CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 9 **CX/CF 18/12/9-Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

12th 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 (AT STEP 4)

Comments submitted at Step 3 by Australia, Canada, Costa Rica, Egypt, Japan, Kenya, Republic of Korea, FoodDrinkEurope, GOED, ICGMA, ISDI and SNE

AUSTRALIA

Australia confirms its previous view that *infant formula* be removed from the title as the code of practice currently contains no guidance unique to infant formula. Additionally, the applicability of the guidelines to infant formula is covered in the commentary on the scope of the guidelines.

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) on the *Proposed Draft Code of Practice for the reduction of 3-MCPDE and GE in refined oils and products made with refined oils, especially infant formula*. Canada would like to express its agreement with the proposed guidance presented in Appendix I of this document.

COSTA RICA

Costa Rica is grateful to the working group for the work that it has done and for the opportunity to make comments. In this respect, it expresses its support for the progress made on the document.

EGYPT

We would like to thank the committee on this great work, and we note that Egypt agrees with the proposed draft Code of practice for the reduction of 3-monochloropropane-1,2-diol esters (3MCPDE) and glycidyl esters (GE) in refined oils and products made with refined oils, especially infant formula.

JAPAN

Japan appreciates the efforts by the United States of America, the European Union and Malaysia in leading the electronic working group (EWG) to prepare the proposed draft of Code of Practice (COP). Japan would like to provide the following comments in response to the request for comments at step 3.

General comments

Structure of COP

Codex COP for the reduction of acrylamide in foods (CXC 67-2009) and that of polycyclic aromatic hydrocarbons in foods (CXC 68-2009) include a section, “GENERAL CONSIDERATIONS…”, after “SCOPE.” For consistency, a new section “GENERAL CONSIDERATIONS FOR REDUCING 3-MCPDE AND GE” should be inserted after the “SCOPE”.

Generally, a detailed description is not included in the “INTRODUCTION” in most existing Codex COPs, while it provides Members and Observers with useful information for discussion. In view of this, the “INTRODUCTION” needs to be shortened before advancing the draft COP to the Commission for final adoption to include only the information essential for using the COP. For example, the current description on evaluation by 83rd JECFA should be deleted as it needs to be updated every time new evaluation by JECFA on 3-MCPDE and GE is available in the future.

Stage of the development of measures

The COP should include those mitigation measures that are currently in use (or to be used) by the industries and proved to be effective on an industrial scale. It is useful to describe other mitigation measures including those that are still in their experimental stages in an Information Document to provide a wide range of options.

The term "refined vegetable oils" in the title of APPENDIX I

The term"refined oils" in the title of the working document shall be used in the title of the COP rather than the term "refined vegetable oils" for the following reasons:

i. The project document on this COP adopted by 40th Session of the Commission includes the term "refined oils" in the scope of this COP; and

ii. Mitigation of 3-MCPDE and GE in infant formula is important in the light of the recommendation by 83rd Session of JECFA as well as the fact that infant formula is essential nutritional source for non-breast-fed infants. For safer infant formula, the COP needs to cover refined vegetable oils and refined fish oils used as raw ingredients of infant formula. Therefore, the term "refined vegetable oils" in the title of APPENDIX I should be replaced with "refined oils."

Oils to which mitigation measures apply

It is necessary to specify whether each mitigation measure applies to specific oil(s) or all oils. For example, if a measure is applicable to "palm oil only", "all vegetable oils", or "all vegetable oils and fish oils", it is necessary to indicate as such.

Specific comments

Japan would like to propose the following amendments:

Paragraph 40

40. 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.

(Rationale)

According to one of the major fish oil manufacturers in Japan, the application of activated clay for bleaching before deodorization are proved to be effective in reducing 3-MCPDE in refined fish oils on an industrial scale. This measures is currently in use for refining some fish oil products depending on the demand of buyers/consumers.

Paragraph 56

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 **(e.g., meat products and fishery products)**.

(Rationale)

For considering mitigation measures in processed foods, CCCF needs to specify the type of food in which 3-MCPDE and GE are formed during frying in addition to those present before frying, which may be difficult. Different outcomes are reported in the scientific literature on the effects of using refined vegetable oils during frying on the formation of additional 3-MCPDE or GE in the fried food. Pending the scientific data enabling a conclusion to be drawn, the description in this paragraph should be modified as necessary.

