

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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World Health
Organization

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

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**PROPOSED DRAFT GUIDELINES FOR COMPOUNDS OF LOW PUBLIC HEALTH CONCERN
THAT MAY BE EXEMPTED FROM THE ESTABLISHMENT OF CODEX MAXIMUM RESIDUE LIMITS
OR DO NOT GIVE RISE TO RESIDUES**

(At Step 4)

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

Codex members and Observers wishing to submit comments at Step 3 on the proposed Guidelines should do so as instructed in CL 2020/14-PR.

Circular letters are available on the Codex webpage/Circular Letters and can also be accessed from the CCPR website (related circular letters):

<http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en>

<http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-meetings/jp/?committee=CCPR>

Background

1. CCPR50 (2018) agreed to prepare a discussion paper to provide guidance for pesticides which do not give rise to residues or whose residues do not give rise to public health concern and could therefore be exempted from the establishment of Codex maximum residue limits (CXLs). The Committee further agreed that this work would be carried through an Electronic Work Group (EWG) chaired by Chile and co-chaired by India and the United States of America for consideration by CCPR51 (2019). In taking this decision, the Committee 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.¹
2. CCPR51 (2019) considered the discussion paper and agreed to recommend new work to provide an international reference for harmonized concepts and criteria for the recognition of this set of pesticides. CAC42 (2019) approved² the new work as contained in the project document³ submitted by CCPR50. The proposed guidelines would be developed through an EWG, chaired by Chile and co-chaired by India and the United States of America, working in English and Spanish, with the following terms of reference⁴:
 - a) To develop common criteria for the identification of compounds of low public health concern that may be exempted of CXLs and/or that do not give rise to residues.
 - b) Provide harmonized Codex definitions as appropriate.
 - c) Provide examples of compounds that meet the criteria to facilitate the development of the guidelines (such examples will not necessarily remain in the final document).
 - d) Based on the above considerations, present a proposed Guidelines for consideration at CCPR52.

¹ REP18/PR, paras. 158 – 160

² REP19/CAC, para. 14 and Appendix V

³ REP19/PR, Appendix IX

⁴ REP19/PR, paras. 203 – 206

Proceedings of the Electronic Working Group (EWG)

3. The EWG was joined by several member countries and observer organizations and a Member Organization. The list of participants is provided in Appendix II.
4. The EWG worked through an online platform and according to a work schedule that include two round of internal comments. A total of 9 member countries⁵ and 3 observer organizations⁶ provided comments.

Discussion***Concepts (definitions) and criteria***

5. In the first round of comments, members and observers generally supported the criteria for the recognition of compounds of low public health concern that are considered exempted from the establishment of CXLs. The majority of the comments received consisted of important contributions for the correct drafting of each of the criteria and their scope as well as the correct and harmonized use of the technical terms throughout the document. Valuable suggestions were also received for the definitions section.

Examples of compounds

6. In the second round of comments, members and observers were requested to provide some examples of compounds for each criterion. These examples have been included in the Annex of the proposed Guidelines as supporting information to facilitate the consideration of the Guidelines.

Recommendation

7. Codex members and observers are invited to provide comments on the definitions and criteria as presented in Appendix I in particular as to their accuracy and as to whether additional definitions or criteria may be needed for the purposes of these guidelines.
8. The Annex provides supporting information to facilitate the consideration of the provisions in the Guidelines (notably concepts and criteria) by CCPR52. The examples are therefore not exhaustive nor indicative of any list recommended for consideration and agreement by CCPR for international harmonization and as such they will not necessarily remain in the Guidelines once adopted by the Codex Alimentarius Commission.
9. In view of the rescheduling of CCPR52 to 2021, comments submitted will be considered by the EWG established by CCPR51 in order to provide a revised draft for consideration by CCPR52. Comments and information are most welcome in order to make as much as progress on the development of these Guidelines at the next session of CCPR.

