CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7 **CX/CF 19/13/7-Add.1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

13th Session
Yogyakarta, Indonesia, 29 April – 3 May 2019

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

Comments submitted by Australia, Canada, Colombia, Costa Rica, European Union, Japan, Indonesia, Kenya, Republic of Korea, Malaysia, United States of America and FEDIOL

Australia

Australia supports progression of this Code of Practice and offers the following minor editorial comments:

1. Paragraph 7 – Are there any factors that contribute to possible formation of 3-MCPDE and GE in fish oils and could these be outlined?
2. Paragraph 13 – Suggest including the deodorisation temperature threshold
3. Paragraph 21 – Suggest clarifying which of the two refining processes (chemical or physical) is preferable for producing finished oils with lower levels of 3-MCPDE and GE. This could strengthen what has been outlined in Paragraph 34.
4. Paragraph 24 – It may be useful to specify the water as 'irrigation water'.
5. Paragraph 37 – It would be useful to define the term 'residence time' and explain why the temperature will vary because of the residence time (i.e. because there is a general move towards lowering the residence time at high temperatures).
6. Paragraph 38 – Clarify whether the dual deodorization of vegetable oils and fish oils applies to the mitigation of both 3-MCPDE and GE, or GE only (the last sentence of this paragraph).
7. Annex I – Crude Oil Production and Treatment – The fifth dot point is incomplete. We suggest the following text: 'Preferentially refine crude vegetable oil or fish oil with low concentrations of precursors'.

Canada

Canada wishes to express its appreciation to the chair, the Unites States of America and co-chairs, the European Union and Malaysia, for leading the electronic Working Group (eWG) to develop a *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*. Canada would like to indicate its agreement with the revisions made to the Code of Practice as presented in Appendix I of this document.

Colombia

The proposed amendments are by text insertions in **bold and underlined** and deletion is in ~~strikethrough.~~

PARAGRAPHS	PROPOSED POSITION	OBSERVATIONS OR COMMENTS	CATEGORY OF [1]COMMENT			
			E	S	TE	TR
INTRODUCTION 19. Producing edible vegetable oils involves several major steps: cultivating, harvesting, transporting, and storing the fruits and seeds for further processing; palm oil milling where fruit is sterilised and crude oil is extracted; by ~~**crushing (machaqueo)**~~ the oil-producing seeds, whereby they are cleaned, thrashed, and steamed to extract the crude oil and, finally, the refining of the crude oil.	INTRODUCTION 19. Producing edible vegetable oils involves several major steps: cultivating, harvesting, transporting, and storing the fruits and seeds for further processing; palm oil milling where fruit is sterilised and crude oil is extracted; by **crushing (prensado)** the oil-producing seeds, whereby they are cleaned, thrashed, and steamed to extract the crude oil and, finally, the refining of the crude oil.	We believe that the technically correct word in Spanish for “crushing” is “prensado”.				**X**
SELECTION AND USES OF REFINED OILS IN FOOD PRODUCTS MADE FROM THESE OILS Oil Selection 46. Selecting refined vegetable oils and fish oils with low 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.	SELECTION AND USES OF REFINED OILS IN FOOD PRODUCTS MADE FROM THESE OILS Oil Selection 46. Selecting refined **edible oils and fats** ~~**vegetable oils and fish oils**~~ with low 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.	It is considered appropriate to clarify that not only refined vegetable oils can contain this type of contaminant. Consequently, we recommend using a generic reference that includes other types of raw material as in “edible oils and fats”.	**X**			
APPENDIX I **POSSIBLE MITIGATION MEASURES TO REDUCE 3-MCPDE AND GE.** **AGRICULTURAL PRACTICES TO OBTAIN VEGETABLE OIL** Mitigation measures • Select oil-producing plant varieties with reduced lipase activity.	**APPENDIX I** **POSSIBLE MITIGATION MEASURES TO REDUCE 3-MCPDE AND GE.** **AGRICULTURAL PRACTICES TO OBTAIN VEGETABLE OIL** Select palm varieties, **including interspecific hybrid OxG**, with reduced lipase activity, **for new plantations or when crops are renewed.**	We propose the addition of the underlined text, given that, for the production of palm oil, oil-producing plant varieties and interspecific hybrid OxG with reduced lipase activity exist. Consequently, we propose that this practice is adopted for new plantations or crop renewal.	**X**			

[1] - “Editorial”: This type of comment explains and simplifies the text without changing its meaning. It includes corrections of spelling and grammar, suggestions for alternative but equivalent wording and for simplifying sentence structure.

