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## Expert Interview with Mr. Gordon Cheung

### The safety of 3-monochloropropane-1,2-diol (3-MCPD) and glycidyl fatty acid esters (GEs)

#### Background Information

- 3-MCPD is a type of process contaminant which can form during food processing involving high temperature chlorination of lipids, such as in acid hydrolysis and baking, existing in either its free form or esterified form (3-MCPD fatty acid esters)<sup>1</sup>
- GEs are also process contaminants which occur during the refining process of edible oils and fats under high temperature, and are digested to release a compound called glycidol<sup>2,3</sup>

#### What are the local and international regulatory limits for 3-MCPD and GEs?

- The **Provisional Maximum Tolerable Daily Intake (PMTDI)** set by FAO/WHO Joint Expert Committee on Food Additives (JECFA) for 3-MCPD: **4.0 µg/kg body weight**<sup>4</sup>
- The **Tolerable Daily Intake (TDI)** set by the European Food Safety Authority (EFSA) for 3-MCPD: **2.0 µg/kg body weight**<sup>5</sup>
- JECFA indicated inappropriateness to establish health-based guidance value for glycidol due to its genotoxicity<sup>6</sup>, and CODEX has adopted a Code of Practice in 2019 for reducing GEs in refined oils and food products made with refined oils<sup>7</sup>
- **EU Regulatory maximum level** of GEs (expressed as glycidol) in infant and follow-on formula powder: **50 µg/kg**<sup>8</sup>

#### Is there any carcinogenicity data on 3-MCPD and GEs in human?

- International Agency for Research of Cancer (IARC) classified 3-MCPD as a **Group 2B agent (possibly carcinogenic to humans)**<sup>9</sup>
  - There is sufficient evidence in experimental animals for the carcinogenicity of 3-MCPD, but no human carcinogenicity data were available for evaluation at that time
- IARC classified glycidol as a **Group 2A agent (probably carcinogenic to human)**<sup>10</sup>
  - There is sufficient evidence in experimental animals for the carcinogenicity of glycidol, but no human carcinogenicity data were available for evaluation at that time
  - Glycidol has been shown to be genotoxic in various assays for genotoxicity

## Do you see health implications regarding the levels of 3-MCPD and GEs found in the tested infant formulas in the recent announced local study?

- 3-MCPD and GEs are the emerging food safety issues and we **solely relied on experimental animal data to evaluate their toxicity**
- Animal studies showed that chronic excessive intake of 3-MCPD would adversely affect the renal function and male reproductive systems of experimental animals<sup>9</sup>. GEs are genotoxic carcinogens that are mutagenic in a wide range of in-vivo and in-vitro test systems<sup>10</sup>
- In the local study, 3-MCPD was detected in all products with only one of them containing a 3-MCPD level that may exceed TDI set by EFSA under normal consumption, while the GEs level of all products are within the EU's maximum level<sup>5,8,11</sup>
- The mean and maximum levels of GEs (as glycidol) found in the local study were lower than two overseas studies conducted by EFSA and New Zealand Food Safety (NZFS)/Food Standards Australia New Zealand (FSANZ)<sup>12,13</sup>
- The Federal Institute for Risk Assessment (BfR) of Germany opined that the possibility and the probability of the current exposure levels of formula-fed infants impairing their health is low<sup>14</sup>
- **The risk of the normal consumption of products with 3-MCPD and GEs levels under the guided level are within acceptable range according to the best available evidence**

## What is your advice for the general public and parents in relation to the recent infant formulas study?

- In line with the government's advice, mothers are **strongly encouraged to feed their babies with breast milk** as breastfeeding is associated with a wide range of benefits to babies and mothers
- **When breastfeeding is not possible, infants should continue to be fed with industrially produced infant formula** to ensure optimal nutrition
- **Switching among different infant formulas with both 3-MCPD and GEs levels under the guided level might not achieve noticeable advantage to infants' health.** If parents decide to change the infant formula, they would be recommended to consult doctors or dietitians for advice and do it with caution to avoid possible intolerance
- **The government may need to monitor the international development of this issue and set up the regulatory limit of 3-MCPD and/or GEs to protect our infants whenever appropriate.** The manufacturers are obligated to adopt relevant mitigation measures such as those recommendations in the Codex Code of Practice released in 2019 to keep the levels of 3-MCPD and GEs technologically minimal

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