⁵ Argentina, Chile, China, Costa Rica, France, Germany, Guatemala, United Kingdom and Uruguay

⁶ Crop Life International, Agro Care and Tea & Herbal Infusions Europe

APPENDIX I

**PROPOSED DRAFT GUIDELINES FOR COMPOUNDS OF LOW PUBLIC HEALTH CONCERN
THAT MAY BE EXEMPTED FROM THE ESTABLISHMENT OF CODEX MAXIMUM RESIDUE LIMITS
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PREFACE

1. Pesticides are compounds used in agriculture to achieve 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, and repellents.
2. Pesticides contain active substances that can be of chemical or biological origin.
3. Among pesticides of chemical origin there are synthetic and mineral substances.
4. Among pesticides of biological origin, a.k.a. Biopesticides, for the purpose of this Guidance Document, make reference to active substances based on microorganisms (Microbial pesticides), compounds made from plants like plant extracts (Botanical pesticides), as pheromones (Semiachemicals) and substances of animal origin. Therefore, substances referred to as biofertilizers or bioregulators as well as invertebrates such as insects and nematodes or other macroorganisms are not covered by this Guidance Document.
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). 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 commodities 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 commodities 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 harmonized or internationally recognized criteria for MRL exemptions; further, there is not a harmonized 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.

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. These guidelines aim to make use of the different criteria used by some countries and international organizations regarding the establishment of MRL exemption for the substances used as pesticides considered of low risk or low public health concern.
11. The criteria are presented in an attempt to provide a consistent and harmonized approach for determining when a substance is considered exempt from the establishment of an MRL.
12. If none of the criteria are fulfilled, further consideration may be possible on a case-by-case basis.

SECTION 2. DEFINITIONS

13. **Acceptable daily intake (ADI):** 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.
14. **Acute Reference Dose (ARfD):** The ARfD is the estimate of the amount of a substance in food or drinking water, expressed on a body weight basis that can be ingested in a period of 24 h or less without appreciable health risk to the consumer. It is derived on the basis of all the known facts at the time of evaluation. The ARfD is expressed in milligrams of the chemical per kilogram of body weight.
15. **Active substance:** The component of the product that provides the pesticide action.
16. **Authorized use:** Authorized use refers to the safe use of a pesticide based upon a use pattern determined at national level. It includes domestically approved, registered or recommended uses, which take into account public and occupational health and environmental safety considerations.

17. **Basic Substance:** Is an active substance which: is not a substance of concern; and does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects; and is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent; and is not placed on the market as a pesticide.
18. **Biological pesticides (Biopesticides):** Active substances made from living or dead microorganisms such as bacteria, algae, protozoa, viruses and fungi (See Microbial pesticides), pheromones and other semiochemicals (See Semiochemicals pesticides), and plants or parts of plants (See botanical pesticides), designed to repel, destroy or control any pest or regulate the growth of plants.
19. **Botanical pesticides:** Active substances that consists of one or more components found in plants and obtained by subjecting plants or parts of plants of the same species to a process such as pressing, milling, crushing, distillation and/or extractions. The process may include further concentration, purification and/or blending, provided that the chemical nature of the components is not intentionally modified/changed by chemical and/or microbial processes.
20. **Food Group/Crop Group:** 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.
21. **Good Agricultural Practice:** Good agricultural practice in the use of pesticides (GAP) includes the nationally authorized safe uses of pesticides under actual conditions necessary for effective and reliable pest 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 national level and include nationally 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.
22. **Joint FAO/WHO meeting on pesticide residues (JMPR):** 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. 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.
23. **Maximum residue limit (MRL):** A Maximum Residue Limit (MRL) is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted 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. Codex MRLs which are primarily intended to apply in international trade, are derived from estimations made by the JMPR following:
 - a) toxicological assessment of the pesticide and its residue; and
 - b) review of residue data from supervised trials and supervised uses including those reflecting national food agricultural practices. Data from supervised trials conducted at the highest nationally recommended, authorized or registered uses are included in the review. In order to accommodate variations in national pest control requirements, Codex MRLs take into account the higher levels shown to arise in such supervised trials, which are considered to represent effective pest control practices.Consideration of the various dietary residue estimates and determinations both at the national and international level in comparison with the ADI, should indicate that foods complying with Codex MRLs are safe for human consumption
24. **Microbial pesticide:** Active 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. 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.
25. **Natural Substances:** Natural substances consist of one or more components that originate from nature, including but not limited to: plants, algae/microalgae, animals, minerals, bacteria, fungi, protozoans, viruses, viroids and mycoplasmas. They can either be sourced from nature or are nature identical synthesized or produced by microorganisms. This definition excludes semiochemicals and microbials.