PARAGRAPHS	PROPOSED POSITION	OBSERVATIONS OR COMMENTS	CATEGORY OF [1]COMMENT			
			E	S	TE	TR
APPENDIX I **AGRICULTURAL PRACTICES TO OBTAIN VEGETABLE OIL** Minimise use of substances such as fertilizers, pesticides and irrigation water that have excessive amounts of chlorine-containing compounds during cultivation of the palm fruits.	**APPENDIX I** **AGRICULTURAL PRACTICES TO OBTAIN VEGETABLE OIL** Minimise use of substances such as **~~fertilizers,~~** pesticides and irrigation water that have excessive amounts of chlorine-containing compounds during cultivation of palm fruits. **In fertilization processes, depending on the nutritional conditions of the crop, non-chlorinated sulfate fertilizers may be used.**	As regards fertilization processes, we recommend including alternatives to the use of non-chlorinated phosphates fertilizers, for the appropriate purposes. For these reasons, we consider that this letter should be included. The nutritional requirements of the palm fruit must be taken into account, as chlorine is an essential element for this plant species and, consequently, good practice in this area should tend towards the optimal application of this element, rather than minimizing its use.	**X**			
APPENDIX I **OIL MILLING AND REFINING** **Crude oil production and treatment** Wash crude vegetable oil with polar solvents like chlorine-free water [or water/alcohol (ethanol) mixtures].	**APPENDIX I** **OIL MILLING AND REFINING** **Crude oil production and treatment** Wash crude vegetable oil with polar solvents **when precursors are present** like chlorine-free water **[~~or water/alcohol (ethanol)mixtures].~~**	We believe it is important to mention that water/alcohol mixtures may give rise to problems for waste disposal especially due to the creation of eutectic mixtures of water and alcohol. Consequently, we should bear in mind potential traces of alcohol in the water. For these reasons, we support the non-inclusion of the text within brackets.		**X**		
APPENDIX I. **SELECTION AND USES OF REFINED OILS** **OIL SELECTION** Selecting refined vegetable oils and fish oils with low levels of 3-MCPDE and GE.	**APPENDIX I.** **SELECTION AND USES OF REFINED OILS** **OIL SELECTION** Selecting refined **edible oils and fats ~~vegetable oils and fish oils~~** with low levels of 3-MCPDE and GE.	It is considered appropriate to clarify that not only refined vegetable oils can contain this type of contaminant. Consequently, we recommend the use of a generic reference including other types of raw materials, as in “edible oils and fats” or to delete it. As currently couched, it could constitute a technical trade barrier, in the case of palm oil.	**X**			

PARAGRAPHS	PROPOSED POSITION	OBSERVATIONS OR COMMENTS	CATEGORY OF [1]COMMENT			
			E	S	TE	TR
APPENDIX I. **SELECTION AND USES OF REFINED OILS** **PROCESSING MODIFICATIONS** Reducing the amount of refined vegetable oils and fish oils used in finished products.	**APPENDIX I.** **SELECTION AND USES OF REFINED OILS** **PROCESSING MODIFICATIONS** Reducing the amount of refined edible ~~**fish**~~ fats and ~~**vegetable**~~ oils used in finished products.	It is considered appropriate to clarify that not only refined vegetable oils can contain this type of contaminant. Consequently, we recommend the use of a generic reference including other types of raw materials, as in “edible oils and fats” or to delete it.	**X**			

