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Agenda Item 10

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

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**REVISION OF THE RISK ANALYSIS PRINCIPLES APPLIED BY THE
CODEX COMMITTEE ON PESTICIDE RESIDUES**

(Prepared by the Electronic Working Group chaired by Costa Rica and co-chaired by Chile)

INTRODUCTION

1. In order to comply with the mandate of the 45th session of the Committee on Pesticide Residues, Costa Rica and Chile, as Chair and Co-Chair, respectively, of the Electronic Working Group (EWG) on the revision of the Risk Analysis Principles applied by the Codex Committee on Pesticide Residues, presents this executive summary of the actions taken by the EWG since the 45th session of CCPR.

BACKGROUND

2. The background to the discussion on the revision of the Risk Analysis Principles applied by CCPR can be found in the reports of the 24th session of the Committee on General Principles¹, the 30th and 31th sessions of the Codex Alimentarius Commission² and the 40th to the 45th sessions of the Committee on Pesticide Residues³. The reports of sessions of the Commission and its subsidiary bodies are available at: <http://www.codexalimentarius.org/meetings-reports/en/>

FRAMEWORK AND TECHNICAL JUSTIFICATION

3. The work was structured according to the mandate received at the 45th session of CCPR, which reads:

150. The Committee further noted that the integration of the different sections of the Risk Analysis Principles would entail some consequential amendments arising from the agreements achieved at the discussion at the last and present session of the Committee in addition to editorial adjustments that would be carried out by an EWG chaired by Costa Rica and co-chaired by Chile, working in English and Spanish, in order to present a single document for consideration by the next session of the Committee that could be forwarded for final adoption by the 37th session of the Commission in 2014.

SUMMARY OF THE TASKS CARRIED OUT

4. For the integration of the different sections of the document the following tasks were performed:

- a. For sections 1 to 5.1, 6 and 8 was taken as a reference document CX/PR 13/45/13.
- b. For sections 5.2, 5.3 and 7 was taken as a reference document REP13/PR-Appendix XIII.
- c. All paragraphs in the document were numbered and correspond to different sections of the original documents as follows:

¹ ALINORM 07/30/33, paras 27-34.

² ALINORM 07/30/REP paras 27-34, 158 and ALINORM 08/31/REP, Appendix X.

³ ALINORM 08/31/24, paras 129-134, ALINORM 09/32/24 paras 177-185, ALINORM 10/33/24 paras 139-152, REP11/PR paras 124-137, REP12/PR, paras 140-163, Appendix XIV and REP13/PR, paras 142-150, Appendix XIII.

Section original document	Corresponding paragraphs in the new document
a. Scope	1
b. General Aspects	2-8
c. Risk assessment policy	9-16
3.1.1 MRL for foods of animal origin	17-19
3.1.2 MRL for spices	20
3.1.3 MRL for fat-soluble pesticides	21-23
3.1.4 MRL for processed or ready-to-eat foods or feeds	24-25
3.1.5 Establishment of Extraneous Maximum Residue Limits (EMRL)	26-30
4.1 Role of JMPR	31-36
4.2 Dietary intake	37-43
5.1 Role of CCPR	44-50
5.2 Selection of pesticides for JMPR evaluation	51
5.2.1 Procedure for the preparation of the Schedules and Priority Lists	52-60
5.2.2 Nomination requirements and criteria for the prioritization and scheduling pesticides for evaluation by JMPR	61-75
5.3.1 Identify pesticides for Periodic Review and solicit data commitments	76-77
5.3.2 Commitment to support pesticides or existing CXL or new proposed MRL	78-79
6.1 Utilization of the accelerated procedure for elaboration of MRL (Step 5/8-procedure)	80-85
6.2 Deleting CXL	86-88
7.1 Concerns with advancement of an MRL or the evaluation of a pesticide	89-94
7.2 Concerns with public health on previously evaluated pesticides	95-98
7.3 Request for clarification	99
7.4 Addressing differences in procedures for risk assessment	100
8. Risk Communication	101-104

- d. The term "pesticide" is used to replace the words: compounds, substances, chemicals, which are used interchangeably to mean the same thing in the document.
- e. As indicated by JMPR at the 44th CCPR meeting, REP12/PR paragraph 152, and as noted by Switzerland, the levels are proposed by JMPR, CCPR establishes MRLs and CAC approved CXL, as such terminology is uniform throughout text.
- f. The term "food" is used to replace the words: food, food commodity, basic products, product, which is used interchangeably to mean the same thing in the document.
- g. Paragraph 19 is indicated in brackets because so defined by CCPR at its 44th meeting. In paragraphs 147-148 of REP12/PR it is indicated that this issue should be addressed at the 45th meeting, however, is an issue that is pending.

5. The Codex Secretariat has included Annex C on “Principles and Guidance for the Application of the Proportionality Concept for the Estimation of Maximum Residue Limits for Pesticides” following the recommendation of the 45th Session of CCPR and the decision of the 36th Session of the Commission.⁴
6. In addition, a few editorial amendments were introduced to put certain provisions in the format and language of Codex texts.

⁴ REP13/PR, para 98 and Appendix VIII, REP14/CAC, para 30 and Appendix II.

REVISED RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES

SCOPE

1. This document addresses the respective applications of risk analysis principles by the Codex Committee on Pesticide Residues (CCPR) as the risk management body and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) as the risk assessment body and facilitates the uniform application of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. This document should be read in conjunction with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

GENERAL ASPECTS

SUMMARY OF THE MAXIMUM RESIDUE LIMIT (MRL)-SETTING PROCESS

2. In addressing pesticide residue issues in Codex, providing advice and taking decisions on risk management is the responsibility of the Codex Alimentarius Commission (CAC) and CCPR, while conducting risk assessment is the responsibility of JMPR.
3. The MRL-setting process begins with a member or other interested party nominating a pesticide for evaluation by JMPR. In considering the nomination, CCPR, in consultation with the JMPR Joint Secretaries may then prioritize and schedule the pesticide for evaluation.
4. The WHO Core Assessment Group considers available data, encompassing a wide range of toxicological endpoints, with the aim of estimating an Acceptable Daily Intake (ADI) and an Acute Reference Dose (ARfD) where appropriate.
5. The FAO Panel of Experts on Pesticide Residues in Food and the Environment considers data on registered use patterns, fate of residues, animal and plant metabolism, analytical methodology and residue data derived from supervised residue trials in order to propose residue definitions and maximum residue levels for the pesticide in food and feed.
6. The JMPR risk assessment includes the estimation of both short-term (single day) and long-term dietary exposures and their comparison with the relevant toxicological benchmarks. MRL in or on foods and animal feeds are based on Good Agricultural Practice (GAP) information, taking into consideration information on dietary intakes. Foods derived from commodities that comply with the respective MRL are intended to be toxicologically acceptable.
7. CCPR considers the recommendations of JMPR in light of information provided in the relevant JMPR reports and monographs. Maximum residue levels recommendations accepted by CCPR are submitted to CAC for adoption as Codex MRL (CXL). An active periodic review program complements this process.
8. CCPR and JMPR should ensure that their respective contributions to the risk analysis process result in outputs that are scientifically based, fully transparent, thoroughly documented and available in a timely manner to members¹.

RISK ASSESSMENT POLICY

9. CCPR shall consider the following when preparing its priority list of pesticides for evaluation by JMPR:
 - a. The CCPR's Terms of Reference;
 - b. The JMPR's Terms of Reference;
 - c. The CAC's Strategic Plan;
 - d. Nomination requirements and criteria for the prioritization and scheduling of pesticides.
10. When nominating pesticides for evaluation by JMPR, CCPR shall provide background information and clearly specify the reasons for the request.
11. When referring pesticides to JMPR, CCPR may also refer a range of risk management options, with a view toward obtaining guidance from JMPR on the attendant risks and the likely risk reductions associated with each option.
12. CCPR shall request JMPR to review any risk assessment policies, methods and guidelines being considered by CCPR for assessing maximum residue levels for pesticides.
13. When establishing its standards, CCPR shall clearly state when, in addition to JMPR's risk assessment and recommended maximum residue levels, it applies any considerations based on other legitimate factors² relevant for the health protection of consumers and for the promotion of fair practices in food trade and specify its reasons for doing so.
14. JMPR shall apply a transparent, science based risk assessment process for establishing ADI and ARfD where appropriate.
15. The JMPR Joint Secretaries shall consider whether minimum data requirements have been met when preparing the provisional agenda for meetings of JMPR.

¹ Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed, FAO Plant Production and Protection Paper, 197, 2009, ISBN 978-92-5-106436-8

² Statement of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account, Codex Alimentarius Commission Procedural Manual.

16. JMPR, in consultation with CCPR, must continue to explore developing minimum data requirements necessary for JMPR to perform risk assessments.

MRL FOR SPECIFIC FOOD GROUPS AND FEED

MRL for foods of animal origin

17. Farm animal metabolism studies are required whenever a pesticide is applied directly to livestock, to animal premises or housing, or when significant residues remain in crops or commodities used in animal feed, (e.g. forage crops, plant parts that could be used in animal feeds, by products or co-products of industrial productions). The results of farm animal feeding studies and residues in animal feed serve also as a primary source of information for estimating maximum residue levels in foods of animal origin.
18. If no adequate studies are available, no MRLs will be established for foods of animal origin. MRLs for feeds (and the primary crops) should not be established in the absence of animal transfer data. Where the exposure of livestock to pesticides through feeds leads to residues at the limit of quantitation (LOQ), MRLs at the LOQ must be established for foods of animal origin. MRLs should be established for general foods of animal origin, for example, edible offal (mammalian), if animals are exposed to pesticide residues via animal feed, and for specific foods, for example, cattle kidney, in cases where animals are directly treated with a pesticide.
19. [Where the recommended maximum residue levels or limits for foods of animal origin resulting from direct treatment of the animal, regardless of whether they are recommended by JMPR or the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and from residues in animal feed do not agree, the higher recommendation will prevail.]

MRL for spices

20. MRL for spices can be established on the basis of monitoring data in accordance with the guidelines established by JMPR.

MRL for fat-soluble pesticides

21. If a pesticide is determined as "fat soluble", it is indicated with the text "The residues are fat soluble" in the residue definition. The following factors should be considered to determine if a pesticide is "fat soluble":
 - a. When available, information concerning the partitioning of the residue (as defined) in muscle versus fat or residue in whole milk versus milk fat in the metabolism studies and livestock feeding studies that determines the designation of a residue as being "fat soluble";
 - b. In the absence of useful information on the distribution of residues in muscle and fat, residues with Octanol-Water Partition Coefficient > 3 ($\log Pow > 3$) are likely to be "fat soluble".
22. For milk and milk products, two maximum residue levels would be estimated for fat-soluble pesticides, if the data permits. One maximum residue level for whole milk and one for milk fat. When needed, MRL for milk products can then be calculated from the two values, by taking into account the fat content and the contribution from the non-fat fraction.
23. For regulation and monitoring of residues of fat-soluble pesticides in milk, where a CXL have been established for both whole milk and milk fat, whole milk should be analyzed and the result should be compared with the CXL for whole milk¹.

MRL for processed or ready-to-eat foods or feeds

24. JMPR evaluates processing studies to derive processing factors used to estimate residues concentrations in processed foods or feeds for dietary risk assessments and, if necessary, recommended maximum residue levels for processed foods or feeds.
25. CCPR should:
 - a. establish MRL for important processed foods and feeds;
 - b. establish MRL for the processed foods and feeds only if the resulting value is higher than the MRL established for the corresponding raw agriculture commodity (RAC)¹, Process Factor > 1.3 ($PF > 1.3$);
 - c. establish MRL for processed foods and feeds where, due to the nature of the residues during some specific process, significant amounts of relevant metabolites appear or increase; and
 - d. support the JMPR practice of evaluating all processing studies provided and including in each evaluation or review a summary table of all validated processing factors.

Establishment of Extraneous Maximum Residue Limits (EMRL)

26. The EMRL refers to a pesticide residue or a contaminant arising from environmental sources due to former agricultural uses other than the use of the pesticide directly or indirectly on the food or feed. It is the maximum concentration of a pesticide residue that is recommended by CAC to be recognized as acceptable in or on a food or animal feed.

27. Pesticides for which EMRL are most likely to be needed are persistent in the environment for a relatively long period after uses have been discontinued and are expected to occur in foods or feeds at levels of sufficient concern to warrant monitoring.
28. All relevant and geographically representative monitoring data (including nil-residue results) are required to make reasonable estimates to cover international trade¹. JMPR has developed a standard format for reporting pesticide residues monitoring data.
29. JMPR compares data distribution in terms of the likely percentages of violations that might occur if a given EMRL is proposed to CCPR.
30. Because residues gradually decrease, CCPR should evaluate every 5 years, if possible, the existing EMRL, based on the reassessments of JMPR.

RISK ASSESSMENT

ROLE OF JMPR

31. JMPR consists of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. It is an independent scientific expert body convened by both Directors General of FAO and WHO according to the rules of both organizations, charged with the task to provide scientific advice on pesticide residues.
32. This document applies to the work of JMPR in the context of Codex and in particular as it relates to advice requests from CCPR.
33. JMPR is primarily responsible for performing the risk assessments and proposing maximum residue levels upon which CCPR and ultimately CAC base their risk management decisions. JMPR proposes maximum residue levels based on residue data from GAP/registered uses or in specific cases, such as EMRL and MRL for spices based on monitoring data.
34. JMPR provides CCPR with science-based risk assessments that include the four components of risk assessment as defined by CAC, namely hazard identification, hazard characterization, exposure assessment and risk characterization that can serve as the basis for CCPR's discussions.
35. JMPR should identify and communicate to CCPR in its assessments any information on the applicability and any constraints of the risk assessment in regard to the general population and to particular sub-populations and shall, as far as possible, identify potential risks to populations of potentially enhanced vulnerability (e.g. children).
36. JMPR communicates to CCPR possible sources of uncertainties in the exposure assessment and/or in the hazard characterization of the pesticide that, if resolved, would allow a refinement of the risk assessment.