26. **Pest:** Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products.
27. **Pesticide:** 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 these Guidelines, the term excludes fertilizers, plant and animal nutrients, food additives, and animal drugs.
28. **Pesticide Residue:** 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.
29. **Semiochemicals:** Active substances or mixtures of substances emitted by plants, animals, and other organisms that evoke a behavioural or physiological response in individuals of the same or other species. Different types of semiochemicals include:
- Allelochemicals produced by individuals of one species that modify the behaviour of individuals of a different species (i.e., an interspecific or interspecies effect). They include allomones (emitting species benefits), kairomones (receptor species benefits) and synomones (both species benefit).
 - Pheromones produced by individuals of a species that modify the behaviour of other individuals of the same species (i.e. an intraspecific or intraspecies effect).
 - Straight-chained lepidopteran pheromones (SCLPs) are a group of pheromones consisting of unbranched aliphatics having a chain of nine to eighteen carbons, containing up to three double bonds and ending in an alcohol, acetate or aldehyde functional group. This structural definition encompasses the majority of known pheromones produced by insects in the order Lepidoptera, which includes butterflies and moths.

SECTION 3. CRITERIA FOR THE RECOGNITION OF COMPOUNDS OF LOW PUBLIC HEALTH CONCERN THAT ARE CONSIDERED EXEMPTED FROM THE ESTABLISHMENT OF CODEX MAXIMUM RESIDUE LIMITS (CXLs)

30. 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.

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

31. Substances and their relevant metabolites for which it is not necessary to establish Human Health Guidance Values (ADI/ARfD).
32. Substances and relevant metabolites that do not bioaccumulate or do not have the capacity to cause significantly toxic effects at environmentally relevant concentration (corrosive, sensitizing, neurotoxic, immunotoxin, carcinogenic, mutagenic, reproductive, developmental or endocrine disrupting effects, among others).
33. This approach could include basic substances, and other substances which, by themselves, are food components. For natural substances which, by themselves are food components but may be used at higher concentrations compared to food or are known to have allergenic potential, should be considered carefully.

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

34. Natural exposure associated with the food substance cannot be differentiated from the one linked to the use as pesticide. Measurable background levels should be assessed carefully and taken into consideration when deciding on the use of this criteria.
35. This approach could include botanical pesticides, natural chemical substances (minerals, among others). Food and/or feed items which are known allergens should be considered carefully.

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

36. This approach could include substances such as pheromones and other semiochemicals dispersed through dispensers for mating disruption purposes.

Criterion 4. Microorganisms which are not pathogenic and do not produce mammalian toxins or other potentially toxic secondary metabolites of human health concern.

37. This approach could include microbial pesticides, excluding 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 to public health.

ANNEX
EXAMPLES OF COMPOUNDS

The list of examples are not exhaustive nor indicative of any agreed list recommended for international harmonization. They are presented to support better understanding of the provisions in the document and may not remain in the Guidelines once adopted by CAC.

Criterion	Examples of compounds
Criterion 1. Active substances without hazardous properties identified (very low or no toxicological concern)	1. Calcium hydroxide
	2. Fructose
	3. Hydrogen peroxide
	4. Sodium chloride
	5. Sodium hydrogen carbonate
	6. Sucrose
	7. Vinegar
	8. L-ascorbic acid (Vitamin C)
Criterion 2. Substances for which it is not possible to differentiate between the exposure associated with its use as pesticide and its other uses in the food chain	9. <u>Plant oils/ Vegetable oils</u> Rapeseed oil, Castor oil, corn oil, rice bran oil, cotton seed oil, Sesame oil, linseed oil, olive oil, peanut oil, Tea tree oil, Neem oil, Karanj oil, Mahua (Madhuca) oil
	10. <u>Plant essential oils</u> Clove oil, citronella oil orange oil, spearmint oil, citrus oil, fennel oil, cederwood oil, lemongrass and, rosemary oil, turmeric oil, thyme oil, vetiver oil, catnip oil. eucalyptus leaf oil and extract
	11. <u>Essential oil constituents</u> Geraniol eugenol, linalool, limonene, citronellal, thymol, carvone, 1,8-cineole, p-cymene, ar-turmerone, gingerols, pinene, terpene-ol,
	12. <i>Annona</i> spp. (Annonins, Squamocin)
	13. <i>Azadirachta indica</i> (Neem leaf and seed kernel oil)
	14. Azadirachtin (neem product)
	15. Brassinolides
	16. Chenopodium oil and extract
	17. Garlic extract
	18. Giberellic acid (GA3)
	19. Karanjin
	20. Pyrethrum (Pyrethrins)
	21. <i>Ryania</i> spp. (Ryanodines)
	22. <i>Reynoutria sachalinensis</i> extract
	23. Rocaglamides (<i>Aglaia</i> spp.)
	24. Soaps (fatty acid salts)
	25. <i>Sophora flavescens</i> (Matrine, oxymatrine)
	26. Sulphur
	27. Triacantanol

