

CODEx ALIMENTARIUS COMMISSION



Food and Agriculture
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Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON PESTICIDE RESIDUES

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DISCUSSION PAPER ON THE DEVELOPMENT OF GUIDANCE FOR COMPOUNDS OF LOW PUBLIC HEALTH CONCERNS THAT COULD BE EXEMPTED FROM THE ESTABLISHMENT OF CXLs

(Prepared by the Electronic Working Group chaired by
Chile and co-chaired by India and the United States of America)

I. INTRODUCTION

1. Following discussions at the 50th Session of the Committee on Pesticide Residues (CCPR50, 2018), the Committee agreed to prepare a discussion paper on guidelines for compounds of low public health concerns that could be exempted from the establishment of Codex maximum residue limits (CXLs), for consideration by CCPR51 (2019).
2. CCPR50 noted that this was a new area, which lacked internationally harmonized guidelines and yet was increasing growth in the use of these compounds globally and therefore it merited exploring.
3. CCPR50 further agreed that this work would be carried within the framework of the Electronic Work Group (EWG) chaired by Chile and co-chaired by India and the United States of America (USA), and working in English and Spanish, with the following mandate:¹
 - (i) Provide background (such as trade problems and possible risk to human health) for justifying new work under the mandate of CCPR.
 - (ii) Develop a proposal for guidelines to harmonize concepts to recognize biological and mineral compounds used as pesticides of low public health concern which are or should be exempted of CXLs and/or that do not give rise to residues.
 - (iii) Provide classification of such compounds and possible lists or criteria, etc.
 - (iv) Provide a project document scoping the work.
 - (v) Based on the above considerations, present a proposal on future work for consideration at CCPR51
4. The EWG was joined by 30 member countries, a Member Organization, and 3 observer organizations. The current discussion paper was initially prepared by Chile, United States of America and India, and took into consideration the comments received in two rounds (in round 1, comments were provided by 8 countries/organizations, in round 2, by 3 countries/organizations).

II BACKGROUND

Relevance

5. Codex Alimentarius has established MRLs for pesticides in specific food or food groups that are traded internationally to ensure the health of consumers according to the recommendations of the Joint FAO/WHO Meeting on Pesticides Residues (JMPR). Meanwhile, some countries establish their own MRLs from evaluations carried out by national or regional risk assessment agencies.
6. Food derived from products that comply with the respective MRLs are intended to be toxicologically acceptable, i.e. considered safe.
7. When authorized uses of pesticides do not produce residues, or they are identical and indistinguishable from certain natural components of food or are considered to be of low or no toxicological significance to humans, some regulations (regulators) explicitly state an exemption from the requirement to establish an MRL, or that there is no need to establish a MRL for the respective substance.

¹ REP18/PR, paras. 158 - 160

8. The Codex Alimentarius Commission (CAC) has not established MRLs or a set a standard for many of these substances. In the latter situation, some mineral substances of natural origin are included, as well as pesticides of biological origin, including bacteria, algae, protozoa, viruses and fungi, natural substances such as pheromones or other semiochemicals, and botanical extracts.
9. The only Codex guidelines related to these types of products are in the document *Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods* (CXG 32-99), prepared by the Codex Committee on Food Labeling (CCFL), which in its Annex 2, Table 2, presents a list of substances allowed 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.
10. This reveals the current lack of internationally harmonized criteria for the establishment or exemption of MRLs for a given substance, nor harmonized lists of substances with this condition.
11. National pesticide registration authorities, from those countries that consider CXLs for their national regulations, do not have an international reference recommendation for substances with this condition, which in some cases hinders the authorization or registration process and use of these low risk substances.
12. This represents an impediment in the incorporation of these low risk technologies into the alternatives authorized for the control of pests in many countries.
13. The elaboration of an international reference guideline for the harmonization of concepts and criteria for the recognition of pesticides of low public health concern considered exempt from the establishment of MRLs will help to support the incorporation of low risk substances into robust safe pest control program.
14. In this sense, within the conclusions of the third Global Minor Use Summit (GMUS-3) held in Canada in October 2017, the need to publish an international list of substances exempted from MRLs at Codex level was identified as a top priority.
15. The increase of low-risk and low public health concern substances that are being incorporated into global agriculture to control pests, will contribute to achieving Sustainable Development Goals (SDGs), signed in 2015 at the Sustainable Development Summit of the United Nations. The summit raised in its 2030 Agenda the following: the sustainability of food production systems (SDG 2 - End hunger, achieve food security and improved nutrition and promote sustainable agriculture); the goal of significantly reducing, by 2030, the number of deaths and diseases caused by hazardous chemicals and by the pollution and contamination of air, water and soil (SDG 3 in its goal number 9: Ensure healthy lives and promote well-being for all at all ages); and eventually, the commitment to achieve an ecologically sound management of the chemical products, and significantly reduce their release to the atmosphere, water and soil in order to minimize their adverse effects on human health and the environment (SDG 12 in its goal number 4 - Ensure sustainable consumption and production patterns).
<https://undocs.org/en/A/RES/70/1>.

