codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6(b) **CX/PR 99/7**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES
Thirty First Session
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CONSIDERATION OF RESIDUES OF PESTICIDES IN FOOD AND ANIMAL FEEDS

CRITERIA FOR SETTING EMRLS
FURTHER DEVELOPMENT OF CCPR PROCEDURES

(Prepared by the United States)[1]

BACKGROUND

A **Codex Extraneous Maximum Residue Limit (EMRL**) refers to a pesticide residue or a contaminant arising from environmental sources (including former agricultural uses) other than the use of a pesticide or contaminant substance directly or indirectly on the commodity. It is the maximum concentration of a pesticide residue that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food agricultural commodity or animal feed[2]. Extraneous Residue Limits (ERLs) are estimated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and elaborated by the Codex Committee on Pesticide Residues (CCPR) which uses the term extraneous maximum residue limit (EMRL). ERLs and EMRLs have the same meaning. EMRLs are distinguished from maximum residue limits (MRLs) in that the latter are based on residues resulting from supervised field trials reflecting nationally approved good agricultural practices (GAP) and ERLs are based on monitoring data. The CCPR lists EMRLs and MRLs separately.

The 30th Session of the CCPR (April 1998) considered document CX/PR 98/8 which elaborated on the need for CCPR criteria for estimation of extraneous maximum residue limits. CX/PR 98/8 briefly described JMPR and CCFAC approaches for estimation of EMRLs and summarized views of several countries on key issues. Key issues were summarized and categorized either as CCPR risk management issues or JMPR risk assessment issues. A suggested CCPR position was proposed for each issue. There was general Committee agreement on the proposed CCPR positions with the exception of how outliers and violation rates should be handled. The committee decided that comments should be sought from Member governments on their current practices in treating outliers and on what violation rates were used (ALINORM 99/24, para 85-89). This was requested via CL 1998/29-PR. While the 30th CCPR agreed not to initiate a full exercise of EMRL criteria elaboration, it was decided that a comparison of CCPR/CCFAC approaches would be useful also from the point of view of consistency of approaches throughout Codex.

The U.S. Delegation was requested (in collaboration with Australia, New Zealand, the Netherlands and South Africa) to prepare a concise paper based on CX/PR 98/8 for consideration of the 31st Session of the CCPR. It was to include: (1) a compilation of agreed CCPR positions regarding

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1 In collaboration with Australia, New Zealand, the Netherlands and South Africa.

2 *Codex Alimentarius*, Second Edition, Vol. 2, page 461. FAO/WHO, 1993 (under revision).

estimation of EMRLs (U.S. lead) (2) government views on outlier and violation rate issues (U.S. lead to compile government responses to CL 1998/29-PR on these two issue) and (3) a comparison of CCPR/CCFAC approaches to EMRLs (Australian lead). Accordingly, this document was prepared on the basis of this request, collaborative efforts of the aforementioned countries, guidance from the Codex Secretariat and reference to CX/PR 98/8.

This document is organized in accordance with the topics requested to be included:

Part 1: Agreed CCPR positions on estimation of EMRLs ;

Part 2: CCPR positions on outliers and violation rates requiring further considerations by CCPR

Annex 1: Government practices on the use of "outliers'; and

Annex 2: Government practices on use of violation rates; and

Appendix I: A comparison of CCPR/CCFAC approaches to estimation of EMRLs (prepared by Australia).

PART 1: AGREED CCPR POSITIONS ON ESTIMATION OF EMRLS[3]

Those CCPR positions agreed to by the CCPR at its 30th Session are compiled below.

CCPR RISK MANAGEMENT ISSUES

1. Candidates for EMRLs - Should EMRL estimation be restricted only to pesticides for which uses are no longer registered or approved by a national authority (completely banned, banned on foods, restricted uses)?

   CCPR requests for JMPR estimation of EMRLs are to be limited to those pesticides (including metabolites, reaction products and accompanying contaminants of pesticide production and use) and pesticide-commodity combinations for which uses are no longer registered or approved at the national level for food/feed purposes, **or for which the CCPR concludes that public health concerns have not been relieved in the absence of EMRLs.** (Bolded text is intended to allow the CCPR, as a risk management decision option, to request JMPR estimation of EMRLs in cases where one or two countries insist on continued use of a pesticide which has been banned in most countries.)