DIETARY INTAKE

37. JMPR is responsible for evaluating exposure to pesticides. JMPR must strive to base its exposure assessment and hence the dietary risk assessments on global data, including that from developing countries. In addition to Global Environment Monitoring System (GEMS)/Food data, consumption monitoring data and exposure studies may be used. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are based on the available high percentile consumption data as provided by members and compiled by GEMS/Food.
38. In undertaking dietary exposure risk assessments to assist CCPR, JMPR uses the WHO Guidelines³ and other documents⁴. JMPR recommends Supervised Trial Median Residues (STMRs) and Highest Residues (HRs) for dietary intake purposes.
39. When the ADI is exceeded in one or more cluster diets, JMPR further refines the dietary intake estimates at the international level. If further refinement is possible CCPR should advance the MRLs to Step 8 provided that the MRLs give no longer rise to intake concerns. If further refinement is not possible or the refinement still give rise to intake concern, JMPR flags this situation when recommending maximum residue levels and CCPR will decide on which MRLs could be advanced and which ones should be deleted.
40. JMPR establishes ARfD, where appropriate, and indicates cases where an ARfD is not necessary. Where the ARfD is set, JMPR calculates the International Estimate of Short-term Intake (IESTI) for the general population and for children (less than 6 years old), following a procedure described previously¹.
41. Where the ARfD is exceeded for a pesticide/food combination, the JMPR report should describe the particular situation that gives rise to that acute intake concern. JMPR shall examine available information on alternative GAP and associated residue trials where the ARfD is not exceeded and shall recommend a maximum residue level associated with this alternative GAP. This procedure has been referred to as the "prospective alternative GAP analysis".

³ WHO.1997. Guideline for predicting dietary intake of pesticide residues. 2nd revised edition

⁴ FAO. 2003. Pesticide Residues in Food 2003- Report. FAO Plant Production and Protection Paper No. 176 FAO, Rome. Chapter 3.

42. Under this procedure, having analyzed the situation, if an acceptable alternative GAP is not available at the moment of the evaluation, interested parties should be able to supply both labels and field trial data that support an alternative GAP within the next year. If a GAP is provided but no field trial data according to this GAP, JMPR may consider a rough estimate on the safety of the use using the proportionality principle according to the criteria in Annex C in which case the proposed MRL may be returned to Step 6 three times. The data will be evaluated by JMPR on request of CCPR as soon as they become available. If no data are supplied, CCPR should proceed to withdraw the proposed MRL.
43. The estimate of the short-term dietary intake requires substantial food consumption data that currently are only sparsely available. Governments are urged to generate relevant consumption data and to submit these data to the WHO.

RISK MANAGEMENT

ROLE OF CCPR

44. CCPR is responsible for recommending risk management proposals, such as MRL, for adoption by CAC.
45. CCPR shall base its risk management recommendations to CAC on JMPR's risk assessments of the respective pesticides, considering, where appropriate, other legitimate factors² relevant for the health protection of consumers and for the promotion of fair practices in the food trade.
46. In cases where JMPR has performed a risk assessment and CCPR or CAC determines that additional scientific guidance is necessary, CCPR or CAC may make a specific request to JMPR to provide further scientific guidance necessary for a risk management decision.
47. CCPR's risk management recommendations to CAC shall take into account the relevant uncertainties as described by JMPR.
48. CCPR shall consider only maximum residue levels recommended by JMPR.
49. CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by members and compiled by GEMS/Food.
50. If no validated methods of analysis are available for enforcing an MRL for a specific pesticide, no MRL will be established by CCPR.

SELECTION OF PESTICIDES FOR JMPR EVALUATION

51. Each year CCPR, in cooperation with the JMPR Joint Secretaries, agrees on a schedule of JMPR evaluations in the following year and considers prioritization of other pesticides for future scheduling.

Procedure for the preparation of the Schedules and Priority Lists

52. CCPR submits the Schedules and Priority Lists of Pesticides for JMPR Evaluation to CAC for approval each year, as new work, and requests the re-establishment of the Electronic Working Group (EWG) on Priorities.
53. The EWG on Priorities is tasked with preparing a Schedule of Pesticides for JMPR (evaluations for the following year) for the consideration of CCPR and the maintenance of a Priority List of Pesticides for future scheduling by CCPR.
54. The Schedules and Priority Lists are provided in the following Tables:
 - a. Table 1 – CCPR Proposed Schedule and Priority Lists of Pesticides (new pesticides, new uses and other evaluations);
 - b. Table 2A – Schedule and Priority Lists of Periodic Reviews;
 - c. Table 2B – Periodic Review List (Pesticides that have been last evaluated 15 years ago or more, but not yet scheduled or listed, "15 years-rule");
 - d. Table 3 – Record of Periodic Review;
 - e. Table 4 – Pesticide/Food combinations for which specific GAP is no longer supported.
55. Each year, the Codex Secretariat issues a letter, one month after CAC, seeking application for membership of the EWG on Priorities.
56. In early September of each year, the EWG Chair will issue a broadcast e-mail to all participating member/observers requesting nominations for:
 - a. New pesticides;
 - b. New uses of pesticides previously reviewed by JMPR;
 - c. Other evaluations to address, for example, review of toxicological endpoint and alternative GAP;
 - d. Periodic reviews of pesticides for which there are concerns including public health.

57. Nominations for new pesticides and new uses of pesticides previously reviewed by JMPR are submitted by members/observers to the EWG Chair and the JMPR Joint Secretaries using the form in the FAO Manual¹.
58. The nomination form shall provide a clear indication of the availability of data and national evaluations, as well as, give an indication of the number of crops and residue trials to be evaluated. The request should also indicate the current status of national registrations for the pesticide.
59. Nominations for other evaluations and periodic reviews should be submitted, on concern forms A and B respectively, with accompanying scientific data addressing the relevant concern. For periodic reviews, the request should also provide information on the most recent evaluation, ADI and ARfD.
60. Nominations complying with the requirements are incorporated into a list, prioritized and scheduled according to the criteria specified below:
 - a. Those received by end of November are incorporated into the draft working paper which is distributed as a circular letter in early January;
 - b. Members and observers are allowed two months from the date of distribution to provide comment to the EWG Chair and the JMPR Joint Secretaries;
 - c. On the basis of comments received in response to the circular letter, the EWG Chair incorporates the new nominations into the Schedule and Priority Lists, and prepares a working paper for consideration by CCPR. The Schedule seeks to provide a balance of new pesticides, new uses, other evaluations and periodic reviews;
 - d. Following plenary discussions on MRL recommendations, the EWG Chair revises the Schedule and Priority List, which is then presented as Conference Room Document (CRD) for consideration by CCPR. To cover the possibility that a member/observer cannot meet the JMPR data call-in deadline for new pesticide evaluations, CCPR will include reserve pesticides;
 - e. Following plenary discussion on the CRD, CCPR will agree on a JMPR Evaluation Schedule for the following year. The final Schedule will take into account available JMPR resources;
 - f. At this point, the Schedule will be closed for the inclusion of additional pesticides. However, with the agreement of the JMPR Joint Secretaries, the inclusion of additional foods or feeds for scheduled pesticides may be accepted.

Nomination requirements and criteria for the prioritization and scheduling pesticides for evaluation by JMPR

New pesticides

Nomination Requirements

61. Before a nomination is accepted the following requirements must be met:
 - a. An intention to register the pesticide for use in a member country;
 - b. The foods or feeds proposed for consideration should be traded internationally;
 - c. There is a commitment by the sponsor of the pesticide to provide supporting data for review in response to the JMPR "data call-in";
 - d. The use of the pesticide is expected to give rise to residues in or on a food or feed moving in international trade;
 - e. The pesticide has not been already accepted for consideration;
 - f. The nomination form has been completed.

Prioritization Criteria

62. The following criteria are applied when preparing the Schedules and Priority Lists:
 - a. The period of time since the pesticide was nominated for evaluation; a pesticide that was nominated first will have higher priority;
 - b. Timing of data availability;
 - c. Commitment by the member/observer to provide supporting data for review with a firm date for data submission;
 - d. The provision of information on the foods or feeds for which CXL are sought and the number of trials for each food or feed.

Scheduling Criteria

63. In order for CCPR to schedule a pesticide for JMPR evaluation in the following year:
- It must be registered for use in a member country and formulation labels made available by the time of the JMPR “data call-in”;
 - Its use must give rise to residues in or on a food or feed moving in international trade;
 - If the use of the pesticide does not give rise to detectable residues in foods and feeds, it will be afforded a lower priority than those listed pesticides for which use does give rise to measurable residues.

NEW USES OF PESTICIDES PREVIOUSLY REVIEWED BY JMPR**Nomination Requirement**

64. At the request of a member/observer, pesticides previously evaluated by JMPR may be listed in Table 1 for the inclusion of additional uses.

Prioritization Criteria

65. When prioritizing new use evaluations, the EWG on Priorities will consider the following criteria:
- The date the request was received;
 - Commitment by the sponsor to provide the required data for review in response to the JMPR “data call-in”.

Scheduling Criteria

66. Scheduling criteria are as specified in the section on new pesticide (paragraph 63).

OTHER EVALUATIONS**Nomination Requirements**

67. Pesticides previously evaluated by JMPR may be listed for further toxicological and/or residue evaluations by JMPR as a result of requests from CCPR or members when:
- A member seeks to obtain revised MRL for one or more foods or feeds; for example, on the basis of alternative GAP;
 - CCPR requests a clarification or reconsideration of a recommendation from JMPR;
 - New toxicological data becomes available to indicate a significant change in the ADI or ARfD;
 - A data deficiency is noted by JMPR during a new pesticide evaluation or periodic review and members/observers will supply the required information;
 - CCPR elects to schedule the pesticide under the four-year rule.

The four-year-rule is applied when insufficient data have been submitted to confirm or amend an existing CXL. The CXL is recommended for withdrawal. However, members/observers may provide a commitment to JMPR and CCPR to provide the necessary data for review within four years. The existing CXL is maintained for a period of no more than four years pending the review of the additional data. A second period of four years is not granted.

Prioritization Criteria

68. When prioritizing pesticides for other evaluations, the EWG on Priorities will consider the following criteria:
- The date the request was received;
 - Commitment by the sponsor to provide the required toxicological and / or residue data for review in response to the JMPR “data call in”;
 - Whether the data is submitted under the 4-year rule for evaluations;
 - The reason for its submission; for example, a request from CCPR.

Scheduling Criteria

69. Scheduling criteria are as specified in the section new pesticides (paragraph 63).

PERIODIC REVIEW

70. Pesticides that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of CXL for 15 years will be listed in Table 2B Periodic Review List.
71. Pesticides listed in Table 2B can be nominated on the basis of concerns including public health. Following acceptance on the relevant concern form, these compounds will be moved from Table 2B to Table 2A and will be considered for scheduling for periodic review.

72. The member/observer will advise the EWG on Priorities whether all or some of the CXLs will be supported. The member/observer will specify each supported and unsupported CXL.
73. Pesticides listed in Table 2B, for which no periodic review has been undertaken for 25 years, will be brought to the attention of CCPR with a view to transfer to Table 2A and subsequent scheduling.
74. Pesticides not listed in Table 2B may be considered for scheduling in Table 2A where a concern form and accompanying scientific data demonstrates a significant public health concern.

Scheduling and Prioritization Criteria for pesticides listed in Table 2A

75. The EWG on Priorities and CCPR will consider the following periodic review criteria:
 - a. If scientific data concerning the intake and/or toxicity profile of a pesticide indicates some level of public health concern;
 - b. If no ARfD has been established by Codex or if an established ADI or ARfD are of public health concern and information is available from members on national registrations and/or the conclusions from national/regional evaluations indicated a public health concern;
 - c. The availability of current labels (authorized GAP) arising from recent national reviews;
 - d. CCPR has been advised by a member that the residues from a pesticide has been responsible for trade disruption;
 - e. The date the data will be submitted;
 - f. If there is a closely related pesticide that is a candidate for periodic review that can be evaluated concurrently.
 - g. CCPR elects to schedule the pesticide under the four-year rule.

PERIODIC REVIEW PROCEDURE

Identify pesticides for Periodic Review and solicit data commitments

76. Pesticides are listed for periodic review according to the process and procedures described in the section on "Selection of pesticides for JMPR evaluation". The process provides members/observers a notice of a periodic review.
77. When a pesticide is listed for periodic review, members/observers are able to support it, regarding the two following possibilities:
 - a. Case A: The pesticide is supported by the manufacturer.
If the manufacturer does not support some uses, members/observers can support them.
 - b. Case B: The pesticide is not supported by the manufacturer.
In this case, interested members/observers may support the review of the pesticide.