Criterion	Examples of compounds
Criterion 3. Substances for which no consumer exposure linked to the mode of application is foreseen	28. <u>Pheromones</u>
	29. (Z)-8-Dodecen-1-yl-acetate
	30. (E)-8-Dodecen-1-yl-acetate
	31. (Z)-8-Dodecen-1-ol
	32. (E/z)-8-Dodecen-1-yl-acetate
	33. (E, E)-8,10-Dodecadien-1-ol
	34. 1-Dodecanol
	35. (E)-11-Tetradecen-1-ol
	36. Gossyplure
	37. 9- Hexadecenal, 11-Hexadecenal, and Hexadecenol
	38. Hexadecadienyl acetate
	39. Rescalure
	40. (E)-11-Tetradecen-1-yl-ol acetate
Criterion 4. Microorganisms which are not pathogenic and do not produce mammalian toxins or other potentially toxic secondary metabolites of human health concern.	41. <i>Trichoderma asperellum</i> (formerly <i>T. harzianum</i>) strains ICC012, T25 and TV1
	42. <i>Trichoderma atroviride</i> (formerly <i>T. harzianum</i>) strains IMI 206040 and T11
	43. <i>Trichoderma gamsii</i> (formerly <i>T. viride</i>) strain ICC080
	44. <i>Trichoderma harzianum</i> strains T-22 and ITEM 908
	45. <i>Trichoderma polysporum</i> IMI-206039
	46. <i>Streptomyces</i> K61 (formerly <i>S. griseovirides</i>)
	47. <i>Bacillus amyloliquefaciens</i> strain FZB24
	48. <i>Bacillus amyloliquefaciens</i> strain MBI600
	49. <i>Bacillus amyloliquefaciens</i> subsp. <i>Plantarum</i> D747
	50. <i>Bacillus firmus</i> I – 1582
	51. <i>Bacillus subtilis</i> str. QST 713
	52. <i>Bacillus thuringiensis</i>
	53. <i>Beauveria bassiana</i> strain ATCC 74040
	54. <i>Beauveria bassiana</i> strain GHA
	55. <i>Helicoverpa armigera</i> nucleopolyhedrovirus
	56. <i>Bacillus sphaericus</i>
	57. <i>Chaetomium globosum</i>
	58. Entomopathogenic nematodes (EPNs)
	59. <i>Fusarium oxysporum</i>
	60. <i>Metarhizium anisopliae</i>
	61. <i>Plaecilomyces lilacimus</i>
	62. <i>Pseudomonas fluorescens</i>
	63. <i>Trichoderma viride</i>
	64. <i>Trichoderma virens</i>
	65. Nucleopolyhedro virus (NPV) of <i>Spodoptera litura</i>
	66. <i>Verticillium lacanii</i>

APPENDIX II**LIST OF PARTICIPANTS**

Chair: Chile	
Mr. Eduardo Aylwin Advisor, Agencia Chilena para la Calidad e Inocuidad Alimentaria (ACHIPIA) (Chair)	
Co-chairs	
United States of America	India
Dr. Daniel Kunkel Associate Director, Food and International Programs	Dr Pranjib Chakrabarty Assistant Director General Indian Council of Agricultural Research (ICAR)

Argentina

Daniel Mazzarella
SENASA

Australia

Jason Lutze
Director and Science Leader
Australian Pesticide and Veterinary Medicines Authority

Canada

Brian Belliveau
Head, Microbial and Biochemical Evaluation Section, Pest
Management Regulatory Agency
Health Canada

Chile

Roxana Vera Muñoz
Head of International Agreements Subdepartment,
Department of International Negotiations
Agricultural and Livestock Service, SAG.