Diversification of national legislations

16. The European Union (EU) legislation contemplates Annex IV of Regulation (EC) No. 396/2005 which contains a list of active substances for which MRLs are not required.
17. The general principles for the establishment and update of Annex IV are laid down in Article 5 of Regulation (EC) No 396/2005, which requires that for an active substance which shall be included in Annex IV account should be taken of:
 - the use of the active substance;
 - the scientific and technical knowledge available;
 - the result of an assessment of any potential risks to consumers with a high intake and high vulnerability and, where appropriate, to animals;
 - the results of any evaluations and decisions to modify the use of plant protection products.
18. The registration and authorization of pesticides in USA is based on two standards that cover naturally occurring substances that control pests (biochemical pesticides); microorganisms that control pests (microbial pesticides); and pesticidal substances produced by plants containing added genetic material (plant-incorporated protectants). The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides for federal regulation of pesticide distribution, sale, and use. All pesticides distributed or sold in USA must be registered by the Environmental Protection Agency (EPA). The requirements are described in a Pesticide Registration Manual. EPA also has a Biopesticides and Pollution Prevention Division that specializes in evaluating biochemical and microbial pesticides and plant-incorporated protectants. In addition, the Federal Food, Drug and Cosmetic Act (FFDCA), amended by the Food Quality and Protection Act (FQPA), authorizes EPA to establish MRLs for pesticide residues in food and/or animal feed, or to grant exemptions in cases where pesticide residues do not pose a dietary risk under reasonably foreseeable circumstances.

19. The regulation on Biopesticides of India is based on the Insecticides Act (1968), according to which any microorganism manufactured or commercialized must be registered in the Central Insecticide Board (CIB) of the Ministry of Agriculture. In order to promote the registration of Biopesticides, the registration process of these products has priority and is subject to simplified procedures, as well as the acceptance of generic data of strains that are already registered.
20. Another precedent besides the US and EU regulation that can be cited has been published by Food Standards Australia & New Zealand (FSANZ) as FZSAN P-1027 from Oct.26,2016 for Managing Low Levels of Ag & Vet Chemicals without MRL.
21. An approach was developed to establish All other foods except animal food commodities MRLs for agricultural and veterinary chemicals (agvet) set out in the Australia New Zealand Food Standards (The Code).
22. This pilot approach was undertaken with a 500 chemicals already listed in the Code with the aim of developing principles and criteria to establish for specific agvet chemicals, All other foods except animal food commodities MRLs that are high enough to allow for inadvertent presence of the chemical in food but are low enough to limit the potential for 'off label' use of the chemical.
23. The approach is consistent with the Australian Pesticides and Veterinary Medicines Authority's (APVMA's) risk assessment framework for approving and registering agvet chemical products, and with the risk assessment approach for establishing MRLs in the Code.
24. In Stage 2, a number of principles were developed, in consultation with the APVMA, to guide setting an All other foods except animal food commodities MRL for each chemical. An individual dietary exposure assessment (DEA) based on internationally agreed methodologies was undertaken for each chemical, which took into consideration current estimates of dietary exposure from risk assessments relating to existing MRL permissions, as well as a conservative 'worst case' assessment of potential contribution to dietary exposure from All other foods except animal food commodities. Both chronic and, where appropriate, acute dietary exposures were considered. Health based guidance values (HBGVs¹) used in the DEAs were those listed on the web pages of the Australian Government's Office of Chemical Safety (OCS) or Food and Agricultural Organization/World Health Organization's (FAO/WHO) Joint Meeting of Pesticide Residues (JMPPR).
25. Overall, an agreed criterion was that the All other foods except animal food commodities MRL should be low enough that the contribution from commodities included to estimate the total chronic dietary exposure would not exceed approximately 20% at the time the MRL was proposed. This was to ensure that future establishment of specific commodity MRLs for a chemical does not result in estimates of dietary exposure exceeding relevant HBGVs.
26. Finally, in Chile, Uruguay and other Latin American countries, no MRLs has been established for these types of substances, since they base their regulations on Codex Alimentarius.

