Food Research 5 (1) : 488 - 496 (February 2021)
Journal homepage: http://www.myfoodresearch.com

MINI REVIEW

Monochloropropanediols (MCPD) esters and glycidyl esters (GE) in infant formulas and challenges of palm oil industry in Malaysia: a review

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Article history:
Received: 10 November 2020
Received in revised form: 19 October 2020
Accepted: 14 November 2020
Available Online: 22 November 2020

Keywords:
3-monochloropropane-1,2-diol,
MCPD esters,
Glycidyl esters,
Infant formula,
Dietary exposure,
Risk assessment

DOI:
https://doi.org/10.26656/fr.2017.5(1).503

Abstract

Infant formula is an exclusive diet that offers the requisite nutrients for infants up to 6 months prior to the introduction of solids in their diet. Vegetable oils in infant formulas that serve as a source of fat could be contamination of monochloropropanediols (MCPD) and glycidol. The toxicity of MCPD and glycidol was highlighted in several studies implied health risk for exposed children, especially with their low body weight. This paper reviewed the occurrence of MCPD and glycidyl esters in infant formulas marketed in various countries, including risk assessment and associated estimated dietary exposure. From the selected studies published between 2015 to 2019, the presence of the contaminants was detected, but their concentrations decreased over the years indicating a low potential health risk to infants. These have been linked to the success of the vegetable oil producers' implementation of mitigation strategies. The paper also discusses the infant formula market in Malaysia, as well as the association of the use of palm oil in infant and follow-up formula in the Malaysian market. As one of the largest producers and exporters of palm oil and palm oil by-products, Malaysia is taking serious steps and the mitigation strategies it is exercising to reduce the level of MCPD and glycidol to comply with the regulation proposed by the European Commission. However, more studies are needed to gain a clearer view of the association between the use of palm oil in infant formulas and the occurrence of MCPD esters and glycidols, as well as their risk assessment.

1. Introduction

Infant formulas are manufactured milk for nourishing babies for approximately up to 12 months and contain essential nutrients for their development and growth. Infant formulas are designed to mimic human breast milk; however, there are differences, notably in the nutritional composition. The basic nutrient components of infant formulas are primarily carbohydrates, protein, fats, calcium, vitamins and other added ingredients. Vegetable oil blends are commonly used as the source of fats in the formulation, considering an infant's ability to absorb breast milk fat (Souza *et al.*, 2017). Some common sources of vegetable oils components in the ingredient are derived from oil palm, canola, sunflower, corn, rapeseed and coconut. Palm oil and its low melting fraction, palm olein, are often used in the formulation as the source of palmitic acid, which is the major saturated fatty acid in breast milk (Souza *et al.*, 2017). However, the presence of fatty acid esters of monochloropropanediols and glycidol, toxic compounds generated during deodorizing steps of the processing of the edible oil in vegetable oils should be viewed with concern.

Monochloropropanediols (MCPD), particularly 3-monochloro-1,2-propanediols (3-MCPD) and 2-monochloro-1,3-propanediols (2-MCPD), together with glycidyl esters (GE) are thermally induced food contaminants that are formed during processing or refining of edible oils and fats. 3-MCPD and 2-MCPD are by-products of the reaction of triacylglycerols, phospholipids or glycerol and hydrochloric acid in fat-based or fat-containing foods. They may present as a free substance in the form of an ester with fatty acids or in both forms, depending on the type of food. Free 3-MCPD is classified as Group 2B, possibly carcinogenic to humans and can affect the kidneys, male fertility and renal function, while glycidol is considered as a Group 2A carcinogen (probably carcinogenic to humans)

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eISSN: 2550-2166

(IARC, 2000). Glycidol has been found to be genotoxic as it boosted the formation of tumours in numerous organs of rodents (IARC, 2000; IARC, 2013; Clemens *et al.*, 2017). Several in-vitro studies have reported that 3-MCPD was found to cause acute and severe nephrotoxicity (Onami *et al.*, 2015; Sawada *et al.*, 2016; Liu *et al.*, 2016; Liu *et al.*, 2017), and testicular toxicity in rats (Braeuning *et al.*, 2015; Sawada *et al.*, 2015).

