CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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**CX 2/7.2** **CL 2010/08-CAC**
**March 2010**

**TO:** Codex Contact Points
Interested International Organizations

**FROM:** Secretariat,
Codex Alimentarius Commission,
Joint FAO/WHO Food Standards Programme,
Viale delle Terme di Caracalla,
00153 Rome, Italy

**SUBJECT:** **Request for comments on the report of the electronic Working Group on Animal Feeding (to be considered at the 33rd Session of the Codex Alimentarius Commission)**

**DEADLINE 15 May 2010**

## BACKGROUND

1. The 32nd Session of the Commission considered the report of an electronic working group which had been charged to prepare: (i) a proposal for the scope and the terms of reference of future work on animal feeding, taking into consideration the conclusion and recommendation of the FAO/WHO expert meeting on Animal Feeding Impact on Food Safety; and (ii) a proposal for a suitable mechanism for Codex to carry out this work.

2. The Commission concluded its discussion recognising the full support for further Codex work on animal feeding. The Commission agreed to establish an electronic working group, hosted by Denmark and co-chaired by the United States of America, to:

(i) Review existing Codex risk analysis principles as to their applicability to animal feed;

(ii) Review Codex texts on emergency situation and exchange of information on rejected food as to their applicability to animal feed (CAC/GL 25-1997 and CAC/GL 19-1995);

(iii) Review the Codex *Code of Practice for Sources Directed Measures to Reduce Contamination of Food with Chemical* (CAC/RCP 49-2001) as to their applicability to animal feed; and

(iv) Propose suitable mechanisms for addressing the remaining three items proposed by the electronic working group to the 32nd Session of the Commission.[1]

## REQUEST FOR COMMENTS

3. Governments and international organizations wishing to submit comments on the report of the electronic Working Group (attached to this Circular Letter) should do so in writing, preferably by e-mail, to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (Email: codex@fao.org; Fax +39 06 570 54593) by **15 May 2010.**

[1] ALINORM 09/32/REP paras 170-176

# REPORT FROM THE CODEX ELECTRONIC WORKING GROUP ON ANIMAL FEED 2009/2010

## 1. INTRODUCTION

At the 32nd Session of the Codex Alimentarius Commission (CAC) held in Rome, Italy, on June 29-July 4, 2009, it was agreed to establish an Electronic Working Group (E-WG) on Animal Feed hosted by Denmark and co-chaired by the United States of America (ALINORM 09/32/REP paragraph 170-176).

The electronic working group (E-WG) was assigned to:

(i) Review existing Codex risk analysis principles as to their applicability to animal feed;

(ii) Review existing Codex texts on emergency situations and exchange of information on rejected food as to their applicability to animal feed (CAC/GL 25-1997 and CAC/GL 19-1995).

(iii) Review the Codex *Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals* (CAC/RCP 49-2001) as to their applicability to animal feed; and

(iv) Propose suitable and specific mechanisms for addressing the remaining three items proposed by the electronic working group to the 31st Session of the Commission:

a) The development of guidelines, intended for governments on how to apply the existing Codex risk assessment methodologies to the various types of hazards related to contaminants/residues in feed ingredients, including feed additives used in feeding stuffs for food producing animals;

b) Develop a prioritized list of hazards (in feed ingredients and feed additives), for governmental use; and

c) Establish criteria for the global identification and notification of emergency situations affecting the feed sector (and ultimately the food sector).

On July 16, 2009, the invitation to participate in the E-WG was distributed to all Codex members. Representatives from 29 countries, seven observers and the EU-Commission registered to join the group. 16 countries, two observers and the EU-Commission contributed to the task. A complete list of participants can be found in Annex V.

## 2. REQUEST FOR COMMENTS[2]

First Draft Documents

The first draft document was distributed on 28 August, 2009, in the three working languages: English, French and Spanish.

At the time of the deadline, on 30 September, 2009, representatives from 15 countries, two observers and the EU-Commission had submitted comments on the first draft documents.

Second Draft Documents

The English version of the 2nd round draft documents was distributed on October 30, 2009. The Spanish and French versions were distributed on November 13, 2009.

11countries, two observers and the EU-Commission submitted comments on the second draft documents.

Draft Report

The English version of the draft report was sent out to E-WG members on January 6, 2010. The French and Spanish versions were distributed on 12 and 20 January, 2010 respectively.

It was specified in the cover letter to the draft report that if no comments were received from the E-WG members it was understood as an agreement to the report.

[2] All comments sumitted during the preparation of this report are available with the EWG host country (E-mail: bbj@pdir.dk)

Representatives from five countries, one observer and the EU-Commission submitted comments on the draft report.

Some E-WG members commented on the draft report and on the structure of the report. Based on the comments, the structure of the report was partly restructured, and the text amended accordingly.

Additional request

Based on the comments on the draft report it appeared that there was not consensus on the suitable mechanisms for addressing the remaining three items item (iv), a); b) and c) . Thus, the E-WG decided for each of the sub items a); b) and c) to item (iv) to include some options for consideration by the CAC on how Codex could undertake the work. These options are based on 1) the comments and proposals received from the E-WG members during the process and 2) a new proposal on a suitable mechanism for Codex to address present and future work in the feed area coming up late in the process. The English version of a letter requesting responses to the new proposal 2) was circulated to all members of the E-WG on 17 February, 2010. The French and Spanish versions were distributed on 19 February, 2010.

At the time of the deadline, on 25 February, 2010 representatives from 13 countries, three observers and the EU-Commission had submitted their opinion and comments.

Draft final report

The report was circulated to the members for minor final comments on the 15 March, 2010.

Final Report

The final report was sent to the Codex Secretariat on 19 March, 2010.

## 3. BACKGROUND

The Joint FAO/WHO Expert Meeting on Animal Feed Impact on Food Safety (Rome, Italy, October 2007) made some specific recommendations to the CAC with the aim to improve food safety and international practices in the food and feed trade. In this connection the meeting noted that the general principles and guidance for the assessment of risks from feed ingredients or categories should be developed.

An E-WG was established by the 31st session of the CAC to review the recommendations from the Expert Meeting and identify those that are within the mandate of Codex. In addition, the E-WG proposed suitable mechanisms for Codex to carry out this work. The report of that working group was presented to the 32nd Session of the CAC (CL 2008/40-CAC). The Commission generally supported further work on animal feed and decided to establish an E-WG to address the issues outlined above.

## 4. DISCUSSION

The E-WG addressed the work items assigned by the CAC (see Section 1. Introduction). After careful consideration of the comments received from the participants, the E-WG has made recommendations for revisions to existing Codex texts, identified some gaps in their applicability to feed and recommended mechanisms for completing the work referred to in item (iv). Additionally, the E-WG identified other possible work that the CAC may want to consider.

4.1 Review of Existing Codex Risk Analysis Principles as to Their Applicability to Feed

The E-WG reviewed the following documents:

1. *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.* Codex Alimentarius Commission Procedural Manual, Eighteenth edition. Joint FAO/WHO Food Standards Programme. Rome, 2009.
2. *Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods.* Codex Alimentarius Commission Procedural Manual, Eighteenth Edition. Joint FAO/WHO Food Standards Programme. Rome, 2009.
3. *Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues,* Codex Alimentarius Commission Procedural Manual, Eighteenth Edition. Joint FAO/WHO Food Standards Programme. Rome, 2009.

4. *Risk analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods.* Codex Alimentarius Commission Procedural Manual, Eighteenth Edition. Joint FAO/WHO Food Standards Programme. Rome, 2009.
5. *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL-30-1999).
6. *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62- 2007).
7. *Codex Principles and Guidelines for the Exchange of information in Food Safety Emergency Situations* (CAC/GL 19-1995).
8. *Guidelines for the Exchange of Information between Countries on Rejection of Imported Food* (CAC/GL 25-1997).
9. *Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals* (CAC/RCP 49-2001).

Some members of the E-WG were of the opinion that the above texts were applicable to animal feed without amendments. These countries noted that an overarching statement would be sufficient to further clarify their applicability. However, many E-WG members supported the introduction of references to feed in the above mentioned texts where necessary to highlight the term feed and its relevance to food safety, even though feed is already mentioned in some of the original documents (CAC/GL 19-1995; CAC/RCP 49-2001). The proposed changes are included in Annexes I to III.

Additionally the E-WG agreed that it was necessary to clarify that the aforementioned documents apply to both feed and feed ingredients as they impact on food safety; that the term "food chain" is inclusive of feed inputs; and that the terms "animal feed" and "feed" pertain only to feed intended for food-producing animals[3].This statement would also ensure that the impact of feed on food safety is adequately addressed within Codex Alimentarius and that the mandate of Codex Alimentarius is appropriately observed.

*Overarching Statement*

The E-WG recommends inserting the following overarching statement in the Procedural Manual:

**"STATEMENT OF PRINCIPLES RELATING THE ROLE OF ANIMAL FEEDING AND ITS IMPACT ON FOOD SAFETY WITHIN SPECIFIC CODEX TEXTS**

The Codex Alimentarius Commission hereby acknowledges that the Codex Risk Analysis Principles in the specific Codex texts mentioned below apply to feed and feed ingredients[4], as they impact on food safety, and that the term "food chain" is inclusive of feed inputs."

Codex-texts covered by the above statement include:

1. *Working Principles for Risk Analysis for Application in Framework of the Codex Alimentarius*[5].
2. *Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods*[6].
3. *Risk analysis Principles Applied by the Codex Committee on Pesticide Residues*.
4. *Risk analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods*.
5. *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL 30-1999).

[3] The definitions for the terms "feed" and "feed ingredients" are included in the Code of Practice of Good Animal Feeding (CAC/RCP 54-2004) and are also inclusive of feed additives incorporated into compound feed and as an ingredient respectively.
[4] The definitions for the terms "feed" and "feed ingredients" are included in the Code of Practice of Good Animal Feeding (CAC/RCP 54-2004) and are also inclusive of feed additives incorporated into compound feed and as an ingredients respectively.
[5] The Codex text referred to in 1. as included in Section V – Working Principles for Risk Analysis, Procedural Manual, 18th edition, Rome, 2008.
[6] The Codex texts referred to in 2., 3. and 4. above as included in Section VI – Provisions applying to Specific Areas of Work, Procedural Manual,18th edition, Rome, 2008.

6. *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007).
7. *Guidelines for the Exchange of Information between Countries on Rejections of Imported Food* (CAC/GL 25-1997)
8. *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CAC/GL 19-1995).
9. *Codex of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals* (CAC/RCP 49-2001).

Furthermore, the Codex Alimentarius Commission hereby states that the terms "animal feed" and "feed" cover only feed for food producing animals, and that feed for pet animals and feed trade are outside the scope of Codex Alimentarius[7].**"**

*Remark Concerning Feed trade*

The introduction to The Joint FAO/WHO Expert Meeting on Animal Feed Impact on Food Safety (Rome, Italy, October 2007) included feed trade. However, most E-WG members have considered this to be outside the scope of Codex according to the CAC Statutes[8] and it has not been included in the revision of the documents or this report.

4.2 Proposal on Suitable Mechanisms for Addressing the Remaining Three Items proposed by the Electronic Working Group to the 32nd Session of the CAC (See Section 1)

The three remaining items that the CAC asked the E-WG to propose a suitable mechanism for were:

a) The development of guidelines, intended for governments on how to apply the existing Codex risk assessment methodologies to the various types of hazards related to contaminants/residues in feed ingredients, including feed additives used in feedingstuffs for food producing animals. The guideline should include specific science-based risk assessment criteria to apply to feed contaminants/residues. These criteria should be consistent with existing Codex methodologies.

   The guidelines should also consider the need to address the establishment of rates of transfer and accumulation from feed to edible tissues in animal-derived products according to the characteristics of the hazard.

   The guidelines should be drawn up in such a way as to enable countries to prioritise and assess risks based upon local conditions, use, exposure of animals and the impact, if any, on human health.

   **Expected outcome**: A detailed guideline for governments on how to apply the existing Codex risk assessment methodologies to the various types of hazards related to feed ingredients including feed additives.

b) Develop a prioritised list of hazards in feed ingredients and feed additives for governmental use. The list should contain hazards of international relevance that are reasonably likely to occur, and are thus likely to warrant future attention.

   In doing so, due consideration should be given to the prioritised list of hazards as recommended by the FAO/WHO Expert Meeting on Animal Feed Impact on Food Safety. Clear criteria should be used to prioritise the list of hazards and take account of the potential transfer of contaminants/residues in feed to edible animal products (e.g. meat, fish meat, milk, and eggs).

