



## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX ALIMENTARIUS COMMISSION

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### PROPOSALS FOR NEW WORK<sup>1</sup>

A list of proposals to elaborate new standards and related texts is presented below, including the reference of the project document in the relevant report. The Commission is invited to decide whether or not to undertake new work in each case, taking into account the critical review conducted by the Executive Committee, and to decide which subsidiary body or other body should undertake the work. The Commission is invited to consider these proposals in the light of its *Strategic Plan 2014-2019* and the *Criteria for the Establishment of Work Priorities and Criteria for the Establishment of Subsidiary Bodies of the Codex Alimentarius Commission*.

Codex Body	Text	Reference and project document
CCPR	Proposal for new work to develop Guidelines for compounds of low public health concern that could be exempted from the establishment of CXLs	REP19/PR Para. 206, Appendix IX
	Priority list of pesticides for evaluation by the 2020 JMPR <sup>2</sup>	REP19/PR Para. 250, Appendix X
CCCF	Establishment of MLs for lead in certain food categories	REP19/CF Para. 96, Appendix VI
	Revision of the <i>Code of practice for the prevention and reduction of lead contamination in foods</i> (CXC 56-2004)	REP19/CF Para. 107, Appendix VII
	Development of a Code of practice for the prevention and reduction of cadmium contamination in cocoa beans	REP19/CF Para. 112, Appendix VIII
	Establishment of MLs for aflatoxins in certain cereals and cereal-based products including foods for infants and young children	REP19/CF Para. 155, Appendix IX
CCFL	Proposed draft guidance on internet sales/e-commerce	REP19/FL Para. 91 (a), Appendix III
	Proposal for new work on allergen labelling: Revision to the <i>General Standard for the Labelling of Prepackaged Foods</i> : allergen labelling, and guidance on precautionary allergen or advisory labelling	REP19/FL Para. 98 (a), Appendix IV

<sup>1</sup> Proposals for elaboration of new standards and related texts from Codex meetings held in April and May 2019 are included in this document.

<sup>2</sup> The priority list is included in REP19/PR Appendix X.

**PROJECT DOCUMENT****PROPOSAL FOR NEW WORK TO DEVELOP  
GUIDELINES FOR COMPOUNDS OF LOW PUBLIC HEALTH CONCERN  
THAT COULD BE EXEMPTED FROM THE ESTABLISHMENT OF CXLs****I. OBJECTIVE AND SCOPE**

The purpose of the proposed new work is to provide an international reference guideline for the harmonization of concepts and criteria for the recognition of pesticides that are of low public health concern to be considered exempt from the establishment of Codex MRLs (CXLs), or noted that a CXL is not necessary.

**II. RELEVANCE AND TIMELINESS**

The global regulatory scenario for pesticides of chemical origin is imposing increasing restrictions on this type of product, both in terms of its authorization, and the maximum residue limits (MRLs) permitted in food and feed. This is a consequence of a growing public health concern expressed by scientific bodies, consumers, consumer health organizations and several risk assessment and management agencies worldwide.

Products of low public health concern, such as biopesticides, continue to play a more important role in plant protection and there is a concern that if they are not being viewed as "safe" or included as part of the Codex standards, then growers will be reluctant to incorporate these important tools in to their farming practices.

This scenario continues to foster the development of new technologies and products for plant protection, many of them made from products of biological or natural origin, which represent a complement to the chemical plant protection. In recent years, there has been a significant increase in the worldwide use of biopesticides, both in traditional agriculture, as well as in organic production. According to Dunham Trimmer (2017) the market for biopesticides has grown between 12 and 17% per year during the last 5 years, representing a growth two to three times faster than the market of chemical pesticides. It should be further noted that non-chemical and biological control tools are playing an increasingly important role in the Integrated Pest Management (IPM) approach.

**III. MAIN ISSUES TO ADDRESS**

Definitions of concepts and Proposals for the criteria to identify pesticides of low public health concern that are considered exempt from the establishment of MRLs.

**IV. EVALUATION AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES****General criterion****Relevance in the strategic objectives of Codex**

The development of this work will contribute to the Strategic Objective 1 of the Strategic Plan 2014 – 2019 "establish international food standards that address current and emerging food issues", specifically to objective 1.2 which is "Proactively identify emerging issues and Members' needs and, where appropriate, develop relevant food standards".

**Criteria applicable to general issues****Diversification of national legislations and resulting or potential impediments to international trade**

A brief comparative analysis of the international legislations on evaluation and authorization of pesticides for substances of low public health concern that include some mineral substances of natural origin, as well as pesticides of biological origin, reveals the existence of different criteria for the exemption of MRLs.

No major international trade issues have been reported to date. However, national provisions already in place and the absence of clear guidance for these substances have the potential to create trade issues in the future.

