CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 14 **CF11/CRD10**

March 2017

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Eleventh Session
Rio de Janeiro, Brazil, 3 – 7 April 2017

To be held at the Windsor Marapendi Hotel, Rio de Janeiro, Brazil

PRIORITY LIST OF CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS FOR EVALUATION BY JECFA

Comments submitted by the USA

USA

Proposal for new work on 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

Introduction

The United States of America is providing the following information to support a proposal for new work on a Code of Practice in response to **Agenda Item 3.1, Matters of interest arising from FAO and WHO (including JECFA)**.

Background

In its 83rd Session, JECFA evaluated 3-monochloro-1,2-propanediol esters (3-MCPDE) and glycidyl esters (GE). In the Summary and Conclusions of the 83rd Session, JECFA stated that (1) formula-fed infants can exceed the provisional maximum tolerable daily intake (PMTDI) for 3-MCPDE and that (2) the margins of exposure (MOE) for GE for infants, children, and adults may be a health concern. In response to the JECFA findings, the U.S. is proposing new work to develop 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.**

Purpose and Recommendation

The scope of the proposed work will encompass measures applicable to agricultural practices, oil milling and refining processes, and sources and uses of the refined oils in products made from these oils, especially infant formula. The proposed work will build on already existing codes of practice or toolboxes to mitigate 3-MCPDE and GE in oils and other foods.

The Code of Practice will provide the means to enable exporters to ensure levels of 3-MCPDE and GE in oils and infant formula to be as low as reasonably achievable and assist compliance with any MLs that may be established in future, either nationally or internationally.

It is recommended that CCCF endorse this new work to develop 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, and to forward the attached Project Document for approval by the Codex Alimentarius Commission.

PROJECT DOCUMENT

Proposal for new work on 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

1. The purpose and scope of the project

The purpose of the proposed new work is to develop a Code of Practice (COP) for the reduction of 3-monochloropropane-1,2-diol esters (3-MCPDE) and glycidyl esters (GE) in refined edible oils and products containing refined oils or products made with these oils, especially infant formula, in light of the conclusions of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). In the Summary and Conclusions of its 83rd Session (November 2016), JECFA stated that (1) formula-fed infants can exceed the provisional maximum tolerable daily intake (PMTDI) for 3-MCPDE and (2) the margins of exposure (MOE) for GE for infants, children, and adults may be a health concern. The scope of the new work encompasses measures applicable to agricultural practices, oil milling and refining processes, and sources and uses of the refined oils in products made from these oils, especially infant formula.

There are currently no regulatory limits for these contaminants. However, countries are continuing to evaluate levels in their food supply and to assess the risk of these contaminants. This COP will reduce contamination to As Low As Reasonably Achievable (ALARA) while individual countries develop appropriate risk management options to control these contaminants in food.

2. Relevance and timeliness

At its 83rd session, JECFA developed dietary exposure estimates for 3-MCPDE and GE. JECFA reported that toxicology data demonstrate that the kidney and male reproductive organs are the primary target organs of 3-MCPD and 3-MCPDE; 3-MCPD has also been shown to be carcinogenic but not through a genotoxic mode of action. JECFA established a group PMTDI of 4 µg/kg bw/day for 3-MCPD and 3-MCPDE based on renal tubular hyperplasia in male rats. JECFA noted that the estimates of mean dietary exposure to 3-MCPD for formula-fed infants could exceed the PMTDI by up to 2.5-fold (depending on country).

JECFA concluded that glycidol is genotoxic and determined carcinogenicity to be the most sensitive endpoint for developing a point of departure ($BMDL_{10}$=2.4 mg/kg bw per day) for mesotheliomas in male rats. JECFA, who based the MOEs on national estimates of dietary exposures, concluded that the lower range of the MOEs for infants, children, and adults (i.e., MOEs = 490, 1100, and 3000, respectively) were low for a genotoxic and carcinogenic compound and may indicate a health concern.

Given potential health concerns associated with 3-MCPDE and GE, it is important to reduce exposures to 3-MCPDE and GE from refined oils, particularly for infants, who are exposed to these oils through their consumption of infant formula. The new work aims to reduce exposures through the development of a COP to reduce levels of 3-MCPDE and GE in refined oils and products made with refined oils, especially infant formula.

