CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 9 **CX/CF 18/12/9**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Twelfth Session
Utrecht, The Netherlands, 12 - 16 March 2018

PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF 3-MONOCHLOROPROPANE-1,2-DIOL ESTERS (3-MCPDE) AND GLYCIDYL ESTERS (GE) IN REFINED OILS AND PRODUCTS MADE WITH REFINED OILS, ESPECIALLY INFANT FORMULA

(Prepared by the electronic working group led by the United States of America, the European Union and Malaysia)

Codex members and Observers wishing to submit comments at Step 3 on this draft should do so as instructed in CL 2018/5-CF available on the Codex webpage/Circular Letters: http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/.

BACKGROUND

1. The 11th Session of the Codex Committee on Contaminants in Foods (CCCF) agreed to establish an Electronic Working Group (EWG) chaired by the United States and co-chaired by the European Union and Malaysia to prepare a Code of Practice for the Reduction of 3-Monochloropropane-1,2-diol Esters and Glycidyl Esters in Refined Oils and Products Made with Refined Oils, Especially Infant Formula. The 40th Session of the Codex Alimentarius Commission (CAC) approved the new work.[1]

2. The United States of America, as Chair of the EWG, prepared the proposed draft code of practice (COP), with the assistance of the European Union and Malaysia. The proposed draft COP is provided in Appendix I. The list of participants that joined the EWG can be found in Appendix III. Two drafts of the COP were circulated. In response to requests for comments on the two drafts, comments and information were received from the following member countries and observers: Australia, Brazil, Canada, China, European Union, Germany, Japan, Malaysia, New Zealand, Switzerland, FEDIOL (the EU Vegetable Oil and Proteinmeal Industry), FoodDrinkEurope, GOED (Global Organization for EPA and DHA Omega-3s), ICGMA (International Council of Grocery Manufacturers Associations), IMACE (the European Margarine Association), ISDI (International Specialty Dietary Foods Industries), and SNE (Specialised Nutrition Europe).

[1] REP17/CF, para 151, Appendix X; CAC17/40, Appendix VI

APPENDIX I

PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF 3-MONOCHLOROPROPANE-1,2-DIOL ESTERS (3-MCPDE) AND GLYCIDYL ESTERS (GE) IN REFINED VEGETABLE OILS AND FOOD PRODUCTS MADE WITH REFINED VEGETABLE OILS, INCLUDING INFANT FORMULA

INTRODUCTION

1. Edible vegetable oils are produced from fruits, seeds, and nuts. Refining of edible vegetable oils (at temperatures of about 200°C or higher) can produce 3-monochloropropane-1,2-diol (MCPD) esters (3-MCPDE) and glycidyl esters (GE). Palm oil has been reported to have the highest concentrations of these esters and the greatest consumption rate worldwide, in comparison to other refined oils (e.g., grapeseed, olive, soya bean, rapeseed, sunflower, walnut, hazelnut).

2. In 2016, at the request of the Codex Committee on Contaminants in Food (CCCF), the FAO/WHO Joint Expert Committee on Food Additives (JECFA) evaluated the toxicity of 3-MCPDE and GE and dietary exposure to these compounds.[1] 3-MCPDE and 3-MCPD have toxic effects on the kidney and male reproductive organs, and 3-MCPD is a non-genotoxic carcinogen. Glycidol is a genotoxic carcinogen.

3. JECFA established a group provisional maximum tolerable daily intake (PMTDI) of 4 µg/kg bw for 3-MCPD and 3-MCPDE (singly or in combination, expressed as 3-MCPD equivalents) based on renal tubular hyperplasia in male rats. JECFA noted that the estimated dietary exposures to 3-MCPD for the general population, even for high consumers, do not exceed the PMTDI. However, mean dietary exposures to 3-MCPD for formula-fed infants in some countries do exceed the PMTDI by 2.5 times. For GE, a genotoxic carcinogen, it is not appropriate to establish a health-based guidance value. Therefore, JECFA calculated margins of exposure (MOE) for GE (expressed as glycidol) ranging from 490 to 24,000 based on a benchmark dose lower limit ($BMDL_{10}$) of 2.4 mg/kg bw/day for mesotheliomas in male rats. JECFA considered that the lower ends of the ranges of the MOEs for infants, children, and adults may be a health concern, as they were less than 10,000.

