APPENDIX XII

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 5)

(for adoption by CAC)

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. Among pesticides of chemical origin there are synthetic and natural mineral substances and other natural 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 fr om plants like plant extracts (Botanical pesticides), pheromones (Semiochemicals) and substances of animal origin. Therefore, 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 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 (are considered to be safe for consumers). 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 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; further, there is not a harmonized list of active substances for which exemptions have been deemed appropriate.

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 regarding the establishment of pesticides MRL exemption for active substances or their authorized uses, considered of low risk or 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 establishment of CODEX MRLs.

12. These guidelines are intended to be used by the countries' competent authorities that do not have established criteria for the MRLs exemption for active substances or its authorized uses in their respective legislation.

SECTION 2. DEFINITIONS

13. **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. **Acute Reference Dose (ARfD):** It 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 apprec iable 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/ingredient:** The component(s) of the product that directly or indirectly (metabolites) 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:** 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 (For example Calcium hydroxide, Lecithins).

18. **Biological pesticide (Biopesticide):** 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 (For example *Bacillus amyloliquefaciens* strain FZB24, *Trichoderma atroviride* strain).

19. **Botanical pesticide:** 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/altered by chemical and/or microbial processes (For example *Annona* spp. (Annonins, Squamocin), neem (Azadirachta indica)).

20. **Feed**: Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food producing animals

21. **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. 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.

22. **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.

23. **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.

24. **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.

25. **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.

26. **Background exposure:** Natural levels of substances and levels arising from past human activities present in the enviroment (e.g. agriculture), in situations relevant for the respective environmental compartment.

27. **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 micro - organisms. This definition excludes semiochemicals and microbials.

28. **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 diseaseand animals causing public health nuisance.

29. **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.

30. **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 or ecotoxicological significance. The term "pesticide residue" includes residues from unknown or unavoidable sources (e.g. environmental contamination) as well as known, authorized uses of the chemical.

31. **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 enc ompasses 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 CODEX MAXIMUM RESIDUE LIMITS (CXLs)

32. To grant the exemption from the establishment of MRLs to an active substance and / or its authorized uses, active substances mandatorilly must meet the requirements indicated in Criterion 1 and must also meet the requirements indicated at least for one of the other criteria as appropriate.

33. Special consideration must be taken for those situations where the MRL exemption is linked to a certain pesticide GAP use.

34. It can be GAP dependent whether or not residues are expected; in case residues are expected or will occur according to GAP expected/measured residue levels have to be assessed in comparison with possible background levels.

35. Therefore, every time a new use is requested, this 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).

36. According to the criteria proposed below, active substances or their authorized uses that after a risk assessment process are concluded that they do not have an immediate or delayed harmful effect on human or animal health, directly or through drinking water , foods, or through aggregate effects, may be exempted from setting MRLs.

Criterion 1. Basic substances and active substances without hazardous properties identified

37. Active substances and their relevant metabolites for which, according to risk assessments, it has been considered that it is not necessary to establish Guidance Values for Human Health (ADI/ARfD). It should be taken into account that there are active substances that do not have ADI / ARfD established because they are genotoxic substancesor due to lack of data to define these values.

38. 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 environmental background levels.

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

39. Basic substances, and other substances which, by themselves, are food components or have low-toxicity of nopublic health concern (no tox-endpoint needs to be set).

40. Active substances for which background exposure associated with the food substance cannot be differe ntiatedfrom the one linked to the use as a pesticide (Botanical pesticides, natural chemical substances)

41. Food and/or feed items which are known allergens should be considered carefully.

42. Measurable background levels should be assessed carefully and taken into consideration when deciding on the use of this criteria.

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

43. This criterion includes substances such as pheromones and other semiochemicals disperse d through dispensers for mating disruption purposes where the consumer's exposure from the application level is similar to the background exposure level of the substance.

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

44. This criterion includes microbial active substances. For microorganisms that are closely related to known toxigenic human pathogens, it must be demonstrated that toxins/metabolites toxic to humans, animals are not likely to be produced by the microorganism, and should they be present in the products, these toxins/metabolites should not be present on edible parts of the treated crops, following application, at levels on or in the treated crop that will either exceed natural background levels or potentially cause harm to public health. Attention should be given to any mammalian toxins or other potentially toxic secondary metabolites of human health concern produced by microorganisms.

45. This criterion excludes microorganisms that are either primary mammalian pathogens or are taxonomically close relatives to microbes that are primary mammalian pathogens.

ANNEX EXAMPLES OF 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 may not remain in the Guidelines once adopted by the Codex Alimentarius Commission)

Criterion	Examples of subtances/microorganisms
Criterion 1. Basic substances and Active substances without hazardous propertiesidentified (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 notpossible to differentiate between the exposure associated with its use as pesticide and its other uses in the food chain	9. Plant oils/ Vegetable oils Rapeseed oil, Castor oil, corn oil, rice bran oil, cottonseed oil, Sesame oil, linseed oil, olive oil, peanut oil, Tea tree oil, Neem oil, Karanj oil, Mahua (Madhuca) oil
	10. Plant essential oils Clove oil, citronella oil orange oil, spearmint oil, citrusoil, fennel oil, cedarwood oil, lemongrass and, rosemary oil, turmeric oil, thyme oil, vetiver oil, catnipoil. eucalyptus leaf oil and extract
	11. Essential oil constituents Geraniol eugenol, linalool, limonene, citronellal, thymol, carvone, 1,8-cineole, p-cymene, ar-turmerone, gingerols, pinene, terpine-ol,
	12. *Annona* spp. (Annonins, Squamocin)
	13. *Azadirachta indica* (Neem leaf and seed kernel oil)
	14. Brassinolides
	15. Chenopodium oil and extract
	16. Garlic extract
	17. Giberellic acid (GA3)
	18. Karanjin
	19. *Ryania* spp. (Ryanodines)
	20. *Reynoutria sachalinensis* extract
	21. Rocaglamides (Aglaia spp.)
	22. Soaps (fatty acid salts)
	23. *Sophora flavescens* (Matrine, oxymatrine)
	24. Sulphur
	25. Triacontanol
	26. Pheromones

Criterion	Examples of subtances/microorganisms
Criterion 3. Substances for which no consumer exposure linked to the modeof application is foreseen	27. (Z)-8-Dodecen-1-yl-acetate
	28. (E)-8-Dodecen-1-yl-acetate
	29. (Z)-8-Dodecen-1-ol
	30. (E/z)-8-Dodecen-1-yl-acetate
	31. (E, E)-8,10-Dodecadien-1-ol
	32. 1-Dodecanol
	33. (E)-11-Tetradecen-1-ol
	34. Gossyplure
	35. 9- Hexadecenal, 11-Hexadecenal, and Hexadecenol
	36. Hexadecadienyl acetate
	37. Rescalure
	38. (E)-11-Tetradecen-1-yl-ol acetate
Criterion 4. Microorganisms which are not pathogenic and do not produce mammalian toxins or other potentiallytoxic secondary metabolites of humanhealth concern.	39. *Trichoderma asperellum* (formerly T. *harzianum*) strains ICC012, T25 and TV1
	40. *Trichoderma atroviride* (formerly T. *harzianum)* strainsIMI 206040 and T11
	41. *Trichoderma gamsii* (formerly T. viride) strain ICC080
	42. *Trichoderma harzianum* strains T-22 and ITEM 908
	43. *Trichoderma polysporum* IMI-206039
	44. *Streptomyces* strain K61 (formerly S. griseovirides)
	45. *Bacillus amyloliquefaciens* strain FZB24
	46. *Bacillus amyloliquefaciens* strain MBI600
	47. *Bacillus amyloliquefaciens* subsp. Plantarum D747
	48. *Bacillus firmus* I – 1582
	49. *Bacillus subtilis* str. QST 713
	50. *Beauveria bassiana* strain ATCC 74040
	51. *Beauveria bassiana* strain GHA
	52. *Helicoverpa armigera* nucleopolyhedrovirus
	53. *Bacillus sphaericus*
	54. *Chaetomium globosum*
	55. Entomopathogenic nematodes (EPNs)
	56. *Fusarium oxysporum strain Fo47*
	57. *Metarhizium anisopliae*
	58. *Plaecilomyces lilacimus*
	59. *Pseudomonas fluorescens*
	60. *Trichoderma viride*
	61. *Trichoderma virens*
	62. Nucleopolyhedro virus (NPV) of *Spodoptera litura*
	63. *Verticillium lacanii*

APPENDIX XIII

DISCUSSION PAPER ON THE
REVIEW OF THE INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKE EQUATIONS (IESTI)[1]

(For publication as an information document on the Codex website (Sections 1 and 3) and
For information/use by JMPR)

1. Benefits/advantages and challenges of the current IESTI methodology

Table 1: Benefits/advantages of the current IESTI equations

General benefits/advantages
The IESTI methodology is transparent. IESTI calculations require low computational capacity; the calculations can be performed easily using standard IT tools.
Benefits from risk management perspective
IESTI calculations provide clear answers to risk management questions (i.e. whether the short-term exposure is above or below the toxicological reference value (ARfD)). Because of the IESTI methodology, risk management decisions became more consistent, transparent and reproducible. IESTI methodology generally promotes global harmonisation of risk management decisions. The use of the JMPR IESTI calculation tool which is based on the IESTI equations allows to perform ad-hoc risk assessments which give answers to risk managers whether risk management actions are needed.
Benefits from risk communication perspective
The IESTI calculations are performed in a transparent way which can be shared with interested parties. The IESTI calculations are used to support the messaging that Codex MRLs are health protective. The IESTI calculation tool was proven to be beneficial not only in the framework of establishing safe Codex MRLs, but also for supporting food inspection services and national competent authorities to answer risk management questions on the safety of national MRLs or the safety of food placed on the market.[2] The input values are simple and can be generated at reasonable costs for different geographical regions.
Benefits from perspective of consumer protection
IESTI calculations are generally assumed to give conservative estimates compared to expected exposure events occurring in real life, because the methodology • combines conservative estimates for food intake (large portion covers 97.5th percent of the consumers that according to food surveys consume a certain product) with • conservative estimates for the expected residue concentration (highest residue or median residue expected on a crop for the most critical Good Agricultural Practice) and • postulates that the food item consumed may contain higher residues than the residues measured in the residue trials where composite samples were analysed which usually contains at least 12 units of the food item. This assumption is taken into account by applying a variability factor. IESTI calculations support risk-based decisions on the setting of Codex MRLs taking into account national food consumption habits.
Benefits regarding impact on trade

[1] Working document CX/PR 52/21/15 containing the full discussion paper is available on the Codex website: http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCPR&session=52

[2] It is common practice in the EU that the IESTI equations (EU version of IESTI equations with European food consumption data and agreed European variability factors) are used to take decisions on risk management actions for consignments/lots where the food control services find residue levels exceeding the MRL.

Setting Codex MRLs promotes international trade.

Harmonised risk assessment methodologies promote the acceptance of food standards at international level, hence reducing non-tariff trade barriers.

Table 2: Challenges of the current IESTI equations

General challenges

Some countries experienced that the JMPR IESTI model is too rigid or too conservative.

Some countries question if the JMPR IESTI model is conservative enough.

Data to verify the level of protection achieved with the IESTI methodology have not been available so far. Recent studies that were performed to address this issue are reported in Section 2.

Due to the different perception of the level of conservatism, national models have been developed which implement modifications of the IESTI equations, e.g. using different variability factors, unit weight data, consumption data.

A main challenge is to find agreement on a harmonised methodology which is acceptable for all Codex member countries.

Challenges from risk management perspective

The IESTI methodology is deterministic and does not give risk managers quantitative information on:

- the distribution of the exposure across the population;
- the uncertainty of the calculations, and
- the frequency of cases where the short-term exposure exceeds the ARfD or level of protection (i.e. for a target population).

The development of this type of quantitative information requires the use of probabilistic methods and tools to assess population-based data on pesticide residue levels and food consumption. The possibility to generally link the IESTI better to the population-based exposure would benefit from further exploration.

For making IESTI calculations representative for all Codex member countries, it would be desirable to integrate a wide range of food consumption data from different regions worldwide.

Internationally agreed protocols for a harmonised approach on how to derive consumption data for the IESTI methodology are not in place.

Although the IESTI methodology leads to a high level of harmonization in acute risk assessments at international level, complete harmonisation is not realistic because countries may use differing inputs (such as national consumption data, residue definitions, variability factors, crop group extrapolation and toxicological reference points) which impacts on MRL setting.

Diverging input variables used in the national models (modified IESTI equations) by different Codex member countries lead to different exposure outcomes. This divergency may result in rejection of Codex MRLs by some Codex member countries. Consequently, the need for negotiations on acceptance of Codex MRLs increases.

Changing the currently used IESTI methodology by replacing or modifying input variables in order to find wider acceptance of the methodology would lead to different results compared to previous risk assessments performed by JMPR. Hence, Codex MRLs that were considered safe may not be safe or vice versa, if the same input values are used in a revised methodology.

Challenges from risk communication perspective

Some Codex member countries face risk communication challenges to explain that Codex MRLs are sufficiently protective because the risk assessment with IESTI equations is not performed with the Codex MRL but with the highest residue (HR) or the supervised trials median residue (STMR) obtained from residue trials; both the HR and the STMR are usually lower than the MRL.

Further examination of this challenge was discussed at the international workshop in Geneva (EFSA RIVM, 2015), which proposed potential simplification of the IESTI equation. Some Codex members within the EWG suggested that

simplification of the IESTI equations, particularly for case 2a and 2b, would enhance the understanding of the methodology by the general public and stakeholders and would positively impact risk communication.

In 2006 JMPR recommended to discuss the adequacy of IESTI equations to assess the safety of food containing residues at levels found in monitoring and/or enforcement programmes (FAO, 2006). Although some Codex member countries would welcome further work to develop tools/models aligned with the IESTI methodology that can be used for national enforcement programmes, previous EWG considered that the development of these risk assessment tools does not fall under the remit of CCPR/JMPR and therefore this point is not further discussed.

Challenges from perspective of consumer protection

Quantitative consumer protection goals have not been clearly formulated.

Reliable information on the actual level of protection resulting from the use of IESTI methodology at international level is not available.

