

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
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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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REPORT OF THE VIRTUAL PRE-MEETING

GUIDELINES FOR THE RECOGNITION OF ACTIVE SUBSTANCES OR AUTHORIZED USES OF ACTIVE SUBSTANCES OF LOW PUBLIC HEALTH CONCERN THAT ARE CONSIDERED EXEMPTED FROM THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS OR DO NOT GIVE RISE TO RESIDUES

(AT STEP 7)

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

This CRD should be read in conjunction with CX/PR 22/53/11; CX/PR 22/53/11-Add.1; CRD04 and CRD presented by Codex Members and Observers

INTRODUCTION

1. On 27 and 28 June 2022, the pre-meeting of the Electronic Working Group (EWG) on “Guidelines for the recognition of active substances or authorized uses of active substances of low public health concern that are considered exempted from the establishment of Maximum Residue Limits or do not give rise to residues” took place virtually. The meeting was held in English, French and Spanish and the program was published on the Codex website.
2. The objective was to provide Members and Observers with an opportunity to make progress on the development of these Guidelines based on the information provided in the working document and relevant comments received in reply to the circular letter CL 2022/37-PR in order to facilitate the consideration of this item by CCPR. The conclusions and recommendations of this meeting will be presented to the consideration of the CCPR53.
3. Previously to this meeting, the EWG Co-Chairs prepared a revised proposal (see Appendix I of CR04) that considered comments received in reply to CL 2022/37-PR.

METHODOLOGY

4. In order to facilitate the discussion, Chile, as the Chair of the EWG, presented a summary of the work carried out. Subsequently, the draft of the Guidelines was reviewed section by section (see Appendix I of CRD04) in order that Members and observers had the opportunity to make general and/or specific comments.

SUMMARY OF DISCUSSION

5. Overall, the most of Members and observers expressed their support for the work and recommendations done by the EWG.
6. Some specific comments, mostly editorial, were made on the scope and definitions sections, which were incorporated in Appendix I of this CRD.
7. Regarding the list of examples the WG chair clarified that according to the EWG terms of reference, they will not remain as part of the Guidelines. Nevertheless, the list will remain in the working documents for reference.

CONCLUSIONS

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8. It was agreed that the guidelines should advance to Step 8 for final adoption by CAC45.

RECOMMENDATIONS FOR THE CCPR53

9. Codex Members and Observers are invited to consider:
- i. The revised “Guidelines for the recognition of active substances or authorized uses of active substances of low public health concern that are considered exempted from the establishment of Maximum Residue Limits or do not give rise to residues” as presented in Appendix I.
 - ii. To advance the Guidelines to Step 8 for final adoption by CAC45 (2022).

APPENDIX I**GUIDELINES FOR THE RECOGNITION OF ACTIVE SUBSTANCES OR AUTHORIZED USES OF ACTIVE SUBSTANCES OF LOW PUBLIC HEALTH CONCERN THAT ARE CONSIDERED EXEMPTED FROM THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS OR DO NOT GIVE RISE TO RESIDUES**

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PREFACE

1. Pesticides are substances 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, semiochemicals, and repellents.
2. Pesticides contain active substances that can be of chemical or biological origin.
3. Chemical pesticides could be synthetic or of natural origin.
4. For the purpose of these Guidelines, pesticides of biological origin, also known as biopesticides, ~~include 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), pheromones (semiochemicals) and substances of animal origin. ~~Therefore, s~~Substances referred to as biofertilizers, bioregulators or biostimulants as well as invertebrates such as insects and nematodes or other macroorganisms are not covered by this guidance document.
5. Sometimes authorized uses of pesticides on food crops result in residues. The Codex Alimentarius Commission (CAC) has set Maximum Residue Limits (MRLs) for pesticides on specific foodstuffs or food groups traded internationally to protect the health of consumers based on 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 (are considered to be safe for consumers). These Guidelines establish criteria for the exemption of substances, or specific authorized uses of substances, from the establishment of MRLs when the establishment of MRLs is not necessary to protect consumer health. The question of whether an active substance or a specific authorised use of an active substance fulfills one or more criteria with the aim to exempt the substance or a specific authorized use of an active substance from the setting of 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 result in residues that are identical and indistinguishable from certain natural components of the food 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 active substance or its authorized uses. However, there are no harmonized or internationally recognized criteria for MRL exemptions.
8. These guidelines represent a first step toward harmonisation or international recognition of criteria for exempting active substances, or their authorized uses, 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 to decide that it is not necessary to establish MRLs for an active substance or a specific authorized use of an active substance because a risk assessment concludes that they are of low risk and low public health concern
11. These criteria are presented in an attempt to provide a consistent and harmonized approach for determining when an active substance or its authorized uses could be considered exempt from the need for establishment of MRLs.
12. The guidelines do not cover uses of toxic substances that do not give rise to residues, for example use of fungicides or insecticides as seed treatments.
13. These guidelines are intended to be used by ~~the countries'~~ competent authorities in countries that do not have established criteria for MRL exemption for active substances or ~~its specific~~ authorized uses of active substances in their respective legislation.