Costa Rica

Location	Original wording	Proposed wording	Justification
Page 3	Edible oils are produced from various commodities, including fruits, seeds, nuts, and fish. Refining of edible oils (at temperatures of about 200°C or higher) can produce 3-monochloropropane-1,2-diol (MCPD) esters (3-MCPDE) and glycidyl esters (GE).	Edible oils are produced from various commodities, including **vegetable oils (fruits, seeds and nuts) and fish**. Refining of edible oils (at temperatures of about **200 °C** or higher) can produce 3-monochloropropane-1,2-diol (MCPD) esters (3-MCPDE) and glycidyl esters (GE).	We recommend changing the wording to separate vegetable oils from fish oils.
Page 4	AGRICULTURAL PRACTICES FOR VEGETABLE OIL	Agricultural practices for palm oil	The content only refers to palm oil and therefore we recommend a change to "Agricultural practices for oil palm"

Cuba

In document CX/CF 19/13/7, in the table about Oil Milling and Refining, it is stated: Sterilize oil palm fruit at temperatures at or below 140°C, which is the same as ≤140ºC. We propose using a range of values and establishing minimum and maximum values, which would help to manage the process better, given that lipase is inactivated at an approximate temperature of 60°C, through

European Union

The European Union and its Member States (EUMS) welcome and appreciate the work on the 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 by the electronic Working Group chaired by the United States of America and co-chaired by the European Union and Malaysia

The EUMS agree in general with draft Code of Practice as presented and have following comments:

- §11: While it is correct that the potential for forming glycidyl esters increases from a threshold of 3-4% of diacylglycerols, the exponential increase of glycidyl ester formation is related to increasing temperature.

Therefore, it is proposed to rephrase the sentence “*When DAGs exceed 3-4 % of total lipids, GE formation increases exponentially with increasing temperature*” by “When DAGs exceed 3-4% of total lipids, **the potential for GE formation increases. GE formation increases exponentially with increasing temperature.”**

- §21: It is mentioned that deodorization is done to remove free fatty acids (FFA), colours, and volatile compounds. The EUMS suggest to also explicitly mention that contaminants are removed (it is correct that contaminants are included in the “volatile compounds”, but also FFA are volatile under these conditions and are explicitly mentioned).

Furthermore, it is appropriate to mention in the sentence related to physical refining that physical refining requires a higher temperature because there is no neutralization step.

Indonesia

INTRODUCTION

1. Edible oils are produced from various commodities, including fruits, seeds, nuts, and fish. Refining of edible oils (at temperatures of about 200°C or higher) can produce 3-monochloropropane-1,2-diol (MCPD) esters (3-MCPDE) and glycidyl esters (GE).

2. Exposure to 3-MCPDE and GE can occur through consumption of refined oils and food products containing refined oils, including infant formula, dietary supplements, fried potato products, and fine bakery wares.

   Indonesia comment:

   Indonesia proposes to delete the following sentence:

   Exposure to 3-MCPDE and GE can occur through consumption of refined oils. ~~including infant formula, dietary supplements, fried potato products, and fine bakery wares.~~

   Rationale:

   Exposure to 3-MCPDE and GE is not limited to products such as for infant formula, dietary supplements, fried potato products, and fine bakery wares, thus it is not necessary to mention those products. Moreover, the scope of COP is intended for general commodities.

3. 3-MCPDE and 3-MCPD have toxic effects on the kidney and male reproductive organs, and 3-MCPD is a non-genotoxic carcinogen. GE and glycidol are genotoxic carcinogens.[2]

4. The 83rd JECFA session evaluated 3-MCPDE and GE and 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. Different types of unrefined oils have different capacities to form 3-MCPDE and GE during deodorization (part of the refining process). For example, refined palm oil has historically been reported to have higher concentrations of these esters than other refined edible oils.

   Indonesia comment:

   Indonesia proposes to delete the following sentence:

   Different types of unrefined oils have different capacities to form 3-MCPDE and GE during deodorization (part of the refining process). ~~For example, refined palm oil has historically been reported to have higher concentrations of these esters than other refined edible oils.~~

   Rationale:

   3- MCPDE and GE contents are not only related to oil type, but also to environmental conditions, genotypes, factor processing or refinery processes, and post-harvest handling. It is not necessary to provide such example.