Commitment to support pesticides or existing CXL or new proposed MRL

78. The commitment of members/observers to provide data for the periodic review should be addressed to the Chair of the EWG on Priorities and the JMPR Joint Secretaries according to the FAO Manual¹ and the considerations of JMPR on compounds no longer supported by the original sponsor⁵.
79. The following information must be provided in the response:
 - a. **Case A**
 - A list of pesticides and uses supported;
 - A complete nomination form according to the FAO Manual¹;
 - Toxicology studies and other data according to the requirements of JMPR;
 - A summary of all current GAP at the time of the notification and any potential new GAP expected before JMPR evaluation which they are willing to provide and which is pertinent to residue data they are willing to provide (e.g. commodities and countries for with detailed GAP summaries and representative labels can be provided). Comments on the status of registration at the national level are encouraged;
 - In cases where some uses are not supported by the manufacturer, but are supported by members/observers:
 - If the current GAP support the current CXL, justification for it as well as relevant labels are required;
 - If GAP were modified, supervised residue trial studies conducted according to current GAP, and relevant studies to support new MRL in animal and processed foods are required.

⁵ General Considerations, Section 2.1, Report of the 2012 JMPR, FAO Plant Production and Protection Paper 215, 2012, ISBN 978-92-5-107400-8.

b. Case B

- A list of pesticides and all uses supported;
- Toxicological information that address the key questions for the human health assessment, including establishment of an ADI and/or ARfD, when required. In addition, information to derive the definition of residues for enforcement of MRL and to conduct the dietary risk assessment;
- Data on a sufficient number of supervised trials in or on food and feed crops reflecting the current use patterns specified on the relevant labels required for estimation of maximum residue levels and STMR and HR values. Trial data may be complemented by relevant selective survey residue data;
- Other relevant information, such as available assessments by competent authorities and publications from a recently conducted literature.

ELABORATION PROCEDURE

UTILIZATION OF THE ACCELERATED PROCEDURE FOR ELABORATION OF MRL (STEP 5/8-PROCEDURE)

80. In order to accelerate the adoption of proposed MRL, CCPR can recommend to CAC to omit steps 6 and 7 and adopt the proposed MRL at Step 5/8. The preconditions for the omission of steps 6 and 7 are:
- a. The new proposed MRL are circulated at Step 3;
 - b. The JMPR report has been available electronically by early February;
 - c. No intake concerns have been identified by JMPR.
81. If a delegation has a concern with advancing a given MRL, a concern form must be submitted following the procedure described in the section on "Procedure for submitting concern and clarifications", at least one month before the CCPR session.
82. If that concern can be addressed at the CCPR session and the JMPR position remains unchanged, CCPR will decide if the MRL will be advanced to Step 5/8.
83. If the concern cannot be addressed at the meeting, the MRL will be advanced to Step 5 at the CCPR session and the concern will be addressed by JMPR according to the procedure described in the section on "Procedure for submitting concern and clarifications". Any other proposed MRLs for the pesticide, satisfying the above conditions, should be advanced to Step 5/8.
84. The result of the consideration of the concern by JMPR will be considered at the next CCPR session. If the JMPR position remains unchanged, CCPR will decide if the MRL will be advanced to Step 8.
85. When the ADI is exceeded in one or more cluster diets, or the ARfD is exceeded in the one or more food commodities, the MRL will not advance to Step 5/8.

DELETING CXL

86. CXL are proposed for deletion in the following scenarios:
- a. As a result of the periodic review;
 - b. Where new scientific data, following JMPR risk assessment, indicate that the active compound pesticide use may compromise human health;
 - c. The pesticide is no longer produced and commercialized, and there is no remaining stock;
 - d. The pesticide is produced but is not used in the production of food or feed;
 - e. There is no international trade of foods or feeds in which the pesticide may have been used.
87. When a pesticide meets one or more of conditions (a-e), the next CCPR session will consider a recommendation to CAC for withdrawal of the CXL. Decisions of CAC on deletion of CXL will take effect a year after the close of the session of CAC where such decisions were made.
88. If CXL are deleted and the pesticide is persistent in the environment is required to establish EMRL to cover international trade after CXL are deleted.

PROCEDURE FOR SUBMITTING CONCERN AND CLARIFICATIONS

Concerns with advancement of an MRL or the evaluation of a pesticide

89. If members or observers intend to express a concern with advancement of an MRL or the evaluation of a pesticide, they should complete and submit the concern form in Annex A to the Codex and the JMPR Joint Secretaries accompanied by scientific data at least one month before the CCPR session.

90. JMPR will evaluate the scientific data provided with the concern form. CCPR will decide whether JMPR should address the concern and schedule it based on JMPR recommendations and workload.
91. When a concern form is not submitted one month prior to the CCPR session, JMPR will consider the concern at a following meeting and CCPR would subsequently decide on the status of the MRL.
92. When considering concerns expressed by members, CCPR should recognize the position taken by JMPR as the best available scientific opinion advice (applicable at the international level) until a different position is indicated.
93. Science based concerns based on the same data/information should be considered only once by JMPR in relationship to any specific pesticide, MRL or CXL.
94. If the same information is submitted, JMPR should simply note that this information has already been reviewed and therefore no further review is warranted.

Concerns with public health on previously evaluated pesticides

95. If members or observers intend to express a public health concern on a previously evaluated pesticide for prioritization, they should complete and submit the form in Annex B along with the accompanying scientific data to the Chair of EWG on Priorities and the JMPR Joint Secretaries, in accordance with the section on "Selection of pesticides for JMPR evaluation" based on their potential higher concern regarding public health.
96. JMPR, in consultation with the EWG on Priorities, will consider whether the submitted information indicates some level of public health concern and present proposals at the subsequent CCPR session.
97. If the concern in regard to a pesticide is supported by CCPR, the pesticide will be assigned a high priority and scheduled for the next available year.
98. However, if a member or observer disagrees with the proposal by the EWG on Priorities, it must lodge additional scientific data to the Chair of the EWG on Priorities one month before the next CCPR session. At the following CCPR session, the EWG on Priorities will report its proposal. CCPR will make its final decision on prioritization.

REQUEST FOR CLARIFICATION

99. If members or observers seek clarification on a pesticide, they must complete the form provided in Annex A and indicate the specific parts of JMPR evaluation for which they seek clarification. Such requests must be included in the response to relevant Codex Circular Letters or other Codex documents. JMPR will address such requests for clarification during the next JMPR meeting and provide a response to such requests by the following CCPR session. CCPR will record any responses or change in decision made resulting from the request for clarification. Pending JMPR's response to the request for clarification, the MRL relevant to the request can proceed through the Step 5/8 procedure for the elaboration of CXL.

Addressing differences in procedures for risk assessment

100. MRL should not be prevented from advancement when there is a science-based concern regarding JMPR risk assessment procedures that JMPR has addressed through the concern form process. However, where differences exist in procedures for risk assessment (i.e., use of variability factor, use of human studies) it is imperative that CCPR/JMPR attempt to address these differences in order to limit them where possible. Appropriate action by CCPR to address these issues may include referring the issue:

- a. to JMPR if there is additional or new information, or if CCPR wishes to provide risk management input to JMPR on the conduct of risk assessments;
- b. to national governments or regional authorities for input with a discussion and decision at the next CCPR; and/or
- c. where justified by its nature, to a scientific consultation if the resources are available. Members recommending any such action by CCPR should provide information supporting their recommendation for the consideration of the Committee.

RISK COMMUNICATION

101. In accordance with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, CCPR, in cooperation with JMPR, shall ensure that the risk analysis process is fully transparent and thoroughly documented and that results are made available in a timely manner to Members, observers and interested stakeholders.
102. In order to ensure the transparency of the assessment process in JMPR, CCPR provides comments on the guidelines related to assessment procedures being drafted and published by JMPR.
103. CCPR and JMPR recognize that good communication between risk assessors and risk managers is an essential requirement for successfully performing their risk analysis activities.
104. CCPR and JMPR must continue to develop procedures to enhance communication between the two bodies.

Annex A

FORM FOR EXPRESING CONCERNS WITH ADVANCEMENT OF AN MRL OR REQUEST FOR CLARIFICATION OF CONCERNS

Submitted by:			
Date:			
Pesticide/Pesticide Code Number	Food/Food Code Number	MRL (mg/kg)	Present step
Is this a request for clarification?			
Request for clarification (Specific statement of clarification requested)			
Is this a concern?			
Is this a continuing concern?			
Concern (Specific statement of reason for concern to the advancement of the proposed MRL)			
Do you wish this concern to be noted in the CCPR Report?			
Data/Information (Description of each separate piece of data/information which will be provided to the appropriate JMPR Secretary within one month of the CCPR session)			

Annex B

FORM FOR EXPRESING CONCERNS WITH PUBLIC HEALTH ON A PESTICIDE FOR PRIORITIZATION OF PERIODIC REVIEW

Submitted by:		
Date:		
Pesticide/Pesticide Code Number	Food(s)/Food Code Number(s)	CXL (mg/kg)
Is this a concern?		
The concern relates to which prioritization criterion/criteria (Specific statement of concern)		
Is supporting data being provided?		
Data/Information (Description of each separate piece of data/information which is attached or will provided to the EWG Priorities and the appropriate JMPR Secretary within one month of the CCPR session)		
Is this a continuing concern?		
Outline ongoing concern and provide supporting data		

ANNEX C**PRINCIPLES AND GUIDANCE FOR APPLICATION OF THE PROPORTIONALITY CONCEPT FOR ESTIMATION OF MAXIMUM RESIDUE LIMITS FOR PESTICIDES**

1. Use of the concept for soil, seed and foliar treatments has been confirmed by analysis of residue data. Active substances confirmed included insecticides, fungicides, herbicides, and plant growth regulators, except desiccants.
2. The proportionality concept can be applied to data from field trials conducted within a rate range of between 0.3x and 4x the GAP rate. This is only valid when quantifiable residues occur in the dataset. Where there are no quantifiable residues, i.e. values that are less than the limit of quantification may only be scaled down. It is not acceptable to scale up in this situation.
3. The variation associated with residue values derived using this approach can be considered to be comparable to using data selected according to the $\pm 25\%$ rule for application rate.
4. Scaling is only acceptable if the application rate is the only deviation from critical GAP (cGAP). In agreement with JMPR practice, additional use of the $\pm 25\%$ rule for other parameters such as PHI is not acceptable. For additional uncertainties introduced, e.g. use of global residue data, these need to be considered on a case-by-case basis so that the overall uncertainty of the residue estimate is not increased.
5. Proportionality cannot be used for post-harvest situations at this time. It is also recommended that the concept is not used for hydroponic situations due to lack of data.
6. Proportionality can be applied for both major and minor crops. The main difference between minor and major crops is the number of trials required by national/regional authorities, which has no direct relevance to the proportionality of residues. If scaling is applied on representative crops, there is no identified concern with extrapolation to other members of an entire crop group or subgroup.
7. Regarding processed commodities, it is assumed that the processing factor is constant within an application rate range and resulting residues in the commodity being processed. Therefore existing processing factors can also be used for scaled datasets.
8. With respect to exposure assessments, no restrictions appear to be necessary. The approach may be used for distribution of residues in peel and pulp, provided the necessary information for scaling is available from each trial. Scaled datasets for feeds may also be used for dietary burden calculations for livestock.
9. The approach may be used where the dataset is otherwise insufficient to make an MRL recommendation. This is where the concept provides the greatest benefit. The concept has been used by JMPR and different national authorities on a case-by-case basis and in some cases MRLs may be estimated from trials where all of the data (100%) has been scaled.
10. Although the concept can be used on large datasets containing 100% scaled residue trials, at least 50% of trials at GAP may be requested on a case-by-case basis depending for example on the range of scaling factors. In addition, some trials at GAP might be useful as confirmatory data to evaluate the outcome in cases where the uses result in residue levels leading to a significant dietary exposure.

**APPENDIX
ORIGINAL LANGUAGE**

CODEX COMMITTEE ON PESTICIDES RESIDUES (CCPR)

EWG TO REVISE THE RISK ANALYSIS PRINCIPLES APPLIED BY CCPR

COMMENTS PRESENTED BY COUNTRIES ABOUT THE DOCUMENT "CHAIR PROPOSAL" (COSTA RICA - CHILE)

STATUS OF COMMENTS FROM ARGENTINA, AUSTRALIA, CHILE, CHINA, COSTA RICA, JAPAN, SWITZERLAND AND USA

ARGENTINA

<p>Paragraph 42 Under this procedure, if acceptable alternative GAPs is not available, interested parties have the opportunity to supply both labels and field trial data that support an alternative GAP. If there is a commitment to provide information supporting alternative GAP, the information must be provide before the draft MRL is returned to Step 6 three times. Submitted data are evaluated by JMPR, on request of CCPR, as soon as possible after they become available. If there is no commitment to support alternative GAP, or no data are supplied despite a commitment being made the CCPR withdrawal of the draft MRL.</p>	<p>Párrafo 42 La modificación planteada anula la posibilidad que la JMPR realice una "estimación aproximada sobre la inocuidad de su uso aplicando el principio de proporcionalidad" en caso de no contar con datos de ensayo sobre el terreno. Este esquema, con el que se aprobaron algunos LMR del Diclorvos en la última Sesión quedaría anulado. Consideramos que es un perjuicio al mantenimiento de LMRs, con una práctica que ya ha aceptado la JMPR y actuado con ella.</p>	<p>We will keep the original paragraph</p>
<p>Paragraph 49 CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by members and compiled by GEMS/Food.</p>	<p>Párrafo 49 Entendemos que ha sido coloreado por error pues el párrafo no difiere del propuesto inicialmente a la 45° Reunión.</p>	<p>This paragraph was omitted in the first round Comment. During this round we are including the paragraph again.</p>
<p>Paragraph 71 Pesticides listed in Table 2B can be nominated for inclusion in Table 2A and thus considered for scheduling for periodic review on the basis of concerns including public health. The nominating member/observer will submit the relevant concern form and accompanying relevant scientific data for the consideration of JMPR Secretariat / eWG on Priorities.</p>	<p>Los cambios propuestos en la primera parte no modifican el sentido del texto que fuera aprobado en la 45° Reunión, aunque resultan absolutamente innecesarios. Lo mismo sucede con la propuesta que el formulario de expresar preocupaciones sea acompañado con datos científicos, lo que específicamente se excluyó en la citada Reunión pues ya estaba claramente indicado al explicar el uso de estos formularios. (Párrafos 89 a 100)</p>	<p>We will keep the original paragraph</p>
<p>Paragraph 72 Pesticides listed in Table 2B can be nominated for inclusion in Table 2A and thus considered for scheduling for periodic review on the basis of data availability. The nominating member/observer will submit the relevant toxicological and residue data package along with an inventory of studies for the consideration of JMPR Secretariat/eWG on Priorities. The member/observer will advise the eWG on Priorities whether all or some of the CXLs will be supported and will specify each supported and unsupported CXL.</p>	<p>El texto propuesto desconoce lo resuelto en la 45° Reunión: Modifica íntegramente el texto y el sentido del artículo. Agrega la necesidad de presentar paquetes de datos Algo que fue específicamente descartado en la Reunión en la que se decidió tomar como referencia las definiciones de la JMPR de septiembre 2012 de acuerdo a lo indicado por la FAO. Incluye en este párrafo lo que el Comité aceptó para el párrafo 71</p>	<p>We will keep the original paragraph</p>