The proposal of the guidelines could include the following elements (non-exhaustive):

- a. Definitions of concepts
- b. Criteria to identify pesticides of low public health concern that are considered exempt from the establishment of MRLs
- c. Preparation of a list of substances exempt from MRLs.

III. RECOMMENDATION

27. According to Appendix I² and Appendix II³, the EWG makes the following recommendations to CCPR:
 - a. Recommend approval of new work by CAC42 (2019).
 - b. Establish an EWG to prepare guidelines for compounds of low public health concerns that could be exempted from the establishment of CXLs.

² See Appendix I, Project document proposal to develop guidelines for the harmonisation of concepts and criteria for the recognition of compounds of low public health concern that are considered exempted from the establishment of CXLs

³ See Appendix II, Guidelines for the harmonisation of concepts and criteria for the recognition of compounds of low public health concern that are considered exempted from the establishment of CXLs

IV REFERENCES

- Report of the 50th Session of the Codex Committee on Pesticide Residues, Haikou, P.R. China, 9 - 14 April 2018.
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- Dunham Trimmer, International Bio Intelligence (2017) Biopesticides Market, Key to Growth.
- https://www.marketsandmarkets.com/Market-Reports/biopesticides-267.html?gclid=Cj0KCQiAvqDiBRDAARIsADWh5Td2jQA8KwbeHp9NMQEkU6x2xvKgvF7NynbApfnpwewjW3hOxGS3QYkaAoIGEALw_wcB
- <https://undocs.org/es/A/RES/70/1>
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- Food Standards Australia & New Zealand (FSANZ) as FZSAN P-1027 from Oct.26,2016 for Managing Low Levels of Ag & Vet Chemicals without MRL.
- "Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (GL 32-99)"
- <http://www.fao.org/fao-who/codexalimentarius/meetings/detail/es/?meeting=CCPR&session=50>
- http://www.fao.org/input/download/standards/41/CXA_004_1993e.pdf
- <https://eur-lex.europa.eu/legal-content/ES/TXT/PDF/?uri=CELEX:32005R0396&from=ES>
- https://businessdocbox.com/Biotech_and_Biomedical/81770383-Joint-fao-who-food-standards-programme-codex-committee-on-pesticide-residues-50-th-session-haikou-p-r-china-9-14-april-2018.html
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- <https://indiacode.nic.in/bitstream/123456789/1551/1/196846.pdf>
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APPENDIX I
PROJECT DOCUMENT

**PROPOSAL TO DEVELOP GUIDELINES FOR THE HARMONISATION OF CONCEPTS AND CRITERIA
FOR THE RECOGNITION OF COMPOUNDS OF LOW PUBLIC HEALTH CONCERN THAT ARE
CONSIDERED EXEMPTED FROM THE ESTABLISHMENT OF CODEX MAXIMUM RESIDUE
LIMITS (CXLs)**

(FOR CONSIDERATION BY CCPR AND APPROVAL BY CAC)

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 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; Proposals for the criteria to identify pesticides of low public health concern that are considered exempt from the establishment of MRLs; Preparation of a list of substances exempt from 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 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 this Guideline, 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.