   **Expected outcome**: A report including a high priority list, intended for governmental use, of hazards in feed ingredients, including feed additives. The report should be forwarded to the appropriate Codex Committees for further consideration.

c) Establish criteria for the global identification and notification of emergency situations affecting the feed sector (and ultimately the food sector). Such criteria are essential to the efficient operation of

[7] Section I – Foundation Texts and Definitions, Statutes of the Codex Alimentarius Commission, Procedural Manual, Eighteenth edition, Rome, 2009.
[8] Section I – Foundation Texts and Definitions, Statutes of the Codex Alimentarius Commission, article 1, (a), Procedural Manual, Eighteenth edition, Rome, 2009.

existing systems regarding the exchange of information about food safety (e.g. INFOSAN) that might be expanded to cover feed.
**Expected outcome**: A guideline including specific criteria for identification and notification of emergency situations in relation to feed.

Representatives from 17 Member Countries, three observers and the EU-Commission contributed to item (iv). Only the opinions of Member Countries are counted in relation to the different suitable mechanisms mentioned in the following:

Item (iv), a) Guideline on how to apply the existing Codex Risk Assessment Methodologies

Many E-WG members support the development of guidelines intended for governments to assess adequately the risk of animal feed as it impacts on food safety, considering that it is an important step in completing the safety of the food chain. Such guidelines could provide useful guidance to governments' response for the mitigation of contamination events involving animal feed. However, consensus could not be achieved among the E-WG Members on the most suitable mechanism to address this work.

Many members believe that a dedicated Task Force is a suitable mechanism. Other members offered recommendations such as to have this work completed by: An electronic working group, to refer work to an FAO/WHO expert Committee, assign work to the appropriate Codex Committees, or regional workshops.

Few members are of the opinion that there is no need for further work in relation to this item provided the changes proposed to the documents mentioned in item (i) and (iii) (see Annex I – III) as well as the proposed changes to the definitions (see Annex IV) are accepted by the CAC.

One country suggested that the CAC direct the relevant Codex Committees to carry out work on animal feed that is appropriate to the terms of reference for their committees, and that the existing Codex Committee structure provides a forum that can be available to address feed issues whenever new issues arise. They noted that for the past several years, Member Countries have been strongly encouraged to find ways to limit the number of Codex committee and task force meetings, and adding another meeting to the already crowded Codex calendar could be counter-productive and make it difficult for some countries to participate.

After the 3rd round of comments a proposal was circulated in the E-WG. The proposal recommended that all future work on animal feed issues be assigned to CCRVDF[9], and that the terms of reference of this committee be amended to include feed issues. According to the proposal, amending the TOR of a permanent committee to handle work on animal feed, would not only elevate the importance of animal feed in relation to food safety, it would also provide a mechanism for ensuring long term work in the area would be carried out.

Because the E-WG had not yet achieved consensus, the proposal was distributed in the E-WG to get an indication of whether E-WG group members would be supportive to this proposal. 15 countries, three observers and the EU-Commission responded to the request to give their views to the proposal. It should be noted that the E-WG members did not have the opportunity to discuss and review the proposal in detail.

Some countries supported that all future work on animal feed should be assigned to CCRVDF. Some were against, while others thought that the proposal was worthy of consideration but that other committees such as CCCF[10] or CCPR[11] may also be appropriate bodies to undertake such work. Other countries noted that they would like the opportunity to review the proposal in greater detail and assess it against the other options before indicating a clear position.

However, many countries supported inclusion of this proposal as one of the options for a suitable mechanism to handle the work of animal feed related to item (iv) a), b), and c).

**Conclusion on item (iv) a)**

Recognizing that it was not possible to achieve consensus, and taking into account the above comments, the E-WG recommends that the CAC consider the following options on a suitable mechanism for Codex to undertake the work addressed in item (iv) a):

[9] Codex Committee on Residues of Veterinary Drugs.
[10] Codex Committee on Contaminants in Foods.
[11] Codex Committee on Pesticide Residues.

- A time limited Task Force; or
- Assigning work to one of the existing permanent committees, e.g. CCCF or CCRVDF.

Item (iv), b) List of Hazards

A majority of the E-WG members supported the development of a prioritized list of hazards associated with feed ingredients, including feed additives. However, there was no general consensus on the most suitable mechanism to address this work.

Many countries recommended the establishment of a dedicated Task Force with a clear mandate to address this item adequately. Other countries recommended to have the work carried out by: An electronic working group, re-establishing the 2007 FAO/WHO Expert Consultation, assignment to the relevant Codex committees, or regional workshops.

In addition to the proposal from the previous E-WG, the present E-WG recommends that the focus should be on hazards that have a direct impact on food safety. It is suggested that the list of current hazards as developed by the FAO/WHO Expert Meeting of October 2007 on Animal Feed Impact on Food Safety be considered as a starting point for the work.

A number of E-WG members have underlined the importance of ensuring that such a list of prioritized hazards should be maintained and updated on a regular basis in the light of developments.

In relation to this, it has been pointed out that there is generally no mechanism for maintaining such lists, and that development of lists can, in fact, hinder the development of Codex standards. In addition, it was raised that because conditions on use of feed vary from country to country and from region to region that it would be more useful to develop criteria based on risk assessment principles, for determining and evaluating hazards, rather than developing a list of specific hazards.

**Conclusion to item (iv) b)**

Recognizing that it was not possible to achieve consensus, and taking into account the above comments, including the comments to the proposal that all future work on animal feed issues be assigned to CCRVDF mentioned under item (iv) a), the E-WG recommends that the CAC consider the following options for a suitable mechanism for Codex to undertake the work addressed in item (iv) b):

- A time limited Task Force; or
- Assigning work to one of the existing permanent committees, e.g. CCCF or CCRVDF.

Item (iv) c) Criteria for Global Identification and Notification of Emergency Situations Affecting the Feed Sector.

Several E-WG members supported the development of criteria for the global identification and notification of emergency situations affecting the feed sector. However, there was no general consensus on the most suitable mechanism on how to address this work.

Some countries recommended the work be undertaken by a dedicated Task Force. Other countries recommended the work be carried out by: A joint group of feed experts; an electronic working group; regional work shops; the relevant Codex Committees; or that this task should be referred to the World Health Organisation (WHO) and the Food and Agriculture Organization (FAO) that developed the criteria for the identification of food safety emergency situations.

Among the comments submitted, one member noted that notification of emergency situations affecting the feed sector needed to be coordinated with animal health by the World Organisation for Animal Health (OIE).

Another E-WG member noted that there is no need for further work in relation to this item provided the changes proposed to the documents mentioned in item (i) and (iii) are adopted by the CAC.

The E-WG encourages the CAC to consider whether this work should be dealt with by Codex or referred to the WHO and the FAO that developed the criteria for the identification of food safety emergency situations.

**Conclusion to item (iv) c)**

Recognizing that it was not possible to achieve consensus, and taking into account the above comments, including the comments to the proposal that all future work on animal feed issues be assigned to CCRVDF mentioned under item (iv) a), the E-WG recommends that the CAC consider the following options for a suitable mechanism for Codex to undertake the work addressed in item (iv) c):

- A time limited Task Force;
- Assigning future work to one of the existing permanent committees e.g. CCCF or CCRVDF; or
- Referring the work to the WHO and FAO.

## 5. SUMMARY OF OTHER COMMENTS

The E-WG identified other areas in the existing Codex documents, which some Members felt did not cover feed adequately. Although these are not covered by the terms of reference of this E-WG, the comments are listed in this report as areas of consideration for future work.

*Amending and Adding New Definitions to the Procedural Manual*

From reviewing the documents, it is proposed to amend some of the Codex definitions included in the Procedural Manual and to add new definitions specifically related to feed. Many E-WG members were of the opinion these amendments are necessary to ensure that the definitions are harmonised with the proposed changes in the documents and are applicable to feed. Other members noted their concerns with some of the proposed amendments, noting that the proposed changes may have broader implications than originally intended and were not part of the terms of reference, but indicated if these proposed definitions are found to be necessary, they should be referred to the Codex Committee on General Principles. Alternatively, if the revised or additional definitions are considered relevant to an individual Codex Committee, they should be referred to that committee.

The proposed changes are included in Annex IV.

*Residues of Feed Additives*

Many E-WG members identified a potential gap in the Codex system in relation to residues of feed additives in food where relevant for food safety. Some members questioned whether these residues were covered by the definition of contaminants[12]. However, some Members found that they had not had the opportunity to fully review this gap during the process. In some cases, the feed additives may already be covered:

| | | |
|---|---|---|
| Feed additives with effect on feed or animals | Additives that may also be used as veterinary drugs, as antibiotic growth promoters or coccidiostats. | Residues may be covered by CCRVDF |
| | Other additives | Not covered |
| Feed additives with effect on food | Additives also approved for use in food, as e.g. colorants. | Residues may be covered by CCFA |
| | Additives not approved for food use. | Not covered. |

*Overview of all Documents Related to Feed*

Some members suggested that the report should include an overview of all Codex documents related to feed to indicate whether all aspects of the risk analysis field of feed (production, use, hygiene and the whole process of feed/food production) are covered adequately or if gaps exist that require new Codex guidelines. Drafting such a document which identifies possible gaps is a comprehensive piece of work and was not included in the Terms of Reference for the E-WG.

[12] *General Standard for Contaminants and Toxins in Food and Feed* (Codex Stan 193-1995).

**LIST OF ANNEXES**

Annex I: Proposed Changes to Documents on the Existing Codex Risk Analysis Principles and their Applicability to Feed.

Annex II: Proposed Changes to existing Codex texts on emergency situations and exchange of information on rejected food as to their applicability to animal feed (CAC/GL 25-1997 and CAC/GL 19-1995).

Annex III: Proposed Changes to the Codex *Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals* (CAC/RCP 49-2001) as to their applicability to animal feed.

Annex IV: Proposed Changes and additions to the Definitions for the Purposes of the Codex Alimentarius and proposed changes to the Definitions of Risk Analysis Terms related to Food Safety (not included in the Terms of Reference for the E-WG).

Annex V: List of Participants.

**Please Note**: All comments sumitted during the preparation of this report are available with the EWG host country (E-mail: bbj@pdir.dk)

**Annex I**

**Codex Electronic Working Group on Animal Feed 2009/2010**

**Proposed Changes to Documents on the Existing Codex Risk Analysis Principles and their Applicability to Feed**

**Proposal**

**WORKING PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION IN THE FRAMEWORK OF THE CODEX ALIMENTARIUS**

Proposed changes in ***italics and bold)***

**Scope**

1. These principles for risk analysis are intended for application in the framework of the Codex Alimentarius.

2. The objective of these Working Principles is to provide guidance to the Codex Alimentarius Commission and the joint FAO/WHO expert bodies and consultations, so that food safety, ***including safety aspects related to feed***[13] ***for food producing animals***, and ***human*** health aspects of Codex standards and related texts are based on risk analysis.

3. Within the framework of the Codex Alimentarius Commission and its procedures, the responsibility for providing advice on risk management lies with the Commission and its subsidiary bodies (risk managers), while the responsibility for risk assessment lies primarily with the joint FAO/WHO expert bodies and consultations (risk assessors).

**Risk Analysis - General Aspects**

4. The risk analysis used in Codex should be:

   - applied consistently;
   - open, transparent and documented;
   - conducted in accordance with both the Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account and the Statements of Principle Relating to the Role of Food Safety Risk Assessment[14] ; and
   - evaluated and reviewed as appropriate in the light of newly generated scientific data.

5. The risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission[15], each component being integral to the overall risk analysis.

6. The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality, documentation should be accessible to all interested parties[16].

7. Effective communication and consultation with all interested parties should be ensured throughout the risk analysis.

8. The three components of risk analysis should be applied within an overarching framework for management of food ***and feed*** related risks to human health.

9. There should be a functional separation of risk assessment and risk management, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.

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[13] The term "feed" refers to both "feed (feedingstuffs)" and "feed ingredients" as defined in the *Code of Practice on Good Animal Feeding* (CAC/RCP 054 2004)

[14] See Appendix: General Decisions of the Commission

[15] See Definitions of Risk Analysis Terms Related to Food Safety

[16] For the purpose of the present document, the term “interested parties” refers to “risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations” (see definition of “Risk Communication”)

10. When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.

11. Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food ***or feed*** related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. Where there is sufficient scientific evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.

