



Directorate-General for Health & Food Safety

EU Policy on MCPD and glycidyl fatty acid esters

Frans Verstraete

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

- 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

- 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

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 2- and 3-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).



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EFSA opinion – 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.**

EFSA opinion – risk characterisation

3-MCPD and fatty acid esters

- **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 – risk characterisation

Glycidol and glycidyl esters

- **Margin of exposure (MoE) approach for genotoxic and carcinogenic substances was applied.**
- 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 P95¹² 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 µg/kg bw) is different from the TDI established by the EFSA (TDI of 0.8 µg/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).

Discussion on possible regulatory measures –glycidyl fatty acid esters

- Following the outcome of EFSA's opinion and the decision of EFSA not to reopen its opinion as regards glycidyl esters, appropriate regulatory measures are under discussion to limit the presence of glycidyl esters in vegetable oils and food products containing vegetable oils in order to ensure a high level of human health protection in particular for infants and young children.

Discussion on possible regulatory measures – glycidyl fatty acid esters

Following maximum levels are under discussion:

- maximum level for vegetable oils and fats (placed on the market for the final consumer or for use as an ingredient in food)
- stricter maximum level for vegetable oils used for the production of baby food and processed cereal-based food for infants and young children
- strict maximum level for infant formula, follow-on formula and foods for special medical purposes intended for infants and young children (powder and liquid)

Discussion on possible regulatory measures – glycidyl fatty acid esters

Following maximum levels are under discussion cont'd):

- much stricter maximum levels proposed to be applied as from 2020 resulting in an exposure of no health concern
 - to be assessed before 1 April 2019
 - availability of an analytical method with sufficient sensitivity to ensure effective enforcement of these stricter levels and/or
 - evidence provided that the maximum level is not achievable by applying all available mitigation measures and/or reformulation and therefore endangering the supply of infant formula, follow-on formula and food for special medical purposes intended for infants and young children.

Discussion on possible regulatory measures – 3-MCPD fatty acid esters

- Following the decision of EFSA to reopen its opinion as regards 3-MCPD fatty acid esters, the outcome of the EFSA re-opening of the opinion shall be awaited before discussing appropriate regulatory measures to limit the presence of 3-MCPD and 3-MCPD fatty acid esters in vegetable oils and food products containing vegetable oils (and other foods) in order to ensure a high level of human health protection in particular for infants and young children.

High levels of 2-MCPD , 3-MCPD and glycidyl fatty acid esters in fish oil

- Findings of high levels of 3-MCPD esters and glycidyl fatty acid esters in fish oil have been reported to the European Commission. In the EFSA assessment no reference was made to findings of high levels of 3-MCPD fatty acid esters and glycidyl fatty acid esters in fish oil.
- In order to have a clear view on the extent of the problem, the monitoring of presence of 3-MCPD fatty acid esters and glycidyl fatty acid esters in food supplements containing fish oil (fish body oil or fish liver oil) or other fish oil containing foodstuffs is recommended.

High levels of 2-MCPD , 3-MCPD and glycidyl fatty acid esters in fish oil

- The relevant European stakeholder organisations have been informed of these findings and on the ongoing discussions at EU level.
- Once EFSA has finalised their re-opening of the 3-MCPD fatty acid esters opinion and appropriate risk management measures are discussed as follow up, the appropriateness of setting maximum levels for glycidyl fatty acid esters and 3-MCPD fatty acid esters (sum of free and bound 3-MCPD) in food supplements containing fish oil (fish body oil or fish liver oil) and other fish oil containing foodstuffs shall be considered.

Codex Committee on Contaminants in Food and Feed (Codex Alimentarius)

- Following the JECFA opinion, the Codex Committee on Contaminants in Food and Feed (CCCF) endorsed the proposal for new work for adoption by the Codex Alimentarius Commission (CAC) on a Code of Practice (COP) for the Reduction of 3-MCPD esters and glycidyl esters in refined oils and products made with refined oils, especially infant formula and to establish an electronic working group (EWG), chaired by USA and co-chaired by the European Union and Malaysia, to follow-up on this new work
- The scope of the new work encompasses measures applicable to agricultural practices, oil milling and refining processes, and sources and uses of the refined oils in products made from these oils, especially infant formula.
- Work on the COP will commence following approval by the CAC in July 2017. Final adoption by the CAC can be expected by 2020.

Conclusions and outlook

- * Outcome of EFSA opinion as regards glycidyl esters → need for regulatory measures to limit presence of glycidyl-esters in food, in particular food for infants and young children – discussions on appropriate measures to ensure a high level of consumer protection ongoing
- * EFSA re-opening of the opinion as regards 3-MCPD esters → awaiting the outcome before initiating / continuing discussions on appropriate risk management measures (possible maximum levels will be the sum of free and bound 3-MCPD).
- * Fish oil
- * Measures on sampling and analysis
- * Timelines



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**Thank you for
your
attention !**