~~12.~~

SECTION 2. DEFINITIONS

- ~~13-14.~~ **Acceptable daily intake (ADI):** It is the daily intake which, during an entire lifetime, appears to be without appreciable health risks to the consumer 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.

- 14-15. Active substance/ingredient:** means the part of the product that provides the pesticidal action.
- 15-16. Active substances of low public health concern:** Active substances and their relevant metabolites considered of low or no toxicity to human and animal health based on risk assessments.
- 16-17. Acute Reference Dose (ARfD):** The acute RfD of a chemical is an estimate of the amount of a substance in food and/or drinking-water, normally expressed on a body-weight basis, that can be ingested in a period of 24 hours or less without appreciable health risk to the consumer on the basis of all known facts at the time of the evaluation.
- 17-18. 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 generally take into account public and occupational health and environmental safety considerations.
- 18-19. Biological pesticide (Biopesticide):** A pesticide containing active substances made from living or dead microorganisms such as bacteria, algae, protozoa, viruses and fungi (See microbial pesticides definition), pheromones and other semiochemicals (See semiochemicals pesticides definition), and plants or parts of plants (See botanical pesticides definition), designed to repel, destroy or control any pest or regulate the growth of plants (For example *Bacillus amyloliquefaciens* strain FZB24, *Trichoderma atroviride* (formerly *T. harzianum*) strains IMI 206040 and T11).
- 19-20. Botanical pesticide:** A pesticide containing 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 (For example *Annona* spp. (Annonins, Squamocin), neem (*Azadirachta indica*)).
- 20-21. Environmental exposure:** Levels of substances, including and levels arising from past human activities present in the environment (e.g. agriculture), present in the environment in situations relevant for the respective environmental compartment.
- 21-22. Feed:** Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food producing animals.
- 22-23. Food Group/Crop Group:** A collection of foods/crops subject to MRLs that have similar characteristics and similar potential for residue for which a common group MRL can be set. Representative commodities can be used to establish MRLs on an entire crop group or subgroup. The Codex classification of food and animal feed commodities describe the various food groups moving in trade and lists commodities included in each group.
- 23-24. Good agricultural practice (GAP) in the use of pesticides:** 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.
- 24-25. 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.
- 25-26. 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 on 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 relevant metabolites; and

- (b) Review of residue data from supervised trials and supervised uses including those reflecting national good 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 and the ARfD, should indicate that foods complying with Codex MRLs are safe for human consumption.

~~26-27.~~ **Microbial pesticide:** A pesticide containing 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.

~~27-28.~~ **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 micro-organisms.

~~28-29.~~ **Pest:** means any species, strain or biotype of plant, animal or pathogenic agent injurious to plants and plant products, materials or environments and includes vectors of parasites or pathogens of human and animal disease and animals causing public health nuisance.

~~29-30.~~ **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. The term normally excludes fertilizers, plant and animal nutrients, food additives, and animal drugs.

~~30-31.~~ **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.

~~31-32.~~ **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 ACTIVE SUBSTANCES OR AUTHORIZED USES OF ACTIVE SUBSTANCES OF LOW PUBLIC HEALTH CONCERN THAT ARE CONSIDERED EXEMPTED FROM THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

~~32-33.~~ To grant the exemption from the establishment of MRLs to an active substance or a specific authorized use, the active substances or the specific use should meet the requirements of at least one of the following criteria.

~~33-34.~~ Special consideration should be ~~taken given in for~~ those situations where the MRL exemption is linked to a certain pesticide GAP use.

~~34-35.~~ It can be GAP dependent whether or not residues are expected; ~~ifn-case~~ residues are expected or will occur according to GAP expected/measured residue levels ~~have to~~should be assessed in comparison with possible environmentally relevant exposure levels.