The IESTI calculations case 1, 2a and 2b[3] are performed with the HR (highest residue, input value used in IESTI calculations, see Table 3 which refers to the residue definition for risk assessment and reflects the residue in the edible part of the crop. The HR is a point estimate; the variability of the residue concentrations measured in the individual residue trials and expected when the pesticide is applied in accordance with the Good Agricultural Practices approved in Codex member countries is not taken into account.

In contrast to the HR, MRLs are usually established following a statistical assessment implemented in the OECD calculator. The MRL is intended to entail at least 95% of the residue levels expected on treated crops in accordance with the Good Agricultural Practice, to ensure that agricultural products produced in accordance with the GAP are compliant with the legal limit. Since 2010, JMPR also uses to OECD calculator to derive MRL proposals. The MRL derived with the OECD calculator is usually higher than the HR. Based on synthetic residue data with 4 trials, 8 trials and 16 trials it was concluded that the ratio between MRL and HR is 2.1, 1.8 and 1.5, respectively. The ratio between MRL and STMR was calculated to account for 4.1, 4.8 and 5.3 for datasets of 4, 8 and 16 trials. The gap between MRL and HR/STMR depends to a large extent on the number of residue trials (Van der Velde-Koerts et al, 2018b). As a consequence, the phenomenon exists that the IESTI calculations exceed the ARfD if the exposure is calculated with the Codex MRL, instead of using the HR or STMR. For these cases it is difficult to communicate to the public that the MRL is safe (Richter et al, 2018).

Challenges regarding impact on trade

A change in the current JMPR IESTI model may trigger the need to lower certain CXLs, and consequently would introduce new trade barriers. For those cases, alternative Good Agricultural Practices (GAPs) need to be developed, leading to acceptable residues with regard to short-term dietary intake.

Recent publications considered the impact of modifications of IESTI variables and suggested that only a minor percentage of CXLs would be affected van der Velde et al (2018a)). However, it is not known how any of such modifications and losses of CXLs might be measured in trade value, lost pest control, or reduced abilities for growers to substitute alternate chemistries and the impact on weed or insect resistance issues.

Establishing Codex MRLs for the alternative GAPs will take time and causes additional costs.

2. Benchmarking of IESTI calculations against probabilistic exposure estimates

2.1. Overview

FAO/WHO performed a study on a probabilistic exposure assessment to address the request of CCPR49 to FAO/WHO which specified that FAO/WHO should:

(i) review the basis and the parameters of the IESTI equations,

(ii) benchmark the outcomes of IESTI equations to a probabilistic distribution of actual exposures and

(iii) present the outcome to CCPR.

In general, benchmarking is a process of comparing performance metrics of a product or a process (in the given case the performance of the IESTI methodology as it is currently used by JMPR) to practices generally considered as superior or being acknowledged as the best practice. The purpose of benchmarking is to identify opportunities for improvement. A successful benchmarking process of the IESTI methodology requires a reference methodology which is generally

[3] The difference between IESTI case 1 and 2a/2b is the use of a variability factor: while for case 2a/2b the HR value is multiplied by a variability factor, this is not the case for food products where the exposure calculations are performed according to case 1. More details on the calculation algorithm for the different IESTI cases can be found in section 3.

accepted as leading to a forecast of the short-term dietary exposure of consumers that is closer to reality. The predicted exposure derived with IESTI calculations should be compared with the exposure derived with the reference methodology to identify whether the IESTI methodology fulfils its purpose, i.e.

- IESTI reliably predicts consumer health risks, and
- at the same time the calculations are not overly conservative, indicating arbitrary consumer health concern, because of overestimation of the exposure.

Overall, the study should validate the ability of the IESTI methodology to predict exposure events above and below the ARfD that are likely to occur within a population.

2.2. FAO/WHO Benchmarking Assessment of the IESTI Equations

FAO/WHO prepared a final draft assessment that was discussed at CCPR51 (CX/PR 19/51/3-Add.2); in August 2019 an updated, final analysis was provided to the EWG-4 that was subsequently presented to JMPR at its 2019 Regular Meeting on September 17-26, 2019.

In this study, FAO/WHO (2019) estimated acute dietary exposure for 47 pesticides using a probabilistic methodology (Monte Carlo methodology) based on real-world data on pesticide residue levels and food commodity consumption collected as a part of national pesticide monitoring programmes and food surveys. The assessment included food surveys from eight countries (Australia, Brazil, Canada, and the European countries Czech Republic, France, Italy and the Netherlands) and monitoring data on unprocessed products (RAC) from five countries/regions. For three countries food consumption data were available for both adults and children. Overall 6 scenarios for adults and 5 scenarios for children were calculated.

For each scenario, the matching food consumption data/pesticide monitoring data were identified which were then used to perform the probabilistic exposure calculations. The number of food items taken into account in these calculations ranged from 11 (Italian adults)[4] to 127 (Canadian adults). FAO/WHO then performed its assessment by first comparing the IESTI equation with the probabilistic exposure estimates and then performing a level of protection analysis (LoP) that assumed all foods consumed contained pesticide residue concentrations at the MRL. Each component of FAO/WHO's assessment and conclusions reported in JMPR's 2019 Summary Report are further described below.

- The first component of FAO/WHO's assessment provided exposure estimates derived with probabilistic exposure models for each of the eight countries and compared the results with the relevant Acute Reference Dose (ARfD). This comparison considered two use scenarios - 10% use of the pesticide and 100% use of the pesticide[5] – and concluded that there was a zero risk of exceeding the relevant ARfD in all countries and subpopulations of adults/children. For adults, the 97.5th percentile of acute dietary exposure was <10% ARfD, for children <50% ARfD. Based on these results, JMPR concluded that the IESTI equation was considered protective for acute risk (FAO/WHO, 2020).
- The second component of FAO/WHO's assessment was a LoP analysis that used the same consumption data as the first component, but assumed that all food consumed contained pesticide residues at the CXL for each of the 47 pesticides selected by WHO. The LoP was defined by the study authors as the percentage of person-days with intakes at or below the ARfD when the residue occurs at the level of the CXL. Based on the LoP calculations performed by FAO/WHO, a LoP of 100% indicates that no acute dietary exposure estimates exceeded the ARfD.

Based on the LoP analysis, for 4 of the 47 pesticides covered by the study, the LoP of MRLs was lower than 90% for at least 1 population in 1 country. For 7 pesticides, the LoP was found to range between 90 and 99% for all populations in all countries. For the remaining 36 pesticides, the LoP was higher than 99% (among those, for 14 pesticides the LoP was 100%).

The 2019 JMPR concluded that given the extremely conservative estimates produced when assuming all commodities have residues present at the MRL, a LoP of less than 100% does not necessarily indicate that approved uses will lead to an exceedance of the ARfD in practice.

The 2019 JMPR suggested that a more realistic assessment of the LoP could be made by assuming residues at the MRL for a single commodity and residues from monitoring data for other commodities in the assessment (FAO/WHO, 2020).

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4 In the Italian diet the following food items were considered in the exposure calculation which are probably not sufficiently representative for the typical Italian diet: Almonds, coconuts, ginseng, lentil (dry), milk (cattle), pine nut kernels, pistachio nuts, sunflower seed, watermelons and walnuts.

5 As reported by JMPR, two scenarios were tested: 10% use of the pesticide, i.e., only 10% of non-quantifiable samples were assumed to contain the pesticide (90% concentrations assigned a zero value; 10%, the LOQ) and 100% use (all commodities are treated and 100% of the non-quantifiables were assigned the LOQ).

A final published report on the FAO/WHO assessment was not available during the development of this EWG discussion paper, but the results and conclusions are consistent with the final draft assessment that was prepared by FAO/WHO and discussed at CCPR51 (CX/PR 19/51/3-Add.2). JMPR's summary also reaffirms the preliminary assessment conclusions, which are summarized below and were further re-iterated by the WHO Representative during CCPR51 plenary discussion.[6]

> *The IESTI equation is used as a proxy for estimating the acute dietary exposure at international level. According to the principles for international dietary exposure assessment, the international exposure models should be conservative in order to ensure that actual exposure of consumers in each country is lower than the international estimate and therefore that there is no appreciable risk for the population worldwide. The results of the probabilistic assessment do confirm the conservativeness of the model when compared with national assessments based on accurate data and the absence of appreciable risk for the population.* (CX/PR 19/51/3-Add.2).

Some EWG members felt that the unavailability of the final report, describing in detail the study design and the findings, impacted the discussions on the strength of the FAO/WHO study; this limited the ability of the EWG to fully deliberate on whether the findings were sufficiently conclusive with respect to the degree to which the current IESTI is protective.

Some members of the EWG were of the opinion that the study was not designed as a benchmarking exercise which compares the outcome of the currently used IESTI equation with the distribution of the exposure calculated with the Monte Carlo methodology. Others found the FAO/WHO study is congruent with many other national probabilistic assessments which have consistently demonstrated that actual exposures are far lower than those from deterministic models.

Given that members of the EWG had additional questions on the methodology and results, more detailed documentation of the study should be provided that could allow an improved interpretation of the results. In particular, understanding of the FAO/WHO report would benefit from further explanations of the following:

- Information whether the food products, for which the calculations were performed, were sufficiently representative for the total diet of the subgroup of the population assessed in the scenarios: The information on the study design did not allow to conclude whether the exposure calculations are reliable enough to predict the total exposure of the population subgroups covered by the study. If the probabilistic calculations cover only a small proportion of the food products consumed by the respective population group, the calculated exposure derived with the probabilistic calculation would underestimate the actual exposure and consequently, the results of the probabilistic exposure calculations cannot be used for a benchmarking exercise.
- In general, the calculation of the acute exposure using a probabilistic methodology can provide information on the distribution of the exposure related to the food placed on the market in the respective country. However, considering the lack of full harmonisation of national MRLs with Codex MRLs, the use of national monitoring data adds uncertainty for a benchmarking exercise validating the adequacy of the IESTI methodology used by JMPR to derive Codex MRL proposals. If national MRLs are lower than the Codex MRLs, it is expected that the respective food products placed on the market would in general contain lower residues than the residue levels in countries in which the Codex MRLs were taken over in the legislation and vice versa. Hence, the exposure calculation based on these monitoring data would not allow to draw a conclusion on the risk assessment performed by JMPR using IESTI methodology for Codex MRL proposals.
- Further details on the residue definitions for MRL compliance applicable in the countries in the countries which provided pesticide monitoring data would be useful to ensure that they match with the residue definitions of Codex.

Without these details some members felt it would be difficult to develop a conclusion on whether the FAO/WHO study provides a reliable answer to the question of whether the IESTI methodology is fit for purpose. Hence, the EWG recommends that a more detailed information be prepared by FAO/WHO which is made available to CCPR and JMPR.

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6 REP19/PR, Paragraph 190 states: "The WHO Representative informed CCPR that the FAO/WHO study on acute probabilistic dietary exposure assessment for pesticides was still a draft; found the current IESTI equation was protective as it is; and that while there might be amendments to the text, the conclusions were firm and unlikely to change during the finalization of the paper. The Representative further noted that the written comments received to date on the paper would be forwarded to the authors for their consideration when finalizing the paper."

2.3. Relevant Exposure Assessments in the Peer-Reviewed Literature

Cleveland et al (2019) published a paper which aimed at benchmarking the outcomes of IESTI calculations (current IESTI calculations and calculations according to the recommended methodology derived in the international workshop in Geneva (EFSA/RIVM, 2015)) for strawberries (12 pesticides), tomatoes (16 pesticides) and apples (8 pesticides) against refined exposure assessments (quasi-probabilistic and probabilistic calculations). For the refined exposure assessments distributions of US consumption data were combined with (i) Codex MRLs (quasi-probabilistic calculation), (ii) distribution of field trial data and (iii) distribution of US monitoring data (both probabilistic calculations). US consumption data were used in the quasi-probabilistic and the probabilistic calculations (for apples and tomatoes: consumption data of children of the age 1-6 years, for strawberries: consumption of children age of 3-6 years). A possible unit-to-unit variability for apples and tomatoes was not taken into account. For the quasi-probabilistic calculation, the exposure was calculated for the 97.5th percentile of eaters. In the scenario with supervised field trials, the 95th percentile and for monitoring data the 99.9th percentile per capita exposure was calculated.

Overall, the paper gave a ranking of exposure estimates obtained for the three food products with different calculation scenarios, normalised against the currently used IESTI methodology. Using the Codex MRL in the quasi-probabilistic calculation, exposure was in general lower than the exposure calculated with the current IESTI methodology (1.1 – 3.7 times lower). Using data from supervised field trials, the exposure (95th percentile) was 8 – 120 times lower than the IESTI estimate. In the scenario using monitoring data the difference ranged from 4.1 times lower (acetamiprid/strawberries) to 1750 times lower (methoxyfenozide/tomatoes).

The calculation based on monitoring data might be biased for cases where the US tolerance is set at a different level than the Codex MRL (see examples in footnote[7]), since the monitoring data do not necessarily reflect the Codex MRL. The quasi-probabilistic and the probabilistic calculation with results from residue trials provide answers to a question, which is close to the question of CCPR regarding the adequacy of the IESTI equations in terms of conservatism. However, the study does not allow to conclude on the reliability of the IESTI calculations to predict or exclude consumer health risks. It would be necessary to investigate in more detail the distribution at the upper tail of the exposure calculations derived with the quasi-probabilistic and probabilistic calculation scenarios and to compare the results with the ARfD.

A number of additional studies are available which may provide further details to interested readers on previous discussions on the variability factors used in IESTI equations (EFSA, 2005, 2007).

Breysse et al (2018) and van der Velde et al (2018a) investigated the impact of modifications of the IESTI equation as discussed in the international workshop in Geneva (EFSA & RIVM, 2015) on the existing EU and Codex MRLs. However, since these papers did not perform a benchmarking of IESTI calculations against a distribution of dietary exposures expected if food is consumed that complies with the Codex MRLs, they are not discussed in further detail.[8]

2.4. Summary

In summary, FAO/WHO has performed an assessment of the IESTI equations using probabilistic data on national pesticide residue levels and food commodity consumption. This includes a final draft FAO/WHO assessment that was discussed at CCPR51 and a presentation of these results at the 2019 JMPR Regular Meeting.

The results of FAO/WHO's assessment help characterize the current IESTI equation and reaffirm the conclusion reported by the WHO Representative at CCPR51 that, "found the current IESTI equation was protective." The EWG also reviewed a limited number of more recent publications in the scientific literature that provide further evaluation of the IESTI equations using probabilistic methods.