APPENDIX II**(For information)****PROPOSED GUIDELINES FOR THE HARMONISATION OF CONCEPTS AND CRITERIA FOR THE
RECOGNITION OF COMPOUNDS OF LOW PUBLIC HEALTH CONCERN THAT ARE
CONSIDERED EXEMPTED FROM THE ESTABLISHMENT OF CODEX MAXIMUM RESIDUE
LIMITS (CXLs)****TABLE OF CONTENTS****PREFACE****SECTION 1 SCOPE OF APPLICATION****SECTION 2 CRITERIA FOR INCLUSION OF SUBSTANCES IN ANNEX 1****ANNEX 1 COMPOUNDS OF LOW PUBLIC HEALTH CONCERN CONSIDERED EXEMPTED FROM
THE ESTABLISHMENT OF CODEX MAXIMUM RESIDUE LIMITS (CXLs)****ANNEX 2 DEFINITIONS**

PREFACE

1. Pesticides are compounds used in agriculture to achieve the health, quality and performance in crops through preventive and control of biotic factors that affect them. They include, inter alia, insecticides, fungicides, herbicides, acaricides, growth regulators, pheromones, semiochemicals and repellents.
2. Pesticides contain active substances that can be of biological or chemical origin.
3. Among pesticides of chemical origin there are synthetic substances, mineral substances and basic substances of natural origin.
4. Pesticides of biological origin include compounds based on microorganisms, such as bacteria, algae, protozoa, viruses and fungi; natural substances as pheromones or semiochemicals as well as botanical extracts; and in some cases include analogues of these natural substances.
5. Sometimes authorized uses of the pesticides on food crops result in residues. Codex Alimentarius has set Maximum Residue Limits (MRLs) for pesticides on specific foodstuffs or food groups traded internationally to protect the health of consumers in accordance with the recommendations of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). Meanwhile, some countries establish their own MRLs as a result of the evaluations carried out by national or regional agencies on risk assessment.
6. Codex MRLs (CXLs) have been adopted based on the recommendations of the JMPR evaluations and in accordance with Good Agricultural Practices (GAP) data. Food resulting from products that comply with the MRLs will be toxicologically acceptable. The question whether an active substance fulfills one or more criteria with the aim to exempt the substance from the setting of Codex Maximum Residue Limits is the result of an evaluation of toxicology and residue behavior.
7. When authorized uses of pesticides do not produce residues or are identical and indistinguishable from certain natural components of the foods either considered to be of low or no toxicological significance, some regulations explicitly grant an exemption from the requirement to establish an MRL or state that an MRL is not required for the respective substance. However, there are no harmonised or internationally recognized criteria for MRL exemptions; further, there is not a harmonised list of substances for which exemptions have been deemed appropriate.
8. These guidelines represent a first step toward harmonisation or international recognition of criteria for exempting substances of low public health concern from the requirement to establish MRLs; a first list of substances fitting this criteria will be included in Annex 1.

SECTION 1 SCOPE

9. These guidelines apply without prejudice to any other provisions of the Codex Alimentarius Commission (CAC) establishing MRLs for pesticides on foodstuffs.
10. This guidance document defines the different criteria used by some countries and international organizations regarding to the establishment of MRL exemption for the substances used as pesticides considered of low risk or low public health concern.
11. The proposed criteria are presented in an attempt to provide a consistent and harmonised approach for determining when a substance is considered exempt from the establishment of a MRL.
12. A list of active substances exempts from the establishment of MRLs, or for which MRLs are not required, based on existing national lists that comply with agreed criteria is proposed. This list will be updated regularly

SECTION 2 CRITERIA FOR INCLUSION OF SUBSTANCES IN ANNEX 1

13. According to the criteria proposed below, substances that do not have immediate or delayed injurious effect on human or animal health, directly or through drinking water, food or through aggregated effects are identified.

Criteria 1. Active substances without hazardous properties identified (very low or no toxicological concern)

14. Substances for which it is not necessary to establish Reference Values based on their low-risk Human Health profile (**HHGV**) (ADI/ARfD).
15. Substances and relevant metabolites that do not bioaccumulate or have the capacity to cause significantly toxic effects at environmentally relevant concentration. (corrosive, sensitizing, neurotoxic, immunotoxin, carcinogenic, mutagenic, reproductive, developmental or endocrine disrupting effects).