12. The needs and situations of developing countries should be specifically identified and taken into account by the responsible bodies in the different stages of the risk analysis.

**Risk Assessment Policy**

13. Determination of risk assessment policy should be included as a specific component of risk management.

14. Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent.

15. The mandate given by risk managers to risk assessors should be as clear as possible.

16. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

**Risk Assessment**[17]

17. The scope and purpose of the particular risk assessment being carried out should be clearly stated and in accordance with risk assessment policy. The output form and possible alternative outputs of the risk assessment should be defined

18. Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise, experience, and their independence with regard to the interests involved. The procedures used to select these experts should be documented including a public declaration of any potential conflict of interest. This declaration should also identify and detail their individual expertise, experience and independence. Expert bodies and consultations should ensure effective participation of experts from different parts of the world, including experts from developing countries.

19. Risk assessment should be conducted in accordance with the Statements of Principle Relating to the Role of Food Safety Risk Assessment and should incorporate the four steps of the risk assessment, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization.

20. Risk assessment should be based on all available scientific data. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information.

21. Risk assessment should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse ***human*** health effects.

22. Risk assessment should seek and incorporate relevant data from different parts of the world, including that from developing countries. These data should particularly include epidemiological surveillance data, analytical and exposure data. Where relevant data are not available from developing countries, the Commission should request that FAO/WHO initiate time-bound studies for this purpose. The conduct of the risk assessment should not be inappropriately delayed pending receipt of these data; however, the risk assessment should be reconsidered when such data are available.

23. Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.

[17] Reference is made to the Statements of Principle Relating to the Role of Food Safety Risk Assessment: See Appendix: General Decisions of the Commission.

24. Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk ***human*** population groups. Acute, chronic (including long-term), cumulative and/or combined adverse ***human*** health effects should be taken into account in carrying out risk assessment, where relevant.

25. The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.

26. The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

**Risk Management**

27. While recognizing the dual purposes of the Codex Alimentarius are protecting the health of consumers and ensuring fair practices in the food trade, Codex decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers. Unjustified differences in the level of consumer health protection to address similar risks in different situations should be avoided.

28. Risk management should follow a structured approach including preliminary risk management activities[18], evaluation of risk management options, monitoring and review of the decision taken. The decisions should be based on risk assessment, and taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles[19].

29. The Codex Alimentarius Commission and its subsidiary bodies, acting as risk managers in the context of these Working Principles, should ensure that the conclusion of the risk assessment is presented before making final proposals or decisions on the available risk management options, in particular in the setting of standards or maximum levels, bearing in mind the guidance given in paragraph 10.

30. In achieving agreed outcomes, risk management should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects.

31. The risk management process should be transparent, consistent and fully documented. Codex decisions and recommendations on risk management should be documented, and where appropriate clearly identified in individual Codex standards and related texts so as to facilitate a wider understanding of the risk management process by all interested parties.

32. The outcome of the preliminary risk management activities and the risk assessment should be combined with the evaluation of available risk management options in order to reach a decision on management of the risk.

33. Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be considered.

34. In order to avoid unjustified trade barriers, risk management should ensure transparency and consistency in the decision-making process in all cases. Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, the Commission and its subsidiary bodies should seek and take into consideration the potential impactof such measures on trade among its Member countries and select measures that are no more trade-restrictive than necessary.

35. Risk management should take into account the economic consequences and the feasibility of risk managementoptions. Risk management should also recognize the need for alternative options in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers' health. In taking these elements into consideration, the Commission and its subsidiary bodies should give particular attention to the circumstances of developing countries.

[18] For the purpose of these Principles, preliminary risk management activities are taken to include: identification of a food safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment.

[19] See Appendix: General Decisions of the Commission.

36. Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. Food ***and feed*** standards and related texts should be reviewed regularly and updated as necessary to reflect new scientific knowledge and other information relevant to risk analysis.

**Risk Communication**

37. Risk communication should :

(i) promote awareness and understanding of the specific issues under consideration during the risk analysis;

(ii) promote consistency and transparency in formulating risk management options/recommendations;

(iii) provide a sound basis for understanding the risk management decisions proposed;

(iv) improve the overall effectiveness and efficiency of the risk analysis ;

(v) strengthen the working relationships among participants;

(vi) foster public understanding of the process, so as to enhance trust and confidence in the safety of the food ***and feed*** supply;

(vii) promote the appropriate involvement of all interested parties; and

***(viii)*** exchange information in relation to the concerns of interested parties about the risks associated with food ***and with feed related to food safety.***

38. Risk analysis should include clear, interactive and documented communication, amongst risk assessors (Joint FAO/WHO expert bodies and consultations) and risk managers (Codex Alimentarius Commission and its subsidiary bodies), and reciprocal communication with member countries and all interested parties in all aspects of the process.

39. Risk communication should be more than the dissemination of information. Its major function should be to ensure that all information and opinion required for effective risk management is incorporated into the decision making process.

40. Risk communication involving interested parties should include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The need for specific standards or related texts and the procedures followed to determine them, including how the uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis, and minority opinions that had been expressed in the course of the risk assessment (see para. 25).

41. The guidance on risk communication in this document is addressed to all those involved in carrying out risk analysis within the framework of Codex Alimentarius. However, it is also of importance for this work to be made as transparent and accessible as possible to those not directly engaged in the process and other interested parties while respecting legitimate concerns to preserve confidentially (see para. 6)

**Proposal**

**RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON FOOD ADDITIVES AND THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

Proposed changes in ***italics and bold***

**Section 1. Scope**

1. This document addresses the respective applications of risk analysis principles by the Codex Committee on Food Additives (CCFA) and the Codex Committee on Contaminants in Foods (CCCF) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). For matters which cannot be addressed by JECFA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies, as approved by the Commission.

2. This document should be read in conjunction with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.

***a) This document also applies to contaminants in food originating from feed additives and contaminants in feed[20] for food producing animals where it can impact food safety.***

**Section 2. CCFA/CCCF and JECFA**

3. CCFA/CCCF and JECFA recognize that communication between risk assessors and risk managers is critical to the success of their risk analysis activities.

4. CCFA/CCCF and JECFA should continue to develop procedures to enhance communication between the two committees.

5. CCFA/CCCF and JECFA should ensure that their contributions to the risk analysis process involve all interested parties and are fully transparent and thoroughly documented. While respecting legitimate concerns to preserve confidentiality, documentation should be made available, upon request, in a timely manner to all interested parties.

6. JECFA, in consultation with CCFA/CCCF, should continue to explore developing minimum quality criteria for data requirements necessary for JECFA to perform risk assessments. These criteria are used by CCFA/CCCF in preparing its Priority List for JECFA. The JECFA Secretariat should consider whether these minimum quality criteria for data have been met when preparing the provisional agenda for meetings of JECFA.

**Section 3. CCFA/CCCF**

7. CCFA/CCCF are primarily responsible for recommending risk management proposals for adoption by the CAC.

8. CCFA/CCCF shall base their risk management recommendations to the CAC on JECFA's risk assessments, including safety assessments[21], of food additives, naturally occurring toxicants, and contaminants in food ***and feed.***

9. In cases where JECFA has performed a safety assessment and CCFA/CCCF or the CAC determines that additional scientific guidance is necessary, CCFA/CCCF or CAC may make a more specific request to JECFA to obtain the scientific guidance necessary for a risk management decision.

10. CCFA's risk management recommendations to the CAC with respect to food additives shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Food Additives.

11. CCCF's risk management recommendations to the CAC with respect to contaminants and naturally occurring toxicants shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Contaminants and Naturally Occurring Toxins in Food ***and Feed***.

12. CCFA/CCCF's risk management recommendations to the CAC that involve health and safety aspects of food ***and feed*** standards shall be based on JECFA's risk assessments and other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*.

13. CCFA/CCCF's risk management recommendations to the CAC shall take into account the relevant uncertainties and safety factors described by JECFA.

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[20] The term "feed" refers to both "feed (feedingstuffs)" and "feed ingredients" as defined in the *Code of Practice on Good Animal Feeding* (CAC/RCP 054/2004)

[21] A Safety Assessment is defined as a scientifically-based process consisting of: 1) the determination of a NOEL (No Observed Effect Level) for a chemical, biological, or physical agent from animal feeding studies and other scientific considerations; 2) the subsequent application of safety factors to establish an ADI or tolerable intake; and 3) comparison of the ADI or tolerable intake with probable exposure to the agent (Temporary definition to be modified when JECFA definition is available).

14. CCFA shall endorse maximum use levels only for those additives for which 1) JECFA has established specifications of identity and purity and 2) JECFA has completed a safety assessment or has performed a quantitative risk assessment.

15. CCCF shall endorse maximum levels only for those contaminants for which 1) JECFA has completed a safety assessment or has performed a quantitative risk assessment and 2) the level of the contaminant in food ***or feed*** can be determined through appropriate sampling plans and analysis methods, as adopted by Codex. CCCF should take into consideration the analytical capabilities of developing countries unless public health considerations require otherwise.

16. CCFA/CCCF shall take into account differences in regional and national food consumption patterns and dietary exposure as assessed by JECFA when recommending maximum use levels for additives or maximum levels for contaminants and naturally occurring toxicants in food ***and feed***.

17. Before finalising proposals for maximum levels for contaminants and naturally occurring toxicants, CCCF shall seek the scientific advice of JECFA about the validity of the analysis and sampling aspects, about the distribution of concentrations of contaminants and naturally occurring toxicants in foods ***or feeds*** and about other relevant technical and scientific aspects, including dietary exposure, as necessary to provide for a suitable scientific basis for its advice to CCCF.

18. When establishing its standards, codes of practice, and guidelines, CCFA/CCCF shall clearly state when it applies any other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*, in addition to JECFA's risk assessment, and specify its reasons for doing so.

19. CCFA/CCCF's risk communication with JECFA includes prioritising substances for JECFA review with the view towards obtaining the best available risk assessment for purposes of elaborating safe conditions of use for food additives and elaborating safe maximum levels or codes of practice for contaminants ***including residues of feed additives*** and naturally occurring toxicants in food.

20. CCFA/CCCF shall consider the following when preparing its priority list of substances for JECFA review:

- Consumer protection from the point of view of health and prevention of unfair trade practices;
- CCFA/CCCF's Terms of Reference;
- JECFA's Terms of Reference;
- The Codex Alimentarius Commission's Strategic Plan, its relevant plans of work and *Criteria for the Establishment of Work Priorities*;
- The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;
- The prospect of completing the work in a reasonable period of time;
- The diversity of national legislation and any apparent impediments to international trade;
- The impact on international trade (i.e., magnitude of the problem in international trade);
- The needs and concerns of developing countries; and,
- Work already undertaken by other international organizations;

21. When referring substances to JECFA, CCFA/CCCF shall provide background information and clearly explain the reasons for the request when chemicals are nominated for evaluation;

22. CCFA/CCCF may also refer a range of risk management options, with a view toward obtaining JECFA's guidance on the attendant risks and the likely risk reductions associated with each option.

23. CCFA/CCCF requests JECFA to review any methods and guidelines being considered by CCFA/CCCF for assessing maximum use levels for additives or maximum levels for contaminants and naturally occurring toxicants. CCFA/CCCF makes any such request with a view toward obtaining JECFA's guidance on the limitations, applicability, and appropriate means for implementation of a METHOD OR GUIDELINE FOR CCFA/CCCF'S WORK.

**Section 4. JECFA**

24. JECFA is primarily responsible for performing the risk assessments upon which CCFA/CCCF and ultimately the CAC base their risk management decisions.

25. JECFA's scientific experts should be selected on the basis of their competence and independence, taking into account geographical representation to ensure that all regions are represented.

26. JECFA should strive to provide CCFA/CCCF with science-based risk assessments that include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for CCFA/CCCF's risk-management discussions. For contaminants and naturally occurring toxicants, JECFA should determine to the extent possible the risks associated with various levels of intake. Because of the lack of appropriate information, including data in humans, however, this may be possible in only a few cases for the foreseeable future. For additives, JECFA should continue to use its safety assessment process for establishing ADIs.

27. JECFA should strive to provide CCFA/CCCF with science-based quantitative risk assessments and safety assessments for food additives, contaminants ***in food and feed***, ~~***and***~~ naturally occurring toxicants ***and residues of feed additives*** in a transparent manner.