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7 US tolerance for strawberries for thiamethoxam: 0.3 mg/kg; CXL: 0.5 mg/kg
US tolerance for tomatoes for sulfoxaflor: 0.7 mg/kg; CXL: 1.5 mg/kg
US tolerance for apples for pyraclostrobin: 1.5 mg/kg; CXL: 0.5 mg/kg

8 Even though the TOR focusses on advantages and challenges of the current IESTI methodology and not on potential IESTI changes, information from these publications might be useful to have an indication on the change in number of accepted CXLs if the input variables (and the equations) are amended according to the recommendations of the international scientific workshop in Geneva in September 2015.

While information is available on the FAO/WHO assessment, the EWG was unable to review FAO/WHO's final, published report during the development of this EWG discussion paper and only brief information on results was presented to JMPR during its 2019 Regular Meeting. This limited the ability of EWG to fully deliberate on the strength of the study and whether the findings can be used to make general conclusions on the degree to which the current IESTI is protective. It is recommended that FAO/WHO provide clarifying statements to aspects raised by CCPR52. This will help inform CCPR discussion on the FAO/WHO benchmarking assessment and the more general conclusions on the IESTI methodology.

3. Review of the parameters of the IESTI equations: findings of FAO/WHO and of published in peer reviewed literature

For performing the short-term dietary intake calculations JMPR applies the following IESTI equations (equation 1 to 7) (FAO, 2016).

Case 1 applies for the following cases:

- for fruits and vegetables with a unit weight of the raw agricultural commodity less than 25 g (U_{RAC} < 25 g);
- for post-harvest uses of pesticides on cereal grains, oil seeds and pulses, as well as for meat, liver, kidney, edible offal and eggs):

Unprocessed products $$\mathrm{IESTI} = \frac{\mathrm{LP} \times \mathrm{HR}}{\mathrm{bw}}$$ Equation 1

Processed products $$\mathrm{IESTI} = \frac{\mathrm{LP} \times \mathrm{HR} - \mathrm{P}}{\mathrm{bw}}$$ Equation 2

Case 2a applies for the following cases:

- for fruits, vegetables with a unit weight of the raw agricultural commodity greater than 25 g (U_{RAC}>25 g) and a unit weight of the edible part of the raw commodity less than the large portion consumed (U_e<LP)

Unprocessed products $$\mathrm{IESTI} = \frac{\mathrm{Ue} \times \mathrm{HR} \times \mathrm{v} + (\mathrm{LP} - \mathrm{Ue}) \times \mathrm{HR}}{\mathrm{bw}}$$ Equation 3

Processed products $$\mathrm{IESTI} = \frac{\mathrm{Ue} \times \mathrm{HR} - \mathrm{P} \times \mathrm{v} + (\mathrm{LP} - \mathrm{Ue}) \times \mathrm{HR} - \mathrm{P}}{\mathrm{bw}}$$ Equation 4

Case 2b applies for the following cases:

- for fruits, vegetables with a unit weight of the raw agricultural commodity greater than 25 g (U_{RAC}>25 g) and a unit weight of the edible part of the raw commodity (U_e) greater than the large portion (U_e>LP)

Unprocessed products $$\mathrm{IESTI} = \frac{\mathrm{LP} \times \mathrm{HR} \times \mathrm{v}}{\mathrm{bw}}$$ Equation 5

Processed products $$\mathrm{IESTI} = \frac{\mathrm{LP} \times \mathrm{HR} - \mathrm{P} \times \mathrm{v}}{\mathrm{bw}}$$ Equation 6

Case 3 applies for the following cases

- for pre-harvest uses of pesticides for processed commodities where due to bulking and blending the STMR-P represents the likely highest residue;
- for cereal grains, oil seeds and pulses but also to milk.

Processed products $$\mathrm{IESTI} = \frac{\mathrm{LP} \times \mathrm{STMR} - \mathrm{P}}{\mathrm{bw}}$$ Equation 7

In the table below the individual parameters are explained, including findings on advantages and challenges that were raised in previous discussions and the resulting limitations. In this table the analysis of JMPR (JMPR Report 2006) has been integrated where JMPR concluded that IESTI and ARfD are associated with uncertainty and variability.

It is emphasised that the technical issues related to the model parameters (e.g. variability factor, unit weight, large portion) fall under the responsibility of the JMPR. Hence the information presented in Table 3 is primarily intended to support JMPR in future discussions on possible revisions of IESTI methodology or development of further guidance to describe how to derive the input values for IESTI calculations.

Table 3: Parameters used in the current IESTI equations

Parameter	Definition, explanations	Advantages	Challenges
LP	Highest large portion reported (97.5th percentile of eaters), expressed as kg food per day. The LP refers to the food as eaten (e.g. orange without peel). The LP are reported per person. LP data are usually derived for different subgroups of the population covered by a survey. Normally separate LP data are available for the general population and for children.	LP data can be derived easily, without sophisticated statistics. For the most frequently consumed products, LP are available, mainly for the RAC (raw agricultural commodities). LP data are also available for many processed products.	Different approaches exist how to derive a reliable LP, in particular on the aspects listed in the following bullet points: • Number of subjects (consumer days): To derive a reliable LP, the number of subjects having eaten a food product needs to be greater than 120 (Ambrus et Szenczi-Cseh, 2017). In the JMPR IESTI model, for exceptional cases, LP values were derived based on less than 120 days, if the data seem to be reliable. In this case, the LP is affected by a higher level of uncertainty. Richter et al (2018) recommended to calculate different percentiles (95th, 90th) in case the number of individuals that reported consumption of a pertinent food product is insufficient for calculating statistically reliably the 97.5th percentile consumption value (<41 individuals). In this case, the LP is also affected by a higher level of uncertainty. • Body weight in relation to LP: The body weight is not considered in the LP (LP is expressed as g per person per day). For food surveys that cover wider groups of the population with a high variability of body weights (e.g. general population including children), the LP per person may not reflect the most critical consumers (e.g. children with a higher consumption per kg body weight). The use of LP derived from the general population covering all age groups should be avoided when large portions are not expressed on an individual body weight basis (Van der Velde-Koerts et al, 2018b).

Parameter	Definition, explanations	Advantages	Challenges
			• Information on the method used to collect the LP consumption data are not always reported to GEMS/Food. Consequently, the LP data are considered to be affected by uncertainties (FAO, 2006). In addition, the following challenges were identified: • For less frequently consumed food products, LP data are not available. More guidance would be desirable on how to estimate the IESTI for food items for which no or no reliable large portion can be derived, because the food items are not available in the food consumption surveys or the food items are consumed by only a few consumers in a few surveys; • LP are not available for all types of processed products (e.g. for processed products falling under IESTI case 3). • LP data are available for a limited number of Codex member countries (Richter et al, 2018); for some countries data are available for the general population only. • LP data are available for different population groups, e.g. children of 2-6 years for country A and children of 1-4 years of country B. An agreement would be desirable which population groups are relevant for the IESTI and what should be the age limits and/or bodyweight limits for that population group (e.g. infants, toddlers, young children, adults).
bw	Mean body weight	Simple parameter, biometric data of the population are usually available for most food surveys.	A possible correlation of the LP and body weight is not considered in the calculations (i.e. consumption of a food item by a person with higher body weight

Parameter	Definition, explanations	Advantages	Challenges
	It is calculated for the subgroup of the population covered by the survey for which the LP is derived	If no survey specific body weight data are available, default values can be used.	may be higher compared to a person with a lower body weight). JMPR therefore recommended that the correlation between the LP and the body weight of each population should be established (FAO, 2006). See also challenges reported in the section on LP (body weight in relation to LP).
U	Unit weight of the whole commodity (as defined for MRL setting, including inedible parts). This parameter is required to decide if for a food commodity IESTI case 1 or IESTI case 2A/2B needs to be used. It is also used to derive Ue (by correcting the unit weight considering the percentage of the edible portion).	Simple parameter. If no empirically measured unit weight data are available, approximate values derived by expert judgement are used.	Median unit weight data are not always available. It is not always clear how the U values were derived and whether it refers to the whole commodity or to the edible portion (JMPR, 2006 and Richter et al, 2018). Approximate unit weight values derived by expert judgement may be questioned and can lead to disagreement. For some products it is not clear what is considered as the unit (spinach, grapes). The unit weights of food products have a high variability (depending on varieties, commercial classes, country specific requirements in trade). Using the median unit weight introduces a major source of uncertainty in the exposure assessment. Methodology how to derive the median unit weight is not standardised (e.g. defining the minimum number of units, defining how different varieties should be taken into account cherry tomatoes/medium sized tomatoes/varieties with high unit weight) (Richter et al, 2018). Lack of transparency was noted which unit weight value used in risk assessments (Richter et al, 2018).
Ue	Unit weight of the edible portion, in kg. Median value provided by the country where	Simple parameter.	See above on Unit weight (U).

Parameter	Definition, explanations	Advantages	Challenges
	the trials which gave the highest residue were carried out. Ideally, the Ue should be available at country level to combine the LP with the associated Ue. Ue is calculated from unit weight whole commodity (U) by multiplying with the percentage edible portion.		Methodology on how to derive the factor for percentage edible portion is not standardised.
v	Variability factor- the factor applied to the composite residue to estimate the residue level in a high-residue unit; defined as the residue level in the 97.5th percentile unit divided by the mean residue level for the lot. The default variability factor of 3 can be replaced by empirical variability factors, if data are available.	The originally used variability factors of 5, 7 and 10 were replaced in 2003 by the default variability factor of 3, following a review of data sets (2003 JMPR Report). Additional data were provided which confirmed the previous conclusion (2005 JMPR) of residue data from over 22000 crop units in single plots from different crops and different countries.	In some national/regional models developed for calculating the short-term dietary exposure, the variability factors of 5 and 7 are used, which lead to different outcomes of the short-term exposure calculations. Under certain conditions the default variability factor of 3 might even be too conservative (e.g. post-harvest treatments of fruits by dipping/drenching). A methodology how to derive empirical variability factors is lacking.
HR	Highest residue in composite sample of edible portion found in the supervised trials used for estimating the maximum residue level, expressed in mg/kg It refers to the residue definition for risk assessment.	Simple parameter that can be derived from residue trials without statistical knowledge from residue trials reflecting the critical GAP. When no information is available on the residue in the edible portion, usually the HR in the whole commodity is used as a conservative surrogate (JMPR, 2007).	The HR does not reflect the distribution of the results of residue trials. Due to the high variability of residue concentrations found in residue trials and the limited number of residue trials that are usually available, the use of the HR leads to a high level of uncertainty (FAO, 2006). JMPR was concerned that conducting the assessment using the HR value instead of the MRL might not assure the safety of consumers, mainly when the MRL is much larger than the HR (JMPR, 2006). JMPR recommended to incorporate statistical calculation for deriving MRLs, which would improve the consistency in the estimations of the MRL made by the JMPR based on the available data. With the introduction of the OECD calculator a statistical

Parameter	Definition, explanations	Advantages	Challenges
			methodology is used to derive MRLs. However, the gap between the HR and the MRL still exists, and hence the concerns raised by JMPR are still not fully addressed. HR data are not always available for the edible portion of the RAC; in this case the HR referring to the whole product, including the non-edible part can be used, but this leads to additional conservatism (e.g. oranges with peel) (JMPR, 2007).
HR-P	Highest residue in a processed commodity, in mg/kg, calculated by multiplying the highest residue in the raw commodity by the processing factor (PF). It also refers to the residue definition for risk assessment.	See HR and PF	In many cases, only the HR value is available, but no HR-P, due to the lack of processing studies. The use of the HR value for calculating the dietary exposure for processed products leads to additional uncertainties, as does the introduction of the processing factor. See also HR and PF.
STMR	Supervised trials median residue, in mg/kg. The STMR is the expected residue level in the edible portion of a food commodity when a pesticide has been used according to maximum GAP conditions. The STMR refers to the residue definition for risk assessment. The STMR is estimated as the median of the residue values (one from each trial) from supervised trials conducted according to the maximum GAP conditions. It is used for commodities where consignments are likely to be bulked and blended before they reach the consumer.	Simple parameter that can be derived from residue trials without statistical knowledge from residue trials reflecting the critical GAP.	See below STMR-P

Parameter	Definition, explanations	Advantages	Challenges
STMR-P	Supervised trials median residue in processed commodity, in mg/kg. The STMR-P is the expected residue in a processed commodity calculated by multiplying the STMR of the raw agricultural commodity by the corresponding processing factor (PF). The STMR also refers to the residue definition for risk assessment.	In some cases, studies are available for processed products which can be used to derive the STMR-P. See also PF.	There is no clear guidance for which products mixing and bulking/blending is reasonable (Richter et al, 2018). JMPR should be requested to review the current practice of calculating the short-term exposure according to IESTI case 3 using the STMR-P for the products listed in the Appendix, taking into account the information provided in response to the CL 2019/73-PR (see section 3). In many cases, only the STMR value is available, but no STMR-P, due to the lack of processing studies. The use of the STMR value for calculating the dietary exposure for processed products leads to additional uncertainties as does the introduction of the processing factor.
PF	The processing factor for a specified combination of a pesticide residue, commodity and food process is the residue level in the processed product divided by the residue level in the starting commodity usually a raw agricultural commodity. Basically, two processing factors can be calculated: • PF ENF: this PF is based on the residue definition for enforcement. It is used to recommend maximum residue levels for processed commodities in which the residue concentrates during processing. • PF RISK: this PF is used for dietary risk assessment.	Since processing studies are usually part of the data requirements, some data are normally made available by data providers.	Different regulatory requirements exist on the number of processing studies (number of studies, extrapolation, types of processed products for which studies are required). Reliable processing factors are not available for all processed products. Processing practices may widely differ, resulting in a high variability of residues in processed products.

Parameter	Definition, explanations	Advantages	Challenges
	For recalculating the HR and the STMR to derive the HR-P and the STMR-P the processing factor that relates to the residue definition for risk assessment is required. PF is calculated according to the following equation: $PF = \frac{residue\ concentration\ in\ processed\ pro}{residue\ concentration\ in\ unprocessed\ pr}$		

Further work to address the challenges listed in Table 3 would be valuable, but considering limited resources, any future work should be carefully prioritized.