16. This approach could include basic substances, pesticides of microbial and botanical origin, chemical substances and natural substances and active substances which, by themselves, are food components. For natural substances and active substances which, by themselves, are food components higher concentrations used compared food and known allergenic potential should be taken into account.

Criteria 2. Substances for which it is not possible to differentiate between the exposure associated with its use as pesticide from its other uses in the food chain

17. Natural exposure associated with the food substance cannot be differentiated from the one linked to the use as pesticide.
18. This approach could include pesticides of botanical origin and natural chemical substances (additives, minerals, among others). Food and/or feed items which are known allergens should be considered carefully.

Criteria 3. Substances for which no consumer exposure linked to the mode of application is foreseen

19. This approach could include natural substances such as pheromones and semiochemicals dispersed through dispensers for sexual confusion purposes.

Criteria 4. Substances of low public health concern for which there is a long history of equivalent level of exposure (similar to the level of exposure that would be incurred by the proposed use of the pesticide) to humans, e.g., 50 years or longer.

20. This approach could include natural substances used in consumer products such as natural health products, cosmetics and other extractable commodity chemicals that have a range of non-pesticidal uses (e.g., garlic oil). It could also include semiochemicals where applications to food crops are not expected to result in residue levels that exceed natural background levels during outbreaks of the pest and that any residues present are not expected to be toxic.

Criteria 5. Microorganisms which are not acutely toxic and do not produce mammalian toxins or other potentially toxic secondary metabolites of human health concern.

21. This approach could include most saprotrophic microorganisms inhabiting agroecosystems and exclude microorganisms that are either primary mammalian pathogens or are taxonomically close relatives to microbes that are primary mammalian pathogens. For microorganisms that are closely related to known toxigenic human pathogens, it must be demonstrated that toxins of concern are absent in final pesticide products and are not likely to be produced by the microorganism, following application, at levels on or in the treated crop that will either exceed natural background levels or potentially cause harm.

ANNEX 1 COMPOUNDS OF LOW PUBLIC HEALTH CONCERN CONSIDERED EXEMPT FROM THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRLs)

22. The following lists* do not attempt to be complete or selective, nor a definitive regulatory tool but rather provide examples to governments in relation to the substances used as pesticides internationally known to be exempt from the establishment of MRLs or for which the specification of MRLs have not been required by regulatory authorities. A system of review criteria as detailed in Section 2 of these Guidelines should be the main determinant for acceptability or rejection of substances by governments.

**Annex 1 with the list of substances will be elaborated once agreement on the criteria for incorporating substances is reached.*

ANNEX 2 DEFINITIONS**Acceptable daily intake (ADI)**

23. The ADI is the estimate of a chemical in food or drinking-water that can be ingested over a life-time without appreciable health risks to the consumer. It is derived on the basis of all the known facts at the time of the evaluation. It is expressed in milligrams of the chemical per kilogram of body-weight.

Active ingredient

24. The component of the product that provides the pesticide action.

Authorized use

25. Authorized use refers to the safe use of a pesticide based upon a use pattern determined at the domestic level or at each economy's level. It includes domestically approved, registered or recommended uses, which take into account public and occupational health and environmental safety considerations.

Basic Substance

26. Active ingredients that are not substances of concern, i. e. are not classified or labelled according to the Globally harmonized system for classification and labeling of chemical products (GHS), that do not have an inherent capacity to cause endocrine disruption, neurotoxic or immunotoxic effects and that are not used primarily as a pesticide

Biochemical pesticides

27. Biochemical pesticides include substances that interfere with mating, such as insect sex pheromones, as well as semiochemicals that influence insect behavior such as attracting, repelling, and aggregating. In addition, plant extracts, oils and minerals can also manage pests, and are naturally occurring substances that control pests by indirect, or non-toxic mechanisms. Conventional pesticides, by contrast, are generally synthetic materials that directly kill or inactivate the pest.