28. JECFA should provide CCFA/CCCF with information on the applicability and any constraints of the risk assessment to the general population to particular sub-populations and should as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g. children, women of child-bearing age, the elderly).

29. JECFA should also strive to provide CCFA with specifications of identity and purity essential to assessing risk associated with the use of additives.

30. JECFA should strive to base its risk assessments on global data, including data from developing countries. These data should include epidemiological surveillance data and exposure studies.

31. JECFA is responsible for evaluating exposure to additives, contaminants, and naturally occurring toxicants.

32. When evaluating intake of additives or contaminants and naturally occurring toxicants during its risk assessment, JECFA should take into account regional differences in food ***and feed*** consumption patterns.

33. JECFA should provide to CCCF its scientific views on the validity and the distribution aspects of the available data regarding contaminants ***in food and feed,*** ~~***and***~~ naturally occurring toxicants in foods ***and residues of feed additives*** which have been used for exposure assessments, and should give details on the magnitude of the contribution to the exposure from specific foods ***and feeds*** as may be relevant for risk management actions or options of CCCF.

34. JECFA should communicate to CCFA/CCCF the magnitude and source of uncertainties in its risk assessments. When communicating this information, JECFA should provide CCFA/CCCF with a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment.

35. JECFA should communicate to CCFA/CCCF the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties.

36. JECFA's risk assessment output to CCFA/CCCF is limited to presenting its deliberations and the conclusions of its risk assessments and safety assessments in a complete and transparent manner. JECFA's communication of its risk assessments should not include the consequences of its analyses on trade or other non-public health consequence. Should JECFA include risk assessments of alternative risk management options, JECFA should ensure that these are consistent with the Working Principles for Risk Analysis for the Application in the Framework of the Codex Alimentarius and Risk Analysis Principles applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods.

37. When establishing the agenda for a JECFA meeting, the JECFA Secretariat work closely with CCFA/CCCF to ensure that CCFA/CCCF's risk management priorities are addressed in a timely manner. With respect to food additives, the JECFA Secretariat should normally give first priority to compounds that have been assigned a temporary ADI, or equivalent. Second priority should normally be given to food additives, groups of additives that have previously been evaluated and for which an ADI, or equivalent, has been estimated, and for which new information is available. Third priority should normally be given to food additives that have not been previously evaluated. With respect to contaminants ***including residues of feed additives*** and naturally occurring toxicants, the JECFA Secretariat should give priority to substances that present both a significant risk to public health and are a known or expected problem in international trade.

38. When establishing the agenda for a JECFA meeting, the JECFA Secretariat should give priority to substances that are known or expected problems in international trade or that present an emergency or imminent public health risk.

**Proposal**

**RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**

Proposed changes in ***Italics and bold***

**1. PURPOSE – SCOPE**

***1.*** The purpose of this document is to specify Risk Analysis Principles applied by the Codex Committee on Residues of Veterinary Drugs in Foods.

***a) This document also applies to veterinary drugs in food originating from residues of veterinary drugs in feed[22] of animal origin where it can impact food safety.***

**2. PARTIES INVOLVED**

1. The *Working Principles for Risk Analysis for application in the framework of the Codex Alimentarius* has defined the responsibilities of the various parties involved. The responsibility for providing advice on risk management concerning residues of veterinary drugs lies with the Codex Alimentarius Commission and its subsidiary body, the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), while the responsibility for risk assessment lies primarily with the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

2. According to its mandate, the responsibilities of the CCRVDF regarding veterinary drug residues in food are:

(a) to determine priorities for the consideration of residues of veterinary drugs in foods;

(b) to recommend maximum residue limits (MRLs) for such veterinary drugs;

(c) to develop codes of practice as may be required;

(d) to consider methods of sampling and analysis for the determination of veterinary drug residues in foods.

3. The CCRVDF shall base its risk management recommendations to the Codex Alimentarius Commission on JECFA's risk assessments of veterinary drugs in relation to proposed MRLs.

4. The CCRVDF is primarily responsible for recommending risk management proposals for adoption by the Codex Alimentarius Commission.

5. JECFA is primarily responsible for providing independent scientific advice, the risk assessment, upon which the CCRVDF base their risk management decisions. It assists the CCRVDF by evaluating the available scientific data on the veterinary drug prioritised by the CCRVDF. JECFA also provides advice directly to FAO and WHO and to Member governments.

6. Scientific experts from JECFA are selected in a transparent manner by FAO and WHO under their rules for expert committees on the basis of the competence, expertise, experience in the evaluation of compounds used as veterinary drugs and their independence with regard to the interests involved, taking into account geographical representation where possible.

**3. RISK MANAGEMENT IN CCRVDF**

7. Risk management should follow a structured approach including:

- preliminary risk management activities;
- evaluation of risk management options; and
- monitoring and review of decisions taken.

8. The decisions should be based on risk assessment, and take into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for fair practices in food trade, in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*[23].

**3.1 Preliminary risk management activities**

9. This first phase of risk management covers:

- Establishment of risk assessment policy for the conduct of the risk assessments;

[22] The term "feed" refers to both "feed (feedingstuffs)" and "feed ingredients" as defined in the *Code of Practice on Good Animal Feeding* (CAC/RCP 054 2004).

[23] Statements 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 Procedural Manual Appendix

- Identification of a food safety problem ***in the integrity of the food chain and determine if feed may be a source of the food safety problem;***
- Establishment of a preliminary risk profile;
- Ranking of the hazard for risk assessment and risk management priority;
- Commissioning of the risk assessment; and
- Consideration of the result of the risk assessment.

### 3.1.1 Risk Assessment Policy for the Conduct of the Risk Assessment

10. The responsibilities of the CCRVDF and JECFA and their interactions along with core principles and expectations of JECFA evaluations are provided in *Risk Assessment Policy for the Setting of MRLs in Food*, established by the Codex Alimentarius Commission.

### 3.1.2 Establishment of Priority List

11. The CCRVDF identifies, with the assistance of Members, the veterinary drugs that may pose a consumer safety problem and/or have a potential adverse impact on international trade. The CCRVDF establishes a priority list for assessment by JECFA.

12. In order to appear on the priority list of veterinary drugs for the establishment of a MRL, the proposed veterinary drug shall meet some or all of the following criteria:

- A Member has proposed the compound for evaluation;
- A Member has established good veterinary practices with regard to the compound;
- The compound has the potential to cause public health and/or international trade problems;
- It is available as a commercial product; and
- There is a commitment that a dossier will be made available.

13. The CCRVDF takes into account the protection of confidential information in accordance with WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) - Section 7: Protection of Undisclosed Information - Article 39, and makes every effort to encourage the willingness of sponsors to provide data for JECFA assessment.

### 3.1.3 Establishment of a Preliminary Risk Profile

14. Member(s) request(s) the inclusion of a veterinary drug on the priority list. The available information for evaluating the request shall be provided either directly by the Member(s) or by the sponsor. A preliminary risk profile shall be developed by the Member(s) making the request, using the template presented in the Annex.

15. The CCRVDF considers the preliminary risk profile and makes a decision on whether or not to include the veterinary drug in the priority list.

### 3.1.4 Ranking of the Hazard for Risk Assessment and Risk Management Priority

16. The CCRVDF establishes an ad-hoc Working Group open to all its Members and observers, to make recommendations on the veterinary drugs to include into (or to remove from) the priority list of veterinary drugs for the JECFA assessment. The CCRVDF considers these recommendations before agreeing on the priority list, taking into account pending issues such as temporary Acceptable Daily Intakes (ADIs) and/or MRLs. In its report, the CCRVDF shall specify the reasons for its choice and the criteria used to establish the order of priority.

17. Prior to development of MRLs for new veterinary drugs not previously evaluated by JECFA, a proposal for this work shall be sent to the Codex Alimentarius Commission with a request for approval as new work in accordance with the *Procedures for the Elaboration of Codex Standards and Related Texts*.

### 3.1.5 Commissioning of the Risk Assessment

18. After approval by the Codex Alimentarius Commission of the priority list of veterinary drugs as new work, the CCRVDF forwards it to JECFA with the qualitative preliminary risk profile as well as specific guidance on the CCRVDF risk assessment request. JECFA, WHO and FAO experts then proceed with the assessment of risks related to these veterinary drugs, based on the dossier provided and/or all other available scientific information.

### 3.1.6 Consideration of the Result of the Risk Assessment

19. When the JECFA risk assessment is completed, a detailed report is prepared for the subsequent session of the CCRVDF for consideration. This report shall clearly indicate the choices made during the risk assessment with respect to scientific uncertainties and the level of confidence in the studies provided.

20. When the data are insufficient, JECFA may recommend temporary MRL on the basis of a temporary ADI using additional safety considerations[24]. If JECFA cannot propose an ADI and/or MRLs due to lack of data, its report should clearly indicate the gaps and a timeframe in which data should be submitted, in order to allow Members to make an appropriate risk management decision.

21. The JECFA assessment reports related to the concerned veterinary drugs should be made available in sufficient time prior to a CCRVDF meeting to allow for careful consideration by Members. If this is, in exceptional cases, not possible, a provisional report should be made available.

22. JECFA should, if necessary, propose different risk management options. In consequence, JECFA should present, in its report, different risk management options for the CCRVDF to consider. The reporting format should clearly distinguish between the risk assessment and the evaluation of the risk management options.

23. The CCRVDF may ask JECFA any additional explanation.

24. Reasons, discussions and conclusions (or the absence thereof) on risk assessment should be clearly documented, in JECFA reports, for each option reviewed. The risk management decision taken by the CCRVDF (or the absence thereof) should also be fully documented.

### 3.2 Evaluation of Risk Management Options

25. The CCRVDF shall proceed with a critical evaluation of the JECFA proposals on MRLs and may consider other legitimate factors relevant for health protection and fair trade practices in the framework of the risk analysis. According to the 2nd statement of principle, the criteria for the consideration of other factors should be taken into account. These other legitimate factors are those agreed during the 12th session of the CCRVDF[25] and subsequent amendments made by this Committee.

26. The CCRVDF either recommends the MRLs as proposed by JECFA, modifies them in consideration of other legitimate factors, considers other measures or asks JECFA for reconsideration of the residue evaluation for the veterinary drug in question.

27. Particular attention should be given to availability of analytical methods used for residue detection.

### 3.3 Monitoring and Review of the Decisions Taken

28. Members may ask for the review of decisions taken by the Codex Alimentarius Commission. To this end, veterinary drugs should be proposed for inclusion in the priority list. In particular, review of decisions may be necessary if they pose difficulties in the application of the *Guidelines for the Establishment of a Regulatory Programme for the Control of Veterinary Drug Residues in Foods* (CAC/GL 16-1993).

29. The CCRVDF may request JECFA to review any new scientific knowledge and other information relevant to risk assessment and concerning decisions already taken, including the established MRLs.

30. The risk assessment policy for MRL shall be reconsidered based on new issues and experience with the risk analysis of veterinary drugs. To this end, interaction with JECFA is essential. A review may be undertaken of the veterinary drugs appearing on prior JECFA agendas for which no ADI or MRL has been recommended.

## *4. RISK COMMUNICATION IN THE CONTEXT OF RISK MANAGEMENT*

31. In accordance with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*, the CCRVDF, in cooperation with JECFA, 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. The CCRVDF recognises that communication between risk assessors and risk managers is critical to the success of risk analysis activities.

32. In order to ensure the transparency of the assessment process in JECFA, the CCRVDF provides comments on the guidelines related to assessment procedures being drafted or published by JECFA.

[24] Definition of "Codex maximum limit for residues of veterinary drugs", Codex Procedural Manual.
[25] ALINORM 01/31 paragraph 11.

**ANNEX**

***TEMPLATE FOR INFORMATION NECESSARY FOR PRIORITIZATION BY CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS***

**Administrative information**

1. Member(s) submitting the request for inclusion
2. Veterinary drug names
3. Trade names
4. Chemical names
5. Names and addresses of basic producers

**Purpose, scope and rationale**

6. Identification of the food safety issue (residue hazard)
7. Assessment against the criteria for the inclusion on the priority list

**Risk profile elements**

8. Justification for use
9. Veterinary use pattern
10. Commodities for which Codex MRLs are required

**Risk assessment needs and questions for the risk assessors**

11. Identify the feasibility that such an evaluation can be carried out in a reasonable framework
12. Specific request to risk assessors

**Available information**[26]

13. Countries where the veterinary drugs is registered
14. National/Regional MRLs or any other applicable tolerances
15. List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available

**Timetable**

16. Date when data could be submitted to JECFA

[26] When preparing a preliminary risk profile, Member(s) should take into account the updated data requirement, to enable evaluation of a veterinary drug for the establishment of an ADI and MRLs, published by JECFA.