2. Environmental Persistence - Should EMRLs be estimated only for chemicals which are persistent in the environment? If so, by what measure should that be defined?

   EMRLS should be estimated only for discontinued pesticides (as defined in 1(b) above) which are persistent in the environment. It is suggested as a guide that EMRL consideration be given to former pesticides for which it is anticipated that residual residues of regulatory concern will likely occur for a period of 3 or more years after discontinuation of the use (under ideal conditions approximately the minimum time for an EMRL candidate to be scheduled, reviewed, recommended and adopted).

3. Residues in food/feed - Should residues need first to be found at some level of regulatory significance in foods/feeds in trade? If so, what kinds of measures of regulatory significance should be considered?

   Yes, residues of regulatory significance should be occurring in food/feeds in trade. Measures of regulatory significance may include, but not be limited to, a potential health concern and/or other regulatory concerns such as environmental concerns which may be monitored with EMRLs in food/feed.

4. Trade issue - Should there be a trade problem (reported to CCPR) before EMRLs are estimated for a pesticide/commodity combination, or should it be based on the potential for a trade problem, because of its persistence and the presence of measurable residues.

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[3] Ref: CX/PR 98/8

Either condition is a basis for considering a request for JMPR EMRL estimation. A greater burden of proof would be expected when no trade problem has been occurring, perhaps based on a history of monitoring data.

5. Proof of source of residues - Should the country requesting EMRL estimation be requested/required to provide proof or some credible evidence or rationale that reported residues (the data base) are not the result of purposeful uses?

   Yes, the requesting country has an obligation to provide some credible assurance that residues in a data base to support EMRL estimates do not result from intentional use. For example, in some cases it may be possible to document when a national use(s) was discontinued and/or in some cases possibly that monitoring data show residues are less than the norm when the use was approved.

6. Health aspect - related to 3 above, should a health risk concern be a requirement or the only basis or requesting EMRL estimations? This relates to consistency with WTO SPS[4] consistency concerns that have been expressed.

   A potential health concern (e.g., possibility of intake exceeding the ADI) may be a major reason for requesting estimation of EMRLs. However, as described in 3 above and in more detail below under "periodic review", other reasons may also qualify. For example, just the lack of a trading standard can create trade problems, even if there is no health concern *per se*. As long as EMRLs are not established so low as to create significant trade barriers, the Committee does not consider concerns other than "ADI exceedances" as a basis for requesting an EMRL estimate inconsistent with WTO SPS principles.

7. CCPR Priorities - Should the CCPR use the same criteria for scheduling JMPR review as used for MRLs? If not, how should it differ?

   If the CCPR decides to develop criteria for EMRLs this question will need to be referred to a working Group on Priorities or to whatever working group is formed to develop the criteria.

8. Periodic reviews of EMRLs - Should the CCPR support a periodic JMPR re-evaluation of EMRLs?

   The CCPR supports the concept of a periodic review of EMRLs with reevaluations approximately every 5 years if it can be scheduled. In no case should it be greater than 8 years. While a periodic review of all EMRLs for given chemicals at regular intervals is recommended, reconsideration of individual EMRLs may be considered outside a periodic review if extraordinary circumstances require it. If the EMRLs do not significantly restrict trade the CCPR does not consider periodic review of EMRLs inconsistent with WTO SPS principles.

9. CCPR Data Issue - Location/amount - Should the CCPR specify that a minimum data base (e.g., minimum number of countries, minimum number of samples/commodity?) be committed before requesting the JMPR to conduct EMRL estimates or should a request and data commitment from one country with a problem/concern suffice (meaning if other countries have a different opinion on the need they have the opportunity to submit data to support their view)?

   The CCPR should leave to the JMPR whether data are adequate to make an EMRL estimate. The country making a request normally has a valid reason from its perspective for doing so. It has an obligation to provide good supporting documentation and the CCPR has an obligation to consider its concern, whether other countries have a similar problem or not.