China

Ercheng Zhao
Beijing Academy of Agriculture and Forestry Science

Colombia

Hugo Sepulveda
Instituto Colombiano Agropecuario (ICA)

Costa Rica

Amanda Lasso Cruz
Ministerio de Economía Industria y Comercio
Verónica Picado
Jefe Laboratorio de Análisis de Residuos de Agroquímicos
Servicio Fitosanitario del Estado

Tatiana Vásquez

Servicio Fitosanitario del Estado

Ecuador

Jakeline Arias
Coordinadora del CCPR
Agrocalidad

Egypt

Mariam Barsoum
Food Standards Specialist
Egyptian Organization for Standardization

European Union

Volker Wachtler
European Commission

Marc Leguen
European Commission
EU Codex Contact Point
European Commission

Austria

Ingo Grosssteiner
Austrian Agency for Health and Food Safety (AGES)

Hungary

Agnes Stier
Human Toxicologist
National Food Chain Safety Office

France

Florence Gerault
Ministry of agriculture
Xavier Sarda
ANSES

Germany

Karsten Hohgardt
Federal Office of Consumer Protection and Food Safety
Monika Schumacher
Federal Ministry of Food and Agriculture

Spain

Alice Yague
Head of the Waste Management Service for Plant Protection
Products and Veterinary Drugs
MSCBS

Guatemala

Julio Ruano
Coordinador Nacional del CCPR

Honduras

Juan Carlos Paguada
Coordinador del CCPR
SENASA
Yolandina Lambur
Secretaría Nacional del Codex

India

Dr. K. K. Sharma
Network Coordinator Indian Agricultural Research Institute
Sarita Vhalla
Consultant
Codex-India
Food Safety Standards and Authority of India
Vandana Tripathy
Senior Scientist

Indonesia

Asep Nugraha
Researcher

Japan

Hidetaka Kobayashi
Ministry of Agriculture, Forestry and Fisheries
Keysuke Awa
Ministry of Health, Labour and Welfare

Morocco

Ahmed Jafari
Head of the Service of Monitoring and Control of Chemical
Inputs (ONSSA)
Ouazzani Sanae
Service of Standardization and Codex Alimentarius (ONSSA)

New Zealand

Warren Hughes
Principal Adviser
Ministry for Primary Industries
David Lunn
Principal Adviser Residues
Ministry for Primary Industries

Nicaragua

Ramon Noguera
Responsable del Departamento de Inspeccion y Certificación
Fitosanitaria
IPSA
Mirian Canda
Especialista en Normalización Internacional
MIFIC

Paraguay

José Jimenez
Head of Vegetables Traceability Department
SENAVE

Perú

Humberto Reyes
Especialista en Inocuidad Agroalimentaria
SENASA
Miguel Portocarrero
SENASA
Juan Carlos Huiza
Secretario Técnico
DIGESA

Republic of Korea

Republic of Korea codex contact point
Ministry of Agriculture, Food and Rural Affairs(MAFRA)
Hwang Kiseon
SPS Researcher
Kyeong-ae Son
Researcher
Hyoyoung Kim
Scientific Officer
Kim Jinsook
Deputy director
Jung Kyunghee
Scientific Officer
Park Yumin
Codex researcher

Thailand

Chonnipa Pawasut
Office of Standard Development, National Bureau of
Agricultural Commodity and Food Standards

Namaporn Attaviroj
Office of Standard Development, National Bureau of
Agricultural Commodity and Food Standards

United Kingdom

Paul Brian
Chemicals Regulation Division of the UK HSE
David Williams
Pesticide Team Leader Department for Environment Food
and Rural Affairs

United States of America

Aaron Niman
Environmental Health Scientist
U.S. Environmental Protection Agency

Uruguay

Susana Franchi
Jefe de Laboratorio de Residuos de Plaguicidas
Dirección General de Servicios Agrícolas / Ministerio de
Ganadería, Agricultura y Pesca

Observer Organizations**Agro-Care AISBL**

Laura Ruiz
Asesor

CropLife International

Wibke Meyer
Regulatory Affairs Manager

FIVS

Laura Gelezuinas
Manager
Timothy Ryan
FIVS Codex Task Force Chair

OECD

Magdalini Sachana
Administrator OECD

Tea & Herbal Infusions EUROPE

Cordelia Kraft