4. Exposure to 3-MCPDE and GE can occur through consumption of refined vegetable oils and food products containing refined vegetable oils, including infant formula. JECFA recommended that efforts to reduce 3-MCPDE and 3-MCPD in infant formula be implemented and that measures to reduce GE and glycidol in fats and oils continue, particularly when used in infant formula.

5. JECFA alluded to the co-occurrence of 2-MCDPE with 3-MCPDE, but because of a lack of data on the occurrence of 2-MCPDE in foods and on its toxicity, JECFA did not evaluate 2-MCPDE. Although this document does not address 2-MCPDE, it is likely that mitigation of 3-MCPDE may lead to reduction of 2-MCPDE.

6. 3-MCPDE and GE are found in food products made from refined oils, for example, infant formula, potato products (e.g., french fries and potato crisps), and fine bakery wares (e.g., cookies, croissants, and donuts). Levels of 3-MCPDE and GE in foods made from refined oils correspond to the concentrations of 3-MCPDE and GE in the refined oils. Data suggest that the use of refined vegetable oils themselves during frying does not contribute to the formation of additional 3-MCPDE and GE, but rather the formation of additional 3-MCPDE and GE may result from the type of food that is fried.

7. Different types of unrefined vegetable oils have different capacities to form 3-MCPDE and GE during deodorization (part of the refining process). Factors contributing to this variation include climate, soil and growth conditions of the plants, their genotype, harvesting techniques, and processing conditions—all of which affect the levels of precursors of 3-MCPDE and GE (e.g., acylglycerols, chlorine-containing compounds). Most unrefined oils do not contain detectable levels of 3-MCPDE or GE.

8. 3-MCPDE forms primarily from the reaction between chlorine containing compounds and acylglycerols like triacylglycerols (TAGs) and diacylglycerols (DAGs). GE forms primarily from DAGs or monoacylglycerols (MAGs).

9. Some chlorinated compounds are precursors for 3-MCPDE formation. Research studies in oil palm trees have shown that chloride ions (in the form of chlorinated compounds) are absorbed during tree growth from the soil (including from fertilizers and pesticides) and water, and are metabolized into hydrophilic chlorinated compounds that may generate hydrochloric acid during oil refining, leading to formation of 3-MCPDE.

[1] Because toxicokinetic data indicate that 3-MCPDE and GE are broken down to their non-esterified forms, the toxicological assessments were based on 3-MCPD and glycidol (compounds for which toxicological data are available) (JECFA 2017).

10. Oil seeds and fruits contain the enzyme lipase; lipase activity increases with fruit maturation and seed germination. Lipase interacts with oil from mature fruits or seeds to rapidly degrade triacylglycerols into free fatty acids (FFAs) and DAGs and MAGs.

11. GE formation begins at about >200°C, and increases exponentially with increasing temperature when DAGs exceed 3-4% of total lipids, while 3-MCPDE formation occurs at temperatures as low as 160-200°C, and formation does not increase with higher temperatures.

12. Indirect and direct analytical methods are used to determine levels of 3-MCPDE and GE concentrations in refined oils and in foods made from refined oils. Indirect methods require alkaline or acidic cleavage of the fatty acid esters from the glycidol (before or after reaction with bromide) or 3-MCPD component prior to analysis, while for direct methods, analysis is conducted on intact 3-MCPDE or GE. The AOCS (American Oil Chemists' Society) has established three inter-laboratory validated (indirect) methods for determining 3-MCPDE and GE in edible oils and fats. Few methods, whether indirect or direct, have been validated for use in foods containing refined oils.

13. Because 3-MCPDE and GE are formed via different mechanisms, different mitigation strategies are needed to control their formation. Due to the different formation mechanisms, there generally is not a relationship between relative levels of 3-MCPDE and GE in individual oil samples.