JMPR RISK ASSESSMENT ISSUES

10. Types of data - What types of data should be provided for estimation of EMRLs? - The same toxicology data requirements as for MRLs? Routine random monitoring data? targeted monitoring data? Multi-year monitoring data? Other than toxicology and residue data what other

[4] Agreement of the Application of Sanitary and Phytosanitary Measures.

data should data submitters be requested to provide, the same as for MRLs or just those related to the integrity of the residue data (e.g., analytical methodology, storage stability, sampling)?

The CCPR supports the JMPR practice of estimating EMRLs on the basis of random monitoring data. It does not consider "targeted" monitoring data in most cases to be appropriate for that purpose, recognising that it is useful for other purposes, including possible development of residue mitigation strategies.

If the CCPR concludes as a risk management decision, that a JMPR EMRL estimate based on random monitoring data would result in an unacceptable economic disruption and is convinced that residue reduction strategies are not possible, it may request the JMPR to consider re-estimating an EMRL on the basis of other than random monitoring data and request a new risk assessment based on that new estimate.

The CCPR leaves other data type requirement issues to the JMPR.

11. Standard format - Should data submissions be required or requested to be in a standard format? If so, which formats should be recommended?

The CCPR recommends that the JMPR specify what standard format they would prefer for EMRL data submissions if something more than guidance in the FAO Manual is needed.

12. Statistical treatment - Should data submitters be required or requested to provide a statistical treatment of the data in addition to the "raw" data provided? If so, what information should be requested (e.g., number of samples analyzed, number of samples found with residues, number within residue ranges, number with no detections (what level?), limit of detection/determination, percentile figures)?

Countries requesting EMRL estimations should be referred to JMPR general guidance for EMRLs provided in the 1997 FAO Manual on the Submission and Evaluation of Pesticide Residues Data for the Estimation of Maximum Residue Levels in Food and Feed. They should be encouraged to provide all of the information listed above, but it should be required only if the JMPR requires it.

13. Limits of Determination - It has been recommended that the JMPR should continue to recommend suitable limits of determination for EMRLs.

The CCPR supports that recommendation as long as there is a reasonable expectation that residues may occur in a given commodity (or commodity group). Revocation of EMRLs should be considered, once there is no longer evidence that residues are likely to occur in practice.

14. Commodity Group EMRLs - One country recommends that EMRLs be estimated for commodity groups where possible.

The Committee endorses this recommendation.

PART 2: CCPR POSITIONS ON OUTLIERS AND VIOLATION RATES REQUIRING FURTHER CONSIDERATIONS BY CCPR[5]

The Committee is invited to consider "1999 Suggested CCPR positions" for "outliers" and "violation rates" as contained in the following paragraphs. For background information, refer to Annexes 1 and 2[6].

JMPR RISK ASSESSMENT ISSUES

15. Outliers - The JMPR and some countries do not consider the frequently used term to be appropriate for EMRL situations. Some prefer the term "extreme values".

1998 Suggested CCPR position (not agreed): The CCPR accepts the principle that it may not always be appropriate to include all extreme values in an EMRL. The CCPR accepts that the JMPR will need to determine inclusion or exclusion of extreme values on a case-by-case basis.

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5 Ref: CX/PR 98/8; ALINORM 99/24, para. 89; and Annexes 1 and 2 to Part 2 of this paper

6 The complete texts of those government comments summarized in the annexes will be available in CRD 1.

JMPR use of a 95 percentile or violation rate approach would be acceptable to the CCPR as long as a significant barrier to trade is not created in the process. As long as significant barriers to trade are not created, the CCPR does not believe exclusion of some extreme values is inconsistent with WTO SPS.