The estimated dietary exposure assessment was built on the assumption that upon consumption, 3-MCPD esters and GE are 100% hydrolyzed in the intestinal tract releasing the free 3-MCPD and glycidol. Toxicity of esters is typically evaluated based on the conversion of fatty acid ester concentrations into free MCPD and glycidol equivalents. Some health agencies have established an intake limit for 3-MCPD based on chronic studies in rats. The Food and Agriculture Organization/ World Health Organization (FAO/WHO) Joint Expert Committee on Food Additives (JECFA) has set the provisional maximum tolerable daily intake (PMTDI) of 4.0 µg/kg body weight while European Food Safety Authority (EFSA) derived a tolerable daily intake (TDI) of 2.0 µg/kg body weight per day (EFSA, 2018; Joint FAO/WHO Expert Committee on Food Additives (JECFA), 2017). The new TDI of EFSA has increased its previous safe level to two and a half fold, from 0.8 to 2.0 µg/kg body weight per day. Although there is a difference between these two standards, both bodies reached similar conclusions on the possible adverse effects of 3-MCPD and its level a concern for public health.

Recently, the European Commission published the maximum levels permitted for GE in vegetable oils and fats, infant formulas, follow-on formulas and foods intended for medical and baby nutrition. The set limit is 50 µg/kg for powdered food and 6 µg/kg in liquid food for infant formula, follow-on formula and foods for special medical purposes intended for infants and young children (European Union, 2018). As for glycidol, the risk assessment is based on the values of the Margin of Exposure (MoE), calculated by dividing the reference point of the exposure levels. The reference point refers to the T_{25} value of 10.2 mg/kg body weight per day for peritoneal mesothelioma in male rats. The T_{25} values were calculated incidences of tumours observed in rats and mice following long-term exposure to glycidol. A MoE of 25,000 or higher is considered a low health concern (EFSA, 2016; Nguyen and Fromberg, 2019). EFSA and JECFA also evaluated available information on 2-MCPD and its esters. However, due to limited toxicological information, a risk characterization was not undertaken even though the exposure was estimated by EFSA (EFSA, 2016; EFSA, 2018). No limit has been established for 2- and 3-MCPD esters in refined oils and foodstuff, but regulation for these toxicants is likely to come into enforcement soon in the future.

This paper evaluates the occurrence of fatty acid esters of 2-, 3-MCPD and GE in infant formulas marketed in different regions dating 2015 until present including risk assessment. Monitoring and detection for any associated health concern arising from constant consumption of contaminated infant formulas as well as ensuring vegetable oil producers implement mitigation measures to reduce the presence of contaminants are crucial and must not be disregarded.

2. The occurrence of 2-, 3-MCPD esters and GE in infant formula

In 2015, an article on the occurrence of fatty acids esters of 2-MCPD, 3-MCPD and GE in infant formula in a German market sample was published by Wöhrlin *et al.* (2015). The study conducted in 2013 comprised of 70 samples derived from two types of formula: “PRE” (lactose as the carbohydrate source) and “1” (other additional carbohydrate sources). It was the first study that incorporated the analysis for bound 2-MCPD in infant formula samples. Findings from the study revealed the presence of bound 2-MCPD, 3-MCPD and glycidol with a concentration in the range of 23-85 µg/kg, 65-177 µg/kg, and 32-213 µg/kg respectively in all the tested infant formulas. The concentration of bound analytes was found to be lower in extracted fat basis than the declaration on the label. The statistical analysis also indicated that the average concentration values of each analyte differed among the manufacturers. The authors agreed there was a reduction in the concentration of 3-MCPD compared to previously collected data reported by Zelinková *et al.* (2009). However, no explanation was provided on the possible reasons related to the reduction of contaminants from the previous study. As for the glycidol content, the authors compared the data obtained from reports published by Weißhaar (2011) from 2009 to 2010. A reduction in the maximum content of glycidol was observed; from 5.3 and 2.6 mg/kg in 2009 and 2010 respectively to 1.3 mg/kg in 2013. The decreased value could be explained from mitigation measures taken by manufacturers such as the minimization of precursor in raw materials, modification in refining steps and fat source replacement (Wöhrlin *et al.*, 2015).

