HISTORICAL PERSPECTIVE & PROPOSED RESPON TO MCPDE & GE RELATED ISSUES OF PALM OIL

Purwiyatno Hariyadi

Workshop dan Rapat Koordinasi:
Tindak Lanjut Issue Kandungan 3-MCPD Ester (MCPDE) dan Glycidyl Ester (GE) pada Produk Hilir Minyak Sawit.
Direktorat Industri Hasil Hutan dan Perkembunan
Kementerian Perindustrian RI

16 Februari 2017

Historical perspective on Issues of MCPDE & GE

1978-1980 Hydrolysed vegetable protein, e.g soy sauce (free)

The European Commission’s Scientific Committee on Food (SCF, 1994): long-term carcinogenicity assay of 3-MCPD in rats.

3-MCPD was classified by the European SCF as a non-genotoxic, threshold carcinogen (SCF, 2001).

**Risk assessment of JECFA**

- 3-MCPD → results from hydrochloric acid hydrolysis of vegetable protein and mainly occurred in soy sauce.
- Provisional maximum TDI (PMTDI) : 2 ug/kg bw per day
  - Lowest observed effect level (LOEL): 1.1 mg/kg bw per day
    [for renal tubular hyperplasia and a safety factor of 500].
  - the estimated mean intake of 3-MCPD by consumers of soy sauce would be at or above the PMTDI.

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3-MCPD esters were first detected in refined vegetable oils (2004-2006).

Historical perspective on Issues of MCPDE & GE

Infant formula and follow-up formula may contain harmful 3-MCPD fatty acid esters

Historical perspective on Issues of MCPDE & GE

The latest studies by the official food control authorities identified high levels of 3-MCPD fatty acid esters for the first time in refined edible fats like margarine and oil and in fat-containing foods including infant formula and follow-up formula. BfR has evaluated the data submitted by the food control authorities. It has come to the conclusion that - based on the scientific knowledge currently available - babies in particular may ingest amounts of 3-MCPD esters from infant formula and follow-up formula for which, in the worst case scenario, the margin of safety to the effects observed in animal experiments is deemed to be too small. BfR, therefore, believes there is a need for action to reduce the levels but does not see any acute health risk.

- Conclusions: levels of 3-MCPD should be reduced, especially in infant formula and follow-up formula, although no acute danger was expected from current levels.
- BfR assumed a “worst-case scenario” that 100% of 3-MCPD esters are cleaved to release free 3-MCPD during digestion.
Historical perspective on Issues of MCPDE & GE

(2008) The CONTAM Panel confirmed the assessment of BfR (2007) → the need for additional toxicokinetic studies → EFSA

Historical perspective on Issues of MCPDE & GE

ILSI Europe Workshop in 2009

- Although there is a lack of data about 3-MCPD esters for many foodstuffs, it is obvious that thermally processed foods and refined fats and oils (as such or as a component of other foodstuffs) are the most significant sources of 3-MCPD esters for consumers.

- In particular, refined palm oil in different kinds of foodstuffs is responsible for a significant part of the exposure.

**Historical perspective on Issues of MCPDE & GE**

**Codex Committee on Contaminants in Foods (CCCF)**

- included 3-MCPD fatty acid esters in the priority list for evaluation by JECFA for toxicological assessment and exposure assessment

**Historical perspective on Issues of MCPDE & GE**

- **BfR opinion**: established a TDI of 2 ug/kg bw per day.
- **Codex Alimentarius Commission**: Code of practice, based on good manufacturing practices, for the reduction of 3-MCPD during the production of acid-HVP and its products

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From a limited database of occurrence, the adult exposure to 3-MCPD, assuming complete cleavage of the esters in the gut, could be estimated as 1–9.8 μg/kg bodyweight 3-MCPD/day, which is between 0.5 and 5 times the PMTDI of 3-MCPD. For infants on a diet of infant formula the estimated exposure was 7.3–25 μg/kg bodyweight 3-MCPD/day which is 3.6–7.7 times the PMTDI (Lampen, 2009).
Address issues related to 3-MCPD esters and related compounds:
→ 2-MCPD esters and glycidyl esters

IARC (International Agency for Research on Cancer): there was ‘no evidence to suggest that 3-MCPD is not genotoxic.'
Historical perspective on Issues of MCPDE & GE

• Esters of 3- and 2-MCPD and glycidyl esters were found at the highest levels in palm oil/fat, but most vegetable oil/fats contain substantial quantities.