1999 Suggested CCPR position: The CCPR accepts the principle that there may be sound reasons for excluding extreme values when estimating an EMRL. The CCPR accepts that the JMPR will need to determine inclusion or exclusion of extreme values on a case-by-case basis and that in accordance with Part I (10) above, under certain unique circumstances the CCPR may request the JMPR to consider the use of data other than random monitoring data. The CCPR recognizes that the JMPR must retain the flexibility to consider various factors or approaches for exclusion of extreme values (including percentile approaches, violation rates or others) according to the circumstances of a given data base. The CCPR recognizes the need for such judgements to be based on sound science and for the scientific and other bases to be well documented.

16. Violation rates - The JMPR has described its practice of using likely violation rates as one tool for helping it arrive at an EMRL recommendation. It assumes 0.5 to 1% violation rates would be unacceptable to most countries, but invites countries to express a view on this topic.

1998 Suggested CCPR position (not agreed): "The CCPR accepts this concept as one appropriate tool for estimating EMRLs and recommends that countries (especially those requesting establishment (or re-evaluation) of EMRLs), provide information on what violation rates are acceptable to them. The CCPR believes that the JMPR should continue to use a flexible approach and concludes that the proposed 0.2-0.4 percent violation rate will normally be a reasonable level for Codex EMRL purposes".

1999 Suggested CCPR position: The Committee accepts that any EMRL must be protective of the public health in the first instance. Once this criteria is fully met the Committee supports analyzes which result in EMRLs which are not so low as to be readily indistinguishable from background and not so low as to result in unnecessary trade disruption. At the same time the Committee supports EMRLs that are not so high that they will not detect continued uses of discontinued products, localised hot spots or do not reflect evidence of the expected continued decline of contaminants resulting from former pesticide uses.

The CCPR recognizes that an arbitrary violation rate or range would not be applicable to every situation. However, the CCPR accepts that the taking into account by the JMPR of violation rates which are consistent with actual enforcement practices of importing countries can be a useful tool to augment other tools in the exclusion of extreme values in submitted monitoring data. The Committee accepts that in practice violation rates below 0.2% or above 1% will in many cases not be consistent with these goals. The CCPR recommends that the JMPR, in applying any violation rates to the setting of EMRLs, document the scientific and other bases on which the violation rate was set, in accord with CAC decisions and taking into account relevant WTO rulings. The CCPR encourages countries to submit violation rates with respect to incidences of trade disruption.

ANNEX 1

GOVERNMENT PRACTICES ON THE USE OF OUTLIERS

Comments on national practices in the use of outliers were received from Australia, Canada, Denmark, New Zealand, The Netherlands, The Slovak Republic, South Africa and the United States (all summarised and paraphrased unless indicated otherwise):

Australia – Australia notes that current Australian EMRLs have not been reviewed in some time and that they are in the process of initiating a review of procedures for establishing EMRLs. They stress the need for any mechanism for excluding extreme values (including violation rates) to be based on well documented sound science.

Canada – Canada explained why it was unable to provide comments on the treatment of outliers or violation rates. While EMRLs and other contaminant levels are set on a case by case basis, at present there is no written guidance in Canada as to how they are established. Canada is willing to give full consideration to any guidance prepared by the CCPR.

Denmark – "The handling of outliers and violation rate used for the setting of EMRLs has not yet been standardized in Denmark. However in order to have the EMRLs as low as possible and a food safety level as high as possible the Danish position is that the outliers as well as data generated from targeted monitoring should generally not be included into the data-material used for setting of EMRLs.

New Zealand – New Zealand emphasises that consideration of outlier and violation rate issues should be considered within the context of Article 2(2) of the WTO SPS agreement which states that "Members shall ensure that any sanitary or phytosanitary measure is applied **only to the extent necessary** to protect human, animal or plant life or health" With regard to outlier values New Zealand considers the basic principles for establishing EMRLs are: (1) acceptance from a toxicological point of view and (2) accommodation of the distribution of values found in foods of interest.

New Zealand questions whether random sampling is a true indicator of the range (and distribution) of residue levels of compounds needing EMRLs, unless the number of samples is sufficiently large. Reaffirmed was New Zealand's view that the "JMPR should give due weight to targeted monitoring data when establishing EMRLs within a risk-based framework".