Pesticides cannot remain indefinitely as an 'unsupported' listing in Table 2B. The eWG on Priorities will recommend CCPR move a compound from Table 2B to Table 2A where no periodic review of the compound has been undertaken for at least 25 years.	Paragraph 73 Valen los comentarios realizados al Párrafo 71.	We will keep the original paragraph
Paragraph 74 Pesticides which have been the subject of a periodic review during the previous 15 years, and thus are not listed in Table 2B, may be considered for scheduling in Table 2A where a concern form and accompanying scientific data, upon review, demonstrates a public health concern.	Valen los comentarios realizados al Párrafo 71.	We will keep the original paragraph

AUSTRALIA

	<p>As Chair of the eWG on Priorities, Australia sought to ensure that the text in paragraphs 51 to 75 remains consistent with current procedures. Australia confirms that this is the case.</p> <p>Australia supports the editorial suggestions made by Switzerland but reserves judgement on the 'pesticide'- 'compound', 'food'- 'commodity' and 'product'- 'formulation' terminology changes.</p> <p>The terms compound, commodity and product are used in other Codex documents.</p> <p>As such, Australia seeks the consideration of Codex Secretariat on this matter.</p>	Because the observations of various countries, we will keep adopted at the 45th session version.
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CHILI

<p>Párrafo 54. The Schedules and Priority Lists are contained provided in the following appendices Tables:</p> <p>a. Appendix Table 1 – CCPR Proposed Schedule and Priority Lists of Pesticides (new compounds pesticides, new uses and other evaluations) and periodic reviews</p> <p>b. Appendix Table 2A – Schedule and Priority Lists of Periodic Reviews</p> <p>c. Appendix Table 2B – Periodic Review List (Compounds Pesticides listed under that have been last evaluated 15 years ago or more, rule but not yet scheduled or listed, 15 years-rule)</p> <p>d. Appendix Table 3 – Record of Periodic Review</p> <p>e. Appendix Table 4 – Compound Pesticide/Commodity Food combinations for which specific GAP is no longer supported</p>	<p>a. Tabla 1- Programa de la lista de prioridades de revisiones programadas de plaguicidas propuestos por CCPR (plaguicidas nuevos, usos nuevos y otras evaluaciones).</p> <p>b. Tabla 2A- programa y listas de prioridades de revisiones periódicas de plaguicidas que han sido evaluados hace 15 años o más.</p> <p>c. Tabla 2B – Lista de revisiones periódicas de plaguicidas que han sido evaluados hace 15 años o más, pero no programados o priorizados todavía (regla de los 15 años).</p> <p>d. Tabla 3 – Registro de reevaluación periódica (ver si el término reevaluación corresponde o no, si se refieren a las revisiones "periódica" habría que cambiar el término por revisión, ahora si son efectivamente reevaluaciones hay que quitar el término periódico).</p> <p>e. Tabla 4 – Combinaciones de plaguicida/alimento para las que ya no se apoyan BPA específicas.</p>	We will keep the original paragraph
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<p>Párrafo 70. Compounds Pesticides that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits CXLs for 15 years will be listed in Appendix Table 2B of the Schedules and Priority Lists.</p>	<p>Al final del párrafo, en vez de: “la tabla 2B de los Programas y las listas de prioridades”, debe decir: la tabla 2B Lista de revisión periódica, ya que al traducir al Castellano se entiende que el nombre de la tabla 2B es Programas y la lista de prioridades.</p>	<p>We will keep the original paragraph</p>
<p>Párrafos 71: Pesticides listed in Table 2B can be nominated for inclusion in Table 2A and thus considered for scheduling for periodic review on the basis of concerns including public health. The nominating member/observer will submit the relevant concern form and accompanying relevant scientific data for the consideration of JMPR Secretariat / eWG on Priorities.</p>	<p>Los pesticidas listados en la tabla 2B pueden ser nominados para inclusión en la tabla 2A y considerados para la programación de revisión periódica, en base a preocupaciones que incluyen la salud pública. El miembro/observador que nominó el plaguicida enviará el formulario de preocupación correspondiente, acompañado de la información científica relevante para consideración de la Secretaría de la JMPR/ grupo de trabajo electrónico de prioridades. Una vez que la Secretaría acepte el formulario de preocupación, estos pesticidas serán movidos desde el apéndice 2B al apéndice 2A.</p> <p>Es fundamental que la última frase, que fue la consensuada en la reunión se mantenga, ya que de lo contrario se está introduciendo un cambio de forma, y es muy importante que quede claro cuando pasa del 2B al 2A.</p>	<p>We will keep the original paragraph</p>
<p>Párrafo 72. Pesticides listed in Table 2B can be nominated for inclusion in Table 2A and thus considered for scheduling for periodic review on the basis of data availability. The nominating member/observer will submit the relevant toxicological and residue data package along with an inventory of studies for the consideration of JMPR Secretariat/eWG on Priorities. The member/observer will advise the eWG on Priorities whether all or some of the CXLs will be supported and will specify each supported and unsupported CXL.</p>	<p>Los pesticidas listados en la tabla 2b pueden ser nominados para la inclusión en la tabla 2A y considerados para revisión periódica en base a la disponibilidad de información. El miembro/observador que nominó el plaguicida enviará los estudios toxicológicos relevantes el paquete de datos de residuos junto con el inventario de estudios para consideración de la secretaría de la JMPR/GTE en prioridades. El miembro/observador advertirá al Gte en prioridades si apoya todos los CXL's o algunos y especificará cuales son apoyados y cuáles no.</p>	<p>We will keep the original paragraph</p>
<p>Párrafo 73. Pesticides cannot remain indefinitely as an 'unsupported' listing in Table 2B. The eWG on Priorities will recommend CCPR move a compound from Table 2B to Table 2A where no periodic review of the compound has been undertaken for at least 25 years.</p>	<p>Los cambios sugeridos para este párrafo son de fondo y deben ser discutidos y consensuados en la reunión plenaria, ya que indican que los plaguicidas NO pueden permanecer indefinidamente como un listado “no apoyado” en la Tabla 2B. Los 25 años tampoco fue un plazo consensuado y hacer este cambio al párrafo que fue consensuado durante la reunión significa en el fondo que estamos cambiando los 15 años por los 25, que es a lo que nos hemos opuestos siempre.</p>	<p>We will keep the original paragraph</p>

	<p>Las revisiones no pueden ser solamente por el mero paso del tiempo, si no que por que existe una preocupación valida. Si estamos de acuerdo en que aquellos plaguicidas que cumplieron los 25 años durante la reunión se haga un llamada de atención y en la reunión se decida que hacer con ellos (tal como estaba redactado en su forma original) pero no exprofeso decir que los plaguicidas de 25 años se van a incluir para revisión. La JMPR tiene bastante trabajo y debieran privilegiarse compuestos nuevos o los que existe preocupación valida.</p>	
<p>Párrafo 74. Pesticides which have been the subject of a periodic review during the previous 15 years, and thus are not listed in Table 2B, may be considered for scheduling in Table 2A where a concern form and accompanying scientific data, upon review, demonstrates a public health concern.</p>	<p>Eliminar este párrafo ya que no corresponde porque esta situación ya fue considerada en el párrafo 67.</p>	<p>We will keep the original paragraph</p>
<p>Párrafo 75, The EWG on Priorities and CCPR will consider the following periodic review criteria:</p> <ol style="list-style-type: none"> a. If scientific data concerning the intake and/or toxicity profile of a compound pesticide indicates some level of a public health concern; b. If no ARfD has been established by Codex or if an established ADI or ARfD are of public health concern and information is available from members on national registrations and/or the conclusions from national/regional evaluations indicated a public health concern; c. The availability of current labels (authorized GAPs) arising from recent national reviews; d. The CCPR has been advised by a member that the residues from a compound pesticide has been responsible for trade disruption; e. The date the data will be submitted; f. If there is a closely related compound pesticide that is a candidate for periodic review that can be evaluated concurrently. g. The CCPR may elect to schedule the compound pesticide under the four-year rule. 	<p>letra g. Comentario general para considerar en próxima reunión (reunión 45): Verificar si existe o crear definición expresa de norma de los 4 años.</p>	

<p>Párrafo 86. Codex MRLs CXLs are proposed for deletion in the following scenarios:</p> <p>f. As a result of the periodic reevaluation review procedure including CXLs of pesticides that have been reviewed for more than 25 years and are not supported by any member/observer;</p> <p>g. Where new scientific data, following the JMPR risk assessment, indicate that the active compound pesticide use may compromise human health;</p> <p>h. The active compound pesticide is no longer produced and commercialized, and there is no remaining stock;</p> <p>i. The active compound pesticide is produced but is not used in food or feed;</p> <p>j. There is no international trade of commodities in which the active compound pesticide may have been used.</p> <p>a.</p>	<p>a. Este cambio no debe aceptarse ya que es un cambio de fondo, que debe comentarse y consensuarse en la reunión plenaria.</p> <p>b. Eliminaron la letra b ¿por qué?.</p>	<p>We will keep the original paragraph</p>
<p>Párrafo 88. If CXLs are suppressed and the pesticide is persistent in the environment is required to establish EMRLs to cover international trade after CXLs are deleted.</p>	<p>Es razonable, pero también es un cambio de fondo que debe discutirse y llegar a acuerdo en el GTE.</p>	<p>We will keep the original paragraph</p>

CHINA

<p>19. [Where the recommended maximum residue level or limits for foods of animal origin commodities resulting from direct treatment of the animal, regardless of whether they are recommended by JMPR or the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and from residues in animal feed do not agree, the higher recommendation will prevail.]</p>	<p>China agrees the integration of paragraph 19 into the document. This is in line with the description in FAO Manual.</p>	<p>The EWG has no comments. This issue must be resolved in 46 of the CCPR meeting.</p>
<p>37. JMPR is responsible for evaluating exposure to pesticides. JMPR must strive to base its exposure assessment and hence the dietary risk assessments on global data, including that from developing countries. In addition to Global Environment Monitoring System (GEMS)/Food data, monitoring data and exposure studies may be used. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the available high percentile consumption data as provided by members and compiled by GEMS/Food.</p>	<p>37. Suggestion for rewriting. JMPR is responsible for evaluating exposure to pesticides. JMPR must strive to base its exposure assessment and hence the dietary risk assessments on global data, including that from developing countries. In addition to Global Environment Monitoring System (GEMS)/Food data, consumption monitoring data and exposure studies may be used. The GEMS/Food diets are used to assess the risk of chronic exposure. Its representativeness is an on-going refinement subject. The acute exposure calculations are based on the country specific large portion consumption data as provided by members and compiled by GEMS/Food.</p>	<p>The EWG agrees to add the word “consumption” for clarity. The EWG is not accepted include the phrase: “ representative ness is an on-going refinement subject.” Regarding the last proposed amendment, the AWG disagree with the proposed change.</p>

	Reason: Reducing uncertainty of the exposure assessment through continuing refinement of nation-based consumption data is here emphasized.	
49. CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by members and compiled by GEMS/Food.	49. CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns. The GEMS/Food diets are used to assess the risk of chronic exposure. Its representativeness is an on-going refinement subject. The acute exposure calculations are based on the country specific large portion consumption data as provided by members and compiled by GEMS/Food. Reason: The same reason as for paragraph 37.	The EWG is not accepted include the phrase: <u>“representative ness is an on-going refinement subject.”</u> Regarding the last proposed amendment, the AWG disagree with the proposed change.
50. If no validated methods of analysis are available for enforcing MRLs for a specific compound pesticide, no MRLs will be established by CCPR.	50. If no validated methods of analysis are available for enforcing MRLs for a specific pesticide, no MRLs will be established by CCPR. Method validations are but responsibilities of member countries and related parties taking consideration of PERFORMANCE CRITERIA FOR Selection of METHODS in DETERMINATION OF PESTICIDES RESIDUES IN FOOD(CCPR recommendation in progress). Doing so as the same case recommended by other multilateral inter-governmental situations.	The EWG considers that it is not necessary to clarify who is responsible for the validation of analytical methods, so the EWG proposal not accepted
62. The following criteria are applied when preparing the Schedules and Priority Lists: e. The period of time since the compound pesticide was nominated for evaluation; will have higher priority a pesticide that was nominated first	Para.62, a, line 2 a pesticide that was nominated first will have higher priority. Reason: editorial	Accepted The English version is clearer.
101. In accordance with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, the CCPR, in cooperation with JMPR, shall ensure that the risk analysis process is fully transparent and thoroughly documented and that results are made available in a timely manner to Members.	Para.101 Following “Members”, add “, observers, and interested stackholders” Reason: Make Codex activities transparent to all stockholders.	Accepted The EWG agrees as indicated in the “Working Principles for Risk Analysis” and in the definition of “risk communication” included in the Procedural Manual, section called “Definitions of the terms of the Risk Analysis relating to food safety. “