Biological pesticide

28. Substance made from microorganisms such as bacteria, algae, protozoa, viruses and fungi, natural substances such as pheromones and other semiochemicals, as well as botanical extracts designed to repel, destroy or control any pest or regulate the growth of plants.

Codex MRL (CXL)

29. Codex MRLs are primarily intended to apply in international trade, are derived from estimations made by FAO/WHO expert committees such as the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The JMPR recommends maximum residue levels for consideration by Codex following a toxicological assessment of the pesticide and its residues; a review of residue data reflecting domestic authorized uses; and dietary intake risk assessments to indicate that foods complying with Codex MRLs are safe for human consumption.

Definition of the residue

30. For each pesticide used on food or feed commodities, regulatory authorities need to choose which residue(s) will be used for i) dietary risk assessment and ii) setting and enforcing MRLs. The "definition of the residue" or the "residue definition" refers to those residues chosen for these two regulatory purposes.

Definition of residues (for compliance with MRLs)

31. The definition of a residue (for compliance with MRLs) is that combination of the pesticide and its metabolites, derivatives and related compounds to which the MRL applies.

Definition of residues (for estimation of dietary intake)

32. The definition of a residue (for estimation of dietary intake) is that combination of the pesticide and its metabolites, impurities and degradation products of toxicological significance for risk assessment purposes and HR apply.

Food Group/Crop Group

33. A collection of foods/crops subject to MRLs that have similar characteristics (for example Stone fruits) and similar potential for residue for which a common group MRL can be set. The Codex classification of food and animal feed commodities describe the various food groups moving in trade and lists commodities included in each group. The commodities included within food groups may differ between Codex and APEC economy databases.

Good Agricultural Practice

34. Good agricultural practice in the use of pesticides (GAP) includes the domestically authorized safe uses of pesticides under actual conditions necessary for effective pest, disease or weed control. It encompasses a range of levels of pesticide applications up to the highest authorized use, applied in a manner which leaves a residue which is the smallest amount practicable. Authorized safe uses are determined at the domestic level and include registered or recommended uses, which take into account public and occupational health and environmental safety considerations. Actual conditions include any stage in the production, storage, transport, distribution of food commodities and animal feed.

Joint FAO/WHO meeting on pesticide residues (JMPR)

35. The "Joint Meeting on Pesticide Residues" (JMPR) is an expert *ad hoc* body administered jointly by Food and Agriculture Organisation and World Health Organisation. The JMPR has met annually since 1963 to conduct scientific evaluations of pesticide residues in food.
36. It provides advice on the acceptable levels of pesticide residues in internationally traded food. The JMPR consists of experts who attend as independent internationally-recognized specialists acting in a personal capacity and not as representatives of national governments. Visit the Food and Agriculture Organisation of the United Nations website for more information.

Maximum residue limit (MRL)

37. A Maximum Residue Limit (MRL) is the maximum concentration of a pesticide residue legally permissible in or in food commodities and animal feeds. MRLs are based on good agricultural practice (GAP) data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable.

Microbial pesticide

38. Substances used for the control or management of pests such as invertebrates, weeds or microbial pathogens of crops, made from microorganisms such as bacteria, protozoa, fungi and viruses or genetically modified or natural mutants of any of these microorganisms. They include complete organisms (either viable or non-viable), organelles of the organism, metabolites produced by the organism, spores of the organism or occlusion bodies.

Pest

39. Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products.

Pesticide

40. Pesticide means any substance intended for preventing, destroying, attracting, repelling, or controlling any pest including unwanted species of plants or animal during the production, storage, transport, distribution and processing of food, agricultural commodities, or animal feeds or which may be administered to animals for the control of ectoparasites. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant, fruit thinning agent, or sprouting inhibitor and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. In this Guideline the term excludes fertilizers, plant and animal nutrients, food additives, and animal drugs.

Pesticide Residue

41. Pesticide Residue means any specified substance in food, agricultural commodities, or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products, and impurities considered to be of toxicological significance.

Semiochemical

42. Chemicals emitted by plants, animals, and other organisms - and synthetic analogues of such substances - that evoke a behavioral or physiological response in individuals of the same or other species.

APPENDIX III**List of Participants****Chair: Chile**

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