in November 2016 – differences with EFSA

Glycidol and glycidyl esters

- JECFA outcome slightly different from EFSA outcome (JECFA outcome stricter than EFSA outcome). While EFSA stated that the data were unsuitable for deriving a Benchmark Dose Lower Bound (BMDL) and T25 was used (T25 of 10.2 mg/kg bw day and MOE's of 25000 or higher considered of low health concern), JECFA considered the same data as suitable to define a BMDL and consequently derived a BMDL₁₀ (BMDL₁₀ of 2.4 mg/kg and MOE of 10000 or higher considered of low health concern);
- EFSA has decided not to re-open the opinion as regards glycidyl esters (February 2017)

JECFA assessment in November 2016 – differences with EFSA

3-MCPD esters

- JECFA outcome significantly different from EFSA outcome (JECFA outcome much less strict than EFSA outcome). The TDI established by JECFA for 3-MCPD and its fatty acid esters (Tolerable Daily Intake (TDI) of 4 $\mu\text{g}/\text{kg}$ bw) is different from the TDI established by the EFSA (TDI of 0.8 $\mu\text{g}/\text{kg}$ bw). The divergence is related to the dose-response modelling. While EFSA used the unrestricted model for the identification of the Benchmark Dose Lower bound (BMDL), JECFA used the restricted model;
- EFSA agreed in February 2017 that it is appropriate to reopen its assessment related to 3-MCPD and their fatty acid esters, to address the identified scientific divergence with JECFA and in view of the updated guidance of the EFSA Scientific Committee on the use of benchmark dose approach in risk assessment (published in January 2017).

EFSA updated assessment on 3-MCPD esters – November 2017

3-MCPD esters

BMDL₁₀ of 0.20 mg/kg bw per day selected as the new Reference Point (RP).

The RP was considered to derive an updated group TDI of 2 µg/kg bw per day for 3-MCPD and its fatty acid esters and was considered protective.

The established TDI of 2 µg/kg bw per day is not exceeded in the adult population. A slight exceedance of the TDI was observed in the high consumers of the younger age groups and in particular for the scenarios on infants receiving formula only.

EFSA's new TDI is closer to JECFA's TDI. EFSA and JECFA used the same toxicological data but different BMD modelling techniques. Despite these technical differences, both bodies came to the same overall conclusions on the possible adverse effects of 3-MCPD and the level of concern for public health.

Glycidyl esters

- Maximum levels glycidyl esters – Commission Regulation (EU) 2018/290 of 26 February 2018 amending Regulation (EC) No 1881/2006 as regards maximum levels of glycidyl fatty acid esters in vegetable oils and fats, infant formula, follow-on formula and foods for special medical purposes intended for infants and young children, applicable since 19 March 2018



European
Commission

Glycidyl esters – Existing MLs -additional MLs under discussion

4.2	Glycidyl fatty acid esters expressed as glycidol	µg/kg
4.2.1.	Vegetable oils and fats placed on the market for the final consumer or for use as an ingredient in food with the exception of the foods referred to in 4.2.2 + fish oil and oils from other marine organisms (under discussion) + exception of virgin olive oils	1000
4.2.2.	Vegetable oils and fats destined for the production of baby food and processed cereal-based food for infants and young children + fish oil and oils from other marine organisms (under discussion)	500

Glycidyl esters – maximum levels

4.2	Glycidyl fatty acid esters expressed as glycidol	$\mu\text{g}/\text{kg}$
4.2.3	Infant formula, follow-on formula and foods for special medical purposes intended for infants and young children and young child formula (under discussion) (powder)	50
4.2.4	Infant formula, follow-on formula and foods for special medical purposes intended for infants and young children and young child formula (under discussion) (liquid)	6.0



3-MCPD – esters – maximum levels - under discussion

4.3	Sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters, expressed as 3-MCPD	µg/kg
4.3.1.	<p>Vegetable oils and fats, fish oils and oils from other marine organisms placed on the market for the final consumer or for use as an ingredient in food falling within the following categories - with the exception of the foods referred to in 4.3.2 and of virgin olive oils</p> <ul style="list-style-type: none">- 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- other vegetable oils (including pomace olive oils), fish oils and oils of other marine organisms and mixtures of oils and fats with oils and fats only from this category- mixtures of oils and fats from the two categories	<p>1250</p> <p>2500</p> <p>--- (*)</p>

3- MCPD – esters maximum levels - Under discussion

(*) The oils and fats used as ingredient for the mixture shall comply with the maximum level established for the oil and fat. Therefore, the level of the sum of free 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters, expressed as 3-MCPD in the mixture shall not exceed the level calculated according to Article 2 (c) of this Regulation.