JAPAN

<p>EWG Chair proposes to use the word “food” to standardize terminology throughout the text to: food, food commodity, commodity and product. In the text is highlighted in yellow.</p>	<p>While terminology consistency is important, it should be noted that MRLs are established for ‘commodity’ which includes food or feed commodity. Therefore Japan proposes to use the term “commodity(ies),” “food commodity(ies),” or “feed commodity(ies)” when referring to establishing MRLs. The term “commodity(ies)” should be retained in those paragraphs where the term “commodity(ies)” is used to cover both food and feed commodities.</p>	<p>Partially accepted. When referring to food for human consumption, food “food” and will only use the term “Feed” animal food consumption was used. Where necessary should be indicated both terms. The term “product” will be used in cases where it is strictly necessary.</p>
<p>6. The JMPR risk assessment includes the estimation of both short-term (single day) and long-term dietary exposures and their comparison with the relevant toxicological benchmarks. MRLs in or on foods commodities and animal feeds are based on Good Agricultural Practices (GAPs) information, taking into consideration information on dietary intakes., and Residues in foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable.</p>	<p>Accodring to the <i>DEFINITIONS FOR THE PURPOSES OF THE CODEX ALIMENTARIUS</i>, “Codex Maximum Limit for Pesticide Residues (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 GAP data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable.” This text should be in consistent with the above definition and therefore the original text should be retained.</p>	<p>We will keep the original paragraph</p>
<p>MRLs FOR SPECIFIC FOODS COMMODITIES GROUP</p>	<p>MRLs FOR SPECIFIC FOODS COMMODITIES GROUP It is appropriate to use “commodity group” rather than “food group” because it is necessary to cover both food and feed commodities.</p>	<p>Partially accepted. The title will be: LMR GROUP SPECIFIC FOOD AND FEED</p>
<p>MRLs for commodity foods of animal origin</p>	<p>MRLs for commodity food commodities of animal origin See the above comment on paragraph 6 of introductory section proposing consistent use of terms related to commodities.</p>	<p>The text is maintained because it is referenced only animal foods</p>
<p>17. Additionally to JMPR data requirements, farm animal metabolism studies are required whenever a pesticide is applied directly to livestock, to animal premises or housing, or when significant residues remain in crops or commodities used in animal feed, (e.g. forage crops, plant parts that could be used in animal feeds, by products or co-products of industrial productions). The results of farm animal feeding studies and residues in animal feed serve also as a primary source of information for estimating maximum residue levels in foods of animal origin products.</p>	<p>Farm animal metabolism studies are required whenever a pesticide is applied directly to livestock, to animal premises or housing, or when significant residues remain in crops or commodities used in animal feed, (e.g. forage crops, plant parts that could be used in animal feeds, by products or co-products of industrial productions). The results of farm animal feeding studies and residues in animal feed serve also as a primary source of information for It is not necessary to add this text because farm animal metabolism studies are already included as one of the studies necessary for JMPR evaluation as described in the FAO manual.</p>	<p>Partially accepted The text is as follows: 17. Metabolism studies of farm animals are required whenever a pesticide is applied directly to livestock, or premises or livestock, or when significant residues remain in crops or products used in animal feed (eg.. Forages and plant parts could be used in feed, by-products and by-products of industrial processes). The results of studies of feeding farm animals and residues in animal feed serve also as a primary source of information for estimating maximum residue levels in food of animal origin.</p>

	See the above comment on paragraph 6 of introductory section proposing consistent use of terms related to commodities..	
<p>18. If no adequate studies are available, no MRLs will be established for commodities foods of animal origin. MRLs for feeds (and the primary crops) should not be established in the absence of animal transfer data. Where the exposure of livestock to pesticides through feeds leads to residues at the limit of quantitation (LOQ), MRLs at the LOQ must be established for foods of animal origin commodities. MRLs should be established for animals for food production where pesticides on feeds are present. Where direct treatments of pesticides are related to specific species (e.g cattle, sheep), MRL should also be established. MRLs should be established for general foods of animal origin feed commodities, for example, edible offal (mammalian), if animals are exposed to pesticide residues via animal feed, and for specific commodities foods, for example, cattle kidney, in cases where animals are directly treated with a pesticide.</p>	<p>18. If no adequate studies are available, no MRLs will be established for commodities food commodities of animal origin. MRLs for feeds (and the primary crops) should not be established in the absence of animal transfer data. Where the exposure of livestock to pesticides through feeds leads to residues at the limit of quantitation (LOQ), MRLs at the LOQ must be established for food commodities of animal origin commodities. MRLs should be established for animals for food production where pesticides on feeds are present. Where direct treatments of pesticides are related to specific species (e.g cattle, sheep), MRL should also be established. MRLs should be established for groups of food commodities of animal origin feed commodities, for example, edible offal (mammalian), if animals are exposed to pesticide residues via animal feed, and for specific commodities food commodities, for example, cattle kidney, in cases where animals are directly treated with a pesticide.</p> <p>See the above comment on paragraph 6 of introductory section proposing consistent use of terms related to commodities. (mammalian), “general foods of animal origin” should be amended as “group of food commodities of animal origin” in order to improve the clarity.</p>	<p>Not accepted In the Spanish version, to give clarity, the text: “... General animal foods...” will be replaced by: “animal foods in general”</p>
<p>19. [Where the recommended maximum residue level or limits for foods of animal origin commodities resulting from direct treatment of the animal, regardless of whether they are recommended by JMPR or the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and from residues in animal feed do not agree, the higher recommendation will prevail.]</p>	<p>Where the recommended maximum residue level or limits for food commodities of animal origin commodities resulting from direct treatment of the animal, regardless of whether they are recommended by JMPR or the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and from residues in animal feed do not agree, the higher recommendation will prevail.</p> <p>See the above comment on paragraph 6 of introductory section proposing consistent use of terms related to commodities.</p>	<p>This should be resolved at the meeting of the Committee as stated in the report of the 44th meeting</p>

	<p>For ensuring fair practices in the food trade, the maximum residue limits recommended for commodities in trade must be high enough to cover residues arising from the various legitimate uses, such as veterinary and/or pesticide uses. This paragraph adequately reflects this concept and therefore the square brackets should be removed.</p>	
<p>21. If a pesticide is determined as “fat soluble” after consideration of the following factors, it is indicated with the text “The residues are fat soluble” in the residue definition:</p> <p><u>For fat-soluble pesticides must be indicate in their residue definition the text “The residues are fat soluble”. A pesticide is considered fat soluble in the following situations:</u></p> <p>a. When available, information concerning the partitioning of the residue (as defined) in muscle versus fat in the metabolism studies and livestock feeding studies that determines the designation of a residue as being “fat soluble”;</p> <p>b. In the absence of useful information on the distribution of residues in muscle and fat, residues with Octanol-Water Partition Coefficient > 3 (log Pow >3) are likely to be “fat soluble”.</p>	<p>21.If a pesticide is determined as “fat soluble” after consideration of the following factors, it is indicated with the text “The residues are fat soluble” in the residue definition: For fat-soluble pesticides must be indicate in their residue definition the text “The residues are fat soluble”. A pesticide is considered fat soluble in the following situations:</p> <p>The original text should be retained. The proposed amendment is not appropriate because it alters the meaning of original text. Bullets a and b are only one of the factors to be considered when determining a pesticide as “fat-soluble.” For example, a pesticide that has log Pow > 3 does not automatically mean that the pesticide is “fat-soluble.”</p> <p>a. When available, information concerning the partitioning of the residue (as defined) in muscle versus fat or residues in whole milk versus milk fat in the metabolism studies and livestock feeding studies that determines the designation of a residue as being “fat soluble”;</p> <p>It is necessary to reflect the following text on current JMPR’s practice as described in the FAO Manual, which is missing in the current draft: “Data for milk and milk</p>	<p>Accepted.</p> <p>The original text is maintained by adding the reference to whole milk and milk fat.</p>
<p>24. The JMPR evaluates processing studies to derive processing factors used to estimate residues concentrations in processed foods commodities for dietary risk assessments and, if necessary, recommended maximum residue levels for processed foods commodities.</p>	<p>24.The JMPR evaluates processingstudies to derive processing factors used to estimate residues concentrations in processed food commodities for dietary risk assessments and, if necessary, recommended maximum residue levels for processed food commodities.</p> <p>See the above comment on paragraph 6 of introductory section proposing consistent use of terms related to commodities.</p>	<p>Not accepted.</p> <p>The text will refer to food and feed:</p> <p>26. The EMRLS relates to pesticide residues or contaminants derived from environmental sources due to previous agricultural uses different uses directly or indirectly in the food or feed pesticide. It is the maximum concentration of a pesticide that CCS recognized as acceptable in or on a food or feed.</p>

<p>25. The CCPR agreed to:</p> <ul style="list-style-type: none"> a. Establish MRLs for important processed food commodities from its consumption; b. Establish MRL for the processed food commodities only if the resulting value is higher than the MRL established for the corresponding raw agriculture commodity (RAC)¹, Processing Factor > 1.3 (PF > 1.3); c. Continue the practice of establishing MRLs for processed food commodities where, due to the nature of the residues during some specific process, significant amounts of other relevant metabolites appear or increase; and d. Support the current JMPR practice of evaluating all processing studies provided and including in each Evaluation/Review evaluation or review a summary table of all validated processing factors. 	<p>The CCPR agreed to:</p> <ul style="list-style-type: none"> a. Establish MRLs for important processed food commodities from its consumption; b. Establish MRL for the processed food commodities only if the resulting value is higher than the MRL established for the corresponding raw agriculture commodity (RAC)², Processing Factor > 1.3 (PF > 1.3); c. Continue the practice of establishing MRLs for processed food commodities where, due to the nature of the residues during some specific process, significant amounts of other relevant metabolites appear or increase; and d. Support the current JMPR practice of evaluating all processing studies provided and including in each Evaluation/Review evaluation or review a summary table of all validated processing factors. <p>See the above comment on paragraph 6 of introductory section proposing consistent use of terms related to commodities.</p>	
<p>26. The Extraneous Maximum Residue Limit (EMRL) refers to a pesticide residue or a contaminant arising from environmental sources due to former agricultural uses other than the use of the pesticide directly or indirectly on the food commodity. It is the maximum concentration of a pesticide residue that is recommended by the Codex Alimentarius Commission CAC to be recognized as acceptable in or on a food, agricultural commodity or animal feed.</p>	<p>26. The Extraneous Maximum Residue Limit (EMRL) refers to a pesticide residue or a contaminant arising from environmental sources due to former agricultural uses other than the use of the pesticide directly or indirectly on the commodity. It is the maximum concentration of a pesticide residue that is recommended by the Codex Alimentarius Commission CAC to be recognized as acceptable in or on a food, agricultural commodity or animal feed.</p> <p>The term “commodity” should be retained because EMRLs are established for both food and feed commodities.</p>	

¹ Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant protection and Protection Paper, 197, 2009, ISBN 978-92-5-106436-8.

² Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant protection and Protection Paper, 197, 2009, ISBN 978-92-5-106436-8.

<p>39. When the ADI is exceeded in one or more cluster diets, the JMPR further refines the dietary intake estimates at the international level. If further refinement is possible the CCPR should advance the MRLs to Stop 8 provided that the MRLs give no longer rise to intake concerns. If further refinement is not possible or the refinement still give rise to intake concern, the JMPR flags this situation when recommending maximum residue levels and the CCPR will decide on which MRLs could be advanced and which ones should be deleted.</p> <p>The JMPR uses the most up-to-date and most refined residue and consumption data available to calculate the <u>International Estimated Daily Intake (IEDI)</u>. When the ADI is exceeded in one or more of the GEMS/Food cluster diets, the JMPR flags this situation when recommending <u>maximum residue levels</u> to the CCPR.</p>	<p>When the ADI is exceeded in one or more cluster diets, the JMPR further refines the dietary intake estimates at the international level. If further refinement is possible the CCPR should advance the MRLs to Stop 8 provided that the MRLs give no longer rise to intake concerns. If further refinement is not possible or the refinement still give rise to intake concern, the JMPR flags this situation when recommending maximum residue levels and the CCPR will decide on which MRLs could be advanced and which ones should be deleted.</p> <p>The JMPR uses the most up-to-date and most refined residue and consumption data available to calculate the International Estimated Daily Intake (IEDI). When the ADI is exceeded in one or more of the GEMS/Food cluster diets, the JMPR flags this situation indicating the type of data which may be useful to further refine the dietary intake estimate when recommending maximum residue levels to the CCPR.</p> <p>We understand that it is intended to reconstruct the paragraph without altering the meaning of the original text, then it is necessary to insert such phrase in order to reflect current JMPR's practice.</p>	
<p>40. The JMPR establishes acute reference doses (ARfDs), where appropriate, and indicates cases where an ARfD is not necessary. Since 1999, the JMPR calculates the International Estimate of Short-term Intake (IESTI) for different populations, following a procedure described previously (FAO, 2003). This procedure allows for the estimation of the IESTI for the General Population and for Children (less than 6 years old).</p>	<p>The JMPR establishes acute reference doses (ARfDs), where appropriate, and indicates cases where an ARfD is not necessary. Since 1999, the JMPR calculates the International Estimate of Short-term Intake (IESTI) for the general population and children (less than 6 years old), following a procedure described previously³ (FAO, 2003). This procedure allows for the estimation of the IESTI for the General Population and for Children (less than 6 years old).</p> <p>As the term "different populations" is not clear, relevant populations should be specified for clarification.</p>	<p>ADDRESSED</p>

³ Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant protection and Protection Paper, 197, 2009, ISBN 978-92-5-106436-8.