~~35-36.~~ Therefore, every time a new use is requested, the new use should be assessed with regard to its exemption from MRLs (whether or not the active substance has already been exempted from MRL setting [for other uses](#)).

~~36-37.~~ According to the criteria below, active substances or specific authorized uses for which a risk assessment process [conducted by competent authority](#) concludes that there are not immediate or delayed harmful effects on human or animal health, directly or through drinking water, foods, or through aggregate effects, may be exempted from the need to establish MRLs.

Criterion 1. Active substances without hazardous properties identified

~~37-38.~~ Active substances and their relevant metabolites for which, according to risk assessments, it has been considered that it is not necessary to establish health based guidance values (ADI/ARfD). ~~It should be excluding cases that there are a~~[This excludes](#) active substances that do not have ADI/ARfD established because they are genotoxic substances or due to lack of data to define these values.

~~38-39.~~ Active substances and relevant metabolites that do not bioaccumulate or do not have the capacity to cause significantly toxic effects such as, corrosive, sensitizing, neurotoxic, immunotoxin, carcinogenic, mutagenic, reproductive, developmental or endocrine disrupting effects, among others at environmentally relevant levels.

Criterion 2. Active substances for which it is not possible to differentiate between the exposure associated with ~~its~~ use as pesticide with ~~its~~ environmentally relevant exposure levels or ~~its~~ other uses in the food chain

~~39-40.~~ Active substances which, by themselves, are food components or have low-toxicity ~~of and present~~ no human or animal health concern.

~~40-41.~~ Active substances for which environmental exposure associated with the food substance cannot be differentiated from the one linked to the use as a pesticide (botanical pesticides, natural chemical substances)

~~41-42.~~ Food and/or feed items which are known allergens should be subject to additional requirements, not related to risk from pesticides.

~~42-43.~~ Measurable environmental levels should be assessed carefully and taken into consideration when deciding on the use of this criterion. For instance, when the exposure through residues from pesticides use does not add significantly to the exposure from environmentally relevant levels or other authorised uses, exemptions from establishing MRLs may be granted. Case by case considerations are needed taking into account the specificities of each substance and the exposure levels.

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

~~43-44.~~ This criterion includes substances such as pheromones and other semiochemicals dispersed through dispensers for mating disruption purposes where the consumer's exposure from the application is similar to the environmental exposure level to the substance.

Criterion 4. Microorganisms that are not of human or animal health concern

~~44-45.~~ This criterion also concerns microbial active substances that may potentially produce toxins/metabolites. Such microorganisms should only be considered exempted from the establishment of MRL if it can be proven that such toxins/metabolites are not present on edible parts of the treated crops, at levels on or in the treated crop that will ~~either~~ exceed environmental relevant levels ~~and or~~ potentially cause harm to human and animal health.

~~45-46.~~ Microorganisms that are primary human or animal pathogen (excluding target species¹) should not be considered exempted from the establishment of MRL. For microorganisms that are taxonomically close relatives to such pathogenic microorganisms, a MRL exemption would be possible only if evidence is provided ~~to prove~~ that they do not negatively affect human or animal health.

¹ A species that is intentionally targeted for control by a pesticide.

APPENDIX II**(For information)****EXAMPLES OF ACTIVE SUBSTANCES**

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 Guidelines and will not remain in the final document, but they could be made available on the Codex website.

Criterion	Examples of substances/microorganisms
Criterion 1. Active substances without hazardous properties identified	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. Active substances for which it is not possible to differentiate between the exposure associated with its use as pesticide with its environmental relevant exposure levels or 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, cedarwood 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. (<i>Annonins, Squamocin</i>)
	13. Brassinolides
	14. <i>Chenopodium</i> oil and extract
	15. Garlic extract
	16. Giberellic acid (GA3)
	17. Karanjin
	18. <i>Ryania</i> spp. (Ryanodines)
	19. <i>Reynoutria sachalinensis</i> extract
	20. Rocaglamides (<i>Aglaia</i> spp.)
	21. Soaps (fatty acid salts)
	22. <i>Sophora flavescens</i> (Matrine, oxymatrine)
	23. Sulphur
	24. Triacontanol