3. Main aspects to be covered

The COP will address measures, supported by scientific data, to reduce 3-MCPDE and GE in refined oils. Although 3-MCPDE and GE are produced primarily during deodorization, measures applicable to agricultural practices (e.g., harvesting and storage of fruit), oil milling and refining processes (e.g., fruit selection and processing, degumming/bleaching, deodorization) and sources and uses of the refined oils, including in other products, especially infant formula (e.g., oil selection, processing modifications), will be addressed.

4. Assessment against the criteria for the establishment of work priorities

General criterion

To protect consumers' health (particularly infants and young children), exposures to 3-MCPDE and GE should be reduced as low as reasonably achievable through best practices. A COP compiling agricultural and industrial measures to reduce 3-MCPDE and GE will identify steps that can be taken to reduce these contaminants in refined oils and products made from these oils, especially infant formula. A COP will facilitate fair trade by making information on recommended practices available to all member countries.

a. Diversification of national legislations and apparent resultant or potential impediments to international trade.

Implementation of a COP is needed to ensure that information on recommended practices is available to all member countries. It will also provide the means to enable exporters to ensure levels of 3-MCPDE and GE in oils and infant formula to be as low as achievable and assist compliance with any MLs that may be established in future, either nationally or internationally.

b. Scope of work and establishment of priorities between the various sections of the work.

The COP will provide measures to reduce 3-MCPDE and GE in refined oils and products made with refined oils, especially infant formula, as it will address all aspects of production of refined oils from agricultural production to processing to use in other products.

c. Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).

Codes of practice or toolboxes to mitigate 3-MCPDE and GE in oils and other foods have been developed by FEDIOL (the European Vegetable Oil and Protein Meal Industry) and BLL (the German Federation for Food Law and Food Science).

5. Relevance to Codex Strategic Goals

Goal 1: Establish international food standards that address current and emerging food issues

Establishing a COP to reduce levels of 3-MCPDE and GE in refined oils will address a current food issue addressed in JECFA's 2016 summary and conclusions (JECFA/83/SC).

Goal 2: Ensure the application of risk analysis principles in the development of Codex standards

This work will assist in applying risk analysis principles in the development of Codex standards by using scientific data and results from the JECFA assessment to support the reduction in 3-MCPDE and GE in refined oils, thereby reducing exposures and risks to sensitive populations (infants and children).

Goal 3: Facilitate the effective participation of all Codex members

A COP will make information on recommended practices to reduce 3-MCPDE and GE available to all member countries.

Goal 4: Implement effective and efficient work management systems and practices

A COP will help ensure development and implementation of effective and efficient work management systems and practices by agricultural producers and industrial processors to produce refined oils and other products, made with refined oils, with lower levels of 3-MCPDE and GE.

6. Information on the relationship between the proposal and other existing Codex documents

In 2008, Codex established a COP (CAC/RCP 64-2008) and a Maximum Level (CODEX STAN 193

-1995) for related compounds, 3-MCPDs (chloropropanols), in acid hydrolyzed vegetable proteins. Although CCCF requested an evaluation by JECFA of 3-MCPDE and GE as early as 2009, sufficient research was not available to conduct an assessment until more recently. This new work is supported by JECFA's 2016 assessment of 3-MCPDE and GE (JECFA/83/SC, 83rd meeting, Summary and Conclusions).

7. Identification of any requirement for any availability of expert scientific advice

The JECFA Secretariat has already provided needed expert scientific advice (JECFA/83/SC).

8. Identification of any need for technical input to the standard from external bodies

Currently, there is no identified need for additional technical input from external bodies.

9. The proposed timeline for completion of the new work, including the starting date, proposed date for adoption at Step 5 and the proposed data for adoption by the Commission

Work on the COP will commence following approval by the Codex Alimentarius Commission in July 2017. The draft COP will be circulated for comments at Step 3 and consideration by the 12th Session of CCCF at Step 4 in 2018. Adoption at Step 5 or Step 5/8 by the Commission is planned for 2019 and adoption by the Commission can be expected by 2019 or 2020.