**Proposal**

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

Proposed changes in ***italics and bold***

**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. ***This document also applies to pesticides in food originating from residues of pesticides in feed[27] for food producing animals where it can impact food safety.***

**Roles CCPR and JMPR in Risk Analysis**

**Interaction between CCPR and JMPR**

2. In addressing pesticide residue issues in Codex, providing advice on risk management is the responsibility of the Codex Alimentarius Commission (CAC) and CCPR while conducting risk assessment is the responsibility of JMPR.

3. CCPR and JMPR recognize that an adequate communication between risk assessors and risk managers is an essential requirement for successfully performing their risk analysis activities.

4. CCPR and JMPR should continue to develop procedures to enhance communication between the two bodies.

5. 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 members[28].

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

7. These requirements should be used by CCPR as a fundamental criterion as described in the Annex in preparing its Priority List for JMPR. The JMPR Secretariat should consider whether these minimum data requirements have been met when preparing the provisional agenda for meetings of JMPR

**Role of CCPR**

8. CCPR is primarily responsible for recommending risk management proposals for adoption by the CAC.

9. CCPR shall base its risk management recommendations, such as MRLs, to the CAC following JMPR's risk assessments of the respective pesticides, and considering, where appropriate, other legitimate factors such as relevant to the health protection of consumers and for the promotion of fair practices in food trade.

10. In cases where JMPR has performed a risk assessment and CCPR or the 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.

11. CCPR's risk management recommendations to the CAC shall take into account the relevant uncertainties as described by JMPR.

12. CCPR shall consider maximum residue limits (MRLs) only for those pesticides for which JMPR has completed a full safety evaluation.

13. CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns on a global scale when recommending MRLs in food ***or feed***. 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.

14. When establishing its standards, CCPR shall clearly state when it applies any considerations based on other legitimate factors in addition to JMPR's risk assessment and recommended maximum residue levels and specify its reasons for doing so.

15. CCPR shall consider the following when preparing its priority list of compounds for JMPR evaluation:

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[27] The term "feed" refers to both "feed (feedingstuffs)" and "feed ingredients" as defined in the *Code of Practice on Good Animal Feeding* (CAC/RCP 054/2004).

[28] Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant Production and Protection Paper, 170, 2002, ISBN 92-5-104759-6

- CCPR's Terms of Reference;
- JMPR's Terms of Reference;
- The Codex Alimentarius Commission's Strategic Plan;
- The Criteria for the Establishment of Work Priorities;
- The Criteria for Inclusion of Compounds on the Priority List;
- The Criteria for Selecting Food ***or Feed*** Commodities for which Codex MRLs or Extraneous Maximum Residue Limits (EMRLs) should be Established;
- The Criteria for Evaluation of New Chemicals;
- The Criteria for Prioritization Process of Compounds for Evaluation by JMPR
- A commitment to provide the necessary data for the evaluation in time.

16. When referring substances to JMPR, the CCPR shall provide background information and clearly specify the reasons for the request when chemicals are nominated for evaluation.

17. When referring substances to JMPR, the CCPR may also refer a range of risk management options, with a view toward obtaining JMPR's guidance on the attendant risks and the likely risk reductions associated with each option.

18. CCPR shall request JMPR to review any methods and guidelines being considered by CCPR for assessing maximum limits for pesticides.

**Role of JMPR**

19. 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.

20. This guidance document applies to the work of JMPR in the context of Codex and in particular as it relates to advice requests from CCPR.

21. JMPR is primarily responsible for performing the risk assessments upon which CCPR and ultimately the CAC base their risk management decisions. JMPR also proposes MRLs based on Good Agricultural Practices (GAPs)/registered uses or in specific cases, such as EMRLs, based on monitoring data.

22. JMPR provides CCPR with science-based risk assessments that include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for CCPR's risk-management discussions. JMPR should continue to use its risk assessment process for establishing Acceptable Daily Intakes (ADIs) and Acute Reference Doses (ARfDs) where appropriate.

23. JMPR should identify and communicate to CCPR in its assessments any information on the applicability and any constraints of the risk assessment to the general population and to particular sub-populations and will as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g. children).

24. JMPR is responsible for evaluating exposure to pesticides. JMPR should strive to base its exposure assessment and hence the dietary risk assessments on global data, including that from developing countries. In addition to 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.

25. JMPR should communicate to CCPR the magnitude and source of uncertainties in its risk assessments. When communicating this information, JMPR should provide CCPR a description of the methodology and procedures by which JMPR estimated any uncertainty in its risk assessment.

26. JMPR should communicate to CCPR the basis for all assumptions used in its risk assessments.

**ANNEX: LIST OF RISK MANAGEMENT POLICIES USED BY CCPR**

1. This part of the document addresses the risk management policy that is used by the Codex Committee on Pesticides Residues (CCPR) when discussing the risk assessments, the exposure to pesticides and the proposals for MRLs which are the outcomes of the Joint FAO/WHO Meeting on Pesticides Residues (JMPR).

**ESTABLISHMENT OF MRLs/EMRLs**

**Procedure for Proposing Pesticides for Codex Priority Lists**

2. CCPR has developed a policy document in relation to establishing a priority list of pesticides for evaluation or re-evaluation by JMPR[29].

3. Before a pesticide can be considered for the Priority List, it must:

- be available for use as a commercial product; and
- not have been already accepted for consideration.

***4.*** To meet the criteria for inclusion in the priority list, the use of the pesticide must: give rise to residues in or on a food or feed commodity***, including also byproducts or coproducts of industrial productions e.g. biofuels entering into the food chain through feed*** moving in international trade, the presence of which is (or may be) a matter of public health concern and thus create (or have the potential to create) problems in international trade.

5. When prioritising new chemicals for evaluation by the JMPR, the Committee will consider the following criteria:

1. If the chemical has a reduced acute and/or chronic toxicity risk to humans compared with other chemicals in its classification (insecticide, fungicide, herbicide);
2. The date when the chemical was nominated for evaluation;
3. Commitment by the sponsor of the compound to provide supporting data for review with a firm date for data submission;
4. The availability of regional/national reviews and risk assessments, and coordination with other regional/national lists; and
5. Allocating priorities to new chemicals, so that at least 50% of evaluations are for new chemicals, if possible.

6. When prioritising chemicals for periodic re-evaluation by the JMPR, the Committee will consider the following criteria:

1. If the intake and/or toxicity profile indicate some level of public health concern;
2. Chemicals that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits for 15 years;
3. The year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation –Not Yet Scheduled;
4. The date that data will be submitted;
5. Whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption;
6. If there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently; and
7. The availability of current labels arising from recent national re-evaluations.

7. Once the JMPR has reviewed a chemical, three scenarios may occur:

- the data confirm the existing Codex MRL, it remains in place, or
- a new MRL is recommended or an amendment of an existing MRL. The new or amended proposal enters at Step 3 of the Codex procedure. The existing MRL remains in place for no more than four years, or
- insufficient data have been submitted to confirm or amend an existing Codex MRL. The Codex MRL is recommended for withdrawal. However, the manufacturer or countries 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.

[36] Criteria for Prioritization Process of Compounds for Evaluation by JMPR, Procedural Manual

**MRLs for Commodities of Animal Origin**

8. 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***, in*** ~~***or in***~~ forage crops, plant parts that could be used in animal feeds, ***including also byproducts or coproducts of industrial productions e.g. biofuels entering into the food chain through feed***. 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 animal products.

9. If no adequate studies are available, no MRLs will be established for 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, MRLs at the LOQ must be established for animal commodities. MRLs should be established for all mammalian species where pesticides on feeds are concerned and for specific species (e.g cattle, sheep) where direct treatments of pesticides are concerned.

10. Where the recommended maximum residue limits for animal commodities resulting from direct treatment of the animal, regardless of whether they are recommended by JMPR or JECFA, and from residues in animal feed do not agree, the higher recommendation will prevail.

**MRLs for Processed or Ready-to-eat Foods or Feeds**

11. CCPR agreed not to establish MRLs for processed foods and feeds unless separate higher MRLs are necessary for specific processed commodities.

**MRLs for spices**

12. CCPR agreed that MRLs for spices can be established on the basis of monitoring data in accordance with the guidelines established by JMPR.

**MRLs for fat-soluble pesticides**

13 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:

- When available, it is 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 logPow>3 are likely to be "fat soluble".

14. For fat soluble pesticides, two MRLs are recommended if data permit: one for whole milk and one for milk fat. For enforcement purposes, a comparison can be made either of the residue in milk fat with the MRL for milk fat or of the residue in whole milk with the MRL for milk.

**Establishment of MRLs**

15. The CCPR is entrusted with the elaboration of Maximum Residue Limits (MRLs) of pesticide residues in food and feed. The JMPR is using the WHO Guidelines for predicting dietary intake of pesticides residues (revised)(1997)[30]. The JMPR is recommending MRLs establishing Supervised Trial Median Residues (STMRs) for new and periodic review compounds for dietary intake purposes. In cases the intake exceeds the Acceptable Daily Intake (ADI) in one or more of the regional diets, the JMPR, when recommending MRLs, flags this situation indicating the type of data which may be useful to further refine the dietary intake estimate.

16. When the ADI is exceeded in one or more regional diets, then the MRLs will not advance to Step 8 pending further refinement of the intake at the international level. If further refinement is not possible then MRLs are withdrawn until the remaining MRLs give no longer rise to intake concerns. This procedure should be reviewed at regular interval.

17. The JMPR is currently routinely establishing acute reference doses (ARfDs), where appropriate, and indicates cases where an ARfD is not necessary. The 1999 JMPR for the first time calculated the short-term dietary intake estimates following an approach using the International and National Estimates of Short-term Intake (IESTI, NESTI). The procedure allows for estimating the short-term risk for relevant subgroups of the population, like children. The JMPR flags cases when the IESTI for a given commodity exceeds the acute RfD.

18. When the ARfD is exceeded for a given commodity, then the MRLs will not advance to Step 8 pending further refinement of the intake at the international level.

19. When a Draft MRL has been returned to Step 6 three times, the CCPR should ask JMPR to examine residue data from other appropriate GAPs and to recommend MRLs which cause no dietary intake concerns if possible.

[30] Programme of Food Safety and Food Aid; WHO/FSF/FOS/97.7

20. If further refinement is not possible then MRLs are withdrawn. More sophisticated methodologies such as probabilistic approaches are under investigation at the moment.

21. 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.

**Utilization of Steps 5/8 for elaboration of MRLs**

22. Preconditions for utilization of Step 5/8 Procedure

- New MRL circulated at Step 3
- JMPR report available electronically by early February
- No intake concerns identified by JMPR

23. Steps 5/8 Procedure (Recommendation to omit Steps 6 and 7 and adopt the MRL at Step 8)

- If the preconditions listed above are met.
- If a delegation has a concern with advancing a given MRL, a concern form should be completed detailing the concern along with a description of the data that will be submitted to substantiate the concern preferably as comments at Step 3, or at the latest, one month after the CCPR session.
- If the JMPR Secretariat or the CCPR can address that concern at the upcoming CCPR session, and the JMPR position remains unchanged, the CCPR will decide if the MRL will be advanced to Step 5/8.
- 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 as soon as possible but the rest of the MRLs should be advanced to Step 5/8.
- The result of the consideration of the concern by the JMPR will be considered at the next CCPR session. If the JMPR position remains unchanged, the CCPR will decide if the MRL will be advanced to Step 8.

**Establishment of EMRLs**

24. The 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 the 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.

25. Chemicals for which EMRLs are most likely to be needed are persistent in the environment for a relatively long period after uses haven been discontinued and are expected to occur in foods or feeds at levels of sufficient concern to warrant monitoring.

26. All relevant and geographically representative monitoring data (including nil-residue results) are required to make reasonable estimates to cover international trade. JMPR has developed a standard format for reporting pesticide residues monitoring data[31].

27. The JMPR compares data distribution in terms of the likely percentages of violations that might occur if a given EMRL is proposed to the CCPR.

28. Because residues gradually decrease, CCPR evaluates every 5 years, if possible, the existing EMRLs, based on the reassessments of the JMPR.