Criterion	Examples of substances/microorganisms
Criterion 3. Active substances for which no consumer exposure linked to the mode of application is foreseen	26. (Z)-8-Dodecen-1-yl-acetate
	27. (E)-8-Dodecen-1-yl-acetate
	28. (Z)-8-Dodecen-1-ol
	29. (E/z)-8-Dodecen-1-yl-acetate
	30. (E, E)-8,10-Dodecadien-1-ol
	31. 1-Dodecanol
	32. (E)-11-Tetradecen-1-ol
	33. Gossyplure
	34. 9- Hexadecenal, 11-Hexadecenal, and Hexadecenol
	35. Hexadecadienyl acetate
	36. Rescalure
	37. (E)-11-Tetradecen-1-yl-ol acetate
	Criterion 4. Microorganisms that are not of human or animal health concern
39. <i>Trichoderma atroviride</i> (formerly <i>T. harzianum</i>) strains IMI 206040 and T11	
40. <i>Trichoderma gamsii</i> (formerly <i>T. viride</i>) strain ICC080	
41. <i>Trichoderma harzianum</i> strains T-22 and ITEM 908	
42. <i>Trichoderma polysporum</i> IMI-206039	
43. <i>Streptomyces</i> strain K61 (formerly <i>S. griseovirides</i>)	
44. <i>Bacillus amyloliquefaciens</i> strain FZB24	
45. <i>Bacillus amyloliquefaciens</i> strain MBI600	
46. <i>Bacillus amyloliquefaciens</i> subsp. <i>Plantarum</i> D747	
47. <i>Bacillus firmus</i> I – 1582	
48. <i>Bacillus subtilis</i> str. QST 713	
49. <i>Beauveria bassiana</i> strain ATCC 74040	
50. <i>Beauveria bassiana</i> strain GHA	
51. <i>Helicoverpa armigera</i> nucleopolyhedrovirus	
52. <i>Bacillus sphaericus</i>	
53. <i>Chaetomium globosum</i>	
54. Entomopathogenic nematodes (EPNs)	
55. <i>Fusarium oxysporum</i> strain Fo47	
56. <i>Metarhizium anisopliae</i>	
57. <i>Paecilomyces lilacinus</i>	
58. <i>Pseudomonas fluorescens</i>	
59. <i>Trichoderma viride</i>	
60. <i>Trichoderma virens</i>	
61. Nucleopolyhedro virus (NPV) of <i>Spodoptera litura</i>	
62. <i>Verticillium lacanii</i>	

APPENDIX III
LIST OF PARTICIPANTS

Chair: Chile	
Eduardo Aylwin Agencia Chilena para la Calidad e Inocuidad Alimentaria (ACHIPIA) (Presidente)	Roxana Vera Muñoz Servicio Agrícola y Ganadero (SAG) (Asistente del Presidente)
Co-chairs	
India	United States
Dr. S.C. Dubey (Co-chair) Assistant Director General Plant Protection and Biosafety Indian Council of Agricultural Research	Aaron Niman Environmental Health Scientist LCDR, U.S. Public Health Service Health Effects Division, Office of Pesticide Programs Office of Chemical Safety and Pollution Prevention Environmental Protection Agency

Argentina

Carla Serafino
Registry of Agrochemicals and Biologics of the
National Service of Agrifood Health and Quality
(SENASA)

Canada

Emma Babij
Pest Management Regulatory Agency, Health Canada

Chile

Paulina Chávez
Ministerio de Salud

Patricia Villarreal
Asociación Nacional de Fabricantes e Importadores de
Productos Fitosanitarios Agrícolas A.G (AFIPA).

Gonzalo Aranda
Servicio Agrícola y Ganadero (SAG)

Pablo Reyes
Servicio Agrícola y Ganadero (SAG)

Nicole Undurraga
Servicio Agrícola y Ganadero (SAG)

Costa Rica

Amanda Lasso
Codex Advisor

Alejandro Rojas León
State Phytosanitary Service (SFE)

Ivania Morera Rodríguez
State Phytosanitary Service (SFE)

Tatiana Vasquez Morera
State Phytosanitary Service (SFE)

Ecuador

Jakeline Arias
Coordinadora del Subcomité del Codex sobre residuos
de plaguicidas

El Salvador

Daniel Torres
OSARTEC

Claudia Guzmán
OSARTEC

European Union

Siret SURVA
European Commission

Finland

Tii Mäkinen-Töykkä
Finnish Safety and Chemicals Agency (Tukes)

France

Florence Gérard
Ministry of Agriculture

Gaëlle Vial
ANSES

Germany

Karsten Hohgardt
Federal Office of Consumer Protection and Food
Safety (BVL)