In case the quantitative composition is not known it is not possible for the competent authority and the food business operator, not producing the mixture, to know the quantitative composition of the mixture, the level of the sum of free 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters, expressed as 3-MCPD in the mixture shall in any case not exceed 2500 µg/kg.



European
Commission

3-MCPD – esters – maximum levels - under discussion

4.3	Sum of Free 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters, expressed as 3-MCPD	µg/kg
4.3.2.	Vegetable oils and fats destined for the production of baby food and processed cereal-based food for infants and young children (**)	750
4.3.3	Infant formula, follow-on formula and foods for special medical purposes intended for infants and young children and young child formula (powder)	125
4.3.4	Infant formula, follow-on formula and foods for special medical purposes intended for infants and young children and young child formula (liquid)	15

3-MCPD – esters

Maximum levels – under discussion

(**) When the product is a mixture of different oils and/or fats of the same or of different botanical origins, the maximum level applies to the mixture. The oils and fats used as ingredient for the mixture shall comply with the maximum level established for the oil and fat in point 4.3.1.

3-MCPD – esters/glycidyl esters entry into force –under discussion

- The maximum levels for glycidyl esters in fish oil and oils from other marine organisms, young child formula shall apply from 1 January 2021: foodstuffs that were lawfully placed on the market before 1 January 2021 may remain on the market until 30 June 2021.
- The maximum level for the sum of free and fatty acid esters of 3-MCPD shall apply from 1 January 2021: Foodstuffs that were lawfully placed on the market before 1 January 2021 may remain on the market until their date of minimum durability or use-by-date.

Codex Code of Practice – CXC 79-2019

- Codex Committee on Contaminants in Foods (CCCF) agreed at its 13th Session (29 April – 3 May 2019) to advance the Code of practice for the reduction of 3-monochloropropane-1,2-diol esters (3-MCPDEs) and glycidyl esters (GEs) in refined oils and food products made with refined oils to Step 8 for adoption by Codex Alimentarius Commission (CAC42)



Codex Code of Practice – CXC -79-2019

The Codex Alimentarius Commission adopted at its 42 session in July 2019 the Code of Practice for the Reduction of 3-Monochloropropane-1,2- Diol Esters (3-MCPDEs) and Glycidyl Esters (GEs) in Refined Oils and Food Products Made With Refined Oils

Aspects covered in the Codex Code of Practice

- Introduction (background, scientific assessment, information on the formation, ...)
- Scope
 - This Code of Practice intends to provide national and local authorities, producers, manufacturers, and other relevant bodies with guidance to prevent and reduce formation of 3-MCPDE and GE in refined oils and food products made with refined oils. This guidance covers three strategies (where information is available) for reducing 3-MCPDE and GE formation:
 - (i) Good agricultural practices,
 - (ii) Good manufacturing practices, and
 - (iii) Selection and uses of refined oils in food products made from these oils.

Aspects covered in the Codex Code of Practice

- Recommended practices based on Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP) (overview of major steps in producing edible vegetable oils, producing edible fish oils and refining edible oils (chemical or physical refining)).
- Agricultural practices for vegetable oils
- Oil milling and refining
 - **Crude oil Production and Treatment**
 - **Degumming**
 - **Neutralization**
 - **Bleaching**
 - **Deodorization**

Aspects covered in the Codex Code of Practice

- Treatment post refining
- Selection and uses of refined oils in food products made from these oils
 - **Oil selection**
 - **Processing modifications**

ANNEX with overview of potential mitigation measures for reducing 3-MCPDEs and GEs

Next steps and outlook

- Next steps
- Future:
 - possible review of certain maximum levels
 - further extension of the legislation to other foods
- ...



European
Commission

**Thank you for
your
attention !**