Becalski *et al.* (2015) conducted a pilot survey on 2- and 3-MCPD esters and GE in 32 infant formula products in the Canadian market that were sampled in 2012 and 2013. The products consisted of three formula forms: powdered, concentrated, and ready-to-use. Sixteen samples were collected in 2012. The sampling process was repeated for the same products in 2013 to determine the concentrations of the contaminants. The results were expressed as glycidol equivalent and sum of MCPD equivalents (total mean of 2- and 3-MCPD). The average sum of MCPD equivalents detected in 15 samples in 2012 was 43 ng/g and the highest concentration was 135 ng/g. For glycidol equivalent, 12 out of 15 samples were positive with the highest level recorded at 70 ng/g. In contrast, the levels of MCPD in 2013 decreased to 26 ng/g with a maximum concentration of 108 ng/g. It was the same for the level of glycidol equivalent, where eight out of 15 contained GE with the highest concentration of 40 ng/g. The difference in contaminants concentration in infant formulas sampled in both years was statistically proven to be significant. However, due to the limited scope of sampling, comparisons of the concentrations between different infant formula types could not be ascertained.

Leigh and MacMahon (2017) studied the presence of 3-MCPD esters and GE in infant formulas that were commercially available in the US market. Ninety-eight infant formula samples produced by seven different manufacturers were collected in 2013 from the US market. The samples comprised of seven formulation variants (premium, soy, gentle, sensitive, hypoallergenic, toddler, and special needs) available in powdered and concentrated/ready-to-use form. Both the 3-MCPD esters and GE were analysed using liquid chromatography-mass spectrometry (LC-MS/MS) (Leigh and MacMahon, 2016). The presence of bound 3-MCPD and glycidol was present in all samples within the range of 0.20 mg/kg to 0.52 mg/kg and 0.014 mg/kg to 0.15 mg/kg, respectively. Selected products collected in 2013 were re-purchased in 2015-2016 to examine the year-to-year variation. From the results, the concentration of bound 3-MCPD in products from both sampling years showed equivalent values except for samples from Manufacturer C and G that showed decreasing trends. For bound glycidol, all samples, with exception of products from Manufacturer D and G showed increasing concentration levels in 2015/16 sampling (Table 1). The changes of 3-MCPD esters content in product from Manufacturer C could suggest that strategies to reduce 3-MCPD concentrations over the 2–3-year period were implemented, while the observed increase in glycidol in formulas produced by manufacturer D could be a probable indication of change, either in the production process or the vegetable oil suppliers (Leigh and MacMahon, 2017).

In a study by Arisseto *et al.* (2017), 40 infant formulas commercially available in the Brazilian market for infants and follow-ups consumption were collected in 2015. They included different formulating ingredients such as cow milk, soy milk, prebiotics, and essential fatty acids. The findings revealed that the 3-MCPD esters and GEs in the infant formula samples analysed by gas chromatography-mass spectrometry (GC-MS) varied from not detected (n.d.) to 0.60 mg/kg, and from n.d. to 0.75 mg/kg, respectively. The authors compared the results with several previous studies of similar samples. It was consistent with findings reported in 2009, in which 3-MCPD found in baby foods ranged from 0.062 mg/kg to 0.588 mg/kg (Zelinková *et al.*, 2009). However, the concentrations of 3-MCPD esters and GE found in infant formula samples in the Canadian, German and European markets were slightly lower. Arisseto *et al.* (2017) reported that the variation of ingredients in baby formula production, especially the composition and types of vegetable oils used, caused a higher level of contaminants in the product. Highest concentrations of 3-MPCD esters and GE were found in two different infant formula samples that contained palm oil and its derivatives in the formulation. The authors commented that the high levels of contaminants in the infant formula samples may be due to the respective oil producers' failure to implement mitigation steps to counter the problem.

Nguyen and Fromberg (2019) recently published a study on the occurrence of MCPD esters and GE in infant formulas and baby foods in the Danish market. Thirteen infant formula samples intended for infants of 0 to 12 months in liquid and powder form were obtained in Zealand, Denmark in 2019. All samples were analysed for the presence of 2-MCPD esters, 3-MCPD esters, and GE using a developed analytical method that applies

Table 1. Occurrence data of bound 3-MCPD and glycidol in infant formula sample purchased in 2013 and 2015/16 (Leigh and MacMahon, 2017)