APPENDIX II, first sentence

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

(Rationale)

It will be useful for stakeholders to clarify the nature of mitigation measures in this COP in line with the relevant text in the COP for the reduction of acrylamide in foods (CXC 67-2009).

KENYA

GENERAL COMMENT

Kenya would like to thank the EWG led by the United States of America, the European Union and Malaysia for COP mentioned above for the work well done.

SPECIFIC COMMENT

1.We accept the development of 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, especially infant formula.

2.We would like to propose amendment of the scope mentioned below to include producers as the quality starts with producer for better quality product.

SCOPE

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

REPUBLIC OF KOREA

The Republic of Korea supports the proposed draft COP for the reduction of 3-MCPDE and GE in refined oils and products made with refined oils, especially infant formula.

FOODDRINKEUROPE

"*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* ***animal based*** *food that is fried.*"

GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA 3s (GOED)

The Global Organization for EPA and DHA Omega-3s (GOED) is an association of processors, refiners, manufacturers, distributors, marketers, retailers and supporters of products containing eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) omega-3 fatty acids. GOED's membership represents a broad range of businesses, from small entrepreneurs to multinational food companies. The Organization's objectives are to educate consumers about the health benefits of EPA and DHA and to collaborate with government groups, the healthcare community and the industry on issues related to omega-3s, while setting high standards for our business sector.

GOED would like to provide the following comments on the 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, Codex document CX/CF 18/12/9, in relation to Agenda item 9, for discussion at the 12th Session of the Codex Committee on Contaminants on Foods (CCCF) to be held in Utrecht, The Netherlands from 12-16 March 2018. GOED kindly requests our following comments be circulated to Codex members and observers and/or uploaded to the Codex website as a conference room document (CRD).

GENERAL COMMENTS

The Proposed draft Code of Practice did not contain any of the many references to the academic literature and patents that have been collected in Step 1 and 2 by the Chairs of the EWG from the participants of this EWG. GOED would like to request these be included in the proposed draft version to support the document and the overall technical nature of the listed mitigation approaches. References to literature should be available for future readers of this Code of Practice to be able to find details on the listed mitigation approaches. With respect to patents, these are necessary to be included in order to know that some mitigation approaches may belong to the intellectual property portfolio of specific companies or organizations.

SPECIFIC COMMENTS

GOED likes to provide the following input on the draft Code of Practice, Appendix I of CX/CF 18/12/9, regarding the scope and the title, in particular with regard to the newly proposed focus on refined vegetable oils.

Proposed focus of the scope of this Code of Practice to "refined vegetable oils" in the title.

The previous draft Code of Practice, version of December 15th, 2017, and open for comments by participants of the EWG until January 5, 2018, did not restrict the scope of this Code of Practice to refined vegetable oils, and stated "**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 food products made with refined oils, especially infant formula**". The title of this EWG and the proposed draft indicated that the Code of Practice be applicable to refined oils, and not only to refined vegetable oils. The scope of the Code of Practice should not be limited to vegetable oils, since fish oils (a common naming of EPA/DHA omega-3 oils) should also be considered in this Code of Practice, since these are refined oils used in food and as dietary supplements, although they are not of vegetable origin.

The current proposed draft (CX/CF 18/12/9) introduced a restriction in its scope to refined oils of vegetable origin only, which consequently removes the potential utility of any of the listed approaches to mitigate the levels of 3-MCPD and its fatty acid esters and glycidyl-esters from dietary oils that do not have a vegetable origin. The new title states "**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**". From the perspective of manufacturers of refined oils that are not of vegetable origin but are used in food and infant formula, this is not a desirable situation, since manufacturers of all refined edible oils may find helpful information in a Codex Code of Practice that aims to provide information on limiting these process contaminants in the various processing steps shared across edible oil manufacturing.

Eicosapentaenoic Acid (EPA)/Docosahexaenoic Acid (DHA) omega-3 oils are used in dietary supplements, functional foods, and perhaps most importantly for the purpose of this Code of Practice, are an important component of infant formula. These oils are refined, but are sourced from different marine animal organisms such as fish (many species) and krill, as well as from a variety of microalgae and protist species.