**a. Scope of work, set of priorities among the different sections of the work.**

See section I.

**b. Work already initiated by other international organizations in this field and/or proposed by the relevant international intergovernmental organization or organizations.**

The Expert Group on Biopesticides, EGBP of the Organization for Economic Cooperation and Development (OECD), kept in its 2017 work agenda, the preparation of a guide document on criteria for the exemption of MRL for "active substances". At the meeting of the EGBP, in June 2018, the group of experts was informed about the work started in the Codex Committee on Pesticide Residues (CCPR), which is why it decided to suspend the progress in this topic in the OECD and support its progress in CCPR.

**c. Feasibility of the subject of the proposal for standardization**

The proposal is considered feasible, since like other works that have been developed at the level of Codex Alimentarius, the regulations of existing Members could be used as a base, as well as the advances in this matter, made by other intergovernmental international organizations, could be used as reference.

**d. Examination of the global magnitude of the problem or issue**

See Item 2 of this document.

**V. INFORMATION ON THE RELATIONSHIP BETWEEN THE PROPOSAL AND EXISTING DOCUMENTS OF CODEX**

After the bibliographic revision of Codex Alimentarius texts, it can be noticed that the only guidelines of Codex Alimentarius related to this type of products are in the document "*Guidelines for the production, elaboration, labeling and commercialization of organically produced foods (GL 32-99)*", prepared by Codex Committee on Food Labeling (CCFL), which in its Annex 2, Table 2, present a list of substances permitted for organic production, which include mineral substances of natural origin, as well as pesticides of biological origin. However, it does not specify whether these substances are exempt or not from the establishment of MRLs and does not cover the core points to be addressed in the proposed guidelines e.g. harmonization of concepts, criteria for classification of compounds with low public health concern, etc. where the expertise remains with CCPR.

**VI. IDENTIFICATION OF THE AVAILABILITY OF SCIENTIFIC EXPERTS WHEN NECESSARY**

For the elaboration of the Guidelines, the advice from the JMPR Secretariat, FAO and WHO will be taken as reference.

**VII. IDENTIFICATION OF ANY NEED FOR TECHNICAL CONTRIBUTION TO A STANDARD FROM EXTERNAL ORGANIZATIONS.**

At the moment, no need for contributions has been identified.

**VIII. PROPOSED CALENDAR FOR THE DEVELOPMENT OF THE NEW WORK**

Subject to approval by CAC42 (2019), the guidelines will be considered at CCPR52 (2020) and should be finalized by adoption by CAC in 2022 or earlier.

## PROJECT DOCUMENT FOR NEW WORK ESTABLISHMENT OF MAXIMUM LEVELS FOR LEAD IN CERTAIN FOOD CATEGORIES

### 1. Purpose and scope

The purpose of this work is to protect public health by harmonizing the level of lead in food categories not included in the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995) (GSCTFF) and ensure fair practices in international food trade.

### 2. Its relevance and timeliness

Lead was evaluated by the JECFA at its 16<sup>th</sup>, 22<sup>nd</sup>, 30<sup>th</sup>, 41<sup>st</sup>, 53<sup>rd</sup> and 73<sup>rd</sup> meetings. At the JECFA73 meeting a new toxicological evaluation of lead in food was conducted, at the request of Codex Committee on Contaminants in Food (CCCF). In the evaluation<sup>3</sup> JECFA73 stated that exposure to lead is associated with a wide range of effects, including various neurodevelopmental effects, impaired renal function, hypertension, impaired fertility and adverse pregnancy outcomes. Because of the neurodevelopmental effects, fetuses, infants and children are the subgroups that are most sensitive to lead. JECFA withdrew the previously established provisional tolerable weekly intake (PTWI) of 25 µg/kg bw and concluded that since there is no indication for a threshold of effect it was not able to establish a new tolerable intake level. JECFA also concluded that, in populations with prolonged dietary exposures to higher levels of lead, measures should be taken to identify major contributing sources and, if appropriate, to identify methods of reducing dietary exposure that are commensurate with the level of risk reduction.

Food is the major source of exposure to lead. The GSCTFF does not have MLs for lead established for several food categories that impact more in the dietary exposure than several current ML for categories such as mango chutney, pickled cucumbers, etc. Nevertheless, some food categories are broadly consumed and/or may contain high levels of lead and can significantly contribute to the intake of lead.

In this context, a new work for MLs for lead in different food categories which are not covered by the GSCTFF should be developed aiming lower lead exposure.

### 3. The main aspects to be covered

New MLs for lead in the following food categories:

- Food for infants and young children (except those for which an ML has already been established in the GSCTFF)
- Spices and aromatic herbs
- Eggs
- Sugars and confectionary, excluding cocoa

As the food categories above are broad, an analysis of further available data will assist in determining the sub-categories for which the MLs should be established.