6. Processing conditions during refining have an important effect on formation of 3-MCPDE and GE for all oil types. Most unrefined oils do not contain detectable levels of 3-MCPDE or GE.

7. For vegetable oils, factors that contribute to capacity to form 3-MCPDE and GE during refining include climate, soil and growth conditions of source plants, plant genotype, and harvesting techniques. These factors all affect the levels of precursors of 3-MCPDE and GE (e.g. acylglycerols, chlorine-containing compounds).

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

9. Some chlorinated compounds are precursors for 3-MCPDE formation. Oil palm fruits absorb chloride ions (in the form of chlorinated compounds) during tree growth from soil (including from fertilizers and pesticides) and from water, and these chloride ions are converted into reactive chlorinated compounds such as hydrochloric acid during oil refining, leading to formation of 3-MCPDE.

   Indonesia comment:

   Indonesia proposes to modify this paragraph as follow:

[2] 3-MCPDE and GE, following consumption, are broken down in the body to 3-MCPD and glycidol, respectively.

Some chlorinated compounds are precursors for 3-MCPDE formation. ~~Oil palm fruits~~ **Oil producing plants** absorb chloride ions (in the form of chlorinated compounds) during tree growth from soil (including from fertilizers and pesticides) and from water, and these chloride ions are converted into reactive chlorinated compounds such as hydrochloric acid during oil refining, leading to formation of 3-MCPDE.

Rationale:

Chlorine is absorbed as chloride (Cl^-) anion by plant from the soil and water. The average concentrations of chlorine in plants are in the range of 2–20 g kg^{-1} dry matter (DM) (Chen *et al*. 2010). Moreover, chloride (Cl^-) can also be absorbed by other oil plants such as corn (Parket *et al.* 1985), soybean (Bustingorri and Lavado 2011), coconut, etc Thus to make this COP applicable to edible oil (as the title implied). Indonesia proposes to replace "oil palm fruits" to "oil producing plants".

Source :

Bustingorri and Lavado. 2011. Soybean growth under stable versus peak salinity. *Sci. agric. (Piracicaba, Braz.)*. 68(1): 102-108.

Chen *et al*. 2010. Chlorine nutrition of higher plants: progress and perspectives. *Journal of Plant Nutrition*. 33(7): 943-952.

Parket *et al.* 1985. Chloride effects on corn. *Communications in Soil Science and Plant Analysis*. 16(12): 1319-1333.

10. Oil fruits and seeds contain the enzyme lipase; lipase activity increases with fruit maturation, while the lipase activity in seeds remains stable. Lipase interacts with oil from mature fruits to rapidly degrade TAGs into free fatty acids (FFAs), DAGs, and MAGs, while the effect of lipase in seeds that are appropriately stored is negligible.
11. GE formation begins at about 200°C. When DAGs exceed 3-4% of total lipids, GE formation increases exponentially with increasing temperature. Formation of 3-MCPDE occurs at temperatures as low as 160-200°C, and formation does not increase with higher temperatures.
12. 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 no relationship between relative levels of 3-MCPDE and GE in individual oil samples.
13. 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.
14. Although 3-MCPDE and GE are primarily produced during deodorization, mitigation measures can be applied across the edible oil production chain, from agricultural practices for vegetable oils (e.g. cultivation, harvesting, transporting, and storing of fruits and seeds), to oil milling and refining (e.g. crude oil production and treatment, degumming/bleaching, and deodorization), as well as to post-refining measures (e.g. additional bleaching and deodorization and use of activated bleaching earth). Where possible, it may be best to remove precursors at the earlier stages of processing, to minimize the formation of 3-MCPDE and GE.
15. 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 oil source, the refining process, and the type of equipment in use). In addition, multiple methods may need to be combined to reduce 3-MCPDE and GE in oils. Manufacturers should select and apply those techniques that are appropriate to their own processes and products.
16. 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, FFA profiles, 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.
17. Although most work on mitigation of 3-MCPDE and GE in refined oils has focused on palm oil, 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 refined oils, including fish oils.