14. GE is generally easier to mitigate than 3-MCPDE, because its formation is directly associated with elevated temperatures (with formation beginning at about 200°C, and becoming more significant at temperatures >230°C). GE is formed primarily from DAGs, and does not require the presence of chlorinated compounds. Oils can be deodorized at temperatures below 230°C to avoid significant GE formation. However, it is not practical to decrease deodorization temperatures below the threshold that would lead to 3-MCPDE formation, as that could affect the quality and safety of the oil.

15. Although 3-MCPDE and GE are primarily produced during deodorization, mitigation measures can be applied across the edible oil production chain beginning with agricultural practices (e.g., cultivation, harvesting and storage of fruits) to oil milling and refining (e.g., fruit and seed selection and processing, degumming/bleaching, and deodorization) as well as to post-refining measures (e.g., additional bleaching and deodorization, use of activated bleaching earth).

16. Various organizations, including BLL (German Federation for Food Law and Food Science) and FEDIOL (European Union Vegetable Oil and Proteinmeal Industry), have developed guidance on mitigating 3-MCPDE and GE in refined oils and in foods containing refined oils. These guidance documents can be found at: https://www.bll.de/download/toolbox-for-the-migration-of-3-mcpd-esters-and-glycidyl-ester and http://www.fediol.be/data/FEDIOL%20Review%20of%20Mitigation%20Measures%20MCPD%20Esters%20and%20Glycidyl%20Esters%20-%2024%20June%202015.pdf.

17. In 2008 Codex established a Code of Practice (CAC/RCP 64-2008) for 3-MCPD in acid-hydrolyzed vegetable proteins. That COP addresses mitigation measures for 3-MCPD, and the mitigation measures discussed are independent of the mitigation measures for 3-MCPDE and GE addressed in this document.

18. Although most work on mitigation of 3-MCPDE and GE in refined oils has focused on palm oil because of its greater capacity to form 3-MCPDE and GE and its importance economically, some of the information and experience on mitigation of 3-MCPDE and GE in palm oil may be applicable to mitigation of 3-MCPDE and GE in other refined oils. Therefore, where data are available, this document specifies when the mitigation approach is specific to palm oil, and when it may be more widely applicable to other vegetable oils.

19. Knowing what precursors are present in batches of crude vegetable oils may allow one to adjust refining parameters and to target appropriate mitigation strategies. Where possible, it may be best to remove precursors at the earlier stages of processing, to minimize the formation of 3-MCPDE and GE. For example, efforts to mitigate 3-MCPDE should also focus on cultivation, harvesting, and milling, not just refining.

20. Care should be taken so as not to mitigate 3-MCPDE at the expense of GE, or vice versa.

21. There are a wide range of methods to mitigate 3-MCPDE and GE, and the applicable methods used will vary depending on different conditions (including the oilseed or fruit being processed, the refining process, and the type of equipment installed). In addition, multiple methods may need to be combined to reduce 3-MCPDE and GE in oils. This document discusses both methods currently in use by industry and those that are still in experimental stages, as the methods applied will vary among and within industries. New, emerging methods will need to be tested at the industrial scale to assess their practicality and validity. Manufacturers should select and apply those techniques that are appropriate to their own processes and products.

22. In concert with mitigation of 3-MCPDE and GE, it is important to also consider the overall impacts on the quality of refined oils and oil-based products, including product properties such as smell and taste, FFAs and other stability attributes, levels of nutrients, and removal of contaminants such as pesticides and mycotoxins. In addition, environmental impacts of the recommended mitigation practices should be considered.

SCOPE

23. This Code of Practice intends to provide national and local authorities, 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, including infant formula. 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, including infant formula

RECOMMENDED PRACTICES BASED ON GOOD AGRICULTURAL PRACTICES (GAP) AND GOOD MANUFACTURING PRACTICES (GMP)

24. Producing edible oils involves several major steps: cultivating, harvesting, and transporting the fruits and seeds for further processing; oil milling, where palm fruit is sterilized, while oilseeds are cleaned, ground, and steamed; extracting oil from the fruits and seeds; and refining.