<p>41. Where the ARfD is exceeded for a compound pesticide/food commodity combination, the JMPR report should describe the particular situation that gives rise to that acute intake concern. The JMPR shall examine available information on alternative GAPs and associated residue trials where the ARfD is not exceeded and recommends an MRL maximum residue level associated with this alternative GAP. This procedure has been referred to as the “prospective alternative GAP analysis”.</p>	<p>Where the ARfD is exceeded for a compound pesticide/food commodity combination, the JMPR report should describe the particular situation that gives rise to that acute intake concern. The JMPR shall examine available information on alternative GAPs and associated residue trials where the ARfD is not exceeded and recommends an MRL maximum residue level associated with this alternative GAP. This procedure has been referred to as the “prospective alternative GAP analysis”.</p> <p>See the above comment on paragraph 6 of introductory section proposing consistent use of terms related to commodities.</p>	
<p>42. Under this procedure, if acceptable alternative GAPs is not available, interested parties have the opportunity to supply both labels and field trial data that support an alternative GAP. If there is a commitment to provide information supporting alternative GAP, the information must be provide before the draft MRL is returned to Step 6 three times. Submitted data are evaluated by JMPR, on request of CCPR, as soon as possible after they become available. If there is no commitment to support alternative GAP, or no data are supplied despite a commitment being made the CCPR withdrawal of the draft MRL.</p>	<p>Under this procedure, if acceptable alternative GAP is not available, interested parties have the opportunity to supply both labels and field trial data that support an alternative GAP. If there is a commitment to provide information supporting alternative GAPs, the information must be provided before the draft MRL is returned to Step 6 three times. Submitted data are evaluated by JMPR, on request of CCPR, as soon as possible after they become available. If there is no commitment to support alternative GAP, or no data are supplied despite a commitment being made the CCPR withdrawal of the draft MRL.</p> <p><u>typo</u></p>	
<p>54. The Schedules and Priority Lists are contained provided in the following appendices Tables:</p> <ul style="list-style-type: none"> a. Appendix Table 1 – CCPR Proposed Schedule and Priority Lists of Pesticides (new compounds pesticides, new uses and other evaluations) and periodic reviews) Appendix Table 1 – CCPR Proposed Schedule and Priority Lists of Pesticides (new compounds pesticides, new uses and other evaluations) and periodic reviews) b. Appendix Table 2A – Schedule and Priority Lists of Periodic Reviews Appendix Table 2A – Schedule and Priority Lists of Periodic Reviews c. Appendix Table 2B – Periodic Review List (Compounds Pesticides listed under that have been last evaluated 15 years ago or more, rule but not yet scheduled or listed, 15 years-rule) Appendix Table 2B – Periodic Review List (Compounds Pesticides listed under that have been last evaluated 15 years ago or more, rule but not yet scheduled or listed, 15 years-rule) d. Appendix Table 3 – Record of Periodic Review Appendix Table 3 – Record of Periodic Review e. Appendix Table 4 – Compound Pesticide/Commodity combinations for which specific GAP is no longer supported Appendix Table 4 – Compound Pesticide/Commodity combinations for which specific GAP is no longer supported 	<p>e. Appendix Table 4 – Compound Pesticide/Commodity combinations for which specific GAP is no longer supported</p> <p>The term “commodity” should be retained because pesticides are also used for animal feeds.</p>	

<p>54. The Schedule of Pesticides for JMPR Evaluation and the Priority List of Pesticides comprise a number of appendices relating to new compounds, new uses, other evaluations and periodic review.</p>		
<p>60. Nominations complying with the requirements are incorporated into a list, prioritized and scheduled according to the criteria specified below:</p> <p>a. Those received by 30 November are incorporated into the draft agenda paper which is distributed as a circular letter in early January.</p> <p>b. Members and observers are allowed two months from the date of distribution to provide comment to the EWG Chair and JMPR Joint Secretariat.</p> <p>c. On the basis of comments received in response to the circular letter, the EWG Chair incorporates the new nominations into the Schedule and Priority Lists, and prepares an agenda paper for CCPR. The Schedule seeks to provide a balance of new compounds pesticides, new uses, other evaluations and periodic reviews.</p> <p>d. Following plenary discussions on MRL recommendations, the EWG Chair revises the Schedule and Priority List, which is then presented as Conference Room Document (CRD1) for CCPR's consideration. To cover the possibility that a member/observer cannot meet the JMPR data call-in deadline for new compound pesticide evaluations, CCPR will include reserve compounds pesticides.</p> <p>e. Following plenary discussion on CRD1, CCPR will agree on a JMPR Evaluation Schedule for the following year. The final Schedule will take into account available JMPR resources.</p> <p>f. At this point, the Schedule will be closed for the inclusion of additional compounds pesticides. However, with the agreement of the JMPR Secretariat, the inclusion of additional commodities foods for scheduled compounds pesticides may be accepted.</p>	<p>f. At this point, the Schedule will be closed for the inclusion of additional compounds pesticides. However, with the agreement of the JMPR Secretariat, the inclusion of additional commodities for scheduled compounds pesticides may be accepted.</p> <p>The term "commodities" should be retained because both food and feed commodities are included in the priority list.</p>	
<p>61. Before a nomination is accepted the following requirements must be met:</p> <p>a. An intention to register the compound pesticide for use in a member country;</p> <p>b. The commodities proposed for consideration should be traded internationally;</p>	<p>b. The commodities proposed for consideration should be traded internationally;</p> <p>d. The use of the compound pesticide is expected to give rise to residues in or on a food or feed commodity moving in international trade;</p>	

<p>c. There is a commitment by the sponsor of the compound pesticide to provide supporting data for review in response to the JMPR “data call-in”;</p> <p>d. The use of the compound pesticide is expected to give rise to residues in or on a food or feed commodity moving in international trade;</p> <p>e. The compound pesticide has not been already accepted for consideration;</p> <p>f. A completed The nomination form has been completed.</p>	<p>The term “commodities” should be retained as Codex MRLs are established for both food and feed commodities.</p> <p>See the above comment on paragraph 6 of introductory section proposing consistent use of terms related to commodities.</p>	
<p>62. The following criteria are applied when preparing the Schedules and Priority Lists:</p> <p>a. The period of time since the compound pesticide was nominated for evaluation; will have higher priority a pesticide that was nominated first</p> <p>Timing of data availability;</p> <p>c. Commitment by the member/observer to provide supporting data for review with a firm date for data submission;</p> <p>d. The provision of information on the commodities foods for which CXLs are sought and the number of trials for each commodity food.</p>	<p>a. The period of time since the compound pesticide was nominated for evaluation; will have higher priority a pesticide that was nominated first</p> <p>It is not necessary to add this text as the meaning of the original text is clear.</p> <p>d. The provision of information on the commodities Feed for which CXLs are sought and the number of trials for each commodity Feed.</p> <p>The term “commodity(ies)” should be retained as Codex MRLs are established for both food and feed commodities.</p>	Not Accepted
<p>63. In order for CCPR to schedule a compound pesticide for JMPR evaluation in the following year:</p> <p>a. It must be registered for use in a member country and product formulations labels made available by the time of JMPR “data call-in”;</p> <p>b. Its use must give rise to residues in or on a food or feed commodity moving in international trade;</p> <p>c. If the use of the compound pesticide does not give rise to detectable residues in foods and feeds, it will be afforded a lower priority than those listed compounds pesticides for which use does give rise to measurable residues.</p>	<p>a. Its use must give rise to residues in or on a food or feed commodity moving in international trade;</p> <p>See the above comment on paragraph 6 of introductory section proposing consistent use of terms related to commodities.</p>	
<p>67. Compounds Pesticides previously evaluated by JMPR may be listed for further toxicological and/or residue evaluations by the JMPR as a result of requests from CCPR or members when:</p> <p>a. A member seeks to obtain revised MRLs for one or more commodities foods; for example, on the basis of alternative GAP;</p> <p>b. The CCPR requests a clarification or reconsideration of a recommendation from the JMPR;</p>	<p>a. A member seeks to obtain revised MRLs for one or more commodities; for example, on the basis of alternative GAP;</p> <p>The term “commodities” should be retained as Codex MRLs are established for both food and feed commodities.</p> <p>The CCPR may elect to schedule the compound pesticide under the four-year rule.</p>	The EWG does not accept the proposal because it believes what the text is clearer as proposed.

<p>c. New toxicological data becomes available to indicate a significant change in the ADI or ARfD;</p> <p>d. A data deficiency is noted by JMPR during a New compound Pesticide Evaluation or Periodic Review and members/observers will supply the required information.</p> <p>e. The CCPR may elect to schedule the compound pesticide under the four-year rule.</p> <p>Note: The four-year-rule is applied when insufficient data have been submitted to confirm or amend an existing Codex MRL CXL. The Codex MRL CXL is recommended for withdrawal. However, members/observers may provide a commitment to the JMPR and CCPR to provide the necessary data for review within four years. The existing Codex MRL CXL is maintained for a period of no more than four years pending the review of the additional data. A second period of four years is not granted.</p>	<p>Note: The four-year-rule is applied when insufficient data have been submitted to confirm or amend an existing Codex MRL CXL. The Codex MRL CXL is recommended for withdrawal. However, members/observers may provide a commitment to the JMPR and CCPR to provide the necessary data for review within four years. The existing Codex MRL CXL is maintained for a period of no more than four years pending the review of the additional data. A second period of four years is not granted.</p> <p>This text should be written as independent paragraph rather than bullet because the "four-year rule" is different from the nomination 'requirements' as specified in bullets a-d.</p> <p>As these texts are the detailed explanation of "four-year rule," they should be written as "Note."</p>	
<p>75. The EWG on Priorities and CCPR will consider the following periodic review criteria:</p> <p>a. If scientific data concerning the intake and/or toxicity profile of a compound pesticide indicates some level of a public health concern;</p> <p>b. If no ARfD has been established by Codex or if an established ADI or ARfD are of public health concern and information is available from members on national registrations and/or the conclusions from national/regional evaluations indicated a public health concern;</p> <p>c. The availability of current labels (authorized GAPs) arising from recent national reviews;</p> <p>d. The CCPR has been advised by a member that the residues from a compound pesticide has been responsible for trade disruption;</p> <p>e. The date the data will be submitted;</p> <p>f. If there is a closely related compound pesticide that is a candidate for periodic review that can be evaluated concurrently.</p>	<p>g. The CCPR may elect to schedule the compound pesticide under the four-year rule.</p> <p>Note: the four-year rule is applied when insufficient data have been submitted to confirm or amend an existing Codex MRL. The Codex MRL is recommended for withdrawal. However, members/observers may provide a commitment to the JMPR and CCPR to provide the necessary data for review within four years. The existing Codex MRL is maintained for a period of no more than four years pending the review of the additional data. A second period of four years is not granted.</p> <p>This text should be written as independent paragraph rather than bullet because the "four-year rule" is different from the periodic review 'criteria' as specified in bullets a-f.</p>	<p>The EWG does not accept the proposal</p>

<p>79. The following information must be provided in the response:</p> <p>c. In Case A</p> <ul style="list-style-type: none"> • A list of compounds pesticides and uses supported; • A complete nomination form according to the FAO Manual⁴; • Toxicology studies and other data according to the requirements of JMPR; • A summary of all current Good Agricultural Practices (GAPs) Good Agricultural Practices (GAPs) at the time of the notification and any potential new GAPs expected before the JMPR evaluation which they are willing to provide and which is pertinent to residue data they are willing to provide (e.g. commodities and countries for which detailed GAP summaries and representative labels can be provided). Comments on the status of registration at the national level are encouraged; <p>In cases where some uses are not supported by the manufacturer, but are supported by members / observers may support the uses:</p> <ul style="list-style-type: none"> ○ If the current GAPs support the current CXL, justification for it as well as relevant labels are required; ○ If GAPs were modified, supervised residue trial studies conducted according to current GAP, and relevant studies to support new MRLs in animal and processed commodities food commodities. 	<ul style="list-style-type: none"> ○ If GAPs were modified, supervised residue trial studies conducted according to current GAP, and relevant studies to support new MRLs in animal and processed commodities food commodities. <p>See the above comment on paragraph 6 of introductory section proposing consistent use of terms related to commodities.</p>	
<p>80. In order to accelerate the adoption of proposed MRLs, CCPR can recommend to CAC to omit steps 6 and 7 and adopt the proposed MRLs at step 8. This procedure is called "Step 5/8-procedure". The preconditions for utilization of Step 5/8 Procedure are:</p>	<p>In order to accelerate the adoption of proposed MRLs, CCPR can recommend to CAC to omit steps 6 and 7 and adopt the proposed MRLs at step 8. This procedure is called "Step 5/8-procedure". The preconditions for utilization of Step 5/8 Procedure are:</p> <p><u>typo</u></p>	

⁴ Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed, FAO Plant Production and Protection Paper, 197, 2009, ISBN 978-92-5-106436-8