SCOPE

18. This Code of Practice intends to provide national and local authorities, producers, 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. 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.

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

19. Producing edible vegetable oils involves several major steps: cultivating, harvesting, transporting, and storing the fruits and seeds for further processing; palm oil milling where fruit is sterilized and crude oil is extracted; oilseed crushing where oilseeds are cleaned, ground, and steamed and crude oil is extracted; and refining of the crude oils.

20. Producing edible fish oils involves several major steps: harvesting the fish, steam cooking, de-watering/wet reduction (which involves pressing the liquor, separating the oil and water, and optionally, water washing the oil), and refining.

21. Refining edible oils consists of two main types; chemical or physical refining. Chemical refining consists of degumming (removal of phospholipids); neutralization (addition of hydroxide solution to remove FFAs 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, 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 FOR VEGETABLE OILS

22. When planting new trees, consider selecting oil palm plant varieties with low lipase activity in oil fruits, as low lipase activity is one factor that can reduce formation of FFAs and acylglycerol precursors.

    Indonesia comment:

    Indonesia proposes to modify this paragraph as follow:

    When planting new trees, **if available,** consider selecting oil palm plant varieties with low lipase activity in oil fruits, as low lipase activity is one factor that can reduce formation of FFAs and acylglycerol precursors.

23. Consider storing oil seeds at cool temperatures (e.g., < 25°C) and dry conditions (optimally <7% moisture content) to help ensure low levels of lipase.

    Indonesia comment:

    Indonesia proposes to modify this paragraph as follow:

    Consider storing oil seeds **(such as soybean, sesame)** at cool temperatures (e.g., < 25°C) and dry conditions (optimally <7% moisture content) to help ensure low levels of lipase.

24. During cultivation of palm fruits, minimize use of substances such as fertilizers, pesticides, and water that have excessive amounts of chlorine-containing compounds, in order to reduce chlorine uptake by the fruits.

    Indonesia comment:

    Indonesia proposes to modify this paragraph as follow:

    During cultivation of ~~palm fruits~~ **oil plants**, ~~minimize~~ **apply proper** use of substances such as fertilizers, pesticides, and water ~~that have~~ **to minimize** excessive amounts of chlorine-containing compounds, in order to reduce chlorine uptake by the fruits **and seeds.**

    Rationale:

    The use of fertilizer, pesticides, and water are not limited for palm fruits. Other oil plants also use fertilizers, pesticides, and water in their growth.

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

    Indonesia comment:

    Indonesia proposes to modify this paragraph as follow:

    Harvest oil **plants** ~~palm fruit~~ when they are at optimal ripeness. Minimize handling of **harvested seeds/fruits** ~~the fruit~~ to reduce bruising and prevent formation of FFAs. Avoid using damaged or overripe **seeds/**fruits, which may be associated with higher 3-MCPDE and GE formation.

    Rationale:

    This principle should also be applied to other type of oils.

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

    Indonesia comment:

    Need additional paragraphs related to the management of the transport process.

OIL MILLING AND REFINING

Crude Oil Production and Treatment

27. Following receipt of oil palm fruits at the mill, sterilize the fruits immediately (preferably within less than 2 days of harvesting) at temperatures at or below 140°C to inactivate lipases (with temperatures varying depending on the sterilization method). (Fruits may be washed prior to sterilization to remove chlorine precursors.) For oilseeds, clean, grind, and steam to inactivate lipases.

28. Wash crude vegetable oil with polar solvents like chlorine-free water [or water/alcohol (ethanol)mixtures] to remove chlorine-containing compounds.

    Indonesia comment:

    Indonesia proposes to modify this paragraph as follow:

    When applicable, wash crude vegetable oil with polar solvents like chlorine-free water ~~[or water/alcohol (ethanol)mixtures]~~ to remove chlorine-containing compounds.

    Rationale :

    This is not applicable nor practical.

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

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

31. Preferentially refining crude vegetable oil or fish oil with low concentrations of precursors can produce finished oils with lower levels of 3-MCPDE and GE.

Degumming

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

33. 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 the type of vegetable oil.