Manufacturer	n	Concentration of contaminants in the product (mean, range in mg/kg)			
		2013		2015/16	
		Bound 3-MCPD	Bound glycidol	Bound 3-MCPD	Bound glycidol
A	2	0.12, 0.10–0.14	0.014, 0.011–0.017	0.14, 0.12– 0.16	0.01
C	2	0.39, 0.30–0.48	0.12, 0.073-0.17	0.18, 0.14–0.23	0.11, 0.051-0.16
D	4	0.38, 0.12–0.57	0.030, <LOQ–0.083	0.41, 0.097-0.62	0.094, 0.006-0.25
E	1	0.076	0.047	0.079	0.032
F	11	0.61, 0.35–0.84	0.11, 0.022-0.24	0.62, 0.43-0.87	0.14, 0.053-0.22
G	1	0.11	0.006	0.077	0.009

eISSN: 2550-2166

sample extraction and clean-ups, bromination, transesterification and derivatization prior to gas chromatography tandem mass spectrometry (GC-MS/MS) analysis. From the results, the average concentrations of 2-MCPD esters, 3-MCPD esters and GE were 15, 36, and 13.4 µg/kg in powder formula and 2.7, 6.4 and 1.2 µg/kg in the liquid formula, respectively. Nguyen and Fromberg (2019) found the lowest concentration in their study compared to previous studies. The recent findings also exhibited high positive correlation ($p < 0.001$) among contaminants and the fat content in the infant formula, which in agreement with the previous report by Zelinková *et al.* (2009). On the other hand, the authors Nguyen and Fromberg (2019) also believed that both 2-MCPD esters and 3-MCPD esters would present at the same time, considering that both are formed as a result of multiple mechanisms of the precursors (mono-, di- and triglycerides).

To date, only one study on the occurrence of MCPD esters in infant formula products in the Asian region has been identified. Wang *et al.* (2016) studied the occurrence of MCPD esters in infant formula marketed in China. From 88 collected samples, 73 contain 3-MCPD esters ranging from 0 to 316 µg/kg with an average concentration of 185 µg/kg. Among them, three samples were detected having 2-MCPD esters ranging 0 to 52 µg/kg with an average concentration of 41 µg/kg. The authors estimated the dietary exposures of 3-MCPD by calculations based on the average weight of infants (6.5 kg) and the daily intake of 100 g formula powder, assuming the content of 3-MCPD esters in all infant formula products are equal to mean concentration of 3-MCPD esters in the collected samples. Although the values were not disclosed, the authors mentioned that the estimated values calculated are 42% greater than the PMTDI value set by JECFA, which is 2 µg/kg body weight/day.

Concentrations of 2-MCPD esters, 3-MCPD esters, and GE in infant formula samples marketed in different countries as discussed are tabulated in Table 2. From the figures shown it is plausible to deduce that concentrations of the contaminants have decreased noticeably over the years. The declining trend is believed to be associated with the implementation of mitigation steps by the vegetable oil producers. Varying ingredients, especially vegetable oil compositions also affect the presence of the contaminants in infant formula.

Beekman and MacMahon (2020) studied the concentrations of 3-MCPD and GE in refined oils intended for the production of infant formula collected from the manufacturers in 2015. The selected oils included algal/fungal, canola, coconut, corn, medium chain triglyceride (MCT), palm olein, safflower, soybean, and sunflower; also oil mixtures consisting of different amounts of individual refined oil. Selection of the refined oils covered all types of oils that are commonly used in infant formulation. The findings indicated concentrations of bound 3-MCPD and glycidol as <LOQ to 5.13 µg/g and <LOQ to 6.14 µg/g, respectively. Samples containing palm olein had the highest concentration of ester throughout the analysis, including oil blends containing palm olein. The authors compared their findings with an occurrence study in 2013 of 3-MCPD and GE concentration in refined vegetable oils reported by MacMahon *et al.* (2013). The results suggest that the refined oils marketed directly for consumer use and oils for manufacturing of infant formula may have been processed the same way. In order to determine if conditions during infant formula processing affect the concentration of bound 3-MCPD and glycidol, the authors compared the results with the occurrence of bound 3-MCPD and glycidol in commercial infant formula powder studied by Leigh and MacMahon (2017). It confirms that processing conditions may trigger glycidyl esters to destroy or be converted into other compounds, which explains why

Table 2. Comparison: Concentrations of 2-MCPD esters, 3-MCPD esters, and GE in infant formula reported in different countries (2015 to 2019)