#### An assessment against the criteria for the establishment of work priorities

- a) *Consumer protection from the point of view of health, food safety, ensuring fair practice in the food trade and taking into account the identified needs of the developing countries.*

The new work will establish Maximum Level(s) for lead in several categories.

- b) *Diversification of national legislations and apparent resultant or potential impediments to international trade.*

The new work will provide harmonized international maximum levels.

- c) *Work already undertaken by other organizations in this field*

The risk assessment has already been done for lead by JECFA.

### 4. Relevance to the Codex Strategic Objectives

The work proposed falls under the following Codex Strategic Goals of the Codex Strategic Plan 2014-2019:

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<sup>3</sup> JECFA. Evaluation of Certain Food Additives and Contaminants. Seventy-third report of the joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series 960.

*Strategic goal 1 Establish international food standards that address current and emerging food issues*

This work was proposed in response to needs identified by JECFA to decrease lead dietary exposure.

*Strategic goal 2 Ensure the application of risk analysis principles in the development of Codex standards*

The establishment of MLs shall take into account the exposure assessment proposed by JECFA.

**5. Information on the relation between the proposal and other existing Codex documents**

This work follows-up on the ongoing work on the revision of existing MLs for lead in the GSCTFF.

**6. Identification of any requirement for and availability of expert scientific advice**

Expert scientific advice has been already provided by JECFA.

**7. Identification of any need for technical input to the standard from external bodies so that this can be planned for the proposed timeline for completion of the new work**

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

**8. Proposed timeline for completion of work**

Subject to the approval by the 42<sup>nd</sup> Session of the Codex Alimentarius Commission in 2019 and depending on the availability of further occurrence data, MLs for the food categories (or their possible sub-categories) identified in section 3 will be finalized by 2021 or earlier.

**PROJECT DOCUMENT FOR NEW WORK  
REVISION OF THE CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF  
LEAD CONTAMINATION IN FOODS  
(CXC 56-2004)**

### **1. The purpose and scope of the project**

The purpose of the proposed new work is to revise the *Code of Practice for the Prevention and Reduction of Lead Contamination in Foods* (CXC 56-2004) (COP) adopted in 2004 to reflect new information available on measures to reduce lead during agricultural production and food processing. A revised COP would complement ongoing work by CCCF on lead, including revision of maximum levels (MLs) for lead in selected commodities in the *General Standard for Contaminants and Toxins in Food and Feed* (GSCTFF) and a discussion paper on future work on MLs for lead for inclusion in the GSCTFF.

The scope of the work encompasses updating the existing lead COP to add new information on lead reduction in the areas of agricultural production (e.g., techniques to address lead contamination in soil and water) and food processing (e.g., filtration aids for juice manufacture, measures to reduce lead in foods during cooking, and minimizing introduction of lead from food processing equipment).

### **2. Relevance and timeliness**

At its 73<sup>rd</sup> session (2010), JECFA conducted a new evaluation of lead. JECFA stated that exposure to lead is associated with a wide range of effects, including various neurodevelopmental effects, mortality (mainly due to cardiovascular diseases), impaired renal function, hypertension, impaired fertility, and adverse pregnancy outcomes. Fetuses, infants, and children are the most sensitive to lead exposures due to neurodevelopmental effects. JECFA withdrew the provisional tolerable weekly intake (PTWI) for lead and concluded that it was not possible to establish a new PTWI that would be health protective. JECFA concluded that in populations with prolonged dietary exposures to higher levels of lead, measures should be taken to identify major contributing sources, and if appropriate, to identify methods of reducing dietary exposure that are commensurate with the level of risk reduction.

Given the health concerns associated with lead exposures, the new work aims to continue to reduce exposures by updating the existing COP.

### **3. Main aspects to be covered**

The work will address measures, supported by scientific data that have become available since adoption of the COP in 2004. Measures to be addressed may include remediation of agricultural soil contaminated with lead (e.g., soil amendments), removal of lead from water used for irrigation and washing, and food processing modifications (e.g. evaluation of filtration aids).

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

#### **General criterion**

To protect consumers' health (particularly infants and young children), exposures to lead should be reduced through best practices. A revised COP compiling agricultural and food processing and preparation measures to reduce lead will identify additional measures that can be taken to reduce exposures. A revised COP will facilitate fair trade by making this updated information on recommended practices available to all member countries.

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

Development of a revised COP is needed to ensure that information on recommended practices for preventing and reducing lead exposures is available to all member countries. It will also provide the means to enable exporters to ensure reduced lead levels and to assist in compliance with any current MLs and those that may be established in the future.

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

The revised COP will provide measures to reduce lead in food, as it will address all aspects of food production from agricultural production to processing to packaging and distribution.

**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 that address lead exposures have been developed for workplaces, for water sanitation (e.g., WHO) and for agriculture, and can be used in the revision of the COP.