Monika Schumacher
Federal Ministry of Food and Agriculture

Angela Göbel
Federal Ministry of Food and Agriculture

Guatemala

Karen Gatica
Chemical analyst

Cristián Rossi
Technical expert

India

K.K. Shama
Network Coordinator, ICAR-IARI

National Codex Contact Point, NCCP
Food Safety Standards Authority

Dr. PG Shah,
Consultant, AAU

Dr. Narendra Tripathi
General Manager, Tirupati Wellness India Pvt Ltd

Dr. Jonnalagadda Padmaja
Scientist F, ICMR-National Institute of Nutrition

Naveen Kumar Navani
Professor, Indian Institute of Technology Roorkee

Dr. Vandana Tripathy,
Principal Scientist, ICAR-IARI, India

Amol Shende
Manager, Herbalife Nutrition, India

Japan

Hidetaka KOBAYASHI
Agricultural Chemicals Office, Ministry of Agriculture,
Forestry and Fisheries

Koutarou TOMITA
Agricultural and Veterinary Chemical Residue Office,
Food Safety Standards and Evaluation Division,
Pharmaceutical and Environmental Health Bureau,
Ministry of Health, Labour and Welfare

Kingdom of Saudi Arabia

Saif M. AL-Mutairi
Saudi Food and Drug Authority

Nimah Baqadir
Saudi Food and Drug Authority

Morocco

JAAFARI Ahmed
Head of the Chemical Inputs Division at the National
Food Safety Office (ONSSA)

MESSAOUDI Bouchra
Engineer in the service of standardization and the
Codex Alimentarius at the National Food Safety Office
(ONSSA)

New Zealand

Warren Hughes
New Zealand Food Safety, Ministry for Primary
Industries

Paraguay

José Eduardo Giménez Duarte
Servicio Nacional de Calidad y Sanidad Vegetal y de
Semillas (SENAVE)

Republic of Korea

Codex Contact Point
Quarantine Policy Division, Ministry of Agriculture,
Food and Rural Affairs (MAFRA)

Kiseon Hwang
Ministry of Agriculture, Food and Rural Affairs

Hyejin Park
National Agricultural Products Quality Management
Service

Eun Young Lee
Rural Development Administration

Jung Kyunghee
Ministry of Drug and Food Safety

Park Yumin
Ministry of Drug and Food Safety

Im Moo-Hyeog
Daegu University

Singapore

WU Yuan Sheng
Food Safety Monitoring & Forensics Department

South Africa

Aluwani Madzivhandila
Food Control

Sweden

Niklas Montell
Ministry of Health, Welfare and Sport, National
Institute for Public

Thailand

Namaporn Attaviroj
National Bureau of Agricultural Commodity and Food
Standards (ACFS), Ministry of Agriculture and
Cooperatives

Chutima Sornsumrarn
National Bureau of Agricultural Commodity and Food
Standards (ACFS), Ministry of Agriculture and
Cooperatives

Uganda

Geoffrey Onen
Assistant Commissioner Directorate of Government
Analytical Laboratory (DGAL)

Josephine Nyanzi
Principal Regulatory Officer, Vet Medicine National
Drug Authority (NDA)

Moses Matovu
Research Officer National Agricultural Research
Organization (NARO)

John Wabuzibu Mwanja
Ministry of Agriculture, Animal Industry and Fisheries

Rose Nakimuli
Inspection manager Chemiphar (U) Ltd

Joseph Iberet
Uganda National Bureau of Standards

Arthur Mukanga
Uganda National Bureau of Standards

Ruth Awio
Uganda National Bureau of Standards

Hakim Mufumbiro
Uganda National Bureau of Standards

United Kingdom

Paul Brian
Health and Safety Executive

United States of America

David Miller
Chemistry & Exposure Branch and Acting Chief,
Toxicology & Epidemiology Branch U.S. Environmental
Protection Agency

Alexander Domesle
Senior Advisor for Chemistry, Toxicology and Related
Sciences U.S. Food Safety and Inspection Service U.S.
Department of Agriculture

Marie Maratos Bhat
U.S. Codex Office U.S. Department of Agriculture

Uruguay

Susana Franchi
DAD-DGSA-MGAP

Observer Organizations

CropLife International

Wibke Meyer
Director Regulatory Affairs

International Fruit & Vegetable Juice Association (IFU)

John Collins
Executive Director

Tea & Herbal Infusions Europe (THIE)
Cordelia Kraft
Manager Scientific Affairs