As a note, although many people refer to EPA/DHA omega-3 oils as "fish oils", the sources are not uniquely from fish. In particular, for infant formula, the most significant sources are tuna oil and oils from specific microalgae (for example, *Cryptecodinium* and *Ulkenia*) and protists (for example, *Schyzochytrium*) containing high levels of DHA. Microalgal and microbial sources of DHA omega-3 will be of growing importance as demand for these fatty acids keeps increasing (also for infant formula use).

Manufacturers of EPA/DHA omega-3 oils can employ and optimize, and some already use, the various mitigation approaches described in this Code of Practice, so it makes perfect sense not to limit the scope to refined vegetable oils. This Code of Practice should encompass oils from non-vegetable sources, including EPA/DHA omega-3 oils.

We appreciate that in Appendix II (page 13) it is stated "*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*".

INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATIONS (ICGMA)

General Comments

ICGMA would prefer that "including infant formula" is removed from the title. While this phrase is more appropriate than "especially infant formula", we still feel that it is misleading given that the focus of the COP is around the reduction of MPCD and GE in refined vegetable oils. The reduction of MCPD/GE in any food product would follow the same mechanism, which is selection of oils that are lower in these compounds, regardless of whether they are infant formula products or other products. By including only a single product in the title, ICGMA is concerned that other products which are intending to reduce the concentrations of MCPD/GE may not realize this COP is relevant to them.

Specific Comments on the draft Code of Practice

- ICGMA suggests that the first sentence of paragraph 14 read as follows: "*Mitigation by processors can be more readily applied to control GE than 3MCPDE 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"*

- In paragraph 43, clarification or elaboration is needed under the heading “Deodorization.” An example of additional post processing may be helpful.
- Paragraph 49 should be revised as follows to ensure consistency with paragraph 45: “*Experimental 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”*
- The wording in paragraph 56 should be revised to the following: “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 characteristics of the food that is fried.” We suggest this alteration on the basis that formation is not just by food type, but by the characteristics of the food that is at play here.

ICGMA would like to thank the eWG for taking the above comments into consideration. ICGMA would also like to thank the chairs of the eWG for their extensive work on preparing the draft discussion paper and looks forward to discussing the issue further.

INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)

ISDI thanks the United States of America, the European Union and Malaysia for their work in preparing the “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” (CX/CF 18/12/9). ISDI is pleased to have the opportunity to provide the following general comment.

General comment on title of the proposed draft Code of Practice (COP)

ISDI recommends completely removing the reference to ‘infant formula’ in the title of the Code of Practice (COP). The COP does not give any guidance that would be specific to reducing levels of MCPD/GE in infant formula, which could not also be applied to other products. ISDI believes that a more general title will encourage broader visibility to the thoughtful recommendations of this COP, not only to manufacturers producing oils for infant formula but also for other products that were identified (at least in the case of GE) as resulting in consumer risk. Furthermore, by keeping the scope of the title broad, this also ensures applicability of the COP in the case that MLs are set for additional product categories in the future. Emphasis on the applicability to infant formula has been included in the new “scope” section of the document, as well. Lastly, with the exception of one Codex member, the feedback from eWG participants supported either removal of this from the title or indifference. Thus, it would be aligned with the recommendation of the eWG to remove the reference to infant formula from the title.

SPECIALIZED NUTRITION EUROPE (SNE)

SNE welcomes the opportunity to comment on the 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, as prepared by the CCCF electronic working group led by the United States of America, the European Union and Malaysia.

SNE comment on TITLE of the draft COP

SNE supports removing “including infant formula” from the title of the Code of Practice (COP) for reduction of 3-MCPDE and GE. We believe that eliminating this phrase from the title of the COP will maximize the value of this document and ensure broader consideration across the food industry. This will ensure a wide implementation of this excellent guidance document. Removing “including infant formula” from the title also is consistent with the intent of the document, as the guidance applies to any food that uses refined vegetable oils.

Thus, SNE agrees with the majority of the feedback from the electronic Working Group that the title should be simplified by removing this wording.