For determining what is an outlier New Zealand proposes that the criteria should be: (1) "survey and monitoring data that genuinely establishes the upper range of possible values and "(2) "knowledge that such occurrences have very low frequency".

The Netherlands – In the Netherland's view, while outliers and violation rates should be taken into account they should not be the main basis for establishing an EMRL. In their view the principle issue is how the risks from the residues can and should be managed. It is proposed that "the EMRL should be established at the lowest level which can reasonably be achieved by normal production technologies and quality control measures, provided that level is acceptable from a health point of view". It is pointed out that local contamination often cannot be fully eradicated by normal agricultural and control measures. It is noted that completely eliminating EMRL violations for former pesticides may be impossible without setting EMRLs at such high levels which would include illegal use.

The Slovak Republic – "The current practice in treating outliers in monitoring of pesticide residues (as well as other food contaminants) is that the outliers are excluded. The usual statistical approaches are applied for identifying the outliers."

South Africa – "South Africa is in agreement with the views of other countries such as New Zealand that, within the frame work of "risk assessment" the two critical "legs" with respect to the establishment of EMRLs are: toxicological data, and -monitoring data. South Africa is also of the opinion that reliable monitoring data could solve the question of "outliers" and "violation rates". Such data would possibly not be available from developing countries. South Africa therefore suggests that: 1. Monitoring data of developed countries of "persistent pesticide residues" from food imported form (sic) developing countries be made available to JMPR for evaluation. The reason for this suggestion is developing countries often do not have the resources to generate monitoring data themselves, whereas developed countries often have been accumulating information on imports over many years."

The United States – Historically different approaches have been utilised in the United States for considering outliers in estimation of EMRLs. In some cases they have been based on a 99th percentile confidence level for an individual sample. In some cases values of at least 10X the next highest value has been considered an outlier. In other cases (meat and fat) violation rates have been taken into account.

"In summary, in the United States exclusion of outliers for EMRLs is decided on a case by case basis. Statistical approaches may be used, but the more empirical approaches similar to those utilised by the JMPR are more common. It is recognized that this is not an exact science and that a great deal of professional judgement is needed. The United States Delegation accepts that the basic approaches used by the JMPR are reasonable for Codex purposes."

Also provided was information on U.S. approaches to consideration of outliers in establishing MRLs. In this case the emphasis is discarding only those high values for which evidence is provided indicating that a result is invalid, e.g. analytical errors, recording errors etc. Normally a wide variation of residue levels is expected.

ANNEX 2

GOVERNMENT PRACTICES ON THE USE OF VIOLATION RATES

Comments on national practices in the use of violation rates were received from Australia, Canada, Denmark, New Zealand, The Netherlands, The Slovak Republic and the United States (all summarised and paraphrased unless indicated otherwise):

Australia – Australia notes that current Australian EMRLs have not been reviewed in some time and that they are in the process of initiating a review of procedures for establishing EMRLs. They stress the need for any mechanism for excluding extreme values (including violation rates) to be based on well documented sound science. They further believe that any use of violation rates for estimating EMRLs should be consistent with violation rates which trigger EMRL-based regulatory action in importing countries. They provide Australian monitoring data which indicate that violation rates lower than 0.2% are triggering regulatory incidents. Australian believes the evidence "supports the contention that the acceptable violation rate for Codex EMRLs should be on the order of 0.2%".

Canada – See comments above under outliers.

Denmark – See comments above under outliers.

New Zealand – New Zealand believes that the concept on non-compliance rates has merit for CCPR consideration, but believes the scientific and practical implications first have to be considered. The view is expressed that risk-based considerations should apply for EMRLs as in the case of MRLs and that a fixed or arbitrary non-compliance rate would appear to be a more inflexible approach. Stressed is the need to apply the same controls at the national level as for imports and that evaluation of risk for a particular population can be fully determined only at the national level. Further stressed is the need to view MRLs or EMRLs as monitoring tools rather than as health standards.