<p>86. Codex MRLs CXLs are proposed for deletion in the following scenarios:</p> <p>a. As a result of the periodic reevaluation review procedure including CXLs of pesticides that have been reviewed for more than 25 years and are not supported by any member/observer;</p> <p>b. Where new scientific data, following the JMPR risk assessment, indicate that the active compound pesticide use may compromise human health;</p> <p>c. The active compound pesticide is no longer produced and commercialized, and there is no remaining stock;</p> <p>d. The active compound pesticide is produced but is not used in food or feed;</p> <p>e. There is no international trade of commodities in which the active compound pesticide may have been used.</p>	<p>b. Where new scientific data, following the JMPR risk assessment, indicate that the active compound pesticide use may compromise human health;</p> <p>This bullet should be retained for the following reasons:</p> <p>According to the 44th CCPR Report (REP 12/PR, paragraph 160), for <i>Section 6. Elaboration Procedure</i>, the Committee “agreed with this section but noted that it might need further review upon completion of the sections which were still under development, such as the provisions on concern forms.” This bullet is not affected by the agreement of other sections; and</p> <p>Codex MRL shall be based on the principles of sound scientific analysis and evidence involving a thorough review of all relevant information, and should be reviewed as appropriate in the light of newly generated scientific data, in accordance with the <i>Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius and Statements of Principles Concerning the Role of Science in the Codex Decision-Making Process and the Extent Which Other Factors are Taken into Account</i>.</p> <p>d. The active compound pesticide is produced but is not used in food or feed; This bullet should be retained because there may be a case where a pesticide is no longer used for food crops while continues to be used for non-food crops (e.g.turfs/ornamentals). In such a case it is not necessary to retain CXLs.</p>	<p>We will keep the original paragraph</p>
	<p>87. When a compound pesticide meets one or more of conditions (a-e), its MRL CXLs list will be included in the agenda for the next CCPR session for the Committee to consider a recommendation to the CAC for withdrawal of the MRLs CXLs. Decisions of the CAC on deletion of MRLs CXLs will take effect a year after the close of the session of the CAC where such decisions were made.</p> <p>Note: If a pesticide meetings the above stated conditions and is environmentally persistent, the need of EMRLs are needed to cover international trade should be considered before after its MRLs are deleted.</p> <p>The original text should be retained with amendment to improve the clarity as the meaning of proposed text is not clear.</p>	<p>The EWG does not accept the proposal because it believes that the meaning of the proposed text is less clear</p>

<p>88. If CXLs are suppressed and the pesticide is persistent in the environment is required to establish EMRLs to cover international trade after CXLs are deleted.</p>	<p>If CXLs are suppressed and the pesticide is persistent in the environment is required to establish EMRLs to cover international trade after CXLs are deleted.</p> <p>The original text should be retained with amendment to improve the clarity as the meaning of proposed text is not clear.</p>	<p>We do not agree to replenish the original text, but if we believe that this paragraph must be part of paragraph 87 and not a separate paragraph.</p>												
<p>92. When considering concerns expressed by members, CCPR should recognize the position taken by the JMPR as the best available science scientific opinion (applicable at the international level) until and if a different position is indicated.</p>	<p>When considering concerns expressed by members, CCPR should recognize the position taken by the JMPR as the best available science scientific advice (applicable at the international level) until and if a different position is indicated.</p> <p>The JMPR provides scientific advice to the CCPR, as stated in paragraph 31.</p>	<p>Accepted</p>												
	<p align="center">Annex A FORM FOR EXPRESSING CONCERNS WITH ADVANCEMENT OF AN MRL OR REQUEST FOR CLARIFICATION OF CONCERNS</p> <table border="1" data-bbox="603 875 1002 1066"> <tr> <td colspan="4" style="text-align: center;">Submitted by:</td> </tr> <tr> <td colspan="4" style="text-align: center;">Date:</td> </tr> <tr> <td style="text-align: center;">Pesticide/ Pesticide Code Number</td> <td style="text-align: center;">Commodity (ies) Feed-/ Commodity Feed-Code Number</td> <td style="text-align: center;">MRL (mg/ kg)</td> <td style="text-align: center;">Present step</td> </tr> </table> <p>The term “commodity(ies)” should be retained because Codex MRLs are established for both food and feed commodities. The concern form may be submitted for issues related to feed commodity/food commodity of animal origin as a result of evaluation by the JMPR.</p>	Submitted by:				Date:				Pesticide/ Pesticide Code Number	Commodity (ies) Feed-/ Commodity Feed-Code Number	MRL (mg/ kg)	Present step	
Submitted by:														
Date:														
Pesticide/ Pesticide Code Number	Commodity (ies) Feed-/ Commodity Feed-Code Number	MRL (mg/ kg)	Present step											
	<p align="center">Annex B FORM FOR EXPRESSING CONCERNS WITH PUBLIC HEALTH ON A PESTICIDE FOR PRIORITIZATION OF PERIODIC REVIEW</p> <table border="1" data-bbox="603 1507 1023 1644"> <tr> <td colspan="3" style="text-align: center;">Submitted by:</td> </tr> <tr> <td colspan="3" style="text-align: center;">Date:</td> </tr> <tr> <td style="text-align: center;">Pesticide/ Pesticide Code Number</td> <td style="text-align: center;">Commodity(ies)Feed(s)/ Commodity FeedCode Number(s)</td> <td style="text-align: center;">CXL (mg/kg)</td> </tr> </table> <p>The term “commodity(ies)” should be retained because Codex MRLs are established for both food and feed commodities. The concern form may be submitted for issues related to feed commodity/food commodity of animal origin as a result of evaluation by the JMPR.</p>	Submitted by:			Date:			Pesticide/ Pesticide Code Number	Commodity(ies)Feed(s)/ Commodity FeedCode Number(s)	CXL (mg/kg)				
Submitted by:														
Date:														
Pesticide/ Pesticide Code Number	Commodity(ies)Feed(s)/ Commodity FeedCode Number(s)	CXL (mg/kg)												

SWITZERLAND

<p>5. The FAO Panel of Experts on Pesticide Residues in Food and the Environment considers data on registered use patterns, fate of residues, animal and plant metabolism, analytical methodology and residue data derived from supervised residue trials in order to propose residue definitions and MRLs maximum residues levels for the pesticide in food and feed commodities.</p>	<p>5. The FAO Panel of Experts on Pesticide Residues in Food and the Environment considers data on registered use patterns, fate of residues, animal and plant metabolism, analytical methodology and residue data derived from supervised residue trials in order to propose residue definitions and MRLs maximum residues levels for the pesticide in food and feed commodities.</p> <p>As you suggest in point 6.</p>	Accepted
<p>6. The JMPR risk assessment includes the estimation of both short-term (single day) and long-term dietary exposures and their comparison with the relevant toxicological benchmarks. MRLs in or on foods commodities and animal feeds are based on Good Agricultural Practices (GAPs) information, taking into consideration information on dietary intakes., and Residues in foods derived from commodities and Residues in processed foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable.</p>	<p>6. The JMPR risk assessment includes the estimation of both short-term (single day) and long-term dietary exposures and their comparison with the relevant toxicological benchmarks. MRLs in or on foods commodities and animal feeds are based on Good Agricultural Practices (GAPs) information, taking into consideration information on dietary intakes., and Residues in processed foods derived from commodities and Residues in processed foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable.</p> <p>The meaning of this sentence is that als food that is derived from the ones having an MRLs, is intended to be toxicologically acceptable.</p>	Because of to comments received by Japan, we will keep the original paragraph
<p>21. If a pesticide is determined as "fat soluble" after consideration of the following factors, it is indicated with the text "The residues are fat soluble" in the residue definition:</p> <p>For fat-soluble pesticides must be indicate in their residue definition the text "The residues are fat soluble". A pesticide is considered fat soluble in the following situations:</p> <ol style="list-style-type: none"> When available, information concerning the partitioning of the residue (as defined) in muscle versus fat in the metabolism studies and livestock feeding studies that determines the designation of a residue as being "fat soluble"; In the absence of useful information on the distribution of residues in muscle and fat, residues with Octanol-Water Partition Coefficient > 3 (log Pow >3) are likely to be "fat soluble". 	<p>b. In the absence of useful information on the distribution of residues in muscle and fat, residues with Octanol-Water Partition Coefficient > 3 (log Pow >3) are likely to be "fat soluble".</p> <p>repetition: At the beginning it is indicated that "A pesticide is considered fat soluble in the following situations".</p>	We will keep the original paragraph
<p>24. The JMPR evaluates processing studies to derive processing factors used to estimate residues concentrations in processed foods commodities for dietary risk assessments and, if necessary, recommended maximum residue levels for processed foods commodities.</p>	<p>24. The JMPR evaluates processing studies to derive processing factors used to estimate residues concentrations in processed foods or feeds commodities for dietary risk assessments and, if necessary, recommended maximum residue levels for processed foods or feeds commodities.</p> <p>I suppose that in this case the processed commodity can be either food or feed.</p>	Accepted

<p>25. The CCPR agreed to:</p> <ul style="list-style-type: none"> e. Establish MRLs for important processed foods commodities foods from its consumption; f. Establish MRL for the processed commodities foods only if the resulting value is higher than the MRL established for the corresponding raw agriculture commodity (RAC), Processing Factor > 1.3 (PF > 1.3); g. Continue the practice of establishing MRLs for processed foods commodities where, due to the nature of the residues during some specific process, significant amounts of other relevant metabolites appear or increase; and h. Support the current JMPR practice of evaluating all processing studies provided and including in each Evaluation/Review evaluation or review a summary table of all validated processing factors. 	<p>The CCPR agreed to: Everything in this document is agreed by CCPR</p>	<p>Partially accepted.</p>
<p>31. The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) consists of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. It is an independent scientific expert body convened by both Directors General of FAO and WHO according to the rules of both organizations, charged with the task to provide scientific advice on pesticide residues.</p>	<p>The Joint FAO/WHO Meeting on Pesticide Residues JMPR)consists of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. It is an independent scientific expert body convened by both Directors General of FAO and WHO according to the rules of both organizations, charged with the task to provide scientific advice on pesticide residues. the abbreviation JMPR is already introduced in paragraph 1.</p>	<p>Accepted</p>
<p>37. JMPR is responsible for evaluating exposure to pesticides. JMPR must strive to base its exposure assessment and hence the dietary risk assessments on global data, including that from developing countries. In addition to Global Environment Monitoring System (GEMS)/Food data, monitoring data and exposure studies may be used. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the available high percentile consumption data as provided by members and compiled by GEMS/Food.</p>	<p>JMPR is responsible for evaluating exposure to pesticides. JMPR must strive to base its exposure assessment and hence the dietary risk assessments on global data, including that from developing countries. In addition to Global Environment Monitoring System (GEMS)/Food data, monitoring data and exposure studies may be used. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on these diets, but on the available high percentile consumption data as provided by members and compiled by GEMS/Food. I suggest to indicate on what they are based and omit the part “not based on...”.</p>	<p>Accepted</p>

<p>39. The JMPR uses the most up-to-date and most refined residue and consumption data available to calculate the International Estimated Daily Intake (IEDI). When the ADI is exceeded in one or more of the GEMS/Food cluster diets, the JMPR flags this situation when recommending maximum residue levels to the CCPR.</p>	<p>The JMPR establishes an Acceptable Daily Intake (ADI) and The JMPR uses the most up-to-date and most refined residue and consumption data available to calculate the International Estimated Daily Intake (IEDI). When the ADI is exceeded in one or more of the GEMS/Food cluster diets, the JMPR flags this situation when recommending maximum residue levels to the CCPR.</p> <p>In analogy to paragraph 40, the JMPR also establishes ADIs before calculating the IEDI.</p>	<p>Because of to comments received by various countries We will keep the original paragraph When the ADI is exceeded in one or more regional diets, the JMPR best fits the estimation of dietary intake internationally. If further adjustment is possible, the CCPR should advance the MRLs to Step 8 provided that the MRLs do not continue presenting concerns regarding intake. If not possible further adjustment, or adjustment still has concerns regarding the intake, this situation points to JMPR to recommend maximum residue levels, the CCPR will decide which MRL could advance and which should be deleted</p>
<p>40. The JMPR establishes acute reference doses (ARfDs), where appropriate, and indicates cases where an ARfD is not necessary. Since 1999, the JMPR calculates the International Estimate of Short-term Intake (IESTI) for different populations, following a procedure described previously (FAO, 2003). This procedure allows for the estimation of the IESTI for the General Population and for Children (less than 6 years old).</p>	<p>The JMPR establishes acute reference doses (ARfDs), where appropriate, and indicates cases where an ARfD is not necessary. Where the ARfD is set, the JMPR calculates the International Estimate of Short-term Intake (IESTI) for different populations, following a procedure described previously⁵ (FAO, 2003). This procedure allows for the estimation of the IESTI for the General Population and for Children (less than 6 years old).</p> <p>It is not necessary to indicate since when the ARfD is being set. However, I suggest to indicate that IESTI is only calculated when an ARfD has been set.</p>	<p>Accepted</p>