Neutralization

34. Using chemical refining (i.e., neutralization) in place of physical refining can help remove precursors (e.g. chloride) and reduce FFAs, which may allow for lower deodorization temperatures in vegetable oils or fish 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.

Bleaching

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

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

Deodorization

37. Consider conducting deodorization of vegetable oils and fish oils at reduced temperatures to decrease formation of GE. For example, it has been suggested to conduct deodorization at 190-230°C for vegetable oils and less than 190°C for fish oils. The temperature will vary depending on the residence time of oil.

    Indonesia comment:

    Indonesia proposes to delete the following sentence:

    Consider conducting deodorization of vegetable oils and fish oils at reduced temperatures to decrease formation of GE. ~~For example, it has been suggested to conduct deodorization at 190-230°C for vegetable oils and less than 190°C for fish oils.~~ The temperature will vary depending on the residence time of oil.

    Rationale:

    No need to provide example since the first sentence is adequate. This will also encourage industries research and innovation in the deodorization process. In addition, the fact that "the temperature will vary depending on the residence time of oil" suggest that the example given is not always relevant. In addition, the temperature also depends on pressure.

38. As an alternative to traditional deodorization, conduct dual deodorization of vegetable oils and fish oils (2-stage deodorization) to reduce thermal load in oil. This includes both a shorter deodorization period at a higher temperature and a longer deodorization period at a lower temperature. 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.

39. 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 GE, and to a lesser extent 3-MCPDE, in vegetable and fish oils.

40. Short-path distillation[3] (in place of deodorization) has been shown to reduce the thermal load and formation of esters in fish oil, contributing to lower amounts of 3-MCPDE and GE in comparison to conventional deodorization. However, additional post processing using mild deodorization (e.g., 160-180°C) is needed to address sensory considerations.

    Indonesia comment:

    Indonesia proposes to modify this paragraph as follow:

    Short-path distillation[1] (in place of deodorization) has been shown to reduce the thermal load and formation of esters in fish oil, contributing to lower amounts of 3-MCPDE and GE in comparison to conventional deodorization. However, additional post processing using mild deodorization ~~(e.g., 160-180°C)~~ is needed to address sensory considerations.

    Rationale:

    No need to provide example since the first sentence is adequate. This will also encourage industries research and innovation in the deodorization process.

TREATMENT POST REFINING

41. The following recommended practices can be used for reducing levels of 3-MCPDE and GE in refined oils. These practices may be most appropriate for oils with 3-MCPDE and GE levels that are higher than desired for their intended use.

[3] 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.

42. Additional bleaching and deodorization following initial bleaching and deodorization has been shown to achieve lower levels of GE in refined palm oil. (The second deodorization should occur at a lower temperature than the first deodorization.)

43. Application of activated bleaching earth during post refining has been shown to reduce GE in refined vegetable oils.

    Indonesia comment:

    Indonesia proposes to modify this paragraph as follow:

    Application of activated bleaching earth during post refining has been shown to reduce GE in refined vegetable oils **and refined fish oils.**

44. Use of short-path distillation (pressure: <1 mbar and temperature: 120 to 270°C) on bleached and deodorized vegetable oil can reduce acylglycerol components and levels of 3-MCPDE and GE.

45. Treatment of refined MCT (medium-chain triacylglycerols) oil with one or more bases (including carbonate, bicarbonate, hydroxide, oxide, alkoxide, amine bases, hydrides, and phosphines) converts 3-MCPDE and GE to TAGs.

    Indonesia comment :

    Need clarification regarding the technology of treatment of refined MCT oil converts 3-MCPDE and GE to TAGs.

SELECTION AND USES OF REFINED OILS IN FOOD PRODUCTS MADE FROM THESE OILS

Oil selection

46. Selecting refined vegetable oils and fish oils with low 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 use of oils with different levels of 3-MCPDE and GE; therefore, selection of oils low in 3-MCPDE and GE can result in infant formulas with lower 3-MCPDE and GE levels. However, manufacturers also may have to consider 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 Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981).

Processing modifications

47. Reducing the amount of refined vegetable oils and fish oils used 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.