**5. Relevance to Codex Strategic Goals**

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

Updating the COP for the prevention and reduction of lead contamination in foods will address a current need to continue to reduce lead exposures, using updated measures.

**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 continued reduction of lead in foods.

**Goal 3: Facilitate the effective participation of all Codex members**

The proposed draft revision to the COP will make additional information on recommended practices to prevent and reduce lead available to all member countries.

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

A revised COP will help ensure development and implementation of effective and efficient work management systems and practices by agricultural producers, food processors, and consumers to produce foods with lower levels of lead.

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

In 2004, the Codex Alimentarius Commission adopted the Code of Practice for the Prevention and Reduction of Lead Contamination in Foods (CXC 56-2004). In addition, MLs for a variety of foods (e.g., fruit juices, canned fruits, canned vegetables, infant formula) have been updated over the past several years in the GSCTFF and completion of this work is anticipated in 2019. There is also a proposal for new work on the development of MLs for lead for additional foods for inclusion in the GSCTFF. This revised COP supports the ongoing ML work.

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

The JECFA Secretariat has already provided needed expert scientific advice (JECFA, 73<sup>rd</sup> report).

**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 date for adoption by the Commission**

Work will commence following approval by CAC42 in 2019. Completion of work is expected by 2021 or earlier.

## PROJECT DOCUMENT FOR NEW WORK

### DEVELOPMENT OF A CODE OF PRACTICE FOR THE REDUCTION AND PREVENTION OF CADMIUM CONTAMINATION IN COCOA BEANS

#### 1. The purpose and scope of the project

The purpose of the new proposal is to develop a Code of Practice (COP) that will provide guidance to Member States and the cocoa production industry on the prevention and reduction of cadmium contamination in cocoa beans during production and post-harvest processing: fermentation, drying and storing.

The scope of the work intends to provide guidance on recommended measures to prevent and reduce cadmium contamination in cocoa: Before planting or in new plantations, during the production stage until harvest and in the post-harvest stage. This COP applies to the cocoa beans marketed internationally.

#### 2. Relevance and timeliness

At its 77th Session (2013), the Joint FAO/WHO Expert Committee on Food Additives (JECFA) determined that the estimates of mean population dietary exposure to cadmium from products containing cocoa and its derivatives for the 17 GEMS/Food Cluster Diets ranged from 0.005 to 0.39 µg/kg bw (body weight) per month, which equated to 0.02 – 1.6% of the Provisional Tolerable Monthly Intake (PTMI) of 25 µg/kg bw. JECFA's conclusion that intake of cadmium from cocoa and cocoa derived products is not a health concern.

CCCF establishing MLs for cadmium in chocolate and cocoa derived products makes it necessary a COP that outlines measures to prevent and reduce cadmium in cocoa contamination to levels as low as reasonably achievable (ALARA) in order to mitigate cadmium exposures and support fair trade.

The COP will assist countries to comply the MLs for cadmium in chocolates established by CAC and in general will assist to reduce cadmium contamination in cocoa beans to facilitate international trade.

#### 3. Main aspects to be covered

**Code of practice for the prevention and reduction of cadmium contamination in cocoa beans taking into consideration the following:**

- a) Production system (conventional, organic, mixed plantations with agroforestry).
- b) Cocoa crop factors that determine cadmium absorption by plants.
- c) Strategies to immobilize cadmium and decrease its availability in soil
- d) Phyto-extraction of heavy metals cadmium: Agronomic management of the cocoa crop, cocoa physiology, cadmium bioaccumulation in cocoa beans.
- e) Growing and plantation areas, soil amendments and its cost efficiency, especially for small cocoa farmers, pruning, optimal time of harvest.
- f) Cocoa genetics (germplasm, clones)
- g) Post-harvest technology (fermentation, drying, storing),

#### 4. An assessment with regard to the criteria for setting priorities for work.

##### General criterion

To protect consumers' health exposures to cadmium should be reduced through best practices. The COP will introduce agricultural and post-harvest practices to reduce cadmium and through this COP will facilitate fair trade by making this information on recommended practices available to all member countries.

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

This COP will provide a consistent source of guidance to cocoa producers and post-harvest processors in all of Member countries to prevent and reduce cadmium contamination in cocoa beans. It will thus provide assurance to exporters that levels of cadmium in cocoa and cocoa products meet the ALARA principle, and also Codex Maximum Levels (ML) of cadmium in chocolates and cocoa derived products that are under development.

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



The scope of work involves developing a COP that will provide technical guidance on the reduction of cadmium contamination in cocoa beans in agricultural and post-harvest production level. The development of this COP will help to reduce exposures to cadmium and support international trade of cocoa beans and their products.

**c. Work already undertaken by other international organizations in this field and/or suggested by relevant international intergovernmental bodies**

None.