Country	Sampling Year	Sample Type	Concentration of contaminants (µg/kg)						References
			2-MCPD		3-MCPD		GE		
			Mean	Range	Mean	Range	Mean	Range	
Germany	2013	Powder	49	23-85	109	65-177	93	32-213	Wöhrlin *et al.* (2015)
Canada	2012-2013	Concentrate, ready-to-use and powder	-	<2-47	-	<6-89	-	<10-70	Becalski *et al.* (2015)
USA	2013-2016	Powder			370		84		Leigh and MacMahon (2017)
Brazil	2015	Powder	-	-	150	ND-600	220	ND-750	Arisseto *et al.* (2017)
China	Not available	Powder	41	0-52	185	0-316	-	-	Wang *et al.* (2016)
Denmark	2019	Powder	15	1.3-29	36	8.6-65	13.4	3.1-31	Nguyen and Fromberg (2019)
Denmark	2019	Liquid	2.7	1.5-3.7	6.4	3.7-8.5	1.2	0.6-1.6	

bound glycidol concentration in the infant formula powder sample was lower than bound 3-MCPD.

It is necessary to point out that only data of 2015 are discussed in this paper as earlier data for 3-MCPD esters might have included 2-MCPD as well. The recent advanced liquid chromatographic separation of 3-MCPD esters and 2-MCPD esters has enabled comprehensive results to be secured. However, the toxic effects of 2-MCPD esters compared to those of 3-MCPD esters remains vague. It is also unclear if there is any relationship between the ratios of 2- and 3-MCPD esters.

3. Estimated dietary exposure and risk assessment

Spungen *et al.* (2018) evaluated US infants exposure on 3-MCPD and glycidol based on the results of mean concentration from the study by Leigh and MacMahon (2017) and the median consumption of infant formula. The levels of 3-MCPD esters and GE in formula powders and concentrates were converted to consumption basis, assuming that the average formula contains 3.5% fat. The authors categorised the infants' ages into three groups: 0-1 month, 2-3 months, and 5-6 months. The average exposure of respective infant group on 3-MCPD was 10, 8, and 7 µg/kg body weight per day; as for glycidol, the average exposure was 2 µg/kg body weight per day for each group. The mean exposure for the consumption of formula produced by each manufacturer was also calculated and the value ranged from 1-14 µg/kg body weight per day for 3-MCPD and, 1-3 µg/kg body weight per day for glycidol. The authors, however, did not address the potential exposure towards 2-MCPD although this is formed alongside 3-MCPD and glycidol during oil refining. Typically, the concentration of 2-MCPD is roughly half the concentration of 3-MCPD and glycidol each.

An exposure assessment in Brazil studied by Arisseto *et al.* (2017) included the values of mean concentration and 95th percentile representing the average and high consumers, respectively. The concentration values from the powdered formula were converted into a ready-to-use formula using the dilution factor of 7.7 (EFSA, 2016). The authors considered two age groups for the preliminary assessment: (i) 0-5 months where the infants were fed exclusively with the formula, and, (ii) 6-11 months where the infants were fed with infant formula and also other foods. The estimated exposure of 3-MCPD calculated for infants of 0 to 5 months was 2.49 µg/kg body weight per day for average consumers and 5.81 µg/kg body weight per day for high consumers. For infants age 6 to 11 months, the daily estimated exposure was 1.05 µg/kg body for an average consumer and 2.45 µg/kg body weight per day for high consumers. The higher exposure among the 0 to 5 months age group was not due merely to their diet of formula milk but also due to their lower average body weight. When the results were compared with PMTDI and TDI value established by EFSA (2016), the exposure of average and high consumers for both age groups surpassed the safe limit raising questions of health concerns. As for the GE, the MoE was calculated using the values of T_{25} (10.2 mg/kg body weight per day). The result was 2793 and 975 respectively for average and high consumers for infants between 0 to 5 months, and 6635 and 2317 for the 6 to 11 months category. Similarly, calculating the MoE using the value of benchmark dose level ($BMDL_{10}$) value of 2.4 mg/kg body weight per day showed the value of 229 in high consumers in the 0 to 5 months group and 1561 for average consumers of 6 to 11 months. All the values demonstrated high health concern as the MoE values were below 25,000. This corresponds with a study by Aasa *et al.* (2019) which suggested that approximately two times higher value of estimated mean intake of glycidol (1.4 µg/kg/day) compared to those estimated by EFSA for children in Sweden implies a lifetime cancer risk.