The Netherlands – The Netherlands points out that a variety of regulatory or producer actions may reduce or eliminate violations and that an increasing level of violations normally enhances monitoring and control activities. In the Netherlands view .."assuming a violation rate of 0.2-0.4% (in one country) as the basis for CCPR EMRL establishment may lead to Codex EMRLs that are unnecessarily high. It is recognised however that a violation rate of 2-5% may lead to appreciable difficulties in enforcing such an EMRL. In our view a violation rate of ca 1-2% is reasonably balanced as a basis for Codex EMRL establishment and would be consistent with the ALARA principle".

The Slovak Republic – "We find the 2-5% violation rate appropriate from both – the health protection and cost aspects. We feel that, for the purpose of EMRL setting, random monitoring data should be preferred to targeted monitoring".

South Africa – See comments under violation rates.

The United States –While no violation rate has been established as the benchmark for determining acceptability or not of EMRLs in the United States, the United States makes the observation that whether it is intended or not, establishment of any EMRL level effectively establishes a violation rate if there is enforcement. While the United States believes consideration of the violation rate is a useful supplementary tool in establishing EMRLs, it believes the monitoring data should be the primary determining factor. That is, an analysis of the data can often lead to natural cut-off points which might suggest exclusion of very high levels or even low levels that can't be distinguished from background. The United States provided an analysis. of recent U.S. data for DDT in meat as an example of approaches it prefers. That analysis suggested that a 2 ppm EMRL might be supported, which would result in violation rates of approximately <0.4% That violation rate might be acceptable to the U.S. for this specific case if it were to establish a legal limit. As long as residue levels are safe, the United States would find it difficult to understand justification for EMRLs which would result in violation rates exceeding 0.5-1% as some have suggested.

The United States believes any EMRL level should be toxicologically supportable, yet sufficiently high above background levels to differentiate background from continued usage and hot spots. It supports the JMPR principles that in principle the EMRL should normally not be so low as to result in major trade disruption if the unavoidable residues are safe., that environmental levels are expected to decline over time and EMRLs should reflect those declines.

APPENDIX I

A COMPARISON OF CCPR/CCFAC APPROACHES TO ESTIMATION OF EMRLS

(Prepared by Australia)

COMPARISON OF CRITERIA FOR ESTABLISHMENT OF STANDARDS FOR ENVIRONMENTAL CONTAMINANTS: CCPR AND CCFAC

The following is a comparison of the criteria used for establishing Codex levels for environmental contaminants under the two Codex committees active in this area – the Codex Committee on Pesticide Residues (CCPR) and the Codex Committee on Food Additives and Contaminants (CCFAC). CCPR establishes Extraneous Maximum Residue Limits (EMRLs) for pesticide residues arising from environmental sources which are not currently used in agriculture. CCFAC establishes Maximum Levels (MLs) for contaminants not intentionally added to food.

The two committees follow different procedures for elaboration of these standards. The chief difference is that the Joint Meeting on Pesticide Residues (JMPR) not only collates available national monitoring data on pesticide residues, it also proposes to CCPR the appropriate level of the EMRL. Within CCFAC, it is a working party of national governments which seeks, collates and assesses available monitoring data on environmental contaminants, and subsequently proposes to CCFAC the appropriate level for the ML. The Joint Expert Committee on Food Additives (JECFA), which is the expert committee supporting CCFAC, is only consulted on technical matters unable to be resolved by CCFAC. JECFA does not propose MLs to CCFAC. This constitutes the chief divergence between the committees in the process for elaboration of standards for environmental contaminants.

The following table was constructed from the following sources:

- *Pesticide residues in food – 1996, Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues, Rome, Italy, 16-25 September 1996, FAO Plant Production and Protection Paper 140*, FAO, Rome, 1997, pp 7-8.
- *Pesticide residues in food – 1995, Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues, Geneva, Switzerland, 16-27 September 1995, FAO Plant Production and Protection Paper 140*, FAO, Rome, 1996, pp 21-23.
- Criteria for Setting EMRLs: On the Need for Criteria for Estimation of Extraneous Maximum Residue Limits, Agenda Item 8 (b), CCPR30, CX/PR 98/8, Codex Alimentarius Commission, Rome, 1998.
- Annexes I and II to the General Standard for Contaminants and Toxins in Foods, ALINORM 97/12, Appendix VI, Codex Alimentarius Commission, Rome, 1998.
- *FAO Manual on the Submission and Evaluation of Pesticide Residues Data for the Estimation of Maximum Residue Levels in Food and Feed*, FAO, Rome, 1997, pp 54-56.