**5. Relevance to Codex Alimentarius Strategic Goals (Plan 2014 – 2019)**

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

**Objective**

1.2 Proactively identify emerging issues and Member needs and, where appropriate, develop relevant food standards.

1.2.2 Develop and revise international and regional standards as needed, in response to needs identified by Members and in response to factors that affect food safety, nutrition and fair practices in the food trade.

**Goal 3: Facilitate the effective participation of all Codex Members**

**Objective**

3.1 Increase the effective participation of developing countries in Codex.

3.1.1 Encourage Members to develop sustainable national institutional arrangements to promote effective contribution to the Codex standard setting processes

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

GSCTFF (MLs for cadmium in chocolate products)

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

None.

**8. Identification of any need for technical input to the standard from external bodies so that this can be planned for the proposed timeline for completion of the new work**

There is no need for additional technical input from external bodies besides available risk mitigation practices from validated field researches from this and next year.

**9. Proposed timeline for completion of work**

Subject to the approval by the 42<sup>nd</sup> Session of the Codex Alimentarius Commission in 2019, the Code of practice for the prevention and reduction of cadmium contamination in cocoa beans will be considered at CCCF14 and CCCF15 with a view to its completion in 2021 or earlier.

**PROJECT DOCUMENT FOR NEW WORK**  
**ESTABLISHMENT OF MAXIMUM LEVELS FOR AFLATOXINS IN**  
**CERTAIN CEREALS AND CEREAL-BASED PRODUCTS,**  
**INCLUDING FOOD FOR INFANTS AND YOUNG CHILDREN**

### 1. Purpose and scope

The purpose of this work is to protect public health and to ensure fair practices in the international food trade by establishing MLs for aflatoxins in cereal and cereal-based products.

### 2. Its relevance and timeliness

Toxicological data and human dietary exposure to aflatoxins (AFs) were evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) at its 49<sup>th</sup> and 83<sup>rd</sup> meetings. The findings showed that AFs are genotoxic human liver carcinogens, being among the most potent mutagenic and carcinogenic substances known so far. Hepatitis B virus was shown to be a critical contributor to the potency of aflatoxins in inducing liver cancer, AFs potency being 30 times higher in carriers of hepatitis B virus than in non-carrier of hepatitis B virus. No tolerable daily intake was proposed for AFs, as is typical for genotoxic carcinogens. At its last evaluation, JECFA83 also noted that rice, maize, wheat and sorghum needed to be considered in future risk management activities for aflatoxins, considering their great contribution to aflatoxin exposure in some parts of the world.

Cereal and cereal-based products are highly consumed worldwide and thus any level of AFs contamination in these products could significantly contribute to total AFs exposure. Currently, there is no maximum level (ML) for AFs in cereal and cereal-based products, thus, a new work on the establishment of MLs for the categories listed below, could greatly contribute to AFs dietary exposure reduction.

- Maize grain destined for further processing and flour, meal, semolina and flakes derived from maize
- Husked and Polished Rice
- Cereal-based Food for infants and young children
- Sorghum

### 3. The main aspects to be covered

MLs for aflatoxins in cereal and cereal-based products, considering the following:

- the Policy of the Codex Committee on Contaminants in Foods for exposure Assessment of Contaminants and Toxins in Foods or Food Groups (Procedural Manual Section IV); and
- the criteria for the establishment of maximum levels in food and feed established in Annex I of General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995) (GSCTFF).

### 4. An assessment against the criteria for the establishment of work priorities

- a) *Consumer protection from the point of view of health, food safety, ensuring fair practice in the food trade and taking into account the identified needs of the developing countries.*

The new work will establish MLs for AFs in cereal and cereal-based products.

- b) *Diversification of national legislations and apparent resultant or potential impediments to international trade.*

The new work will provide harmonized international maximum levels.

- c) *Work already undertaken by other organizations in this field*

The risk assessment has already been done for AFs by JECFA83.

### 5. Relevance to the Codex Strategic Objectives

The work proposed falls under the following Codex Strategic Goals of the Codex Strategic Plan 2014-2019:

*Strategic goal 1 Establish international food standards that address current and emerging food issues*

This work was proposed in accordance to the JECFA recommendation to reduce AFs dietary exposure.

*Strategic goal 2 Ensure the application of risk analysis principles in the development of Codex standards*

JECFA recommended that efforts continue to reduce aflatoxin exposure using valid intervention strategies, including the development of effective, sustainable and universally applicable pre-harvest prevention

strategies. The establishment of MLs for AFs in cereal and cereal products will contribute to the protection of consumers' health.

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

This new work is recommended following the Procedural Manual and the GSCTFF.

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

Expert scientific advice has been already provided by JECFA.