25. Refining consists of two main types; chemical or physical refining. Chemical refining consists of degumming (removal of phospholipids); neutralization (addition of hydroxide solution to remove free fatty acids (FFA) through formation of soaps); bleaching (using clays) to reduce colors and remove remaining soaps and gums, trace metals, and degradation products; and deodorization (i.e., a steam-distillation process carried out at low pressures, 1.5-6.0 mbar, and elevated temperatures,180-270°C) to remove FFA, colors, and volatile compounds. Physical refining involves degumming, bleaching, and deodorization combined with deacidification, but does not have a neutralization step. While several factors influence the selection of physical refining, it is typically conducted on oils containing low levels of phospholipids.

AGRICULTURAL PRACTICES

26. Consider selecting oil plant varieties with low lipase activity as being one factor (e.g., for palm oil, <10 µmole fatty acid released per minute/gram dry mesocarp) in reducing formation of FFA and acylglycerol precursors.

27. Minimize use of substances such as fertilizers, pesticides, and irrigation water that have excessive amounts of chlorine-containing compounds during cultivation to reduce chlorine absorption by the oil trees and ultimately the palm fruits.

28. Harvest oil palm fruit when they are at optimal ripeness. Minimize handling of the fresh fruit bunches to reduce bruising and prevent formation of FFA. Avoid using damaged or overripe fruits, which may be associated with higher 3-MCPDE and GE formation.

29. Transport oil palm fruits to oil mills as soon as possible.

OIL MILLING AND REFINING

Crude Oil Production and Treatment

30. Following receipt of the oil palm fruits at the mill, sterilize the fruits immediately (preferably within a few hours to less than 2 days of harvesting) at temperatures at or below 120°C to inactivate lipases (with temperatures varying depending on the sterilization method).

31. Wash crude vegetable oil with polar solvents like chlorine-free water or water/alcohol (ethanol) mixtures to remove chlorine-containing compounds. Experimentally, washing palm fruit pulp during oil extraction with organic solvent (e.g., hexane:water (2:1 volume/volume) or isopropanol) also has been shown to remove chlorine.

32. Avoid recycling residual oil recovered from solvents or additional extractions, as this oil tends to have higher levels of precursors (e.g., chlorine-containing compounds, DAGs).

33. Assess precursors in batches of crude vegetable oils (e.g., DAGs, chlorine-containing compounds) to adjust refining parameters and target appropriate mitigation strategies depending on the type of vegetable oil being processed and processing conditions.

34. Preferentially refining crude vegetable oil with low concentrations of precursors can produce finished oils with lower levels of 3-MCPDE and GE. For palm oil, refining crude oil with <4% DAG and <2.5% FFA or <5.5% DAG and <1.5% FFA has been shown under experimental conditions to reduce formation of GE, as the level of DAG has a positive correlation with the level of FFA.

Degumming

35. Use milder and less acidic conditions (e.g., either degumming with a low concentration of phosphoric acid (0.02%) or water degumming) to decrease 3-MCPDE in vegetable oils. The concentration of phosphoric acid needed depends on the quality of the crude vegetable oil. Care should be taken to remove sufficient concentrations of phospholipids and phosphoric acid to ensure quality.

36. Lowering the degumming temperature may help to reduce formation of 3-MCPDE precursors in vegetable oils; however, the degumming temperature will depend on numerous factors including type of vegetable oil.

37. During wet degumming, increasing the amount of water removed 3-MCPDE precursors in palm oil under experimental conditions.

Neutralization

38. Using chemical refining (i.e., neutralization) in place of physical refining can help remove precursors (e.g. chloride) and may allow for lower deodorization temperatures in vegetable oils. However, chemical refining can lead to excessive oil loss (especially for palm oil due to higher FFA levels), and may have a greater environmental impact than physical refining.

39. Neutralization with calcium oxide prior to deodorization of palm oil at a pilot refining plant has been shown to reduce acidic conditions and help remove precursors. Addition of alkaline carbonates or hydrogen carbonates in sunflower oil (i.e., K_2CO_3 and Na_2CO_3 or $KHCO_3$ and $NaHCO_3$) before deodorization has also been shown experimentally in the laboratory to neutralize fatty acids (and possibly remove chloride precursors).

