CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

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

CXC 79-2019

Adopted in 2019.

INTRODUCTION

1. Edible oils, which include vegetable oils and fish 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-MCPDEs) and glycidyl esters (GEs).

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

3. Toxicology studies show that 3-MCPDE and 3-MCPD have effects on the kidney and male reproductive organs and are non-genotoxic carcinogens. GE and glycidol are genotoxic carcinogens.[1]

4. The 83rd JECFA Meeting evaluated 3-MCPD, 3-MCPDE, GE and glycidol 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).

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 or trees, their 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 producing plants or trees absorb chloride ions (in the form of chlorinated compounds) during plant or tree growth from soil (including from fertilizers and pesticides) and from water, and these chloride ions are converted into reactive chlorinated compounds, leading to formation of 3-MCPDE during oil refining.

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. GE formation increases exponentially with increasing temperature. When DAGs exceed 3-4% of total lipids, the potential for GE formation increases. 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 (160-200°C), 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.

[1] 3-MCPDE and GE, following consumption, are broken down in the body to 3-MCPD and glycidol, respectively.

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 of the crude oils.

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, including certain contaminants. Physical refining involves degumming, bleaching, and deodorization (which occurs at higher temperatures than chemical refining), as it 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, farmers should consider selecting oil palm plant varieties with low lipase activity in oil fruits, if available, as low lipase activity is one factor that can reduce formation of FFAs and acylglycerol precursors.

23. During cultivation of oil plants or trees, farmers should 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 and seeds. Non-chlorinated sulfate fertilizers could serve as an alternative to chlorine-containing fertilizers.

24. Farmers should harvest oil palm fruits when they are at optimal ripeness, minimize handling of the fruits to reduce bruising and prevent formation of FFAs, and avoid using damaged or overripe fruits, which may be associated with higher 3-MCPDE and GE formation.

25. Farmers should transport oil palm fruits to oil mills as soon as possible.

OIL MILLING AND REFINING

Crude Oil Production and Treatment

26. Processors should consider storing oil seeds for milling at cool temperatures (e.g. < 25°C) and dry conditions (optimally <7% moisture content) to help ensure low levels of lipase.

27. Following receipt of oil palm fruits at the mill, processors should 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, processors should clean, grind, and heat to inactivate lipases.

28. Processors should consider washing crude vegetable oil with chlorine-free water to remove chlorine-containing compounds.

29. Processors should 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. Processors should assess precursors in batches of crude vegetable oils or fish oils (e.g. DAGs, FFAs, 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. Processors should 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) as an alternative to 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. Processors should 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. Processors can determine the optimal conditions for their processes.

38. As an alternative to traditional deodorization, processors can conduct dual deodorization of vegetable oils and fish oils (2-stage deodorization) to reduce thermal load in oil and to decrease formation of GE, with a smaller reduction in 3-MCPDE. 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[2] (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 is needed to address sensory considerations.

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[2] 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

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.

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.

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 fatty acids and a cation counterion, such as an alkali metal, as well as one or more bases converts 3-MCPDE to MAGs, DAGs and TAGs, and GEs to DAGs.

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 may be an alternative 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).

ANNEX

POTENTIAL MITIGATION MEASURES FOR REDUCING 3-MCPDEs AND GEs

The mitigation measures are not listed in order of priority
It is recommended that reduction measures be tested
to identify the most successful for your own product.

Production Stage	Mitigation measures
AGRICULTURAL PRACTICES FOR VEGETABLE OILS	• Select oil palm plant varieties with low lipase activity, if available. • Minimize use of substances such as fertilizers, pesticides, and irrigation water that contain excessive amounts of chlorine-containing compounds during oil plant/tree cultivation. • Harvest oil palm fruits when they are at optimal ripeness. Minimize handling of the fruit. 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** • Store oil seeds at cool temperatures and dry conditions. • Sterilize oil palm fruit at temperatures at or below 140°C. Clean, dry, and heat oilseeds to inactivate lipases. • Wash crude vegetable oil with chlorine-free water. • Avoid using residual vegetable oil recovered from solvents or extractions. • Assess precursors (e.g. DAGs, FFAs, and chlorine compounds) in batches of crude vegetable oil or fish oil to adjust refining parameters. • Preferentially refine crude vegetable oil or fish oil with low concentrations of precursors.
	Degumming • Use milder and less acidic conditions (e.g. either degumming with a low concentration of acid or water degumming) in vegetable oils or fish oils. • Lower the degumming temperature in vegetable oils.
	Neutralization • Use chemical refining (i.e. neutralization) as an alternative to physical refining in vegetable oils or fish oils.
	Bleaching • Use greater amounts of bleaching clay in vegetable oils and fish oils. • Use more pH-neutral clays to reduce acidity in palm oils, some seed oils, and fish oils.

POTENTIAL MITIGATION MEASURES FOR REDUCING 3-MCPDE AND GE

The mitigation measures are not listed in order of priority

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

Production Stage	Mitigation measures
OIL MILLING AND REFINING	**Deodorization** • Conduct deodorization of vegetable oils or fish oils at reduced temperatures. The temperatures will vary depending on residence time of oil. • Conduct dual deodorization of vegetable oils and fish oils (2-stage deodorization) as an alternative to traditional deodorization. • Use a stronger vacuum to facilitate evaporation of volatile compounds and to contribute to decreased deodorization temperatures in vegetable oils and fish oils. • Use short-path distillation (in place of deodorization) to reduce the thermal load in fish oil.
TREATMENT POST REFINING	• Conduct additional bleaching and deodorization following initial bleaching and deodorization of refined palm oil. • Apply activated bleaching clay to refined vegetable oils. • Use short-path distillation on bleached and deodorized vegetable oils. • Treat refined MCT (medium-chain triglyceride) oil with fatty acids and a cation counterion, such as an alkali metal, as well as one or more bases to convert 3-MCPDE to MAGs, DAGs and TAGs and GE to DAGs.
SELECTION AND USES OF REFINED OILS	**OIL SELECTION** • Select refined vegetable oils or fish oils with lower levels of 3-MCPDE and GE. **PROCESS MODIFICATIONS** • Reduce the amount of refined vegetable oils or fish oils in finished products.