In a more recent study, Nguyen and Fromberg (2019) estimated the exposure of 2- and 3-MCPD and glycidol to infants in Denmark. The Danish Health Authority recommends that infants younger than 4-months should be fed exclusively with milk formula before initiating solid food. The authors reported the calculations of two infant age groups: 0 to 1 month and 2 to 5 months old with the average consumption of infant formula of 170 mL/kg body weight and 110 mL/kg body weight each. The concentration of analytes in powder form was converted into liquid form using a dilution factor of 7.7. The estimated exposure of 2- and 3-MCPD and glycidol for infants age 0 to 1 month are 0.3, 0.75, and 0.49 µg/kg body weight per day while for age group 2 to 5 months the values are 0.19, 0.23, and 0.15 µg/kg body weight per day respectively. The values are notably lower than the limit of 2 µg/kg body weight set by the EFSA (2018) and in other studies of different countries (Arisseto *et al.*, 2017; Spungen *et al.*, 2018) (Figure 1). The authors calculated the MoE for GE exposure using the T_{25} value (10.2 µg/kg BW/day) and the values exceed 25,000, indicating low health concern. The data, however, was not presented in the paper.

By comparing the data from the selected studies, it can be concluded that the contamination levels of 3-MCPD, 2-MCPD and GE in infant formula milk products shows a reduction over the years, and the manufacturers' commitment to reducing the occurrence of the source contaminants have also been demonstrated.

eISSN: 2550-2166

In general, the findings reveal the exposures are within the safe limits and do not pose a health concern. Nevertheless, it is emphasized that the infant formula products which involves the use of heat drying in the manufacturing process, the formation of contaminants can be induced if mitigation strategies are not implemented or not practised continuously.

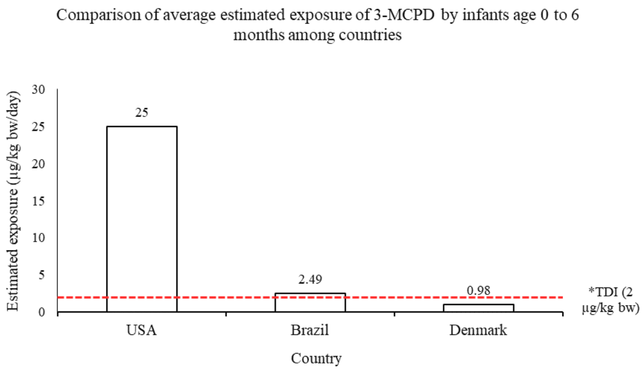

Figure 1. Comparison of average estimated exposure of 3-MCPD in infants age 0 to 6 months together with TDI value of different countries. *Tolerable daily intake (TDI) set by the EFSA (EFSA, 2018)

4. Infant formula in the Malaysian market

Other than the above-mentioned countries, studies on the occurrences of MCPD esters and GE in infant formula in other regions, including Malaysia, is non-existent. Scarce data hampers comparisons of contaminants in marketed infant formula in regional markets. This is further compounded that countries set their limit and therefore unstandardized. Thus far, most countries adopt or regulate the safety limit established by the EFSA or JECFA.

Although Malaysia is one of the biggest producers of palm oil and oil palm products, the usage of palm oil in infant formula domestically is limited since most of the raw ingredients used in infant formula are imported from other countries. According to the Malaysia Competition Commission (2019), there are only two companies that have local manufacturing plants in the country. These two manufacturers undertake both local manufacturing and packaging including importation of infant formula from their sister company. Locally produced infant formulas depend on imported raw materials e.g the dairy ingredients as this is either not available or due to insufficient quantity. The origin of non-dairy sources, especially palm oil used in the formulations of baby milk is typically not stated on the label. They could likely have originated from Malaysia which exports palm oil and its by-products to a host of international markets for the food industry.

According to our survey of ingredient used in the manufacture of formula milk in the Malaysian market, more than 80% of infant formula contain palm oil and its derivatives. As for the follow-up formula, the product which is intended for children of age one and above, more than 50% of them declare palm oil in the ingredient list. In short, the use of palm oil is more prevalence in the production of infant formula than in the follow-up product. Survey findings are entirely based on the ingredients provided on the packaging labels. The inclusion of palm oil in the formulation is generally part of the vegetable oil blends, hence the exact composition of individual oils can not be distinguished.