• Animal studies show extensive hydrolysis of esterified 3-MCPD and glycidol following oral administration; esterified and free forms were assumed to contribute equally to internal exposures.

• 3-MCPD ester and free forms are nephrotoxic

• Tolerable daily intake (TDI) of 0.8 μg/kg bw per day.

• The mean exposure to 3-MCPD was above the TDI for ‘Infants’, ‘Toddlers’ and ‘Other children.’
Experimental evidence indicates that 3-MCPD esters are substantially hydrolysed to 3-MCPD in the gastrointestinal tract and elicit toxicity as free 3-MCPD. The Committee therefore based its evaluation on the conservative assumption of complete hydrolysis of 3-MCPD esters to 3-MCPD. Whereas the experimental data supporting substantial hydrolysis are derived from studies with post-weaning animals, the Committee concluded that the capacity of the neonate to hydrolyse fatty acids in the gut is efficient, and therefore the same assumption of substantial hydrolysis could be extended to this age group.

3-Monochloro-1,2-propanediol (3-MCPD) esters are processing-induced contaminants found in various refined oils and fats and are formed from acylglycerols in the presence of chlorinated compounds during deodorization at high temperature. “3-MCPD esters” is a general term for 3-MCPD esterified with one (sn1- and sn2-monoesters) or two identical or different fatty acids (diesters). Depending on the fatty acid composition of the oil or fat, a variety of different 3-MCPD esters can be formed during processing. In foods that contain refined vegetable oils or fats, mainly diesters are found. Concentrations of 3-MCPD esters in refined oils increase incrementally in the following order: rapeseed oil < soya bean oil < sunflower oil < safflower oil < walnut oil < palm oil.
So What .... ?

JECFA (2016) & EFSA (2016) :
- Palm Oil is the main source of the MCPDE & GE
- So what?

So What .... ?

- Need A National Initiative -- analogous to acid-HVP
  - ~ Codex Alimentarius Commission: Code of practice, based on good manufacturing practices, for the reduction of 3-MCPD during the production of acid-HVP and its products
  - Code of practice, based on good (farming, handling, manufacturing, and ?) practices, for the reduction of MCPDE and GE during the production of palm oil & its products

  - A multifaceted approach:
    - beginning with a reduction of chloride application in fertilizer, continuing with the use of plant varieties low in MAG and DAG precursors, the selection of young fruit of good quality and technical changes to the refining steps, and ending with the removal of the esters using inorganic adsorbents.

So What .... ?

- Need A National Initiative -- analogous to acid-HVP
- ~ Codex Alimentarius Commission: Code of practice, based on good manufacturing practices, for the reduction of 3-MCPD during the production of acid-HVP and its products

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R&D

- A multifaceted approach:
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So What .... ? → mitigation

<table>
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<tr>
<th>Contaminant</th>
<th>Structure</th>
<th>Source</th>
<th>Possible Mitigation Strategies</th>
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</table>
| 3-MCPD Esters   | Monoesters| Formed during deodorization (beginning at 110°C) when DAGs or MAGs undergo chloride substitution | • Reduce DAG levels in crude oil by changing harvesting practices or using enzymatic treatment.  
• Wash raw oils to remove chloride precursors.  
• If possible, use chemical rather than physical refining.  
• Use neutral rather than activated bleaching earth to minimize chloride ions.  
• Remove 3-MCPD esters from refined oil using adsorbents. |
|                 | Diesters  |                                             |                                                                     |
| Glycidyl Esters |           | Formed during deodorization (beginning at 230°C) from DAGs by radicalar mechanism | • Reduce DAG levels in crude oil by changing harvesting practices or using enzymatic treatment.  
• If possible, use chemical rather than physical refining.  
• Minimize deodorization temperatures or use two-step deodorization.  
• Remove glycidyl esters from refined oil using adsorbents or by acid-catalyzed degradation. |

### So What ....? → mitigation

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<td>Glycidiyl Esters</td>
<td>Formed during deodorization (beginning at 230°C) from DAGs by radical mechanism</td>
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### So What .... ?

- Need A National Initiative -- analogous to acid-HVP

### DO IT !

- Code of practice, based on good (farming, handling, manufacturing, and ?) practices, for the reduction of MCPDE and GE during the production of palm oil & its products

  - beginning with a reduction of chloride application in fertilizer
  - continuing with the use of plant varieties low in MAG and DAG precursors
  - the selection of young fruit of good quality and technical changes to the refining steps, and
  - ending with the removal of the esters using inorganic adsorbents.

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**Terimakasih**

phariyadi.staff.ipb.ac.id

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