29. The CCPR generally agreed at the 30th Session on the potential elements for inclusion in a set of criteria for estimation of EMRLs while it also agreed not to initiate a full exercise of criteria elaboration.

**Periodic Review Procedure**

30. The Committee agreed on the Periodic Review Procedure, which was endorsed by the CAC and attached to the list of MRLs prepared for each session of the CCPR. Those Codex MRLs confirmed by JMPR under the Periodic Review shall be distributed to members and interested organizations for comments.

**Deleting Codex MRLs**

31. Every year new compounds are introduced. These compounds are often new pesticides which are safer than existing ones. Old compounds are then no longer supported/produced by industry and existing Codex MRLs can be deleted.

[31] Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant Production and Protection Paper, 170, 2002, ISBN 92-5-104759-6

32. If information is delivered between two sessions of CCPR, that a certain compound is no longer supported, this information will be shared during the first coming session (t=0). The proposal will be to delete the existing MRLs at the following session (t=0+1 year).

33. It may happen that compounds are no longer supported in Codex, but are supported in some selected countries. If there is no international trade in commodities where the active compounds may have been used, CCPR will not establish MRLs.

**MRLs AND METHODS OF ANALYSIS**

34. JMPR needs data and information for their evaluations. Among these are methods of analysis. Methods should include specialized methods used in supervised trials and enforcement methods.

35. If no methods of analysis are available for enforcing MRLs for a specific compound, no MRLs will be established by CCPR.

**Proposal**

**PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESSMENT**

**CAC/GL-30 (1999)**

Proposed changes in ***italics and bold***

**Table of Contents**



***INTRODUCTION***

Risks from microbiological hazards are of immediate and serious concern to human health. Microbiological Risk Analysis is a process consisting of three components: Risk Assessment, Risk Management, and Risk Communication, which has the overall objective to ensure public health protection. This document deals with Risk Assessment which is a key element in assuring that sound science is used to establish standards, guidelines and other recommendations for food safety to enhance consumer protection and facilitate international trade. The Microbiological Risk Assessment process should include quantitative information to the greatest extent possible in the estimation of risk. A Microbiological Risk Assessment should be conducted using a structured approach such as that described in this document. This document will be of primary interest to governments although other organizations, companies, and other interested parties who need to prepare a Microbiological Risk Assessment will find it valuable. Since Microbiological Risk Assessment is a developing science, implementation of these guidelines may require a period of time and may also require specialized training in the countries that consider it necessary. This may be particularly the case for developing countries. Although Microbiological Risk Assessment is the primary focus of this document, the method can also be applied to certain other classes of biological hazards.

***1. SCOPE***

The scope of this document applies to Risk Assessment of microbiological hazards in food ***and in feed[32] for food producing animals where it can impact on food safety.***

***2. DEFINITIONS***

The definitions cited here are to facilitate the understanding of certain words or phrases used in this document.

Where available the definitions are those adopted for microbiological, chemical, or physical agents and Risk Management and Risk Communication on an interim basis at the 22nd Session of the Codex Alimentarius Commission. The CAC adopted these definitions on an interim basis because they are subject to modification in the light of developments in the science of risk analysis and as a result of efforts to harmonize similar definitions across various disciplines.

[32] The term ”feed” refers to both ”feed (feedingstuffs)” and ”feed ingredients” as defined in the *Code of Practice on Good Animal Feeding* (CAC/RCP 054 2004).

**Dose-Response Assessment** - The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse ***human*** health effects (response).

**Exposure Assessment** - The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.

**Hazard** - A biological, chemical or physical agent in, or condition of, food ***or feed*** with the potential to cause an adverse ***human*** health effect.

**Hazard Characterization** - The qualitative and/or quantitative evaluation of the nature of the adverse ***human*** health effects associated with the hazard. For the purpose of Microbiological Risk Assessment the concerns relate to microorganisms and/or their toxins.

**Hazard Identification** - The identification of biological, chemical, and physical agents capable of causing adverse ***human*** health effects and which may be present in a particular food ***or feed*** or group of foods ***or feeds***.

**Quantitative Risk Assessment** - A Risk Assessment that provides numerical expressions of risk and indication of the attendant uncertainties (stated in the 1995 Expert Consultation definition on Risk Analysis).

**Qualitative Risk Assessment** - A Risk Assessment based on data which, while forming an inadequate basis for numerical risk estimations, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties permits risk ranking or separation into descriptive categories of risk.

**Risk** - A function of the probability of an adverse ***human*** health effect and the severity of that effect, consequential to a hazard(s) in food ***or feed***.

**Risk Analysis** - A process consisting of three components: risk assessment, risk management and risk communication.

**Risk Assessment** - A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

**Risk Characterization** - The process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

**Risk Communication** - The interactive exchange of information and opinions concerning risk and risk management among risk assessors, risk managers, consumers and other interested parties.

**Risk Estimate** - Output of Risk Characterization.

**Risk Management** - The process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control[33] options, including regulatory measures.

**Sensitivity analysis** - A method used to examine the behavior of a model by measuring the variation in its outputs resulting from changes to its inputs.

**Transparent** - Characteristics of a process where the rationale, the logic of development, constraints, assumptions, value judgements, decisions, limitations and uncertainties of the expressed determination are fully and systematically stated, documented, and accessible for review.

**Uncertainty analysis** - A method used to estimate the uncertainty associated with model inputs, assumptions and structure/form.

## *3. GENERAL PRINCIPLES OF MICROBIOLOGICAL RISK ASSESSMENT*

1. Microbiological Risk Assessment should be soundly based upon science.
2. There should be a functional separation between Risk Assessment and Risk Management.
3. Microbiological Risk Assessment should be conducted according to a structured approach that includes Hazard Identification, Hazard Characterization, Exposure Assessment, and Risk Characterization.
4. A Microbiological Risk Assessment should clearly state the purpose of the exercise, including the form of Risk Estimate that will be the output.
5. The conduct of a Microbiological Risk Assessment should be transparent.
6. Any constraints that impact on the Risk Assessment such as cost, resources or time, should be identified and their possible consequences described.

[33] Control means prevention, elimination, or reduction of hazards and/or minimization of risks.

7. The Risk Estimate should contain a description of uncertainty and where the uncertainty arose during the Risk Assessment process.

8. Data should be such that uncertainty in the Risk Estimate can be determined; data and data collection systems should, as far as possible, be of sufficient quality and precision that uncertainty in the Risk Estimate is minimized.

9. A Microbiological Risk Assessment should explicitly consider the dynamics of microbiological growth, survival, and death in foods ***or feeds*** and the complexity of the interaction (including sequelae) between ***animal or*** human and agent following consumption as well as the potential for further spread ***in the case of microbiological risks originating from feed.***

    ***a) The microbiological Risk Assessment should clearly state the different steps in the process, i.e. from feed to the animal, from animal to the food of animal origin and finally from food to human.***

10. Wherever possible, Risk Estimates should be reassessed over time by comparison with independent human illness data.

11. A Microbiological Risk Assessment may need reevaluation, as new relevant information becomes available.

## *4. GUIDELINES FOR APPLICATION*

These Guidelines provide an outline of the elements of a Microbiological Risk Assessment indicating the types of decisions that need to be considered at each step.

### 4.1 General Considerations

The elements of Risk Analysis are: Risk Assessment, Risk Management, and Risk Communication. The functional separation of Risk Assessment from Risk Management helps assure that the Risk Assessment process is unbiased. However, certain interactions are needed for a comprehensive and systematic Risk Assessment process. These may include ranking of hazards and risk assessment policy decisions. Where Risk Management issues are taken into account in Risk Assessment, the decision-making process should be transparent. It is the transparent unbiased nature of the process that is important, not who is the assessor or who is the manager.

Whenever practical, efforts should be made to provide a Risk Assessment process that allows contributions by interested parties. Contributions by interested parties in the Risk Assessment process can improve the transparency of the Risk Assessment, increase the quality of Risk Assessments through additional expertise and information, and facilitate risk communication by increasing the credibility and acceptance of the results of the Risk Assessment.

Scientific evidence may be limited, incomplete or conflicting. In such cases, transparent informed decisions will have to be made on how to complete the Risk Assessment process. The importance of using high quality information when conducting a Risk Assessment is to reduce uncertainty and to increase the reliability of the Risk Estimate. The use of quantitative information is encouraged to the extent possible, but the value and utility of qualitative information should not be discounted.

It should be recognized that sufficient resources will not always be available and constraints are likely to be imposed on the Risk Assessment that will influence the quality of the Risk Estimate. Where such resource constraints apply, it is important for transparency purposes that these constraints be described in the formal record. Where appropriate, the record should include an evaluation of the impact of the resource constraints on the Risk Assessment.

### 4.2 Statement of Purpose of Risk Assessment

At the beginning of the work the specific purpose of the particular Risk Assessment being carried out should be clearly stated. The output form and possible output alternatives of the Risk Assessment should be defined. Output might, for example, take the form of an estimate of the prevalence of illness, or an estimate of annual rate (incidence of human illness per 100,000) or an estimate of the rate of human illness and severity per eating occurrence.

The microbiological risk assessment may require a preliminary investigation phase. In this phase, evidence to support farm-to-table modeling of risk might be structured or mapped into the framework of risk assessment.

### 4.3 Hazard Identification

For microbial agents, the purpose of hazard identification is to identify the microorganisms or the microbial toxins of concern with food ***or feed***. Hazard identification will predominately be a qualitative process. Hazards can be identified from relevant data sources. Information on hazards can be obtained from scientific literature, from databases such as those in the food ***and feed*** industry, government agencies, and relevant international organizations and through solicitation of opinions of experts. Relevant information includes data in areas such as: clinical studies, epidemiological studies and surveillance, laboratory animal studies, investigations of the characteristics of microorganisms, the interaction between microorganisms and their environment through the food chain from primary production up to and including consumption, and studies on analogous microorganisms and situations.

### 4.4 Exposure Assessment

Exposure Assessment includes an assessment of the extent of actual or anticipated human exposure. For microbiological agents, Exposure Assessments might be based on the potential extent of food ***or feed*** contamination by a particular agent or its toxins, and on dietary information. Exposure assessment should specify the unit of food ***or feed*** that is of interest, i.e., the portion size in most/all cases of acute illness.

Factors that must be considered for Exposure Assessment include the frequency of contamination of foods ***or feeds*** by the pathogenic agent and its level in those foods ***or feeds*** over time. For example, these factors are influenced by the characteristics of the pathogenic agent, the microbiological ecology of the food ***or feed,*** the initial contamination of the raw material including considerations of regional differences and seasonality of production, the level of sanitation and process controls, the methods of processing, packaging, distribution and storage of the foods ***or feeds***, as well as any preparation steps such as cooking and holding. Another factor that must be considered in the assessment is patterns of consumption. This relates to socio-economic and cultural backgrounds, ethnicity, seasonality, age differences (population demographics), regional differences, and consumer preferences and behavior. Other factors to be considered include: the role of the food ***or feed*** handler as a source of contamination, the amount of hand contact with the product, and the potential impact of abusive environmental time/temperature relationships.

Microbial pathogen levels can be dynamic and while they may be kept low, for example, by proper time/temperature controls during food ***or feed*** processing, they can substantially increase with abuse conditions (for example, improper food ***or feed*** storage temperatures or cross contamination from other foods ***or feeds***). Therefore, the Exposure Assessment should describe the pathway from production to consumption. Scenarios can be constructed to predict the range of possible exposures. The scenarios might reflect effects of processing, such as hygienic design, cleaning and disinfection, as well as the time/temperature and other conditions of the food ***or feed*** history, food ***or feed*** handling and ***food or feed*** consumption patterns, regulatory controls, and surveillance systems.

Exposure Assessment estimates the level, within various levels of uncertainty, of microbiological pathogens or microbiological toxins, and the likelihood of their occurrence in foods at the time of consumption. Qualitatively foods ***or feeds*** can be categorized according to the likelihood that the food- ***or feed***stuff will or will not be contaminated at its source; whether or not the food ***or feed*** can support the growth of the pathogen of concern; whether there is substantial potential for abusive handling of the food ***or feed*** ; or whether the food ***or feed*** will be subjected to a heat process. The presence, growth, survival, or death of microorganisms, including pathogens in foods ***or feeds,*** are influenced by processing and packaging, the storage environment, including the temperature of storage, the relative humidity of the environment, and the gaseous composition of the atmosphere. Other relevant factors include pH, moisture content or water activity (aw), nutrient content, the presence of antimicrobial substances, and competing microflora. Predictive microbiology can be a useful tool in an Exposure Assessment.