5. Palm oil industry in Malaysia

In Malaysia, the oil palm industry is a highly regulated industry where palm oil production is governed by more than 60 national laws and regulations. The Malaysian Palm Oil Board (MPOB), one of the agencies under the country's Ministry of Primary Industries, impose licensing requirements to produce and trade palm products throughout the supply chain: from seed production to plantation, processing, and exportation of its yield to trading partners around the world. The palm oil is also widely used domestically as a food product because of its versatility and nutritious properties. As a local commodity, palm oil is readily available, competitively priced and prominent in the local market.

Palm oil as a food ingredient is regulated under the Malaysia Food Acts and Regulations 1985. The product adheres to the Codex Alimentarius Commission standards and food laws of the importing country. Without exception, the Malaysian palm oil industry is also subjected to various Food Acts and Regulations, including addressing the new food safety requirements of 3-MCPD esters and GE contaminants set by the European Commission. Even as a contender to Indonesia, the world largest palm oil producer, the Malaysia palm oil industry is taking all the required steps to ensure that the palm oil and its by-products especially related to food production is safe and adhering to the limit of 2500 µg/kg of 3-MCPD within a year's frame (Sipalan and Ananthalakshmi, 2019). Malaysia has set a timeline to comply with the proposed maximum limit in 2019.

According to the MPOB's Director of Product Development and Advisory Services, beginning January 2021, Malaysia will regulate 3-MPCD esters in refined palm oil, palm kernel oil and GEs in palm kernel oil (PKO) that will not exceed 2.5, 1.25 and 1 ppm (Day, 2019). This regulation applies to all refiners in Malaysia. Since early 2020, Malaysia has prohibited all mills from mixing sludge oil and pressed fibre oil with crude palm oil. Regulated maximum of chlorine content of 2 ppm for imported CPOs will also serve as a guideline for

eISSN: 2550-2166

domestic millers to help reduce the formation of 3-MCPD through sterilization of oil palm fruits and washing CPOs with water. Commenting on the new requirements, The Edge Markets (Chu and Bernadette, 2020) reported the Palm Oil Refiners Association of Malaysia (PORAM) as saying the implementation will cost refiners millions of ringgits to install or refabricate the essential equipment adding to higher operational and production refining costs. Obviously, the new regulations will be a challenge for operators of small scale mills. Faced with such constraints they may be forced to sell their oil to local independent mills or those belonging to larger companies.

Another challenge faced by the palm oil industries is market competition for palm oil products against other vegetable oils. Since EFSA reported that 3-MCPD and its esters in refined vegetable oils is a potential health risk (EFSA, 2016), the European Commission (EC) has proposed a more stringent (higher) limit for palm oil, i.e. above the limit enforced for all other vegetable oils derived from crops such as soy, canola and sunflower. This extra restriction could pose a veiled disadvantage for palm oil producers and exporters as other oil competitors not obligatory to the higher limits directed at palm oil could now promote their products as 'healthier' or with the claims of 'low 3-MCPD.' Also, imposing two limits or levels instead of a standard limit for all oils might give rise to an unhealthy perception that "palm oil is of poorer quality and inferior to other vegetable or soft oils". For these reasons, the new EU rules can potentially harm the demand for palm oil in food. Palm oil from Malaysia accounts for almost 70% of global consumption with an estimated turnover of 60 billion dollars. The oil is used significantly in common daily foodstuffs such as bread and chocolate spread (Chu and Bernadette, 2020).

Industrial research conducted in palm oil mills and refineries together with technology providers is seeking feasible technology for the industry to adopt. Producers must crucially comply with all national and international food safety regulations and requirements to sustain in the global trade and preserve economic relations as palm oil is Malaysia's largest export commodity (Chu and Bernadette, 2020; Hegarty and d'Enghien, 2020).

6. Conclusion

To date, studies on 2-and 3-MCPD esters and GE and its associated health risk are still limited. It is noted however that over the years contaminant levels in infant formulas have declined. This could be attributed to oil producers implementing effective mitigation strategies to minimise the contaminant level. Despite the improved state, close monitoring must be maintained. There remains every possibility of the new transformation of substances with yet unknown effect. As it stands, Malaysia is gearing up efforts to ensure that its manufactured palm oil for consumption is safe and free of health risk.

Conflict of interest

The authors declare that they have no conflict of interests.

Acknowledgement

This research is supported by Research University (RU) grant by Universiti Sains Malaysia (Grant number: 1001/CRACUN/8011047). In addition, Chuah Lucie is gratefully acknowledged for editing and proofreading the text.

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eISSN: 2550-2166