4. Information on bulking and blending relevant for IESTI case 3

According to FAO Manual, the short-term dietary exposure calculations for processed commodities, in which the pesticide residues result from pre-harvest uses, should be performed according to Equation 7, also referred to as IESTI case 3 (see Section 2). For this case it is assumed that different consignments of raw agricultural commodities (RACs) treated with a pesticide are bulked and blended before they are processed and reach the consumers. Therefore, the STMR-P is considered a more appropriate estimate for the residue present in the products consumed than the HR-P.

In the Appendix, the commodities/product groups are listed for which JMPR calculates the short-term exposure according to IESTI case 3. For pulses, cereals and oilseeds (unprocessed products, raw agricultural commodities), the calculations are performed according to case 1, where post-harvest treatment is relevant.

It is noted that according to the current practice of JMPR, IESTI case 3 calculations are performed not only for processed products, but also for unprocessed products, where the STMR is used instead of the STMR-P (Equation 8).

Unprocessed products $$\mathrm{IESTI} = \frac{\mathrm{LP} \times \mathrm{STMR}}{\mathrm{bw}}$$ Equation 8

The Appendix also comprises certain commodities where short-term dietary intake calculations are performed according to case 1 or 2, which may need to be reconsidered.

In the framework of CL 2019/73-PR information on the most common and usual bulking and blending practices should be collected in order to decide whether the currently used practices of JMPR are justified and for which a median residue (STMR or STMR-P) is appropriate for calculating the dietary risk assessment.

Information on bulking and blending was submitted from eight individual Member States including Australia, Canada, Egypt, Japan, Mexico, Thailand, United Kingdom, and USA. Information was also provided by thirteen trade organizations; BSDA (British Soft Drink Association), BFJA (British Fruit Juice Association), California Almond Board, California Citrus Quality Control, COCERAL (the EU traders association of cereals, grains, rice, fats, olive oil, oilseeds, feedstuff and agro-supply chain), FIVS (an international federation serving trade associations and companies in the alcohol beverage industry from around the world), GAFTA (the Grain and Feed Trade Association), IFU (International Fruit and Vegetable Juice Association), INC (International Nut and Dried Fruit Council), THIE (Tea & Herbal Infusions Europe), US Grain Council, US Wine Institute, US Wild Blueberry Commission of Maine, WPTC (World Processing Tomato Council).

The information received included descriptive and/or quantitative information on bulking and blending practices for several raw and processed commodities such as cereal grains, oilseeds, pulses, GM soya beans, citrus juice, apple juice, wine grapes & wine, raw & frozen blueberries, strawberry puree, frozen durian, canned pineapple, mango puree, tomato puree, tomato paste, tomato juice, dried fruits, tree nuts, sugar cane sugar, tea and herb tea.

Bulking and blending was shown for all commodities investigated, except for pineapples. Quantitative information on bulking and blending before and during jam/jelly/marmalade production, canning of fruits and vegetables, freezing of fruits and vegetables, oil production and milling is limited or absent and would be desirable. Codex Members are encouraged to contact trade organizations in their country to provide quantitative information on bulking and blending for these processes.

The compilation of information on bulking and blending shall be provided to JMPR for their review and consideration. In the Appendix, a general overview on the submitted information is given; more details on the type of information submitted in response to the Circular Letter can be found in a separate document (Annex to this discussion paper), where all contributions are compiled.

It is noted that the information on bulking and blending practices was collected in response to the CL which requested information for the most common practices for industrially produced products and products traded internationally. Since the data collection was not intended for speciality products (e.g. products with direct marketing by farmers, niche products) or for products that are produced at household level, these practices may not be fully representative for all products placed on the market and consumed.

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Appendix I - Information on bulking and blending submitted in response to the CL 2019/73-PR (English only)

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
Dry pulses (RAC)	VD 0071 VD 0523 (VD 0541 VD 0072 VD 0524 VD 0533	Beans (dry) Broad bean (dry) Soya bean (dry) Peas (dry) Chick-pea (dry) Lentil (dry)	In the current JMPR IESTI model dry pulses are treated in two ways: pre-harvest treatment = case 3 post-harvest treatment = case 1	Australia Canada Japan United Kingdom (soya beans) United Kingdom (information provided by GAFTA) USA COCERAL (beans, soya beans, peas (dry))
Cereal grains (RAC)	GC 0650 GC 0654 GC 0640 GC 0641 GC 0647 GC 0649 GC 0646 GC 0651 GC 0645	Rye Wheat Barley Buckwheat Oats Rice Millet Sorghum grain Maize (corn)	In the current JMPR IESTI model cereal grains are treated in two ways: pre-harvest treatment = case 3 post-harvest treatment = case 1	Australia Canada Japan United Kingdom (information provided by GAFTA) USA COCERAL
Oilseeds (RAC)	SO 0090 SO 0495 SO 0691 SO 0693 SO 0696a SO 0696b SO 0697 SO 0698 SO 0699 SO 0700 SO 0702 - -	Mustard seed Rape seed Cotton seed Linseed (Flax-seed) Palm kernels Palm fruit Peanut, shelled Poppy seed Safflower seed Sesame seed Sunflower seed Borage seeds Cucurbitaceae seeds	In the current JMPR IESTI model oilseeds are treated in two ways: pre-harvest treatment = case 3 post-harvest treatment = case 1	Australia (rapeseed, cotton seed) Canada Japan United Kingdom (information provided by GAFTA) USA COCERAL (rape seed, sunflower seed)
Treenuts (RAC)	TN 0295 TN 0660 TN 0660 TN 0662 TN 0664 TN 0666 TN 0669 TN 0672 TN 0673 TN 0675 TN 0678	Cashew nut Almonds Almonds Brazil nut Chestnuts Hazelnut Macadamia nut Pecan Pine nut Pistachio nut Walnut	In the current JMPR IESTI model treenuts (nutmeat) are treated as case 1 commodities. The case 1 classification used by the JMPR is challenged because treenuts are industrially bulked or blended (over several farms or pesticide treatment regimes).	Japan USA (Almonds) INC
	TN 0665	Coconut	The unit weight of a coconut is much higher than 25 g, for which case 2 applies.	-
	VR 0596	Sugar beet (RAC)	The unit weight of a sugar beet is much higher than 25 g, for which case 2 applies. However, as raw sugar beets are not	Japan

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
			consumed, only the extracted sugar, sugar beets are treated as case 3 in the current JMPR IESTI model.	
	GS 0659	Sugar cane (RAC)	The unit weight of a sugarcane is much higher than 25 g, for which case 2 applies. However, as raw sugarcanes are not consumed, only the extracted sugar, sugar cane is treated as case 3 in the current JMPR IESTI model.	Japan Thailand
	SB 0715 (RAC)	Cocoa beans	Cocoa beans (RAC) are roasted. Various products are prepared: cocoa mass, cocoa powder, cocoa butter. Cocoa beans and its products are treated as case 3 in the current JMPR IESTI model.	Japan USA
	SM 0716 (RAC)	Coffee beans	Green coffee beans (RAC) are roasted. Coffee beans and its products are treated as case 3 in the current JMPR IESTI model.	Japan USA
	DH 1100	Hops, dry (RAC)	In the current JMPR IESTI model dry hops are treated as case 3 commodities.	Japan USA
Dried tea	DT 1114	Tea, green, black (RAC)	In the current JMPR IESTI model dried tea is treated as case 3 commodity.	Japan THIE
Dried herb teas	DT 0446 DT 1110 DT 1113 - - (RAC)	Roselle (RAC) Camomile (RAC) Mate (RAC) Rooibos leaves (RAC) Valerian root	In the current JMPR IESTI model dried herb teas are treated as case 3 commodities.	Japan USA THIE (camomile, mate, rooibos, valerian root, roselle hibiscus, rose hips, fruits)
Canned fruits	FC 0003 FC 0005 FT 0337 FI 0345 FI 0350 FI 0353 FI 0341	Subgroup of Mandarins Subgroup of Grapefruits Guava Mango Papaya Pineapple Kiwifruit	Canned fruits, which are divided in parts or cut to pieces before being canned, are treated as case 3 in the current JMPR IESTI model.	Japan (mandarins, strawberries, pears, peaches) Thailand (pineapple),
	DM 0305 FB 0020 FB 0021 FB 0264	Table olives Blueberries Currants, black, red, white Blackberries	Canned fruits, which can be derived from a single fruit because whole fruits or fruit halves are canned, are treated as case 1 or case 2 in the	Canada (blueberries)

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
	FB 0265	Cranberry	current JMPR IESTI model, depending on the weight of the canned fruit units. Some of these case 1 and case 2 classifications used in the JMPR IESTI model are challenged. Canned pineapple is cut to pieces or slices before being canned and is treated as case 3 in the current JMPR IESTI model because it does not refer to the original unit weight. However, canned pineapple could also be treated as case 2, because a single pineapple can end up in a single can. Canned/preserved table olives and canned litchis still represent the original fruits and can still be considered as individual units (U<25 g) and hence are considered case 1 in the current JMPR IESTI model as is the RAC. However, canned/preserved table olives and canned litchis could also be treated as case 3 because the commodities are industrially bulked or blended (over several farms or pesticide treatment regimes).	
	FB 0269	Grapes		
	FB 0272	Raspberries, red, black		
	FB 0275	Strawberry		
	FI 0343	Litchi		
	FP 0230	Pear		
	FS 0013	Subgroup of Cherries		
	FS 0014	Subgroup of Plums		
	FS 0240	Apricot		
	FS 0245	Nectarine		
	FS 0247	Peach		
Canned vegetables	VA 0381	Garlic	Canned vegetables, which are divided in parts or cut to pieces before being canned, are treated as case 3 in the current JMPR IESTI model.	-
	VA 0385	Onion, bulb		
	VA 0384	Leek		
	VB 0041	Cabbages, head		
	VC 0431	Squash, Summer		
	VC 0046	Melons		
	VO 0440	Egg plant (Aubergine)		
	VL 0476	Endive (i.e. Escarole)		
	VL 0502	Spinach		
	VL 0480	Kale		
	VR 0574	Beetroot		
	VR 0578	Celeriac		
	VR 0498	Salsify (Oyster plant)		
	VR 0497	Swede (Rutabaga)		
	VS 0624	Celery		

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
	VS 0622	Bamboo shoots		
	GC 1275	Sweet corn kernels		
	HH 0624	Celery leaves		
	HS 0784	Ginger, root		
	VB 0402	Brussels sprouts	Canned vegetables that can be derived from a single vegetable because whole vegetables or vegetable halves are canned are treated as case 1 or case 2 in the current JMPR IESTI model, depending on the weight of the canned vegetable. Some of these case 1 and case 2 classifications used in the JMPR IESTI model are challenged. Canned green peas without pods still represent the original seeds and can still be considered as individual units (U<25 g) and hence are considered case 1 in the current JMPR IESTI model as is the RAC. However, canned green peas without pods could also be treated as case 3 because the commodity is industrially bulked or blended (over several farms or pesticide treatment regimes). Canned carrots are generally small (whole) carrots and these can still be considered as individual units (U<25 g) and hence are considered case 1 in the current JMPR IESTI model. However, canned carrots could also be treated as case 3 because the commodity is industrially bulked or blended (over several farms or pesticide treatment regimes).	-
	VF 0449	Fungi, edible, except mushrooms (mainly wild)		
	VF 0450	Mushrooms (cultivated)		
	VL 0269	Grape leaves		
	VO 0445	Peppers, sweet (incl. pimiento)		
	VO 0448	Tomato		
	VP 0061	Green beans with pods (immature)		
	VP 0062	Green beans without pods (succulent seeds)		
	VP 0064	Peas without pods (succulent seeds)		
	VP 0523	Broad bean without pods (succulent seeds)		
	VR 0577	Carrot		
	VR 0589	Potato		
	VS 0620	Artichoke globe		
	VS 0621	Asparagus		
	VS 0626	Palm hearts		
	GC 3081	Baby corn		
Canned pulses	VD 0071	Beans (dry)	In the current JMPR IESTI model canned pulses are treated in two ways: pre-harvest treatment = case 3 post-harvest treatment = case 1	See dry pulses (RAC)
	VD 0523	Broad bean (dry)		
	VD 0072	Peas (dry) (Pisum spp)		
	VD 0524	Chick-pea (dry)		
	VD 0533	Lentil (dry)		
Dried fruits	FI 0327	Banana	Dried fruits which are divided in parts or cut to pieces before being dried are treated as case 3 in the current JMPR IESTI	INC
	FI 0345	Mango		
	FI 0353	Pineapple		
	FI 0350	Papaya		

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
	FT 0305	Table olives	model.	
	DF 0014	Subgroup of Plums (i.e. prunes)	Dried fruits that can be derived from a single fruit (because the original fruit or the fruit halve is dried), are treated as case 1 or case 2 in the current JMPR IESTI model, depending on the weight of the dried fruit. Some of these case 1 and case 3 classifications used in the JMPR IESTI model are challenged. Dried grapes (raisins, currants and sultanas) are derived from grape berries and a such the berry is not cut into pieces and can still be considered an individual unit (U<25g) and hence is considered case 1 in the current JMPR IESTI model. However, dried grapes could also be treated as case 3 because the commodity is industrially bulked or blended (over several farms or pesticide treatment regimes). Dried cranberries still represent the original berries and can still be considered an individual unit (U<25g) and hence is considered case 1 in the current JMPR IESTI model as is the RAC. However, dried cranberries could also be treated as case 3 because the commodity is industrially bulked or blended (over several farms or pesticide treatment regimes).	INC (raisins)
	DF 0226	Apple		
	DF 0240	Apricot		
	DF 0269	Grapes (i.e. raisins, currants, sultanas)		
	DF 0295	Date		
	DF 0297	Fig		
	FB 0020	Blueberries		
	FB 0021	Currants, black, red, white		
	FB 0264	Blackberries		
	FB 0265	Cranberry		
	FB 0272	Raspberries, red, black		
	FB 0275	Strawberry		
	FB 1235	Table grapes (i.e. raisins, currants, sultanas)		
	FI 0343	Litchi		
	FP 0230	Pear		
	FP 0307	Persimmon, Japanese (i.e. Kaki fruit)		
	FS 0013	Subgroup of Cherries		
	FS 0245	Nectarine		
	FS 0247	Peach		
	FT 0289	Carambola		
	VF 0449	Fungi, edible, except mushrooms (mainly wild)		
	VF 0450	Mushrooms (cultivated)		
	VO 0444	Peppers, chili		
	VO 0448	Tomato		
	VO 2704	Goji berry		
	VP 0061	Beans with pods		
	VP 0064	Peas without pods (succulent seeds)		