48. 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 during frying may result from the type of food that is fried (e.g. meat and fish products).

Japan

Japan supports advancement of the draft COP to Step 8 for final adoption by the CAC, as it includes the mitigation measures currently used (or to be used) by the industries and proved to be effective on an industrial scale. However, the CCCF should update the COP in the future when new information and data including the results of various ongoing studies become available.

Japan would like to provide the following comment for improving readability of the text and for consistency with other COPs:

Declarative sentences and imperative sentences are mixed in the text from paragraph 22 through paragraph 48, as indicated in the following table: while some mitigation measures are described in ‘declarative sentence’, other mitigation measures are descried in ‘imperative sentence’. For consistency with the format of recently adopted Codex COPs, such as CXC 62-2006 (revised in 2018) and CXC 77-2017, and for ease of reading and using the COP, mitigation measures should be written in ‘declarative sentence’ throughout the body of this COP.

Section	Imperative sentence	Declarative sentence
AGRICULTURAL PRACTICE FOR VEGETABLE OILS	§22-26	-
OILMILLING AND REFINING *Crude Oil Production and Treatment*	§27-30	§31
Degumming	§32	§33
Neutralization	-	§34
Bleaching	-	§35-36
Deodorization	§37-38	§39-40
TREATMENT POST REFINING	-	§41-45
SELECTION AND USE OF REFINED OILS IN FOOD PRODUCTS MADE WITH THESE OILS	-	§46-48

Kenya

GENERAL COMMENT

We would like to thank the EWG led by the United States of America, Malaysia and European Union for the good work for coming up with this document for the member's consideration.

COMMENTS:

Paragraph 18- Scope:

Kenya proposes an amendment of the scope by deleting ''~~national and local authorities, producers, manufacturers, and other relevant bodies with~~h'' in the first statement so that it reads "**This Code of Practice intends to provide guidance to prevent and reduce formation of 3-MCPDE and GE in refined oils and food products made with refined oils''.** See clarification below on what has been deleted

This Code of Practice intends to provide

(i) Good agricultural practices,

(ii) Good manufacturing practices, and

(iii) Selection and uses of refined oils in food products made from these oils.

JUSTIFICATION

Codex standards are developed for all interested parties and not limited to specific actors. Hence no need to specify the actors.

COMMENT

Paragraph 28- Kenya proposes the use of water/alcohol (ethanol)mixtures instead of chlorine –free water

JUSTIFICATION

Water/alcohol (ethanol)mixtures would be more effective to remove chlorine containing compounds.

Republic of Korea

Republic of Korea supports the work of eWG, and would like to provide following suggestion on the proposed draft Codex of Practice(COP):

- Since there could be differences in production of 3-MCPDE and GE depending on several parameters[4,5] such as fish species, fat content and extraction method etc., scientific research or monitoring data should be submitted through eWG and included either on **OIL MILLING AND REFINING** or *Oil selection*.

[4] Kinuko Miyazaki and Kazuo Koyama, 2017, J. Oleo Sci. 66, (10) 1085-1093
[5] R. Jedrkiewicz et al., 2016, Food Control 59, 487-492

Malaysia

Malaysia would like to congratulate members of the Electronic Working Group (EWG) chaired by United States of America and co-chaired by Malaysia and European Union on the progression of the document. Malaysia would like to comment and suggest deletion / addition for the following items in Appendix I of the document:

Introduction (Para 3):

3. 3-MCPDE and 3-MCPD have toxic effects on the kidney and male reproductive organs, and 3-MCPD is a non-genotoxic carcinogen. GE and glycidol are genotoxic carcinogens.

Malaysia's comment:

Malaysia is of the view that this sentence should highlight that the study was

conducted using rat and is not a clinical study.

Introduction (Para 5):

Malaysia's comment:

Malaysia proposes the deletion of the example under Para 5 because it is a historical information. With the current technology, refined palm oil with lower 3-MCPDE and GE can be produced.