**8. Identification of any need for technical input to the standard from external bodies so that this can be planned for the proposed timeline for completion of the new work**

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

**9. Proposed timeline for completion of work**

Subject to the approval by the 42<sup>nd</sup> Session of the Codex Alimentarius Commission in 2019, the MLs for AFs in cereal and cereal-based products including food for infants and young children will be finalized in 2022 or earlier.

## PROJECT DOCUMENT

### PROPOSAL FOR NEW WORK ON INTERNET SALES/E-COMMERCE

#### 1. PURPOSE AND SCOPE OF THE NEW WORK

The scope and purpose of the work is to develop a supplementary text to the *General Standard for the Labelling of Prepackaged Foods* (GSLPF)<sup>4</sup> which provides for the labelling of food sold through internet sales/e-commerce. The work would also review and revise the current Codex provisions under the GSLPF and other text related to food labelling to ensure it provides for the selling of food in an internet sales/e-commerce environment.

#### 2. RELEVANCE AND TIMELINESS

This proposal relates to the development of a text which would provide Governments and other stakeholders with clear and transparent standards/guidance on the labelling of foods sold through the internet/e-commerce. According to the stock take undertaken by CCFL, a significant proportion of Codex members support such work.

Internet sales/e-commerce is a transboundary issue and therefore requires global standards to protect consumers and assure fair trading practices.

#### 3. MAIN ASPECTS TO BE COVERED

1) It is proposed that work to develop supplementary text should at least cover the following aspects:

- a. The applicability of the GSLPF and other Codex texts related to food labelling to food sold by internet sales/e-commerce.
- b. The development, if deemed appropriate and necessary, of a definition of internet sales/e-commerce for the purposes of this new work.
- c. Supplementary text should help to prevent obfuscation of Codex texts and, therefore, misleading of consumers and businesses in respect of the particularities of the internet.
- d. The mandatory labelling requirements which, because of practicalities, may be allowed to be provided after an online sale has concluded, though provided before or at the moment of delivery to the consumer. CCFL may need to define these points in an online sale (the “end/conclusion of an online sale” and the “moment of delivery”) in order to clearly convey the latest point in the process of an online sale at which certain mandatory requirements need to be provided.

2) In addition, the following issues will be considered:

- a. How loose foods should be treated within the scope of future work on internet sales/e-commerce.
- b. Clarification of what GSLPF definitions of “label” and “labelling” mean for food sold online and other applicable definitions.
- c. If current text on language requirements in the GSLPF and other related text to food labelling is adequate, without some adjustment for food sold online.

Issues raised relating to accountability/responsibility and traceability may need to be referred to other Codex committees such as the Codex Committee on Food Import and Export Inspection and Certification Systems.

#### 4. ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF NEW WORK PRIORITIES

##### General criterion

***Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.***

The internet/e-commerce is a new and emerging platform for selling food which is growing in use globally. The lack of standardised guidance for the labelling of food sold via internet sales/e-commerce raises significant issues pertaining to health, food safety, and the protection of fair practices in the food trade.

##### Criteria applicable to general matters

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<sup>4</sup> CXS 1-1985.

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

A number of countries have adopted regulations which specifically relate to e-commerce, often through references to distance/remote selling. These regulations are broadly similar in that they state that all practically feasible mandatory information needs to be provided before the end of an online sale. However, there are slight differentiations in terms of what information does not need to be provided until the point of delivery.

With the growth of e-commerce, it is important that some consistency is maintained at a global level to ensure that consumers are protected and impediments to trade that may arise from different approaches are minimised.

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

It is proposed that a review of Codex texts related to food labelling, primarily the GSLPF, will focus on the GSLPF's applicability for food sold by internet sales/e-commerce in order to formulate a supplementary text to the GSLPF.

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

There are no international regulations which specifically relate to internet sales/e-commerce. However, Article 14 of Regulation (European Union) 1169/2011 contains provisions on distance selling. There are also some instances of national regulations pertaining to internet sales/e-commerce, as highlighted in the discussion paper.

Codex is the relevant international organization responsible for developing international standards in the area of internet sales/e-commerce.

**d) *Amenability of the subject of the proposal to standardization***

The information to be provided to the consumer in an internet sales/e-commerce context should be comparable to that which is already outlined by the GSLPF. A supplementary text should make the GSLPF's applicability to internet sales/e-commerce clear. The purpose of the new work is to develop unambiguous labelling requirements for food sold to consumers through internet sales/e-commerce. Such labelling requirements can be effectively standardized with the involvement of and inputs from Codex Members.

**e) *Consideration of the global magnitude of the problem or issue.***

E-commerce, and the sale of food via online platforms, is growing at an international level and is a transboundary issue. Business-to-consumer web platforms are being increasingly utilised by food business operators and these platforms offer significant convenience to the consumer. The rise in internet sales, while offering tangible benefits to consumers, also presents risks to consumer protection, consumer safety and public health. There may be a particular risk, in the absence of clear, internationally recognised guidelines, of deliberate and non-deliberate misleading practices leading to significant market failure and/or consumer detriment.