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
Dried vegetables	VR 0587	Parsley, turnip-rooted	Dried vegetables which are divided in parts or cut to pieces before being dried are treated as case 3 in the current JMPR IESTI model.	-
	VA 0381	Garlic		
	VA 0385	Onion, bulb		
	VA 0384	Leek		
	VB 0400	Broccoli		
	VB 0404	Cauliflower		
	VB 0041	Cabbages, head		
	VC 0431	Squash, Summer		
	VC 0046	Melons		
	VO 0445	Peppers, sweet		
	VO 0440	Egg plant		
	VL 0465	Chervil		
	VL 0502	Spinach		
	VL 0480	Kale		
	VR 0577	Carrot		
	VR 0578	Celeriac		
	VR 0588	Parsnip		
	VR 0506	Turnip, garden		
	VR 0589	Potato		
	VS 0621	Asparagus		
	GC 0447	Sweet corn (on-the-cob)		
	GC 1275	Sweet corn (kernels)		
	VF 0449	Fungi, edible, except mushrooms (mainly wild)	Dried vegetables that can be derived from a single commodity (because the original vegetable is dried), are treated as case 1 or case 2 in the current JMPR IESTI model, depending on the weight of the dried commodity.	-
	VF 0450	Mushrooms (cultivated)		
	VO 0444	Peppers, chili		
	VO 0448	Tomato		
	VO 2704	Goji berry		
	VP 0061	Beans with pods (immature pods with seeds)		
	VP 0064	Peas without pods (succulent seeds)		
Dried herbs and dried spices	HH 0624	Celery leaves	Herbs and spices are divided in parts or cut to pieces before being dried and are treated as case 3 in the current JMPR IESTI model. Some dried spices are ground to powders before being traded.	THIE (mint, lemongrass, sage, ginger roots)
	DH 0722	Basil		
	DH 0723	Bay leaves		
	HH 0733	Hyssop		
	DH 0736	Marjoram		
	DH 0738	Mints		
	HH 0740	Parsley		
	DH 0741	Rosemary		
	DH 0743	Sage		
	HH 0745	Savory, summer, winter		
	HH 0749	Tarragon		
	DH 0750	Thyme		
	HH 0756	Coriander leaves		

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
	HH 0761	Lemongrass		
	HS 0783	Galangal, rhizomes		
	HS 0794	Turmeric, root		
	HS 0784	Ginger, root		
Fruit juices	FC 0204	Lemon	No unit weight can be assigned to fruit juices and they are treated as case 3 in the current JMPR IESTI model.	United Kingdom (information provided by BSDA and BFJA) USA IFU (orange, pome fruit juice, pineapple, mango juice)
	FC 0205	Lime		
	FC 0003	Subgroup of Mandarins		
	JF 0004	Subgroup of Oranges		
	FC 0005	Subgroup of Pummelo		
	JF 0226	Apple		
	FP 0230	Pear		
	FP 2220	Azarole		
	FS 0013	Subgroup of Cherries		
	FS 0240	Apricot		
	FS 0245	Nectarine		
	FS 0247	Peach		
	FS 0014	Subgroup of Plums		
	FB 0272	Raspberries, red, black		
	FB 0264	Blackberries		
	FB 0020	Blueberries		
	FB 0021	Currants, black,		
	FB 0273	Rose hips		
	FB 0267	Elderberries		
	JF 0269	Grapes		
	FB 1236	Wine grapes		
	FB 0275	Strawberry		
	FB 0265	Cranberry		
	FT 0287	Barbados cherry (acerola)		
	FT 0338	Guava		
	FI 0343	Litchi		
	FI 0327	Banana		
	FI 0345	Mango		
	FI 0350	Papaya		
	JF 0341	Pineapple		
	FI 0365	Soursop (Guanabana)		
	FI 0351	Passion fruit (maracuja)		
	FI 0355	Pomegranate		
	FI 0341	Kiwifruit		
	FI 2483	Cupuaçu		
Vegetable and herb juices	VA 0385	Onion, bulb	No unit weight can be assigned to vegetable and herb juices and they are treated as case 3 in the current JMPR IESTI	USA IFU (tomato juice) WPTC (tomato juice)
	VC 0424	Cucumber		
	VC 0429	Pumpkins		
	VC 0046	Melons		

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
	VC 0432	Watermelon	model.	
	JF 0448	Tomato		
	VO 0445	Peppers, sweet		
	VL 0510	Cos lettuce		
	VL 0482	Lettuce, head		
	VL 0483	Lettuce, leaf		
	VL 0502	Spinach		
	VR 0574	Beetroot		
	VR 0577	Carrot		
	VR 0578	Celeriac		
	VS 0624	Celery		
	HH 0722	Basil		
	HH 0738	Mints		
	HH 0740	Parsley		
Jams, jellies, marmalades	FC 0204	Lemon	No unit weight can be assigned to jams, jellies and marmalades and they are treated as case 3 in the current JMPR IESTI model.	USA
	FC 0003	Subgroup of Mandarins		
	FC 0004	Subgroup of Oranges		
	FP 0226	Apple		
	FP 0231	Quince		
	FS 0013	Subgroup of Cherries		
	FS 0014	Subgroup of Plums		
	FS 0240	Apricot		
	FS 0245	Nectarine		
	FS 0247	Peach		
	FB 0264	Blackberries		
	FB 0272	Raspberries, red, black		
	FB 0020	Blueberries		
	FB 0021	Currants, black, red,		
	FB 0273	Rose hips		
	FB 0267	Elderberries		
	FB 0265	Cranberry		
	FB 0275	Strawberry		
	FT 0297	Fig		
	FI 0353	Pineapple		
	HS 0784	Ginger, root		
Essential oils	FC 0204	Lemon	No unit weight can be assigned to oils and they are treated as case 3 in the current JMPR IESTI model.	USA
	FC 0205	Lime		
	FC 0004	Subgroup of Oranges		
	FC 0005	Subgroup of Pummelo		
Olive oil	OR 0305	Olives for oil extraction	No unit weight can be assigned to oils and they are treated as case 3 in the current JMPR IESTI model.	USA
Refined oils	OR 0541	Soya bean (dry)	No unit weight can be assigned to oils and they are treated as case 3 in the current JMPR IESTI	USA
	GC 0649	Rice (bran oil)		
	OR 0645	Maize (corn)		

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
	TN 0295	Cashew nut	model.	
	TN 0660	Almonds		
	OR 0665	Coconut		
	TN 0672	Pecan		
	TN 0678	Walnut		
	OR 0495	Rape seed		
	OR 0691	Cotton seed		
	SO 0693	Linseed (Flax-seed)		
	OR 1240	Palm kernels		
	OR 0696	Palm fruit		
	OR 0697	Peanut, shelled		
	SO 0698	Poppy seed		
	OR 0699	Safflower seed		
	OR 0700	Sesame seed		
	OR 0702	Sunflower seed		
	-	Borage seeds		
	-	Cucurbitaceae seeds		
	-	Grape seed		
	TN 0669	Macadamia nut		
Industrially prepared sauce/puree	FP 0226	Apple	The large portions derived from food surveys relate to sauce/puree that has been bought in a shop and hence represent industrial procedures. No unit weight can be assigned to sauce/puree and hence sauce/puree is treated as case 3 in the current JMPR IESTI model. The case 3 classification used in the JMPR IESTI model is challenged. Sauce/puree does not necessarily imply industrial processing, but can also relate to household processing. When household processing is taken into account, case 1 would be more appropriate.	Japan United Kingdom (information provided by BSDA and BFJA) USA
	FP 0230	Pear		
	FS 0014	Subgroup of Plums		
	FS 0240	Apricot		
	FB 0272	Raspberries, red, black		
	FB 0020	Blueberries		
	FB 0021	Currants, black, red		
	FB 0265	Cranberry		
	FB 0275	Strawberry		
	FI 0369	Tamarind (sweet)		
	FI 0327	Banana		
	FI 0345	Mango		
	VS 0627	Rhubarb		
	VO 0448	Tomato		
Industrially prepared paste	VO 0448	Tomato	The large portions derived from food surveys relate to paste that has been bought in a shop and hence represent industrial procedures. No unit weight can be assigned to paste and hence paste is treated as case 3 in the current JMPR IESTI model.	USA WPTC (tomato paste)
	VO 0444	Peppers, chili		
Wine	FB 0269	Grapes	A single wine bottle does not contain the wine from a single	USA FIVS
	FB 1236	Wine grapes		

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
			grape bunch. No unit weight can be assigned to wine and wine is therefore treated as case 3 in the current JMPR IESTI model. The case 3 classification used in the JMPR IESTI model is challenged. Case 3 would postulate that wine grapes or wine from different producers are bulked/pooled. Wine could also be treated as case 1 because it is not unlikely that wine is coming from one vineyard, and thus, the HR would be a more appropriate estimator for the residues in wine.	
Industrially frozen	FS 0245 FS 0247 VA 0381 VA 0385 VA 0384 VB 0400 VB 0404 VB 0041 VC 0431 VO 0445 VL 0476 VL 0502 VL 0480 VR 0574 VR 0577 VR 0578 VR 0589 VS 0621 GC 0447 GC 1275 HH 0624 HH 0740	Nectarine Peach Garlic Onion, bulb Leek Broccoli Cauliflower Cabbages, head Squash, Summer Peppers, sweet) Endive (i.e. Escarole) Spinach Kale (Borecole, Collards) Beetroot Carrot Celeriac Potato Asparagus Sweet corn (on-the-cob) Sweet corn (kernels) Celery leaves Parsley	The large portions derived from food surveys relate to frozen commodities that have been bought in a shop and hence represent industrial procedures. Fruits and vegetables are generally cut to pieces and blanched before being frozen industrially. Units weight cannot be assigned to such frozen commodities and the listed frozen commodities are therefore treated as case 3 in the current JMPR IESTI model. Frozen commodities do not necessarily imply industrial processing, but can also relate to household processing. When household processing is taken into account, case 1 would be more appropriate.	Thailand (durian (frozen) USA (blueberries)
	FB 0020 FB 0275 VB 0402 VP 0062	Blueberries Strawberry Brussels sprouts VP 0061Beans with pods: (immature pods + succulent seeds) Beans without pods:(succulent seeds)	Frozen fruits and vegetables that can be derived from a single commodity (because the original fruit or vegetable is frozen), are treated as case 1 or case 2 in the current JMPR IESTI model, depending on the weight of the frozen commodity.	<u>High bush blueberries:</u> Canada <u>Low-bush blueberries:</u> Canada USA

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
	VP 0063 VP 0064 VP 0523	Peas with pods: (immature pods + succulent seeds) Peas without pods (succulent seeds) Broad bean without pods (succulent seeds)	The case 3 classification used in the JMPR IESTI model is challenged.	
Sauerkraut	VB 0041	Cabbages, head	Cabbages are cut to pieces before being transformed into sauerkraut.	
Industrial deep-fried – French fries	VR 0589	Potato	The large portions derived from food surveys relate to French fries that have been bought in a shop and hence represent industrial procedures. Potatoes are cut to pieces before being transformed into French fries.	
Industrial deep-fried – Crisps	VR 0589	Potato	The large portions derived from food surveys relate to crisps that have been bought in a shop and hence represent industrial procedures. Potatoes are cut to thin slices before being transformed into crisps.	
Industrial pickled	VA 0384 VB 0041 VC 0424 VO 0445 VL 0466 VR 0574 VR 0577 VL 0468 VL 0485	Leek Cabbages, head Cucumber Peppers, sweet Chin cabbage (Pak-choi) Beetroot Carrot Flowering white cabbage Mustard greens	The large portions derived from food surveys relate to pickles that have been bought in a shop and hence represent industrial procedures.	
	HS 0773 VA 0385 VC 0425	Caper buds Onion, bulb Gherkin	Pickled vegetables which are divided in parts or cut to pieces before being dried are treated as case 3 in the current JMPR IESTI model. Pickled vegetables that can be derived from a single commodity (because the original vegetable is pickled), are treated as case 1 or case 2 in the current JMPR IESTI model, depending on the weight of the pickled	

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
			commodity.	
Starch	VR 0573 VR 0463 VR 0589 VR 0504	Arrowroot Cassava (Manioc) Potato Tannia	No unit weight can be assigned to starch and starch is treated as case 3 in the current JMPR IESTI model.	
Coconut milk	TN 0665	Coconut	No unit weight can be assigned to coconut milk and it is treated as case 3 in the current JMPR IESTI model.	
Butter/paste	SO 0697 SO 0700 DM 1215	Peanut, shelled Sesame seed Cocoa beans	No unit weight can be assigned to butter/paste and it is treated as case 3 in the current JMPR IESTI model.	
Miso, soya sauce and tofu	VD 0541	Soya bean (dry)	No unit weight can be assigned to miso, soya sauce and tofu and it is treated as case 3 in the current JMPR IESTI model.	
Milk	VD 0541 GC 0650	Soya bean (dry) Rice	No unit weight can be assigned to milk and it is treated as case 3 in the current JMPR IESTI model.	
Flour of pulses and oilseeds	VD 0541 VD 0072 VD 0524 SO 0090	Soya bean (dry) Peas (dry) Chick-pea (dry) Mustard seed	No unit weight can be assigned to flour and it is treated as case 3 in the current JMPR IESTI model.	
Flour of fruits and vegetables	FT 0291 VR 0589 VR 0504 VR 0463 VR 0508	Carob Potato Tannia (Tanier, Yautia) Cassava (Manioc) Sweet potato	No unit weight can be assigned to flour and it is treated as case 3 in the current JMPR IESTI model.	
Bran, germ, grits, flour, starch	GC 0640 GC 0641 GC 0647 GC 0649 GC 0645 GC 0646 GC 0650 GC 0651 GC 0654	Barley Buckwheat Oats Rice Maize (corn) Millet Rye Sorghum grain Wheat	No unit weight can be assigned to cereal milling products and they are treated as case 3 in the current JMPR IESTI model.	See cereal grains (RAC)
Beer and malt	GC 0650 GC 0654 GC 0649	Rye Wheat Rice	No unit weight can be assigned to beer and malt and they are	See cereal grains (RAC)

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
	GC 0646 GC 0651 GC 0645 GC 0640	Millet Sorghum grain Maize (corn) Barley	treated as case 3 in the current JMPR IESTI model.	
Flakes	GC 0650 GC 0654 GC 0640 GC 0641 GC 0647 GC 0645	Rye Wheat Barley Buckwheat Oats Maize (corn)	In the current JMPR IESTI model flakes are treated as case 3 commodities.	See cereal grains (RAC)

General comments (not related to individual commodities listed above):

Mexico: Considering that there are many companies that sell the products listed above, they have several warehouses where they receive products from their different suppliers, it is common that these products come from various farms, warehouses, and therefore from different pre and post-harvest treatment regimes.