Bleaching

40. Use of greater amounts of bleaching clay may reduce formation of 3-MCPDE and GE in all vegetable oils. However, bleaching clays that contain significant amounts of chlorine-containing compounds should be avoided.

41. Use of more pH-neutral clays reduces the acidity, and potential to form 3-MCPDE in palm oil and some seed oils.

Deodorization

42. Consider conducting deodorization of vegetable oils at reduced temperatures to decrease formation of GE. For example, it has been suggested to conduct deodorization at 190-230°C.

43. As an alternative to traditional deodorization, conduct dual deodorization of vegetable oils (2-stage deodorization) to reduce thermal load in oil. This includes both a shorter (e.g., 5 minutes at 250°C) and a longer (e.g., 120 minutes at 200°C) deodorization period. Consideration needs to be given to parameters such as temperature, vacuum pressure, and time, and variations in equipment design and capability. Also, additional post processing may be required to reduce levels of GE.

44. Use of a stronger vacuum facilitates evaporation of volatile compounds due to the increased steam volume and rate of stripping, contributing to decreased deodorization temperatures and reduced formation of 3-MCPDE and GE in vegetable oils.

45. Short-path distillation[1] (in place of deodorization) has been shown in laboratory experiments to reduce the thermal load and formation of esters in palm oil, contributing to lower amounts of 3-MCPDE and GE in comparison to conventional deodorization. However, additional post processing using mild deodorization (i.e., 160-180°C) is needed to address sensory considerations, and the resulting palm oil will be red in color due to carotenoids.

46. Use of antioxidants, such as *tert*-butyl hydroquinone (TBHQ), propyl gallate (PG), and L-ascorbyl palmitate (AP), has been shown experimentally to reduce formation of 3-MCPDE in rapeseed oil during heating.

[1] Short-path distillation enables gentle removal of volatile compounds at relatively low temperatures. This is accomplished through reduced pressure, where the boiling point of the compound to be separated is lowered and there is increased efficiency due to the short distance between the evaporator and the condenser surface.

TREATMENT POST REFINING

47. Conduct additional bleaching and deodorization steps following initial bleaching and deodorization of the refined palm oil, to achieve lower levels of GE in the refined palm oil. (The second deodorization should occur at a lower temperature than the first deodorization.)
48. Application of activated bleaching earth has been shown on an industrial scale to reduce GE in refined vegetable oils. Experimentally this mitigation measure has been demonstrated to convert GE in refined vegetable oils to MAGs and DAGs.
49. Use of short-path distillation (pressure: <1 mbar and temperature: 120 to 270°C) on bleached and deodorized vegetable oils can reduce acylglycerol components and levels of 3-MCPDE and GE.
50. Treatment of refined MCT (medium-chain triglyceride) oil with one or more bases (including, carbonate, bicarbonate, hydroxide, oxide, alkoxide, amine bases, hydrides, and phosphines) converts 3-MCPDE and GE to triglycerides. This method is being tested using other vegetable oils.
51. Use of adsorbents, including calcinated zeolite and synthetic magnesium silicate, following deodorization of palm oil, has been experimentally shown to remove GE.
52. Conducting post-treatment of refined vegetable oils with carboxymethyl cellulose or cation-exchange resin in combination with a nitrogen treatment has been shown experimentally to reduce 3-MCPDE.
53. Enzymes have been shown experimentally to mitigate 3-MCPDE in refined palm oil through conversion to glycerol.

SELECTION AND USES OF REFINED OILS IN FOOD PRODUCTS MADE FROM THESE OILS, INCLUDING INFANT FORMULA

Oil selection

54. Selecting refined vegetable oils with lower levels of 3-MCPDE and GE (e.g., either through natural occurrence or through application of mitigation measures) results in lower levels of 3-MCPDE and GE in finished products containing these oils. For example, variation in levels of 3-MCPDE and GE in infant formula has been observed, which may be due to the types of oils used in these formulas. However, in some cases, it may be difficult to replace particular oils in the finished products due to desired quality or compositional factors. For example, for infant formula, refined oils are selected by manufacturers to ensure these products meet compositional criteria, e.g., national criteria or those established in the Codex Infant Formula Standard (CXS 72-1981).