COMPARISON OF CRITERIA FOR ESTABLISHMENT OF STANDARDS FOR ENVIRONMENTAL CONTAMINANTS: CCPR AND CCFAC

Criterion	CCFAC/JECFA Approach	CCPR/JMPR Approach
Definition	A contaminant is any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine) manufacture, processing, preparation, treatment, packaging, packing, transport or holding of such food or as a result of environmental contamination. This includes contaminants in feed or food producing animals. The standard excepts pesticide residues, as defined by the Codex definition that are within the terms of reference of CCPR. Pesticide residues arising from pesticide uses not associated with food production may be considered for inclusion in the General Standard for Contaminants if not dealt with by the CCPR.	Codex Extraneous Maximum Residue Limit (EMRL) refers to a pesticide residue or a contaminant arising from environmental sources (including former agricultural sources) other than the use of a pesticide or contaminant substance directly or indirectly on the commodity.
Terminology	The Codex Maximum Level (ML) for a contaminant in a food or feed commodity is the maximum concentration of that substance recommended by the Codex Alimentarius Commission to be legally permitted in that commodity.	The Codex Extraneous Maximum Residue Limit (EMRL) is the maximum concentration of a pesticide residue that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food agricultural commodity or animal feed.
Principals for Establishment of Standard	MLs shall only be set for those foods in which the contaminant may be found in amounts that are significant for the total exposure of the consumer. They shall be set in such a way that the consumer is adequately protected. At the same time the technological possibilities to comply with MLs shall be taken into account. MLs shall be based on sound scientific principles leading to levels which are acceptable worldwide, so that international trade in these foods is facilitated.	EMRLs should be established only for those compounds whose registration for agricultural uses had been revoked, which were persistent in the environment with potential to result in residues in food and feed, and which were likely to cause problems in health and trade. Extraneous Residue Limits (ERLs) are estimated by JMPR and elaborated by CCPR. ERLs and EMRLs have the same meaning.

Criterion	CCFAC/JECFA Approach	CCPR/JMPR Approach
Toxicological information	A recommendation from JECFA regarding the maximum allowable or tolerable intake, based on a full evaluation of an adequate toxicological data base, is the main basis for decisions by CCFAC. When toxicological information is presented in relation to proposals for maximum levels for contaminants in foods, indications are desirable about the following aspects: • identification of the toxic substance • metabolism in humans and animals as appropriate • toxicokinetics and toxicodynamics • information about acute and long term toxicity in animals and humans, including epidemiological data on humans and other relevant toxicity data • conclusions and advice of toxicological experts (groups), with references, including information on specially vulnerable groups or animals	While comparison of the dietary intake of chemicals for which EMRLs have been elaborated to a toxicological reference point –provisional tolerable daily intake (PTDI) – is relevant to risk assessment, it is not a factor in estimating an EMRL and therefore not directly relevant to developing criteria for estimating EMRLs. PTDIs are reviewed when EMRL revisions are considered and comparisons of intake with the PTDI are made. It is widely recognized that toxicology data for those chemicals are not as extensive as the data for a modern pesticide, and not likely to be developed further. This is the reason the reference dose is a PTDI and not an acceptable daily intake (ADI).
Analytical data	Validated qualitative and quantitative analytical data on representative samples should be supplied. Appropriate sampling procedures should be applied.	EMRLs are based on monitoring data only, not on supervised field trials. JMPR has emphasized that random monitoring data bases available to it are usually limited to data from 3 or 4, usually developed, countries. Data generally reflect commodities for which residues are found at the national level and which have the potential for creating trade or health problems. Databases are not generated solely for EMRL estimation, but are normally submissions from a limited number of developed countries who routinely conduct monitoring studies for these types of environmental contaminants. A major issue is the lack of good representative data for estimation of JMPR ERLs, not a lack of rational procedure on how to do the estimation. JMPR needs all relevant and geographically representative monitoring data (including nil results). Better EMRL estimates can be made when more extensive data are available.