It is important to note that the export of agricultural products will require information requested by the exporting country, as in the case of the European Union where the directives of the European Parliament and the council indicate that one of the production level requirements to be reported It is the pre and post-harvest treatment of the product to be exported, so this information could be obtained from the quality report provided by the exporter. (Google translation of comments submitted in Spanish).

Egypt:

We think that may some internationally traded or consumed portion of the commodities can be derived from a single commodity unit, a single farm or a single storage facility or a single pesticide treatment regime. In Egypt there are no applied quality control systems to refer all single products back to their producing farms, but there is an applied control system on some commodities such as (Citrus Fruits, Strawberry, Guava and Potatoes).

The internationally traded or consumed portion of the commodities listed in Annex I of the CL are usually bulked or blended over several farms (in case of pre-harvest treatments), over several storage facilities (in case of post-harvest treatments) or over several pesticide treatment regimes (in case of large production farms) before the commodity is internationally traded or consumed.

Bulking and blending is used to fulfil the requested traded quantities for the international traded commodities, it should be derived from several farms (which will be using different pesticides with different storage facilities); to reach a degree of grade for some commodities, food operators has to mix or bulk commodities from different farms. Upon the request of buyer, to fulfil quality requirement related to sizes for instant.

In Egypt, the coded farms have records for the quantitative and quantitative description.

(a) Commodities/group of products which are calculated according to IESTI case 3 (for pre-harvest treatments) or IESTI case 1 (if post-harvest treatment is relevant) are presented without shading.
Commodities/groups of products for which it is current JMPR practice to calculate short-term dietary exposure according to case 1 or 2 are shaded in grey.

APPENDIX XIV

ENGAGEMENT OF JMPR IN PARALLEL REVIEWS OF NEW COMPOUNDS
PROPOSED PROCEDURES AND PRINCIPLES

(For reference by CCPR)

2 – SELECTION OF PESTICIDES FOR JMPR EVALUATION

2.1 – Nomination process - timelines

- The current timelines for the nomination of new compounds would also apply to those part of a parallel review process.
    - September - November 30 – EWG on Priorities' request for nominations: Codex Committee on Pesticide Residues (CCPR) members/observers submit nominations for a new compound, indicating if they would like JMPR to engage in a parallel review, which countries have agreed to engage in the review, and when data packages, including the proposed GAP, will be available. (*Note: Should the process be officially adopted, the nomination form would need to be amended accordingly*).
    - January – EWG on Priorities circulates proposed Schedule and Priority List for Comments
    - April – CCPR agrees to forward the JMPR Evaluation Schedule for the following year to the Codex Alimentarius Committee (CAC) for approval.
    - July – CAC approves the proposed JMPR Evaluation Schedule for the following year.

2.2 – Nomination requirements and criteria for the prioritization and scheduling pesticides for evaluation by JMPR[1]

- **Nomination requirements – new pesticides[2]**

  The current nomination requirements of new pesticides would also apply to those part of a parallel review process:
    - An intention[3] to register the pesticide for use in a member country, or more than one member country for pesticides that will undergo a JMPR parallel review.
    - The foods or feeds proposed for consideration should be traded internationally.
    - There is a commitment by the member/observer of the pesticide to provide supporting data for review in response to the JMPR "data call-in".
    - The use of the pesticide is expected to give rise to residues in or on a food or feed moving in international trade.
    - The pesticide has not been already accepted for consideration.
    - The nomination form has been completed.
- **Prioritization criteria[4]**

  The current prioritization criteria of new pesticides would also apply to those part of a parallel review process, such as:
    - Timing of data availability.
    - Commitment by the member/observer to provide supporting data for review with a firm date for data submission.
    - The provision of information on the foods or feeds for which CXL are sought and the number of trials for each food or feed.

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1 The ~~latest edition of the~~ Risk Analysis Principles applied by CCPR can be found in the Procedural Manual of the Codex Alimentarius Commission (CAC) available on the Codex website at: http://www.fao.org/fao-who-codexalimentarius/publications/en/

2 CAC Procedural Manual, Section IV – Risk Analysis, Risk Analysis Principles applied by CCPR, sub-section 5.2.2, paragraph 61

3 A complete data package may have been submitted to participating countries – or – countries have agreed to participate in a parallel review.

4 CAC Procedural Manual, Section IV – Risk Analysis, Risk Analysis Principles applied by CCPR, sub-section 5.2.2, paragraph 62

- **Scheduling criteria**[5]

1. The current scheduling criteria requires a pesticide to be registered for use in a country and formulation labels available to allow the scheduling of a compound for JMPR evaluation in the following year.

2. Considering that a parallel review implies the JMPR assessment of a pesticide prior to its registration in a country, a new sub-paragraph would be needed to acknowledge this new sub-category as follows:

   Only pesticides nominated for a parallel review will be exempted from the requirement for a national registration at the time of scheduling. In order for CCPR to agree to having a pesticide evaluated by the JMPR as part of a parallel review, the complete data package as required by JMPR (see data categories in section 4.2.) must be made available at, or shortly after the CCPR meeting. This will allow JMPR to initiate the parallel review process as soon as the product nominations are approved by CAC in July of each year.

3 – JMPR CALL FOR DATA

3. The JMPR Secretariat typically develops the JMPR assignment list, and assigns compounds for review by FAO/WHO experts in the last quarter of the calendar year. The JMPR call for data is typically undertaken in November with a submission deadline of late-December. It is suggested that the JMPR Secretariat consider early planning for parallel reviews (i.e. early identification of evaluators and early data-intake).

4 – PARALLEL REVIEW

4.1 – Project management

4. It is suggested to identify a global project manager to oversee the parallel review, in close collaboration with the WHO/FAO JMPR Secretariat/JMPR reviewers and national points of contact (governments). The global project manager would liaise with all parties including the sponsors and ensure that the identified timelines and milestones are met throughout the process which includes the conduct of the data completeness check.

4.2 - Interaction between national and JMPR reviewers

5. The nature of parallel reviews implies that it is conducted concurrently with national reviews and that the interaction between reviewers may occur to discuss scientific matters related to the data packages.

6. To optimize the participation of the JMPR in the parallel review process, the JMPR reviewers would be assigned following the endorsement of the schedule by CAC in July, and submission of the JMPR dossier could also occur shortly thereafter (prior to the regular data call-in). The JMPR Secretariat will carefully select the JMPR reviewers to ensure they are not the same experts as the ones involved in the national registration process.

7. To support information-sharing and the engagement of the JMPR reviewers in the parallel review, the contact information of the JMPR reviewer would be provided to the global project manager responsible for coordinating the joint review.

8. The concept of parallel reviews also requires that the exact same data package for toxicology, product chemistry, residue chemistry, including metabolism and environmental fate, be provided to national regulatory agencies and JMPR.

9. In the event that additional toxicology or residue chemistry information is provided to one party, sponsors must ensure that it is provided to all other parties, including JMPR, such that data packages under review remain identical.

4.3 - Parallel review timelines

10. Other than an earlier review start by national authorities, it is possible that the parallel review will take place over two JMPR Meetings (see table 1; while timelines are outdated they are intended for reference purposes only). Should that be the case, there would be an opportunity for the JMPR reviewer engaged in the parallel review to discuss metabolites /residue definition for MRL enforcement during the JMPR meeting of the first cycle (about a year following the beginning of the parallel review).

4.4 - Changes to the draft label

11. Should final conditions of registration (i.e., application rate, number of applications, etc) in member countries differ from the GAP reviewed by the JMPR, the expert would apply the FAO 25% variation rules, proportionality or any other applicable approach, to determine whether the recommended maximum residue limits must be recalculated and the dietary risk assessments reviewed.

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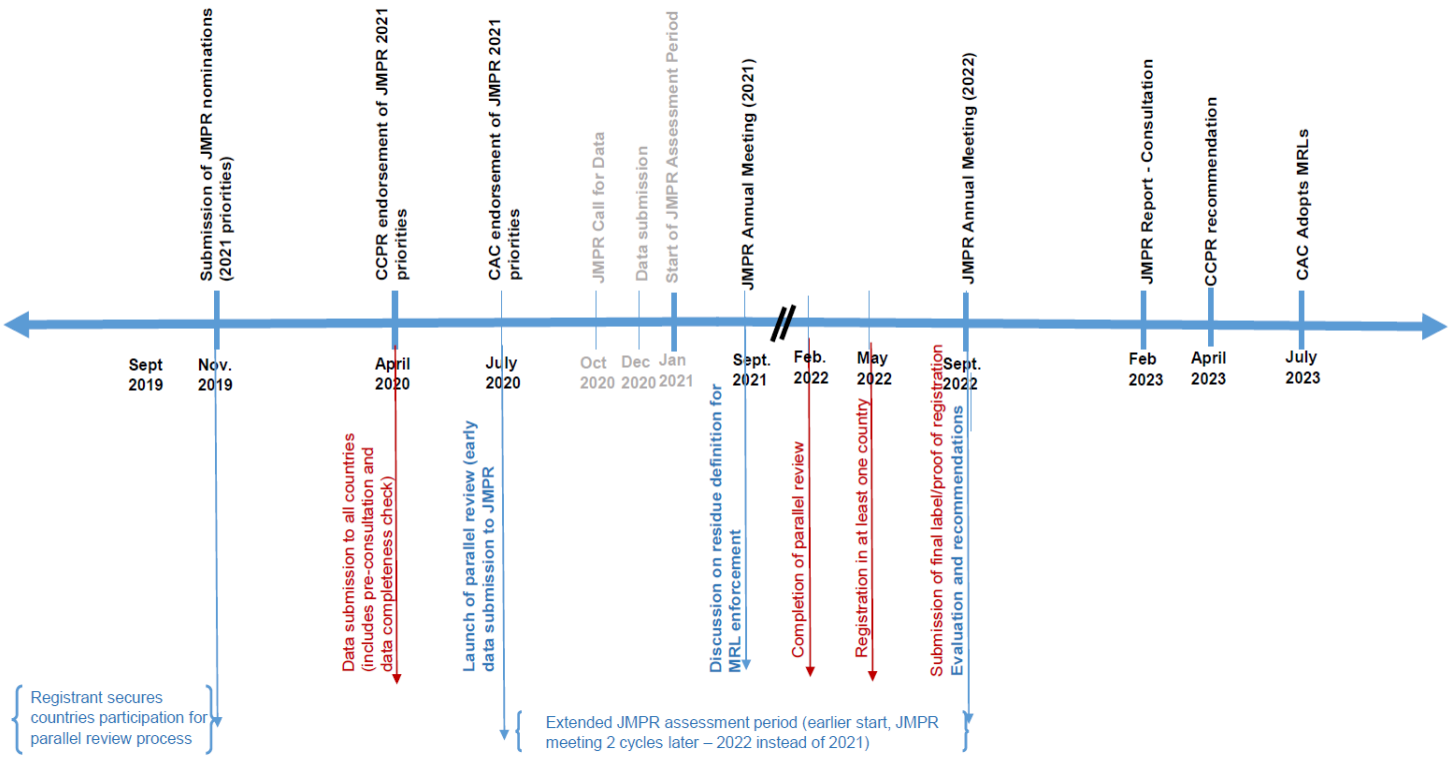
5 CAC Procedural Manual, Section IV – Risk Analysis, Risk Analysis Principles applied by CCPR, sub-section 5.2.2, paragraph 63

12. JMPR recommendations to the CCPR occur by consensus. Should changes to the GAP go beyond the principles established by JMPR, and occur following the JMPR annual meeting, the JMPR reviewer would update the evaluation accordingly, consult with participating countries/sponsor and seek endorsement from the JMPR Meeting. The post-review update should be completed prior to the finalization and distribution of the JMPR final report in February, or postponed to the following JMPR Annual Meeting. Considerations should be given to alternative means for decision-making outside of the annual JMPR Meetings, such as teleconferences and email correspondence.

13. The table below is meant to illustrate potential timelines for a parallel review and how they could align with key CCPR/JMPR milestones. Twenty-two months were used as the proxy for national reviews. The timelines for public consultations and product registration would differ per participating countries; the proxy used for public consultation and product registration is three months.

Table 1: Scenario – projected timelines (over 2 JMPR Meetings)



5 - RISK ASSESSMENT METHOLODOGY

14. The JMPR experts engaged in the parallel review would review data packages and provide scientific advice according to the existing evaluation methodologies of the JMPR:

15. FAO Manual on the Submission and evaluation of pesticide residues data for the estimation of MRLs

- JMPR Guidance Document for WHO monographers and reviewers

16. It is also expected that the parallel review will build on the latest OECD guidance on definition of residues[6], which will facilitate alignment of residue definitions for MRL enforcement to the extent possible. It is recommended that alignment of crop categories be discussed between parties.

17. There is recognition that parallel reviews may contribute to alignment of decisions between parties (e.g. MRLs, residue definitions, etc.). However, as all parties will conduct their risk assessment based on their organizational requirements and methodologies, reaching consensus may not be achievable. While differences should be discussed, individual review/registration processes should continue as planned to avoid delays.

6 OECD currently working on a revision of its 2009 *Guidance Document on Definition of Residue*, in collaboration with JECFA, FAO and WHO experts.

6 – SUBMISSION OF FINAL LABEL

18. JMPR's proposed MRLs are typically presented to CCPR in February of each year. At that time, pesticides assessed under the parallel review process should be registered in at least one country, and final label and proof of registration submitted to the JMPR Secretariat. Inability to complete this step of the parallel review would postpone the JMPR MRL recommendation to the following year.