Processing modifications

55. Reducing the amount of refined vegetable oils in finished products is expected to reduce the levels of 3-MCPDE and GE in the finished product. However, this could impact the organoleptic or nutritional qualities of the finished products.
56. Use of refined vegetable oils themselves during frying does not contribute to formation of additional 3-MCPDE and GE, but rather the formation of additional 3-MCPDE and GE during frying may result from the type of food that is fried.

APPENDIX II

POTENTIAL MITIGATION MEASURES FOR REDUCING 3-MCPDE AND GE

It is recommended that all reduction measures be tested to identify the most successful for your own product.*

Production Stage	Mitigation measures
AGRICULTURAL PRACTICES	• Select oil plant varieties with low lipase activity. • Minimize use of substances such as fertilizers, pesticides, and irrigation water that contain excessive amounts of chlorine during oil palm cultivation. • Harvest oil palm fruits when they are at optimal ripeness. Minimize handling of fresh fruit bunches. Avoid using damaged or overripe fruit. • Transport oil palm fruits to oil mills as soon as possible.
OIL MILLING AND REFINING	**CRUDE OIL PRODUCTION AND TREATMENT** • Sterilize oil palm fruits at temperatures at or below 120°C. • Wash crude vegetable oil with polar solvents (e.g., chlorine-free water or water/alcohol mixtures). • Avoid recycling residual oil recovered from solvents or extractions. • Assess precursors (e.g., DAGs and chlorine compounds) in batches of crude vegetable oil to adjust refining parameters. • Preferentially refine crude vegetable oil with low concentrations of precursors.
	Degumming • Use milder and less acidic conditions, e.g., either degumming with a low concentration of phosphoric acid (0.02%) or water degumming for vegetable oils. • Lowering the degumming temperature in vegetable oils may reduce formation of 3-MCPDE precursors.
	Neutralization • Use of chemical refining (i.e., neutralization) in place of physical refining can help remove precursors (e.g., chloride) and may allow for lower deodorization temperatures in some vegetable oils.
	Bleaching • Use greater amounts of bleaching clay in vegetable oils. • Use more pH-neutral clays to reduce acidity in palm oils and some seed oils.

*Although this document addresses both methods in use by industry and those in their experimental stages, only those methods that are used in industrial applications are shown in the diagram.

POTENTIAL MITIGATION MEASURES FOR REDUCING 3-MCPDE AND GE

It is recommended that all reduction measures be tested to identify the most successful for your own product.*

Production Stage	Mitigation measures
OIL MILLING AND REFINING	**DEODORIZATION** • Consider conducting deodorization of vegetable oils at reduced temperatures. • An alternative to traditional deodorization is dual deodorization (2-stage deodorization) of vegetable oils which includes a shorter (e.g., 5 minutes at 250°C) and a longer (e.g., 120 minutes at 200°C) deodorization period. • Use of a stronger vacuum facilitates evaporation of volatile compounds and contributes to decreased deodorization temperatures in vegetable oils.
TREATMENT POST REFINING	• Conduct additional bleaching and deodorization following initial bleaching and deodorization of refined palm oil. • Application of activated bleaching clay to refined vegetable oils has been shown to reduce GE. • Use short-path distillation on bleached and deodorized vegetable oils. • Treatment of refined MCT (medium-chain triglyceride) oil with bases converts 3-MCPDE and GE to triglycerides.
SELECTION AND USES OF REFINED OILS	**OIL SELECTION** • Select refined vegetable oils with lower levels of 3-MCPDE and GE as this can reduce levels of 3-MCPDE and GE in the finished product. **PROCESS MODIFICATIONS** • Reduce the amount of refined vegetable oils in finished products as this may reduce the levels 3-MCPDE and GE in finished products. • Use of refined vegetable oils themselves during frying does not contribute to the formation of additional 3-MCPDE and GE, but rather the formation of additional 3-MCPDE and GE may result from the type of food that is fried.

*Although this document addresses both methods in use by industry and those in their experimental stages, only those methods that are used in industrial applications are shown in the diagram.

APPENDIX III

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