Therefore the para shall read as follows:

"5. Different types of unrefined oils have different capacities to form 3-MCPDE and GE during deodorization (part of the refining process). ~~For example, refined palm oil has historically been reported to have higher concentrations of these esters than other refined edible oils. "~~

Introduction (Para 9):

Malaysia's comment:

Malaysia proposes revision of the Para 9, as follows:

"9. Some chlorinated compounds are precursors for 3-MCPDE formation. Oil palm fruits absorb chloride ions (in the form of chlorinated compounds) during tree growth from soil (including from fertilizers and pesticides) and from water, and these chloride ions are converted into reactive chlorinated compounds ~~such as hydrochloric acid during oil refining,~~ leading to formation of 3-MCPDE~~.~~ **during oil refining**."

Agricultural Practices for Vegetable Oils (Para 22):

Malaysia's comment:

Malaysia is of the view that Para 22 be deleted as there is no low lipase oil palm varieties commercially available in the market.

~~"22. When planting new trees, consider selecting oil palm plant varieties with low lipase activity in oil fruits, as low lipase activity is one factor that can reduce formation of FFAs and acylglycerol precursors."~~

Oil Milling and Refining

Crude Oil Production and Treatment (Para 28):

Malaysia's comment:

Malaysia proposes to delete the statement in the square bracket in Para 28 because the usage of water/alcohol (ethanol) mixture is not practical at a commercial scale due to safety concern.

Therefore the para shall read as follows:

"28. Wash crude vegetable oil with ~~polar solvents like~~ chlorine-free water ~~[or water/alcohol (ethanol) mixtures]~~ to remove chlorine-containing compounds."

Treatment Post Refining (Para 45):

45. Treatment of refined MCT (medium-chain triacylglycerols) oil with one or more bases (including carbonate, bicarbonate, hydroxide, oxide, alkoxide, amine bases, hydrides, and phosphines) converts 3-MCPDE and GE to TAGs.

Malaysia's comment:

Malaysia is of the view that this sentence should be clarified whether the treatment has been carried out at an industrial scale or just data from laboratory or pilot scale trials.

United States of America

The United States supports advancement of the Code of practice for adoption at Step 8.

The United States proposed the development of the Code of practice in light of the JECFA83 (November 2016) summary and conclusion that formula-fed infants can exceed the group provisional maximum tolerable daily intake (PMTDI) for 3-MCPD and 3-MCPDE and the lower end margins of exposure (MOE) for GE for infants, children, and adults may be a health concern.

FEDIOL

FEDIOL is the European federation representing the interests of the European vegetable oil and protein meal industry. Directly and indirectly, FEDIOL covers about 150 processing sites that crush oilseeds and/or refine crude vegetable oils. These plants belong to around 35 companies. It is estimated that over 80% of the EU crushing and refining activity is covered by the FEDIOL membership structure.

FEDIOL, as an observer to the Codex Alimentarius, would like to submit the following comments on the draft Code of Practice (CoP) for the reduction of 3-MCPDEs and GEs in refined oils and food products made with refined oils.

General comments

FEDIOL has been a member of the electronic working group working on this draft CoP since the beginning and provided regular input into the various steps of the CoP. It welcomes the work undertaken by the chairs and co-chairs of the electronic working group.

FEDIOL considers that the draft CoP as it stands provides a balanced overview of the available mitigation techniques to date to target 3-MCPDE and GE in refined vegetable oils, which FEDIOL can support.

As highlighted in the draft CoP, "*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 oil source, the refining process, and the type of equipment in use)"*. FEDIOL further concurs with the fact that "*multiple methods may need to be combined to reduce 3-MCPDE and GE in oils"* and that *"manufacturers should select and apply those techniques that are appropriate to their own processes and products".*

FEDIOL further welcomes the recognition of different factors to be taken into account *in concert with mitigation of 3-MCPDE and GE* such as the quality and other safety parameters of vegetable oils and fats.

Specific comments:

FEDIOL would like to highlight a missing sentence in the graph page 7, where the sentence "*Preferentially refining crude vegetable oil or fish oil with low*" should read as "*Preferentially refining crude vegetable oil or fish oil with low concentrations of precursors*" (as per point 31 of the Code).