7 – INTERACTION BETWEEN JMPR REVIEWERS AND THIRD PARTIES (NATIONAL REGULATORS, SPONSOR)

19. Evaluators may wish to communicate with the data sponsor throughout the evaluation process to seek clarification or request that additional data be submitted. It is suggested to centralize communications with and from the data sponsor through the global project manager. The objective of centralizing communications would be to streamline communications with the sponsor, promote transparency, and ensure all reviewers receive the same additional data/information or clarifications from the sponsor.

APPENDIX XV

PROPOSED PRIORITY LIST OF PESTICIDES FOR EVALUATION BY THE 2022 JMPR

(for approval by CAC)

2022 - NEW COMPOUND EVALUATIONS										
PRIORITY	DATE STAMP	TOXICOLOGY	RESIDUE	PRIORITISATION CRITERIA			COMMODITIES	RESIDUE TRIALS	MEMBER / MANUFACTURER	COMMENTS
				REGISTERED	MRLS > LOQ	FAO NOMINATION FORM RECEIVED?				
1	30/10/2015	Fluazinam	Fluazinam	Yes	Yes	Yes	USA-BUSHBERRY; LETTUCE, HEAD AND LEAF; MELONS; SQUASHES/CUCUMBERS; PEPPERS/EGGPLANTS; PEANUTS; TUBEROUS AND CORM VEGETABLES; SOYBEAN; TEA	USA&CAN: Blueberry (13); Head lettuce (7); Leaf lettuce (7); Cantaloupe (11); Cucumber (6); Summer squash (6); Bell pepper (9); Non-bell pepper (4); Peanut (9); Potato (12); Soybean (16); JPN: Tea (5)	USA / ISK Biosciences; Ishihara Sangyo Kaisha	Fungicide; Revised nomination form on 25 Nov 2015 / fungicide. 15 June 2021 labels provided.
2	26/11/2019	Isotianil	Isotianil	Yes	Yes	Yes	FRUITING VEGETABLES (GH+Field), POTATO, Mango, BANANA, CUCURBITS (GH+Field), Citrus	Tomato (20 + 2 processing), Bell pepper (16), Chili pepper (7), Potato (20 + 2 processing), Mango (4), Cucumber (20), Melon (20), Squash (20), Banana (13)	Bayer AG	Plant defense inducer/fungicide/bactericide
3	8/09/2016	Isocycloseram (formerly called SYN547407, SYN407)	Isocycloseram (formerly called SYN547407, SYN407)	Yes	Yes	Yes (from Syngenta; US submission completed)	BRASSICA HEAD and stem VEGETABLES, citrus, corn, cotton, CUCURBIT VEGETABLES, FRUITING VEGETABLES, GREEN ONIONS, pome fruit, POTATO, stone fruit and soybeans	Cabbage (10), broccoli (10), cauliflower (10), brussels sprout (4), citrus (25), corn (27), cotton (12), cucumber (8), squash (8), melons (8), tomato (16), peppers (16), green onions (6), apple (18), pear (12), potato (26), cherry (10), plum (10), peach (13) and soybean (21)	Syngenta	Insecticide Syngenta Nov-17: Please move to 2022, due to a change in registration strategy; previously listed as SYN407, expected to be registered June 2021. Notified 15 April 2021 that submission accepted by Guatemala, expect registration approvaly by July 2021. Proof of registration in Honduras provided 27 May 2021.
4	13/11/2019	Acynonapyr	Acynonapyr	Yes	Yes	Yes	Apples, Pears, Eggplant, Mandarins	Apples (8), Pears (8), Eggplant (8), Mandarins (8)	Japan/Nippon Soda Co Ltd	Insecticide
5	26/11/2020	1,4-dimethylnaphthalene (1,4-DMN)	1,4-dimethylnaphthalene (1,4-DMN)	Yes	Yes	Yes (from Germany)	POTATOES	Potatoes (15)	1,4GROUP, Inc. 2307 E. Commercial St. Ste. A Meridian ID 83642 USA	Represented by: RIFCON GmbH Goldbeckstrasse 13 D-69493 Hirschberg Germany
6	30/11/2020	Mepiquat chloride	Mepiquat chloride	Yes	Yes		GRAPES	Grapes (8)	Nisso/BASF	

2022 - NEW USES AND OTHER EVALUATIONS									
PRIORITY	DATE STAMP	TOXICOLOGY	RESIDUE	PRIORITISATION		COMMODITIES	RESIDUE TRIALS	MEMBER / MANUFACTURER	COMMENTS
				REGISTERED	MRLS > LOQ				
1	4/11/2019	NA	Dinotefuran (255)	Yes	Yes	GOJI BERRY; GOJI BERRY, DRIED; TEA	Goji berry (4); tea (8)	China	Requested for 2022 JMPR review. (Mitsui Chemical nominations deferred to 2023).
2	28/11/2017	NA	Fluopyram (243)	Yes	Yes	Carrot (Morocco), WHEAT, BARLEY, SORGHUM	Wheat (12), barley (10), sorghum (4)	Bayer AG	Moved from 2020 to 2022 on request; Morocco proposed carrot; Bayer requested to move coffee to May 2021; Bayer requested to move cereals from 2020 to 2022; Bayer added avocado 26 November 2020; On 10 June 2021 company requested move of all commodities except cereals and carrots to 2024.
3	28/11/2017	NA	Flupyradifurone (285)	Yes	Yes	ASPARAGUS, SUNFLOWER, PINEAPPLE, SESAME, MANGO, PAPAYA	Asparagus (8), sunflower (10+1 processing), pineapple (5+1 processing), sesame (4+1 processing), mango (8), papaya (4)	Bayer AG	On 10 June 2021 company cancelled sweet sorghum and date nomination and requested olives and rapeseed move to 2023.
4	4/11/2019	NA	Difenoconazole (224)	Yes	Yes	PENCIL YAM; PENCIL YAM, DRIED; GOJI BERRY; GOJI BERRY, DRIED; TEA; GINGER FRESH	Pencil yam (4); goji berry (4)	China	Requested for 2022 JMPR review
4	29/11/2019	NA	Difenoconazole (224)	Yes	Yes	SUBGROUP OF CHERRIES (FS 0013); CHIVES (VA 4155); SUBGROUP OF PEACHES (FS 2001); SUBGROUP OF PLUMS (FS 0014); Subgroup 13B brassica leafy vegetables VL 0054; RADISH (VR0494); SUBGROUP OF TUBEROUS AND CORM VEGETABLES (VR 2071). , Subgroup 20E Maize cereals GC 2091, Subgroup 4A Cane Berries	Cherries (6), chive (3), peaches (9), plum (6), plum, damson plum, turnips (5), radish (5) and sweet potato (5) , caneberries(8), corn (24)	Syngenta	Advice 29 September 2020 on label for peach, plum, guava, cherry. Advice on 26 February 2021 other commodities.
5	4/11/2019	NA	Diflubenzuron (130)	Yes	Yes	TEA	Tea (8)	China	Requested for 2022 JMPR review
6	29/11/2019	NA	Propiconazole (160)	Yes	Yes	AVOCADO (FI 0326); PEANUT, SHELLED (GROUNDNUT) (SO 0697); RICE	Avocado (6), peanuts (12)	Syngenta	Advice 29092020 on label for peanuts, avocado. Advice 11062021 on label for rice.

2022 - NEW USES AND OTHER EVALUATIONS									
PRIORITY	DATE STAMP	TOXICOLOGY	RESIDUE	PRIORITISATION		COMMODITIES	RESIDUE TRIALS	MEMBER / MANUFACTURER	COMMENTS
				REGISTERED	MRLS > LOQ				
7	29/11/2019	Emamectin (247)	Emamectin (247)	Yes	Yes	SUBGROUP OF HERBS (HH 2095); SUBGROUP OF FLOWERHEAD BRASSICAS (VB 0042); CHIVES (VA 4155); SPINACH (VL0502), TURNIP GREEN (VL0506), TEA (DT1114), Coffee beans (SB 0716), Soya bean (dry) (VD 0541); VL 0401 broccoli, Chinese-Thailand	Basil (4), broccoli & cauliflower (13), chives (6), spinach (6), turnips (6), tea (5), coffee beans (5), soybean (20); broccoli, Chinese (6)-Thailand	Syngenta	Advice 29092020 on label for brassica leafy vegetables Coffee label should be approved by Dec 2021 and Soybean by April 2021. Advice on 26022021 tea classification.
8	29/11/2019 & China's nomination 12/11/2020	NA	Thiamethoxam (245), China included Clothianidin (238)	Yes	Yes	CELERY (VS 0624); GROUP OF TREE NUTS (TN 0085); SUBGROUP OF BULB ONIONS (VA 2031); ALFALFA HAY (AL3350), Oat (GC 0647); China: Goji berry; goji berry, dried	Celery (6), tree nuts (5), onions (7), alfalfa (24) Oat (12); goji berry (4)	Syngenta; China for goji berry	Advice 29 September 2020 on label for carrots, leafy vegetables, dry bulb onions, brassica leafy vegetables, treenuts, celery. China requested for 2022 JMPR review; clothianidin based on residue trials of thiamethoxam. Advice on 26 February 2021 other commodities.
9	28/11/2017; label provided 15122020	NA	Spiromesifen (294)	Yes	Yes	Caneberries (Canada); carrot, fig, guava, mandarines (Morocco); ORANGES (Morocco & Bayer), COFFEE, MANGO, PAPAYA, DRY BEANS (CHICKPEA, LENTILS, PEAS)	Orange (9 + 2 processing), coffee (8), Mango (8), Papaya (4), Dry beans (10 dry shelled beans; 7 succulent shelled beans)	Bayer AG	Morocco proposed carrot, fig, guava, mandarines, oranges; Bayer proposed oranges, coffee, mango, papaya, dry beans
10	29/11/2019	NA	Mefentrifluconazole (BAS 750 F)	Yes-All registered 2019; new uses expected latest 2021	Yes	ROOT AND TUBER VEGETABLES, SUGAR BEET, LEAFY VEGETABLES, brassica vegetables, stalk and stem vegetables, CANE BERRIES, BUSH BERRIES, STRAWBERRY, FRUITING VEGETABLES, BULB VEGETABLES, OILSEEDS, CUCURBITS, GRASS ALFALFA, CLOVER, SUGARCANE, globe artichoke, MANGO	Carrot (11), radish (7), sugarbeet (16), turnip (5), bulb onion (13), green onion (5), lettuce (16), spinach (8), mustard green (4), cabbage (8), broccoli (4), cauliflower (4), asparagus (4), celery (4), tomato (19), bell pepper (9), nonbell pepper (3), cucumber (9), squash (8), muskmelon (8), blackberry (6), blueberry (9), strawberry (11), grass (13), alfalfa (10), clover (10), cotton (12), sunflower (10), globe artichoke (4), mango (5)	USA/BASF	New uses currently under evaluation in USA, Europe and South America

2022 - NEW USES AND OTHER EVALUATIONS									
PRIORITY	DATE STAMP	TOXICOLOGY	RESIDUE	PRIORITISATION		COMMODITIES	RESIDUE TRIALS	MEMBER / MANUFACTURER	COMMENTS
				REGISTERED	MRLS > LOQ				
11	29/11/2019	Cyantraniliprole (263)	Cyantraniliprole (263)	Yes	Yes	SUBGROUP OF DRY PEAS (VD 2066); SUBGROUP OF DRY BEANS (VD 2065), Okra, Olives, Caneberries, Lettuce, Potato, Tomato, Grapes, Tea (DT1114?)	Dry peas and dry beans (15), chickpea (0) and lentils (0), Okra (), Olives (), Caneberries (), Lettuce (), Potato (), Tomato (), Grapes (), Tea ()	Syngenta	Advice 29 September 2020 on label/registration of top up uses - chickpea. Advice on 26 February 2021 others commodities.
12	29/11/2019	NA	Oxathiapiprolin (291)	Yes	Yes	SUBGROUP OF BUSH BERRIES (FB 2006); GROUP OF TREE NUTS (TN 0085); HOPS (DH 1100); SUBGROUP OF LOW GROWING BERRIES (FB 2009); AVOCADO (FI0326)	Blueberries (8), tree nuts (10), hops (5), strawberries (10), avocado (5)	Syngenta	Advice 29 September 2020 on label/registration of top up uses - blueberry, strawberry
13	16/10/2020	NA	Cyflumetofen (273)	Yes	Yes	STONE FRUITS, CUCURBITS WITH EDIBLE PEEL, FRUITING VEGETABLES - INEDIBLE PEEL, FRUITING VEGETABLES OTHER THAN CUCURBITS, HOPS	Stone fruits (40), cucurbits with edible peel (8), Fruiting vegetables – inedible peel (24), fruiting vegetables other than cucurbits (58) and hops (4)	BASF/OAT	
13	9/12/2020	NA	Cyflumetofen (273)	Yes	Yes	STONE FRUITS, CUCURBITS WITH EDIBLE PEEL, FRUITING VEGETABLES OTHER THAN CUCURBITS, HOPS	Stone fruits, cucurbits with edible peel, fruiting vegetables other than cucurbits, hops	The Netherlands	
14	11/06/2021	NA	Deltamethrin (135)	Yes	Yes	MANGO, PAPAYA	Mango (4), papaya (4)	Bayer AG	New nomination 26 November 2020. Awaiting registration in Brazil. Brazilian label provided by Bayer 11 June 2021.
15	27/11/2020	NA	Acetamiprid (246)	Yes	Yes	PULSES	Pulses (12)	Adama	A top-up evaluation is requested following the approval of acetamiprid on pulses in Australia to set a CXL of 0.1 mg/kg in line with the pending AUS MRL. APVMA label 121545.
16	29/11/2020	NA	Imazapyr (267)	Yes	Yes	RICE GRAIN	Rice (9)	BASF	Rice registered in Asia
17	29/11/2020	NA	Imazapic (266)	Yes	Yes	RICE GRAIN	Rice (9)	BASF	Request to increase current CXL for rice grain. Rice registered in Asia