### 4.5 Hazard Characterization

This step provides a qualitative or quantitative description of the severity and duration of adverse effects that may result from the ingestion of a microorganism or its toxin in food. A dose-response assessment should be performed if the data are obtainable.

There are several important factors that need to be considered in Hazard Characterization. These are related to both the microorganism, and the human host. In relation to the microorganism the following are important: microorganisms are capable of replicating; the virulence and infectivity of microorganisms can change depending on their interaction with the host and the environment; genetic material can be transferred between microorganisms leading to the transfer of characteristics such as antibiotic resistance and virulence factors; microorganisms can be spread through secondary and tertiary transmission; the onset of clinical symptoms can be substantially delayed following exposure; microorganisms can persist in certain individuals leading to continued excretion of the microorganism and continued risk of spread of infection; low doses of some microorganisms can in some cases cause a severe effect; and the attributes of a food ***or feed*** that may alter the microbial pathogenicity, e.g., high fat content of a food ***or feed*** vehicle.

In relation to the host the following may be important: genetic factors such as Human Leucocyte Antigen (HLA) type; increased susceptibility due to breakdowns of physiological barriers; individual host susceptibility characteristics such as age, pregnancy, nutrition, health and medication status, concurrent infections, immune status and previous exposure history; population characteristics such as population immunity, access to and use of medical care, and persistence of the organism in the population.

A desirable feature of Hazard Characterization is ideally establishing a dose-response relationship. When establishing a dose-response relationship, the different end points, such as infection or illness, should be taken into consideration. In the absence of a known dose-response relationship, risk assessment tools such as expert elicitations could be used to consider various factors, such as infectivity, necessary to describe Hazard Characterizations. Additionally, experts may be able to devise ranking systems so that they can be used to characterize severity and/or duration of disease.

### 4.6 Risk Characterization

Risk Characterization represents the integration of the Hazard Identification, Hazard Characterization, and Exposure Assessment determinations to obtain a Risk Estimate; providing a qualitative or quantitative estimate of the likelihood and severity of the adverse effects which could occur in a given population, including a description of the uncertainties associated with these estimates. These estimates can be assessed by comparison with independent epidemiological data that relate hazards to disease prevalence.

Risk Characterization brings together all of the qualitative or quantitative information of the previous steps to provide a soundly based estimate of risk for a given population. Risk Characterization depends on available data and expert judgements. The weight of evidence integrating quantitative and qualitative data may permit only a qualitative estimate of risk.

The degree of confidence in the final estimation of risk will depend on the variability, uncertainty, and assumptions identified in all previous steps. Differentiation of uncertainty and variability is important in subsequent selections of risk management options. Uncertainty is associated with the data themselves, and with the choice of model. Data uncertainties include those that might arise in the evaluation and extrapolation of information obtained from epidemiological, microbiological, and laboratory animal studies. Uncertainties arise whenever attempts are made to use data concerning the occurrence of certain phenomena obtained under one set of conditions to make estimations or predictions about phenomena likely to occur under other sets of conditions for which data are not available. Biological variation includes the differences in virulence that exist in microbiological populations and variability in susceptibility within the human population and particular subpopulations.

It is important to demonstrate the influence of the estimates and assumptions used in Risk Assessment; for quantitative Risk Assessment this can be done using sensitivity and uncertainty analyses.

### 4.7 Documentation

The Risk Assessment should be fully and systematically documented and communicated to the risk manager. Understanding any limitations that influenced a Risk Assessment is essential for transparency of the process that is important in decision making. For example, expert judgements should be identified and their rationale explained. To ensure a transparent Risk Assessment a formal record, including a summary, should be prepared and made available to interested independent parties so that other risk assessors can repeat and critique the work. The formal record and summary should indicate any constraints, uncertainties, and assumptions and their impact on the Risk Assessment.

### 4.8 Reassessment

Surveillance programs can provide an ongoing opportunity to reassess the public health risks associated with pathogens in foods ***or feeds*** as new relevant information and data become available. Microbiological Risk Assessors may have the opportunity to compare the predicted Risk Estimate from Microbiological Risk Assessment models with reported human illness data for the purpose of gauging the reliability of the predicted estimate. This comparison emphasizes the iterative nature of modeling. When new data become available, a Microbiological Risk Assessment may need to be revisited.

**Proposal**

**WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY FOR APPLICATION BY GOVERNMENTS**

**CAC/GL 62-2007**

Proposed changes in ***italics and bold***

***SCOPE***

1. The Working Principles for Risk Analysis for Food Safety for Application by Governments are intended to provide guidance to national governments for risk assessment, risk management and risk communication with regard to food related risks to human health. ***These principles for risk analysis should also apply to feed[34] for food producing animals where it can impact food safety.***

***GENERAL ASPECTS***

2. The overall objective of risk analysis applied to food ***and feed*** safety is to ensure human health protection.

3. These principles apply equally to issues of national food ***and feed*** control and food trade situations and should be applied consistently and in a non discriminatory manner.

4. To the extent possible, the application of risk analysis should be established as an integral part of a national food ***and feed*** safety system.[35]

5. Implementation of risk management decisions at the national level should be supported by an adequately functioning food ***and feed*** control system/program.

6. Risk analysis should be:

- applied consistently;
- open, transparent and documented; and
- evaluated and reviewed as appropriate in the light of newly generated scientific data.

7. The risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission[36], each component being integral to the overall risk analysis.

8. The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality, documentation should be accessible to all interested parties[37].

9. Effective communication and consultation with all interested parties should be ensured throughout the risk analysis.

10. The three components of risk analysis should be applied within an overarching framework for management of food related risks to human health.

11. There should be a functional separation of risk assessment and risk management to the degree practicable, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.

12. Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food ***and feed*** related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. The assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.

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[34] The term "feed" refers to both "feed (feedingstuffs) and "feed ingredients" as defined in the *Code of Practice on Good Animal Feeding* (CAC/RCP 054 2004).

[35] It is recognized that national governments will use different approaches and time frames in the application of these principles taking into account national capacities and resources.

[36] See Definitions of Risk Analysis Terms Related to Food Safety, Procedural Manual.

[37] For the purpose of the present document, the term "interested parties" refers to "risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations" (see definition of "Risk Communication").

13. National governments should take into account relevant guidance and information obtained from risk analysis activities pertaining to human health protection conducted by Codex, FAO, WHO and other relevant international intergovernmental organizations, including OIE and IPPC.

14. With the support of international organizations where appropriate, national governments should design and/or apply appropriate training, information and capacity building programs that are aimed to achieve the effective application of risk analysis principles and techniques in their food ***and feed*** control systems.

15. National governments should share information and experiences on risk analysis with relevant international organisations, other national governments (e.g. at the regional level through FAO/WHO Regional Coordinating Committees) to promote and facilitate a broader and, where appropriate, more consistent, application of risk analysis.

***RISK ASSESSMENT POLICY***

16. Determination of risk assessment policy should be included as a specific component of risk management.

17. Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent.

18. The mandate given by risk managers to risk assessors should be as clear as possible.

19. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

***RISK ASSESSMENT***

20. Each risk assessment should be fit for its intended purpose.

21. The scope and purpose of the risk assessment being carried out should be clearly stated and in accordance with risk assessment policy. The output form and possible alternative outputs of the risk assessment should be defined.

22. Experts involved in risk assessment including government officials and experts from outside government should be objective in their scientific work and not be subject to any conflict of interest that may compromise the integrity of the assessment. Information on the identities of these experts, their individual expertise and their professional experience should be publicly available, subject to national considerations. These experts should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved, including disclosure of conflicts of interest in connection with risk assessment.

23. Risk assessment should incorporate the four steps of risk assessment, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization.

24. Risk assessment should be based on scientific data most relevant to the national context. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information.

25. Risk assessment should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.

26. Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.

27. Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant.

28. The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.

29. The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

***RISK MANAGEMENT***

30. National government decisions on risk management, including sanitary measures taken should have as their primary objective the protection of the health of consumers. Unjustified differences in the measures selected to address similar risks in different situations should be avoided.

31 Risk management should follow a structured approach including preliminary risk management activities[38], evaluation of risk management options, implementation, monitoring and review of the decision taken.

32. The decisions should be based on risk assessment, and should be proportionate to the assessed risk, taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles[39] as they relate to decisions at the national level. National Governments should base their sanitary measures on Codex standards and related texts, where available.

33. In achieving agreed outcomes, risk management should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects.

34. Risk management should take into account the economic consequences and the feasibility of risk management options.

35. The risk management process should be transparent, consistent and fully documented. Decisions on risk management should be documented so as to facilitate a wider understanding of the risk management process by all interested parties.

36. The outcome of the preliminary risk management activities and the risk assessment should be combined with the evaluation of available risk management options in order to reach a decision on management of the risk.

37. Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be considered.

38. Risk management should ensure transparency and consistency in the decision-making process in all cases. Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, national governments should seek and take into consideration the potential impact of such measures on trade and select measures that are no more trade-restrictive than necessary.

39. Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. The relevance, effectiveness, and impacts of risk management decisions and their implementation should be regularly monitored and the decisions and/or their implementation reviewed as necessary.

***RISK COMMUNICATION***

40. Risk communication should:

i) promote awareness and understanding of the specific issues under consideration during the risk analysis;

ii) promote consistency and transparency in formulating risk management options/recommendations;

iii) provide a sound basis for understanding the risk management decisions proposed;

iv) improve the overall effectiveness and efficiency of the risk analysis ;

v) strengthen the working relationships among participants;

vi) foster public understanding of the process, so as to enhance trust and confidence in the safety of the food ***and feed*** supply;

vii) promote the appropriate involvement of all interested parties;

viii) exchange information in relation to the concerns of interested parties about the risks associated with food ***or feed***; and

[38] For the purpose of these Principles, preliminary risk management activities are taken to include: identification of a food ***and feed*** safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment.

[39] See Statements of Principle Concerning the Role of Science in the Codex Decision Making Process and the Extent to which other Factors are Taken in to Account, Procedural Manual.

ix) respect the legitimate concern to preserve confidentiality where applicable.

41. Risk analysis should include clear, interactive and documented communication, amongst risk assessors and risk managers and reciprocal communication with all interested parties in all aspects of the process.

42. Risk communication should be more than the dissemination of information. Its major function should be to ensure that all information and opinion required for effective risk management is incorporated into the decision making process.

43. Risk communication involving interested parties should include a trans-parent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The decisions taken and the procedures followed to reach them, including how the uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis, and minority opinions that had been expressed in the course of the risk assessment (see para. 28).

**Annex II**

**Codex Electronic Working Group on Animal Feed 2009/2010**

**Proposed Changes to existing Codex texts on emergency situations and exchange of information on rejected food as to their applicability to animal feed (CAC/GL 19-1995 and CAC/GL 25-1997)**

**Proposal**

## PRINCIPLES AND GUIDELINES FOR THE EXCHANGE OF INFORMATION IN FOOD SAFETY EMERGENCY SITUATIONS

**CAC/GL 19-1995**

Proposed changes in ***italics and bold***

### PREAMBLE

1. When a food or ***feed***[40] safety emergency arises, in order to minimize potential public health effects, it is essential to communicate the nature and extent of the food safety problem to all relevant parties as expeditiously as possible. This must be done in a manner that avoids unwarranted action against other foods ***or feeds*** from the same or other countries, which are not involved in the emergency situation. The global nature of food ***and feed*** trade requires that this communication occur between nations at the appropriate government level.

2. This document provides guidance for use by national governments and regional economic integration organisations for the exchange of information in food safety emergency situations.

### SCOPE

3. These Principles and Guidelines apply to situations where the competent authorities in either the importing and/or exporting countries become aware of a food safety emergency situation, and communication of the information and risks surrounding the emergency situation must be undertaken.

4. The Principles and Guidelines apply to situations where the food safety hazard (e.g., a microbiological, chemical, radiological or physical agent) has been specifically identified. It may also apply to situations where the hazard has not been identified, but relevant scientific information suggests a link between consumption of a food and the appearance of serious health effects.

5. The Principles and Guidelines apply to food safety emergencies associated with imported or exported food or food that may potentially be imported or exported. The Principles and Guidelines may also apply to such emergencies where feed***~~stuffs~~*** for food producing animals are implicated.[41]

6. The Principles and Guidelines do not apply to routine food rejections where importing country standards have not been met. These situations are covered in the *Guidelines for the Exchange of Information between Countries on Rejections of Imported Food* ***or Feed*** (CAC/GL 25-1997).