Mandatory regulations for the labelling of food sold via internet sales/e-commerce are in place in a number of countries. Further countries have regulations which outline consumer rights online.

## **5. RELEVANCE TO CODEX STRATEGIC OBJECTIVES**

The proposed work is in line with the Commission's mandate for the development of international standards, guidelines and other recommendations for protecting the health of consumers and ensuring fair practices in food trade. The new work proposal will contribute to advancing Strategic Goals 1 and 3 as described below.

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

Guidance for labelling food sold by internet sales/e-commerce is of significant interest and activity in a number of countries globally. Codex's FAO website reads: "Over the last century the amount of food traded internationally has grown exponentially, and a quantity and variety of food never before possible travels the globe today"<sup>5</sup>. This is largely facilitated by e-commerce. A supplementary Codex text would facilitate the development of a more standardised approach to the topic at an international level.

***Strategic Goal 3: Facilitate the effective participation of all Codex members***

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<sup>5</sup> <http://www.fao.org/fao-who-codexalimentarius/about-codex/en/>

Bringing this topic to CCFL will enable all members who have an interest in internet sales/e-commerce to participate in discussions. The work could also provide an opportunity to discuss, more broadly, remote/distance selling.

In relation to the new draft Strategic Plan/Goals (2020-2025) under development:

**Strategic Goal 1:** *Address current, emerging and critical issues*

This work offers CCFL to address one of the most topical developments in the food labelling space.

**Strategic Goal 3:** *Deliver impact through the recognition and use of Codex standards*

To the extent that internet sales/e-commerce is driven by an increasing number of players globally, the development and adoption of Codex standards in this area will deliver significant benefits to consumers and businesses. This, in turn, will deliver impact through recognition of a harmonised Codex approach which can be used universally for the benefit of all stakeholders.

## **6. RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS**

The proposal is to review and then revise the GSLPF and other Codex text related to food labelling, and subsequently assess the need to amend any further Codex documents. It is noted that the provisions relevant to internet sales/e-commerce labelling in the GSLPF are applicable horizontally across all pre-packaged foods.

## **7. REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE**

None identified at this stage. There will be opportunities to consult with relevant bodies if necessary throughout the process.

## **8. NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES**

None identified at this stage. There will be opportunities to consult with relevant bodies if necessary throughout the process taking into account related work in other international fora.

## **9. PROPOSED TIMELINE**

Subject to the Codex Alimentarius Commission approval at its 42<sup>nd</sup> session in 2019, it is expected that the work can be completed in three sessions.

## PROJECT DOCUMENT

### PROPOSAL FOR NEW WORK ON ALLERGEN LABELLING

#### 1. PURPOSE AND SCOPE OF THE NEW WORK

Declaration of foods or ingredients known to cause hypersensitivity (referred to as allergen labelling) is intended to provide consumers with access to clear and accurate information on the presence of allergens (or substances) in foods, so that they can make safe food choices. This is particularly significant given the potential life-threatening consequences for food allergic individuals, and that the prevalence of conditions is increasing in many parts of the world.

This new work proposes to review and clarify the provisions relevant to allergen labelling in the *General Standard for Labelling of Pre-packaged Foods* (CXS 1-1985) (the *Standard*), and to develop guidance on precautionary allergen or advisory labelling, to provide clear and consistent allergen information for consumers, and increase harmonization to facilitate trade. This proposal does not seek to revise the whole of the *Standard*.

#### 2. RELEVANCE AND TIMELINESS

Globally the prevalence of food allergies is increasing, including in developing countries. Given the serious nature of food allergies and its health consequences, and the increasing complexity of the food supply chain, the current allergen labelling provisions in the *Standard* are considered to lack sufficient clarity and detail for industry in how allergens should be presented on food labels to ensure consumer protection. There is also global variation in national/regional standards for allergen labelling which impacts on harmonization and trade.

This work complements the recent work by the Codex Committee on Food Hygiene (CCFH) on a draft *Code of Practice on Food Allergen Management for Food Business Operators* at Step 5 (REP19/FH, paras 48 – 56 and Appendix III), and the proposal by CCFH to request FAO/WHO convene an expert consultation to provide scientific advice regarding allergen threshold levels (REP19/FH, para 56).