2022 - NEW USES AND OTHER EVALUATIONS									
PRIORITY	DATE STAMP	TOXICOLOGY	RESIDUE	PRIORITISATION		COMMODITIES	RESIDUE TRIALS	MEMBER / MANUFACTURER	COMMENTS
				REGISTERED	MRLS > LOQ				
18	29/11/2020	NA	Metconazole (313)	Yes	Yes	WHEAT GRAIN, straw	Wheat grain (16), wheat staw (16)	BASF	EU trials submitted to supplement US trials submitted for 2019 review. Wheat registered in multiple countries.
19	1/12/2020	NA	Chlorantraniliprole (230)	Yes	Yes	AVOCADO, TEA	Avocado (5), Tea (8)	USA/FMC	
20	1/12/2020	NA	Cypermethrin zeta (118)	Yes	Yes	LEAFY VEGETABLES, CELERY, GREEN AND BULB ONION, BLUEBERRY, BLACKBERRY, AVOCADO	Lettuce leaf (8), Spinach (8), Celery (7), Mustard green (9), Green (2) and Bulb onion (3), Blueberry (6), Blackberry (3), Avocado (7)	USA/FMC	
RESERVE	1/12/2020	NA	Phosphonic acid (301)	Yes	Exempt from MRL in the US	CITRUS	Citrus (6 trials in the US and 6 trials in the EU)	USA/Luxembourg-Pamol, Inc	
RESERVE	19/07/2021	NA	Fosetyl Al (302)	Yes	Yes	RICE	Rice (6)	Thailand	
RESERVE		NA	Boscalid (BAS 510 F) (221)	No	Yes	Pomegranite	Pomegranite (4)	BASF	Registration expected EU spring 2021
RESERVE		NA	Methoprene (147)	No	Yes	Tree Nuts	Almonds (1, 5 farm sites), Pistachios (1, 5 farm sites)	USA/Wellmark	

2022 - PERIODIC REVIEW									
PRIORITY	YEAR	TOXICOLOGY	RESIDUE	MEMBER / MANUFACTURER	COMMODITIES	COMMENTS	PREVIOUS EVALUATION	ADI	ARfD
1	2021 (ON REQUEST, MOVED FROM 2020 RESERVE	Aldicarb (117)	Aldicarb (117)	AgLogic Chemical LLC	Citrus (oranges, grapefruit, lemons, limes), Cotton, Dry Beans, Peanuts, Soybeans, Sugar Beets, Sweet Potatoes	Awaiting further advice on commodities from sponsor _ UPDATE; may be moved to 2021 schedule if no advice received from sponsor; UPDATE October 2019-Awaiting data so requested to be moved to 2021.	Tox review conducted in 1997	0.003, 1995	0.003, 1995
2	2022	Dithiocarbamates (105) [Taminco]: (ferbam, maneb/mancozeb, propineb, thiram, ziram) - MOVE to 2020-22 2016 Additional advice; US Supports Mancozeb, Metiram, Propineb, Thiram, Ziram; moved to 2022 on request from manufacturers	Dithiocarbamates (105)	BASF, UPL, Indofil, Eastman Kodak-Taminco and Bayer Crop Science	**Longan (Thailand – mancozeb)¶Mancozeb:** Oranges (24), Mandarins (16), Nuts (10), Apples (48), Pears (4), Peaches (8), Apricot (8), Plums (28), Cherries (16), Grapes (2*), small fruits and berries (25), Potato (16), Carrot (24), Onions (24), Tomatoes (31), Pepper (18), Courgette (14), Cucumber (36), Melon (20), Broccoli (24), Cauliflower (20), Head cabbage (32), Lettuce (22), Witloof (4), Beans/Peas, fresh with pods (29), Beans, fresh without pods (8), Peas, fresh without pods (16), Asparagus (10), Leeks (19), Pulses, dry (24), Olives (15), Wheat (26), Barley (16), Sugar beet (16)¶*Additional trials in progress**¶Metiram:** Grape (23); Potato (23); Apple (15); Tomato (15); Onions (8); Lettuce (20); Cucurbits edible peel (8); Cucurbits inedible peel (8); Passion Fruit (4); Banana (12); Pineapple (4)**¶Propineb:** apples (50); grape (54); mango (5); citrus (31); tomato (36); potato (31); chili pepper (11); cucumber (27); rice (8); shallot (8)**¶Thiram (foliar):** Apple (25); Pear (10); Apricot (7); Peach (12); Cherry (28); Strawberry (40); Plum (12); Olive (8); Grape (13); Eggplant (2); Lettuce (9); Sunflower (4); Avocado (6); Mango (1); Banana (17)**¶Thiram (seed):** Sugar beet (4); Maize (8); Oilseed rape (8)**¶Ziram (foliar):** Peach (6); Apricot (4); Plum (11); Pear (21); Cherry (11); Grape (5); Tomato (7); Blueberries (4)	Residue definition applies to all DTC – propineb; mancozeb; ferbam; ziram; thiram; maneb; metiram; zineb **¶Netherlands - public health concerns**¶Several (serious) public health risks have been identified for several dithiocarbamates (Maneb/mancozeb, propineb, thiram, ziram) using EU data (ARfD and MRLs with conversion factor corrections). ¶JMPR has not derived ARfDs for these substances (except an interim ARfD of 0.1 mg/kg bw for propineb) nor performed acute dietary risk assessment as it was not yet done at that time (before 2000). Various group ADI's for several dithiocarbamates (e.g. 0.03 mg/kg for maneb, mancozeb, metiram and zineb, 0.007 mg/kg for propineb, 0.003 mg/kg for ziram and ferbam, and 0.01 mg/kg for thiram). ¶We acknowledge that a periodic review of propineb has been performed in 2004. Still a risk has been identified for peppers and (dried) tomatoes using the HR for peppers of 13 mg/kg and the HR for tomatoes of 2.9 mg/kg for propineb and the interim ARfD of 0.1 mg/kg bw. Processing data have not been included in this calculation. ¶For thiram risks have been identified for e.g. use on apples and pears (recommended MRL of 5 mg/kg listed under ziram, no STMR or HR listed, Annex I, JMPR report 2004 from http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Reports_1991-2006/report2004jmpr.pdf) falling back on the use of the ADI of 0.01 mg/kg bw/day (no ARfD exists). Using the EU ARfD of 0.6 mg/kg bw no risks are identified any more. ¶¶¶For ziram risk are identified e.g. use pome fruit, even if making use of the EU ARfD (0.08 mg/kg bw) instead of falling back on the ADI of 0.003 mg/kg bw/d in the absence of an JMPR ARfD. ¶Due to time constraints, we have not yet further explored the risks identified for maneb / mancozeb. The majority of the dithiocarbamates have been evaluated prior to the date that acute dietary risk assessment became part of the JMPR evaluations. ¶We propose therefore to update the evaluations with regard to the acute dietary risk assessment of all the dithiocarbamates in one overall assessment. This would enable identification of all the possible risks, establish whether re-evaluation of the existing data for specific uses is appropriate, whether an ARfD should be derived, and to determine whether they should subsequently be placed on the priority lists. ¶Conversion factors (from CS_2 to active substance) are not listed in the Annex: Mancozeb: 1.783, Maneb: 1.743, Propineb: 1.904, Thiram: 1.580, Ziram: 2.009	1996T, 1993R, (2004 propineb); BASF request delay to 2022. Each registrant will submit a separate dossier for the separate DTC compounds for review in 2022 (On behalf of BASF, Corteva, UPL, Indofil, Eastman Kodak-Taminco and Bayer Crop Science). Dossiers for Mancozeb & ETU planned for submission Nov-Dec 2021 by Exponent (on behalf of Corteva, UPL, Indufil, BASF), others to be confirmed.	Range of group ADIs	Interim ARfD - propineb / 0.1, 1995

2022 - PERIODIC REVIEW									
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2	2022	Specific to metiram, submitted 01042021	Dithiocarbamates (105) - further details from BASF on the above item	BASF	01 Fruits •002 Pome fruits •003 Stone fruits o003A Cherries o003B Plums o003C Peaches •004 Berries and other small fruits o004D Small fruit vine climbing •006 Assorted tropical and subtropical fruits - inedible peel o006B Assorted tropical and subtropical fruits – inedible smooth peel - large o006C Assorted tropical and subtropical fruits - inedible rough or hairy peel - large o006E Assorted tropical and subtropical fruits - inedible peel - vines 02 Vegetables •009 Bulb vegetables o009A Bulb onions •011 Fruiting vegetables, Cucurbits o011A Fruiting vegebtales, Cucurbits – Cucumber and Summer squashes o011B Fruiting vegetables, Cucurbits – Melons, Pumpkins and Winter squashes •012 Fruiting vegetables, other than Cucurbits o012A Tomatoes o012C Eggplant and eggplant-like commodities •013 Leafy vegetables (including Brassica leafy vegetabels) o013A Leafy greens •015 Pulses o015A Dry beans •016 Root and tuber vegetables	FP 0009 Pome fruits (9 trials; 5 x 1.575 kg as/ha, 21d PHI, cGAP) FP 0009 Pome fruits (10 trials; 3 x 2.1 kg as/ha, 21d PHI) FP 0226 Apple (10 trials; 3 x 1.4 kg as/ha, 21 d PHI, cGAP) FP 0226 Apple (10 trials; 3 x 1.4 kg as/ha, 28 d PHI) FP 0230 Pear (10 trials extrapolated from apple; 3 x 1.4 kg as/ha, 21 d PHI, cGAP) FS 0243 Cherry (sour) (2 trials; 4 x 0.105 kg as/ha, cGAP) FS 0244 Cherry (sweet) (2 trials; 4 x 0.105 kg as/ha, cGAP) FS 2234 Plum (4 trials; 1 x 3.5 kg as/ha, 21d PHI, cGAP) FS 0247 Peach (4 trials; 4 x 1.65 kg as/ha, 7d PHI, cGAP) FB 0269 Grapes (10 trials; 3 x 1.1 kg as/ha, 30d PHI, cGAP) FB 0269 Grapes (9 trials, 6 x 1.4 kg as/ha, 28d PHI) FB 0269 Grapes (10 trials, 3 x 1.4 kg as/ha, 56d PHI) FB 1236 Wine grapes (27 trials; 1 x 1.1 kg as/ha, 28d PHI, cGAP) FB 1236 Wine grapes (10 trials; 3 x 1-76 kg as/ha, 35d PHI) FI 0327 Banana (10 trials; 13 x 0.98 kg as/ha, 0d PHI) FI 0345 Mango (6 trials; 3 x 1.1 kg as/ha, F PHI, cGAP) FI 0353 Pineapple (9 trials; 4 x 1.65 kg as/ha, 3d PHI) FI 0351 Passion fruit (4 trials; 4 x 1.65 kg as/ha, 7d PHI) VA 0381 Garlic (28 trials, extrapolation from Onion; 6 x 2.1 kg as/ha, 7d PHI, cGAP) VA 0381 Garlic (28 trials, extrapolation from Onion; 6 x 1.54 kg as/ha, 7d PHI) VA0385 Onion (26 trials, 6 x 1.54 kg as/ha, 7d PHI) VC 0431 Summer squash (8 trials, extrapolation from Melon; 3 x 1.4 kg as/ha, 3d PHI) VC 0424 Cucumber (10 trials; 3x 1.26 kg as/ha, 3d PHI) VC 0431 Zucchini (6 trials; 3 x 1.4 kg as/ha, 3d PHI) VC 0432 Watermelon (12 trials; 4 x 1.4 kg as/ha, 7d PHI) VC 0046 Melon (18 trials; 4 x 1.1 kg as/ha, 7d PHI) VC 0429 Pumpkin (8 trials, extrapolation from Melon; 3 x 1.4 kg as/ha, 3d PHI) VO 0448 Tomato (17 trials; 3 x 1.4 kg as/ha, 3d PHI, cGAP) VO 0448 Tomato (9 trials; 6 x 1.05 kg as/ha, 7d PHI) VO 0440 Eggplant (17 trials, extrapolation from Tomato; 3 x 1.6 kg as/ha, 3d PHI) VL 0482 Lettuce (Head) (8 trials; 3 x 1.4 kg as/ha, 14d PHI)			

2022 - PERIODIC REVIEW									
PRIORITY	YEAR	TOXICOLOGY	RESIDUE	MEMBER / MANUFACTURER	COMMODITIES	COMMENTS	PREVIOUS EVALUATION	ADI	ARfD
3	2022	Iprodione (111)	Iprodione (111)	FMC	Tree nuts; cereals; beans, (dried); blackberry; broccoli; carrots; cheery; cucumber; grapes; kiwi; lettuce (head and leafy); onion; stone fruit; pome fruit; rapeseed; raspberry; sugar beet; sunflower; tomato; witloof ¶(All CXLs appear to be supported)	Moved at the request of manufacturer – await completion of EU, Canada and US reviews - FMC Trials:¶Almonds (4); barley (13); blackberries (8); broccoli (4); carrot (12); cherry (5); lettuce, leaf (12); peach (9); raspberries, red/black (8); rice, husked (18);¶Spices, seeds (4); spices, roots & rhizomes (4); apricots (8); artichoke (4); banana (8); bean, succulent - lima and snap (12); Brassica, head and stem vegetables (12); coffee (6); eggplant (8); mandarins (8); mango (4); melon (12); pea (12); peanut (12); plum (12); potato (16); soybean (12); wheat (16) Iprodione was initially evaluated by JMRP in 1992 and reviewed several times for toxicology and residue section (last review 2001). In the EU, the latest toxicological profile assessments are reported in an EFSA opinion from 2016. (see chapter data/information). In this report in respect of one metabolite, found as residue in plants and as impurity in the technical material, EFSA concluded that the genotoxic potential cannot be excluded and therefore the setting of reference values for that metabolite cannot be confirmed based on the information available. Moreover a new ADI of 0.02 mg/kg bw per day and a new ARfD of 0.06 mg/kg bw were established for parent iprodione. Based on these reference values, using the EFSA PRIMo model rev. 2.0 and Codex MRLs, the assessment resulted in an exceedance of the ARfD for at least cherries, peaches, blackberries, raspberries, carrot, tomatoes, broccoli, lettuce. For these crops, the exceedance ranged from 1733% to 132% of the ARfD. The estimated long-term dietary intake was in the range of 0% to 276% of the ADI; for three diets the long-term exposure exceeded the ADI (i.e. NL	1992, 1995T, 1994, 2001R	0.06, 1995	N/A
4	2022	Carbendazim (72)	Carbendazim (72)	Nippon Soda	Await further advice from JMPR at CCPR51.		1995T, 1998, 2003, 2005R		
5	2022	Fenthion (39)	Yes			No longer supported by the manufacturer		0.007, 1995	0.01, 1997