<p>42. Under this procedure, if acceptable alternative GAPs is not available, interested parties have the opportunity to supply both labels and field trial data that support an alternative GAP. If there is a commitment to provide information supporting alternative GAP, the information must be provide before the draft MRL is returned to Step 6 three times. Submitted data are evaluated by JMPR, on request of CCPR, as soon as possible after they become available. If there is no commitment to support alternative GAP, or no data are supplied despite a commitment being made the CCPR withdrawal of the draft MRL.</p>	<p>42. Under this procedure, if acceptable alternative GAPs is not available, interested parties have the opportunity to supply both labels and field supervised trial data residue studies that support an alternative GAP. If there is a commitment to provide information supporting alternative GAP, the information must be provide before the draft MRL is returned to Step 6 three times. Submitted data are evaluated by JMPR, on request of CCPR, as soon as possible after they become available. If there is no commitment to support alternative GAP, or no data are supplied despite a commitment being made the CCPR withdrawal of the draft MRL will be withdrawn.</p> <p>I suggest to use the same wording as elsewhere (e.g. para. 79)</p> <p>linguistic proposal</p>	<p>We will keep the original paragraph 42. Under this procedure, having analyzed the situation, if there is no alternative BPA acceptable at the time of the evaluation, stakeholders should be able to provide data labels and field trials support the alternative BPA within one year. If BPA is provided but no data of field tests are given in accordance with this BPA, the JMPR could be considered a rough estimate on the safety of use by applying the principle of proportionality according to the agreed criteria, in which case the proposed MRL could be returned to Step 6 three times. The information will be evaluated by the JMPR CCPR request as soon as it is available. If no data is supplied CCPR should proceed to withdraw the draft MRL.</p>
<p>49. CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by members and compiled by GEMS/Food.</p>	<p>CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by members and compiled by GEMS/Food.</p> <p>This is a repetition of para. 48: If CCPR only considers maximum residue levels recommended by JMPR, they will be evaluated based on the GEMS/Food diets as indicated in para. 37.</p>	<p>not accepted</p> <p>Paragraph 49 details some important aspects that definitely makes the JMPR.</p>
<p>51. Each year CCPR, in cooperation with the Joint JMPR Secretariat, agrees on a schedule of JMPR evaluations in the following year and considers prioritization of other compounds pesticides for consideration of future scheduling.</p>	<p>51. Each year CCPR, in cooperation with the Joint JMPR Secretariat, agrees on a schedule of JMPR evaluations in the following year and considers prioritization of other compounds pesticides for consideration of future scheduling.</p> <p>suggestion to omit this repetition.</p>	<p>Accepted</p>
<p>61. Before a nomination is accepted the following requirements must be met:</p> <ol style="list-style-type: none"> An intention to register the compound pesticide for use in a member country; The foods and feeds commodities proposed for consideration should be traded internationally; 	<p>b.The foods and feeds commodities proposed for consideration should be traded internationally;</p> <p>As suggested in point 6.</p>	

<p>62. The following criteria are applied when preparing the Schedules and Priority Lists:</p> <p>a. The period of time since the compound pesticide was nominated for evaluation; will have higher priority a pesticide that was nominated first</p>	<p>a. The period of time since the compound pesticide was nominated for evaluation; will have higher priority a pesticide that was nominated first will have higher priority</p> <p>linguistic proposal.</p>	
<p>67. Compounds Pesticides previously evaluated by JMPR may be listed for further toxicological and/or residue evaluations by the JMPR as a result of requests from CCPR or members when:</p> <p>a. A member seeks to obtain revised MRLs for one or more commodities foods; for example, on the basis of alternative GAP;</p> <p>b. The CCPR requests a clarification or reconsideration of a recommendation from the JMPR;</p> <p>c. New toxicological data becomes available to indicate a significant change in the ADI or ARfD;</p> <p>d. A data deficiency is noted by JMPR during a New compound Pesticide Evaluation or Periodic Review and members/observers will supply the required information.</p> <p>e. The CCPR may elect to schedule the compound pesticide under the four-year rule.</p>	<p>Proposal: use capitals only in titles.</p> <p>d. A data deficiency is noted by JMPR during a <u>new compound</u> pesticide evaluation or periodic review and members/observers will supply the required information.</p> <p>Proposal: use capitals only in titles.</p> <p>e. The CCPR may elect to schedule the compound pesticide under the four-year rule.</p> <p>linguistic proposal: The pesticides may be listed, when they are elected by CCPR.</p>	ADDRESSED
<p>79. The following information must be provided in the response:</p> <p>f. In Case A</p> <ul style="list-style-type: none"> • A list of compounds pesticides and uses supported; • A complete nomination form according to the FAO Manual; • Toxicology studies and other data according to the requirements of JMPR; • A summary of all current Good Agricultural Practices (GAPs) Good Agricultural Practices at the time of the notification and any potential new GAPs expected before the JMPR evaluation which they are willing to provide and which is pertinent to residue data they are willing to provide (e.g. commodities and countries for which detailed GAP summaries and representative labels can be provided). Comments on the status of registration at the national level are encouraged; • In cases where some uses are not supported by the manufacturer, but are supported by members / observers may support the uses: • If the current GAPs support the current CXL, justification for it as well as relevant labels are required; 	<p>The verb was missing here.</p> <ul style="list-style-type: none"> ○ If GAPs were modified, supervised residue trial studies conducted according to current GAP, and relevant studies to support new MRLs in animal and processed commodities foods are required. <p>The verb was missing here.</p>	Accepted

<ul style="list-style-type: none"> If GAPs were modified, supervised residue trial studies conducted according to current GAP, and relevant studies to support new MRLs in animal and processed commodities foods. 								
<p>UTILIZATION THE ACCELERATED PROCEDURE OF STEPS 5/8 FOR ELABORATION OF MRLS (STEP 5/8-PROCEDURE)</p> <p>80. In order to accelerate the adoption of proposed MRLs, CCPR can recommend to CAC to omit esteps 6 and 7 and adopt the proposed MRLs al step 8. This procedure is called "Step 5/8-procedure". The preconditions for utilization of Step 5/8 Procedure are:</p>	<p>UTILIZATION OF THE UTILIZATION OF THE ACCELERATED PROCEDURE OF STEPS 5/8 FOR ELABORATION OF MRLS (STEP 5/8-PROCEDURE)</p> <p>80. In order to accelerate the adoption of proposed MRLs, CCPR can recommend to CAC to omit <u>the</u> steps 6 and 7 and adopt the proposed MRLs <u>at</u> step 8. This procedure is called "Step 5/8-procedure". The preconditions for utilization of Step 5/8 Procedure are:</p>	<p>ADDRESSED</p>						
<p>86. Codex MRLs CXLs are proposed for deletion in the following scenarios:</p> <p>a. As a result of the periodic evaluation review procedure including CXLs of pesticides that have been reviewed for more than 25 years and are not supported by any member/observer;</p>	<p>a. As a result of the periodic evaluation review procedure including CXLs of pesticides that have not been reviewed for more than 25 years and are not supported by any member/observer; negation was missing.</p>	<p>ADDRESSED</p>						
<p>99. If members or observers seek clarification on a compound pesticide, they must complete the form provided in Annex A and provide the specifics of the JMPR evaluation for which they seek clarification. Such requests must be included in the response to relevant Codex Circular Letter or other Codex papers. The JMPR will address such requests for clarification during the next JMPR meeting and provide a response to such requests by the following CCPR session. The CCPR will record any responses or change in decision made resulting from the request for clarification. Pending JMPR's respond to the request of the clarification, the MRL(s) relevant to the request can proceed through the Codex 5/8 step process for the elaboration of MRLs CXLs.</p>	<p>If members or observers seek clarification on a compound pesticide, they must complete the form provided in Annex A and provide indicate the specifics parts of the JMPR evaluation for which they seek clarification. Such requests must be included in the response to relevant Codex Circular Letter or other Codex papers. The JMPR will address such requests for clarification during the next JMPR meeting and provide a response to such requests by the following CCPR session. The CCPR will record any responses or change in decision made resulting from the request for clarification. Pending JMPR's respond to the request of the clarification, the MRL(s) relevant to the request can proceed through the Codex 5/8 step process for the elaboration of MRLs CXLs. linguistic modification.</p>	<p>ADDRESSED</p>						
<p>Annex A FORM FOR EXPRESING CONCERNS WITH ADVANCEMENT OF AN MRL OR REQUEST FOR CLARIFICATION OF CONCERNS</p>	<table border="1"> <tr> <td colspan="2">Submitted by:</td> </tr> <tr> <td colspan="2">Date:</td> </tr> <tr> <td>Pesticide/ Pesticide Code Number</td> <td>Commodity Food or Feed/ Commodity Food Code Number</td> </tr> </table>	Submitted by:		Date:		Pesticide/ Pesticide Code Number	Commodity Food or Feed/ Commodity Food Code Number	<p>Accepted</p>
Submitted by:								
Date:								
Pesticide/ Pesticide Code Number	Commodity Food or Feed/ Commodity Food Code Number							

THE UNITED STATES OF AMERICA

<p>MRLs FOR SPECIFIC FOODS GROUP</p>	<p>The U.S. Delegation would also like to offer some minor grammatical edits for your consideration as follows: The title for <i>MRLs for Specific Foods Group</i> should be changed to <i>MRLs for Specific Food Groups</i>.</p>	<p>Accepted</p>
<p>21. If a pesticide is determined as “fat soluble” after consideration of the following factors, it is indicated with the text “The residues are fat soluble” in the residue definition: c. When available, information concerning the partitioning of the residue (as defined) in muscle versus fat or residue in whole milk versus milk fat in the metabolism studies and livestock feeding studies that determines the designation of a residue as being “fat soluble”; d. In the absence of useful information on the distribution of residues in muscle and fat, residues with Octanol-Water Partition Coefficient > 3 (log Pow >3) are likely to be “fat soluble”.</p>	<p>The U.S. Delegation recommends Para 21 be revised to read: The residue definition for fat-soluble pesticides must include the text “The residues are fat soluble.” A pesticide is considered fat soluble in the following situations:</p>	<p>We will keep the original paragraph</p>
<p>33. JMPR is primarily responsible for performing the risk assessments and proposing MRLs maximum residue levels upon which CCPR and ultimately the CAC base their risk management decisions. JMPR proposes maximum residue levels based on residues data from Good Agricultural Practices (GAPs) /registered uses or in specific cases, such as EMRLs and MRLs for spices based on monitoring data.</p>	<p>In para 33 in the second sentence “residues” should be singular so the sentence reads: JMPR proposes maximum residue levels based on residue data GAPs/registered uses or in specific cases, such as EMRLs and MRLs for spices based on monitoring data.</p>	<p>Accepted</p>
<p>42. Under this procedure, having analyzed the situation, if an acceptable alternative GAP is not available at the moment of the evaluation, interested parties should be able to supply both labels and field trial data that support an alternative GAP within the next year. If a GAP is provided but no field trial data according to this GAP, JMPR may consider a rough estimate on the safety of the use using the proportionality principle according to the agreed criteria in which case the proposed MRL may be returned to Step 6 three times. The data will be evaluated by JMPR on request of CCPR as soon as they become available. If no data are supplied the CCPR should proceed to withdraw the draft MRL.</p>	<p>In para 42 in the first and second sentences should be changed to read: Under this procedure, if acceptable alternative GAPs are not available, interested parties have the opportunity to supply both labels and field trial data that support an alternative GAP. If there is a commitment to provide information supporting alternative GAP, the information must be provided before the draft MRL is returned to Step 6 three times.</p>	<p>We will keep the original paragraph</p>

<p>Under this procedure, if acceptable alternative GAPs is not available, interested parties have the opportunity to supply both labels and field trial data that support an alternative GAP. If there is a commitment to provide information supporting alternative GAP, the information must be provide before the draft MRL is returned to Step 6 three times. Submitted data are evaluated by JMPR, on request of CCPR, as soon as possible after they become available. If there is no commitment to support alternative GAP, or no data are supplied despite a commitment being made the CCPR withdrawal of the draft MRL.</p>		
<p>62. The following criteria are applied when preparing the Schedules and Priority Lists: a. The period of time since the pesticide was nominated for evaluation; will have higher priority a pesticide that was nominated first</p>	<p>In para 62. a. the sentence should read: b. The period of time since the pesticide was nominated for evaluation; <u>a pesticide nominated first will have higher priority</u></p>	Accepted
<p>63. In order for CCPR to schedule a pesticide for JMPR evaluation in the following year: a. It must be registered for use in a member country and product formulations labels made available by the time of JMPR "data call-in";</p>	<p>In para 63. a. the formulations should be singular so the sentence reads: a. It must be registered for use in a member country and formulation labels made available by the time of JMPR "data call-in";</p>	Accepted
<p>83. If the concern cannot be addressed at the meeting, the MRL will be advanced to Step 5 at the CCPR session and the concern will be addressed by the JMPR according to the procedure described in section 7 as soon as possible "PROCEDURE FOR SUBMITTING CONCERN AND CLARIFICATIONS". Any other draft MRLs for the pesticide, satisfying the above conditions, should be advanced to Step 5/8;</p>	<p>There is one deletion in the draft document that the U.S. does not agree with and based on the work done during the breakout sessions during the last CCPR meeting we are not aware of any agreement that this language would be removed. In the section <i>ELABORATION PROCEDURE UTILIZATION THE ACCELERATED PROCEDURE OF STEPS 5/8 FOR ELABORATION OF MRLS (STEP 5/8-PROCEDURE)</i> para 83 should include the language that has been deleted regarding the advancement of the other MRLs. Similar language is in the current version of the Risk Analysis Principles. The U.S. proposes to revise the para 83 of the draft document to read: If the concern cannot be addressed at the meeting, the MRL will be advanced to Step 5 at the CCPR session and the concern will be addressed by the JMPR according to the procedure described in section 7 "PROCEDURE FOR SUBMITTING CONCERN AND CLARIFICATIONS." Any other draft MRLs for the pesticide, satisfying the above conditions, should be advanced to Step 5/8.</p>	We will keep the original paragraph