Criterion	CCFAC/JECFA Approach	CCPR/JMPR Approach
Intake data	It is desirable to have information about the contaminant concentrations for foods or food groups that together are responsible for 50% and preferably 80% or more of total dietary intake of the contaminant, both for the average and high consumers. Information about the presence of the contaminant in foods that are widely consumed (staple foods) is desirable on order to be able to make satisfactory assessment of the contaminant intake and of risks associated with food trade. Food consumption data for average, most exposed and susceptible consumer groups are desirable for evaluations of potential intake of contaminants. Dietary intake of contaminants: Reference is made to the Guidelines for the study of dietary intake of chemical contaminants (WHO).	While comparison of the dietary intake of chemicals for which EMRLs have been elaborated to a toxicological reference point – provisional tolerable daily intake (PTDI) – is relevant to risk assessment, but is not a factor in estimating an EMRL and therefore not directly relevant to developing criteria for estimating EMRLs.
Fair Trade Considerations	Criteria taken into consideration are: • existing, expected or potential problems in international trade • foods concerned moving in international trade (including main exporting and importing countries) • information about national regulations.	CCPR EMRLs were established as a result of the CCPR Periodic Review Program when the old MRLs were reviewed and deleted or revised according to monitoring data to establish EMRLs. Data requirements are detailed in section 2.7 of the 1990 JMPR Report.
Technological Considerations	Information about the source of the contaminant and the way in which the food is contaminated is essential for assessing possibilities to control the contamination process and to be able to guarantee a desired product quality. Good Manufacturing Practice (GMP) and/or Good Agricultural Practice (GAP), and other source-related measures, should also be formulated to control a contamination problem.	The levels resulting from environmental contamination dictate what the level will be in foods/feeds. There is no Good Agricultural Practice involved which could be revised to affect changes in the residue levels, although other residue reduction strategies may be available in some cases if residue levels are unacceptable.

Criterion	CCFAC/JECFA Approach	CCPR/JMPR Approach
Risk Assessment and Risk Management Considerations	A tiered approach, involving risk assessment and risk management procedures is recommended. Risk assessment is defined as the scientific evaluation of the probability of occurrence of known or potential adverse health effects resulting from human exposure to food borne hazards. The process consists of hazard identification, hazard characterization, exposure assessment and risk characterization, with estimates expected on how many consumers are likely to exceed the standard, for how long and by how much. Risk management is defined as the process of weighing policy alternatives in the light of the risk assessment and, if required, to select and implement appropriate control options, including the establishment and enforcement of maximum levels of contaminants in foods. In the process, the consequences, costs and benefits should be presented and evaluated in relation to other policy options.	There is no formal CCPR risk management matrix *per se* comparable to that of the CCFAC. Because toxicology data for these chemicals is less extensive than for modern pesticides, risk management decisions in the CCPR must be made on the basis of JMPR ERL estimates, however, total diet studies and market basket studies are regularly reported to CCPR and JMPR. Predictions of persistence in the environment (and potential for uptake by food or feed crops) can often be based on a combination of data sources normally available for chemicals previously approved as pesticides. These may include information on their chemical and physical properties, metabolism studies, data on supervised field trials, data on environmental fate, rotational crop data, the known persistence of similar chemicals, and especially from monitoring data. The levels resulting from environmental contamination dictate what the level will be in foods/feeds. There is no Good Agricultural Practice involved which could be revised to affect changes in the residue levels, although other residue reduction strategies may be available in some cases if residue levels are unacceptable. This is an important consideration in risk management. Although the JMPR does not use targeted monitoring data for estimating EMRLs, it agrees that follow-up studies are important when high residues are found in random monitoring to give a clearer view of the significance of the high levels. If properly conducted, such studies may indicate whether or not the higher residues resulted from intentional unauthorized uses and may allow the identification of areas in which production should be limited or where residue reduction strategies should be implemented.