#### 3. MAIN ASPECTS TO BE COVERED

- 1) Review provisions relevant to allergen labelling in the *Standard* (and related texts as required) to consider:
  - a) Scope, definitions and clarity of the existing provisions.
  - b) Presentation, legibility and the terms to be used, including the suitability of ingredient labelling provisions when making declarations.
  - c) Subject to expert advice, the list of foods and ingredients in section 4.2.1.4 (i.e. additions, deletions or exemptions) and the clarity of the groupings in that list.
- 2) Develop guidance on the use of precautionary allergen or advisory labelling including:
  - a) Principles for the use of precautionary allergen or advisory labelling.
  - b) Labelling provisions, including definition(s) for precautionary allergen or advisory labelling.
  - c) The location and appropriate Codex text(s) for the guidance.
- 3) Request scientific advice relating to the list of foods and ingredients in section 4.2.1.4 from the FAO and WHO on:
  - a) Whether the published criteria<sup>6</sup> for assessing additions and exclusions to the list is still current and appropriate.
  - b) Subject to the advice on the criteria above:
    - i) whether there are foods and ingredients that should be added to or deleted from the list.
    - ii) clarification of the groupings of foods and ingredients in the list.
    - iii) whether certain foods and ingredients, such as highly refined foods and ingredients, that are derived from the list of foods known to cause hypersensitivity can be exempted from mandatory declaration.

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<sup>6</sup> WHO Technical Report Series 896 (2000). Report of an ad hoc Panel on Food Allergens. Annex 4 of Evaluation of certain food additives and contaminants. Fifty-third report of the Joint FAO/WHO Expert Committee on Food Additives. <https://www.who.int/foodsafety/publications/jecfa-reports/en/>.

#### 4. ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF NEW WORK PRIORITIES

##### General criterion

***Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.***

This proposed new work will review the existing provisions for the declaration of foods and ingredients known to cause hypersensitivity (allergen labelling) and develop new guidance for precautionary allergen or advisory labelling. This will provide clearer and more consistent allergen labelling information to ensure consumer protection particularly in developing countries that rely on Codex standards for their domestic situation.

##### Criteria applicable to general matters

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

The proposed new work will provide greater harmonisation of allergen labelling standards at an international level. Currently there are differing national/regional standards for allergen labelling when compared to the Codex *Standard*, which is reported to impact on trade.

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

It is proposed that a review of the *Standard* and related texts (as required) will focus on the provisions relevant to the declaration of foods and ingredients known to cause hypersensitivity (allergen labelling) and developing new guidance for the use of precautionary allergen or advisory labelling.

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

This proposed new work complements and builds on work already underway by CCFH.

**d) *Amenability of the subject of the proposal to standardization***

The purpose of this work is to review, update and clarify existing text and provide additional guidance to ensure a clear and contemporary set of international definitions and guidelines for allergen labelling is available for global application.

**e) *Consideration of the global magnitude of the problem or issue.***

There is an increasing prevalence of food allergy occurring primarily in Western countries, such as the United Kingdom (and other countries across Europe), the United States and Australia. Elsewhere, although there is a lack of food allergy prevalence data, the data that exists indicates other countries are also experiencing an increase in the prevalence of food allergies and food allergy sensitisation. Most of these data have come from Asia (China) and Africa, although there are reports that the prevalence of food allergy is also increasing in Latin American nations.

#### 5. RELEVANCE TO CODEX STRATEGIC OBJECTIVES

The proposed new work is in line with the Commission's mandate for the development of international standards, guidelines and other recommendations for protecting the health of consumers and ensuring fair practices in food trade. The new work proposal will contribute to advancing Strategic Goals 1, 2 and 3.

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

Provision of clear and consistent information is vital for food allergic consumers to make safe food choices. The review, clarification and scientific update of the existing Codex texts, in addition to developing new guidance on precautionary allergen or advisory labelling, will ensure consumer protection in the contemporary food environment.

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

The allergen labelling provisions in the *Standard*, including a list of foods and ingredients requiring declaration known to cause hypersensitivity, have not substantively changed since 1999. Therefore the proposed new work includes seeking scientific advice from FAO/WHO on the criteria for updating and clarifying this list.

***Strategic Goal 3: Facilitate the effective participation of all Codex members***

Consideration by CCFL will allow all Codex members the opportunity to contribute to reviewing the existing *Standard* and developing new guidance on allergen labelling. This new work complements and builds on work already underway by CCFH and provides the opportunity for cross Committee collaboration.



**6. RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS**

The provisions relevant to allergen labelling in the *Standard* that are proposed for review are applicable horizontally across all prepackaged foods.

**7. REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE**

Scientific advice from FAO/WHO will be needed on the criteria for any additions to and/or deletions from the list of foods and ingredients that are known to cause hypersensitivity.

**8. NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES**

There will be opportunity to consult with relevant bodies if necessary throughout the process. Consideration of evidence based consumer understanding of allergen labelling and advisory statements.

**9. PROPOSED TIMELINE**

Subject to the Codex Alimentarius Commission approval at its 42<sup>nd</sup> session in 2019, it is expected that the work can be completed in three sessions.