### DEFINITION

**Food Safety Emergency**: A situation whether accidental or intentional, that is identified, by a competent authority as constituting a serious and as yet uncontrolled food**- or *feed***borne risk to public health that requires urgent action.

### PRINCIPLES

7. In the event that a food safety emergency is identified, the following principles apply to the exchange of information:

a) Its nature and extent should, where possible, be clearly and completely described by the relevant competent authorities.

b) The exchange of information on food safety emergencies should be between official contact points designated by the competent authorities.

c) A country detecting a food safety emergency situation, whether it is an importing or an exporting country, should inform all known affected and potentially affected countries without delay.

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***[40] The term "feed" refers to both "feed (feedingstuffs)" and "feed ingredients" as defined in the Code of Practice on Good Animal Feeding (CAC/RCP 054 2004).***

[41] Provisions for emergency situations affecting animal feed are included in the Code of Practice for Good Animal Feeding (CAC/RCP 54-2004): Section 4.3.1 "Special conditions applicable to emergency situations"

d) All relevant information should be shared by competent authorities detecting a food safety emergency to enable all affected and potentially affected countries to make informed risk management and/or risk communication decisions.

e) Competent authorities should also provide clear, relevant, factual and timely information to relevant stakeholders to the extent possible.

f) Information flow should be transparent and continue during all phases of the food emergency situation to enable continuous evaluation and development of the emergency response.

**NATURE OF THE FOOD SAFETY EMERGENCY**

8. The nature of the food safety emergency including its scientific basis as it becomes available should be described in a clear, concise and accurate manner. Even in circumstances where the specific food safety hazard has not been precisely identified any clear and substantial association between the consumption of a food and the appearance of serious adverse public health effects should be provided by the competent authority in accordance with the principles outlined in paragraph ***8 7.***

9. In cases where the food safety hazard is associated with a specific food or foods, these foods should be identified in as much detail as is available to facilitate the identification and location of the affected foods. In other cases, where a food safety hazard affects many different categories of foods and potentially involves a given geographical area, all affected foods should be identified. ***If the food safety hazard I sassociated with feed, the feed and animals that consumed the feed should be identified.***

**DESIGNATED OFFICIAL CONTACT POINTS FOR INFORMATION EXCHANGE**

10. Each country should designate a primary official contact point for food safety emergency situations, which can act as the national focal point for information exchange in such situations. A list of the primary official contact points for the exchange of information in food safety emergency situations as mentioned in point 8.b is available and an update is distributed to governments on a periodic basis. It is the responsibility of all countries to ensure that they regularly provide updated information on their country primary official contact points to the World Health Organization (WHO) so that the list of contacts can be kept up-to-date. Although the primary official contact point is the first contact, it is understood that in a given food safety emergency national governments may wish to designate a specific contact point for that emergency.

11. The designated contact points for the competent authorities responsible for coordinating the response to the food safety emergency should be clearly identified. Necessary information includes the name of the competent authority and the contact details including name, address, phone numbers, facsimile numbers, and email addresses of the persons or offices that are responsible for managing the emergency situation and who can provide further details about the hazard, the foods ***or feed*** concerned, actions taken and other relevant information. A website address should also be provided if this is used to provide up-to-date information.

**INFORMING ALL KNOWN AFFECTED AND POTENTIALLY AFFECTED COUNTRIES**

12. Given the global nature of food ***and feed*** trade, the impact of a food safety emergency may be widespread. The competent authority of the country where the food safety emergency is identified should, to the best of its ability and in cooperation with other competent authorities, determine all potential recipient countries of the implicated food(s) ***and feeds*** and all countries from which the potentially contaminated food ***or feed*** or its ingredients was imported. All relevant information in relation to the food ***and feed*** safety emergency should be provided to the competent authorities of the countries thus identified.

13. Communication should be made by the most expedient means, as early as possible, and with verification of receipt by key parties. Communications by telephone, email, facsimile and if necessary regular mail should all be considered to achieve early communication and to ensure that the message is received by the competent authorities as quickly as possible.

14. It is recognised that the initial information provided may often be incomplete and it is therefore the responsibility of the country identifying the food emergency to ensure that the initial communication is supplemented by further notification(s), as and when more detailed information becomes available.

15. It is recognized that the nature and the extent of the information disclosure to each competent authority will be as determined to be permissible by the disclosing competent authority according to its national law.

**INFORMATION TO BE EXCHANGED**

16. Competent authorities should exchange with all known affected and potentially affected countries the following information, as relevant upon identification of a food safety emergency.

a. The ***origin and*** nature of the food safety emergency including the hazards and risks identified, the methodology used and any assumptions made;

b. Detailed identification of the food***, ~~or~~*** foods ***or feed*** concerned including product markings, certificate information;

c. Affected and potentially affected populations group(s);

d. Shipping and related information, e.g. the name and contact information for the exporter, importer, consignee and shippers;

e. Action taken to reduce or eliminate the hazard;

f. Full details of the designated official contact point and the relevant competent authority.

17. The communication regarding the nature and extent of a food safety emergency should include relevant scientific substantiation and assessment of risk as they become available, including how international standards have been taken into account.

18. A standard format for the relevant information to be exchanged is recommended for use by both the importing and exporting countries. A model standard format for information exchange in food safety emergency situations is provided in the Annex. Where alternative formats are used, care should be taken to ensure that all the relevant information is included and is clearly presented.

**ROLE OF COMPETENT AUTHORITY**

19. Upon identification of a food safety emergency, the competent authority identifying the emergency should promptly communicate with and consult the appropriate competent authority/ies of other affected or potentially affected country/ies. The competent authorities responsible for coordinating the response should update countries receiving the affected food of action taken, as appropriate. The accuracy and veracity of the scientific and other information regarding a food safety emergency should be verified to assist in taking risk assessment, risk management and risk communication decisions. Any misinformation should be promptly corrected by competent authorities.

20. It is also essential that all other relevant parties be kept informed, as appropriate, of the nature and status of the food safety emergency. Competent authorities should therefore provide clear, relevant, factual and timely information to their industry, consumers, other stakeholders and the media on the status of the food safety emergency.

**INFORMATION FLOW**

21. Communications between exporting and importing countries should be transparent and continue through all phases of the emergency situation, from initial notification of the food safety problem including, whenever possible, details of any relevant risk assessments that have been used through to notification of the resolution of the problem. This will enable countries to re-assess their risk assessment, risk management and risk communication strategies as the situation changes.

**OTHER CONSIDERATIONS FOR INFORMATION EXCHANGE**

**Level of food *or feed* distribution**

22. In deciding on the appropriate communication measures to apply, the competent authorities should consider the quantity of food ***or feed*** that is involved, the extent of its distribution and the level (e.g. wholesale, retail) at which it has been distributed. In some cases, the affected food ***or feed*** may not yet have entered the importing country and communication will focus on the importers. However, in other cases the food will have entered and been distributed within the country or transhipped to other countries. The competent authority should take account of whether the food ***or feed*** has been, or is likely to have been, distributed at the wholesale, retail or consumer level, and implement risk management and communication measures accordingly, including a notice of recall at one or more of these levels of food distribution.

**Re-export of food subject to an emergency situation.**

23. Food that is refused entry into a country, or in some cases food that is recalled after entry, should be dealt with in accordance with *Guidelines for the Exchange of Information between Countries on Rejection of Imported Food* ***and Feed*** (CAC/GL 25-1997) and taking into account the *Code of Ethics for International Trade in Foods* (CAC/RCP 20-1979, Rev. 1-1985)[42] .

**Food Safety Emergency Plan**

24. Importing and exporting countries should develop a food safety emergency plan that would indicate the procedures to be followed in the case of a food safety emergency[43]. The plan should contain specific provision relating to the exchange of information including keeping their public informed, as appropriate, of food safety emergency.

[42] A revision of the Code was under development in the Codex Committee on General Principles at the time this text was developed.
[43] e.g. Guidelines for Strengthening National Food Control Systems (FAO/WHO); "Terrorist Threat to Food" (WHO).

**Role of FAO and WHO**

25. Although the information exchange components of these guidelines are primarily intended for use between the competent authorities of the importing and exporting countries, copies or summaries of relevant information regarding the emergency should be provided to FAO, WHO or other international organizations on request. In these situations, the FAO and WHO may be able to offer technical advice and assistance to one or more of the affected countries or countries yet to be affected.

**Annex**

**STANDARD FORMAT FOR INFORMATION EXCHANGE IN FOOD SAFETY EMERGENCY SITUATIONS**

The following constitutes the information that should be exchanged between competent authorities of both exporting and importing countries involved in a food safety emergency. A food safety emergency is a situation whether accidental or intentional, that is identified by a competent authority, as constituting a serious and as yet uncontrolled food- ***or feed***borne risk to public health that requires urgent action.

**1. Nature of the food safety emergency**

The nature of the food safety hazard causing the food safety emergency should be described, and may include the following:

- biological/microbiological contamination (specify organism or toxin of concern);
- chemical contamination (e.g. pesticides, drugs, industrial chemicals, environmental contaminants);
- physical contamination (e.g. foreign bodies);
- radionuclide contamination (specify radionuclide(s) of concern);
- undeclared allergen (the allergen should be explicitly named);
- other identified hazards (e.g. inherent chemicals in foods or produced through processing, processing/packaging faults);
- unknown agent (specify serious adverse health effects associated with consumption of specified foods).

In each of the above cases the specific food safety hazard and its level or prevalence based on available information and, as appropriate, the sampling and methods of analysis used, and any assumptions made should be notified.

**2. Identification of foods *or feeds* concerned**

The foods ***or feeds*** concerned should be described completely. The following information should be provided if available, as appropriate to the product:

- description and quantity of product(s) including brand, the name(s) of the product listed on the label, grade, preservation method (e.g. chilled or frozen) and shelf life;
- type and size of package(s);
- lot identification, including lot code, dates of production and processing, and identification of premises where last packed or processed;
- other identification marks/stamps (e.g. bar codes, UPC codes);
- name and address of producer, manufacturer, packer, seller, exporter or importer as appropriate;
- pictorial image;
- export certificate(s) reference number(s), official name and mark.

An indication of the countries to which the product has been exported should also be provided, as soon as it is known, to enable countries to quickly identify whether they are likely to be affected, and to help locate the affected foods.

**3. Affected or potentially affected population group(s)**

Food safety emergency situations may predominantly affect certain segments of a population, e.g. children, pregnant women, immune compromised persons or the elderly. In such instances, this information should be communicated.

The nature and extent of any adverse health effects associated with a food safety emergency should be described, e.g. incubation period, severity, other epidemiological data.

**4. Shipping and Related Information**

Information on the following should be provided:

- Exporter name and contact information;
- Importer name and contact information;
- Container and shipping details, including port of origin and destination;
- Consignee(s) and shipper(s) and contact information.

**5. Action taken by exporting or importing country**

Information on action taken, such as:

- measures taken to identify and prevent the sale and export of the food;
- measures taken to recall food from markets including whether these recalls are voluntary or mandatory;
- measures taken to prevent further problems;
- measures taken to reduce the risk by appropriate physical treatment;
- methods of diagnosis and treatment of affected persons;
- measures taken regarding final disposition (e.g. destruction of the food).

**6. Details of the designated official contact point and of the relevant competent authority**

Full contact details including: the name of the competent authority, address, telephone, email address and facsimile numbers of persons or offices that can supply further information that may be sought by affected or potentially affected countries to assist in the management of the food safety emergency. A website address should be used where available to provide up-to-date information.

**Proposal**

**GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOOD *AND FEED*[44]**

**CAC/GL 25-1997** [45]

Proposed changes in ***italics and bold***

**PREAMBLE**

1. The following guidelines provide the basis for structured information exchange on import rejections. The most important information elements to be considered in such guidelines are shown in the Annex and each category is discussed in more detail below. The guidelines are intended to cover all types of food. ***These guidelines also cover feed for food producing animals including rejected food used as feed where it can impact food saftety.***

2. These guidelines deal only with import rejections caused by failure to comply with importing country requirements. Information exchange in food ***or feed*** control emergency situations is dealt with in the Guidelines for the Exchange of Information in Food Control Emergency Situations (CAC/GL 19-1995).

3. The use of these Guidelines for the Exchange of Information on Rejections of Imported Food ***or Feed*** is intended to assist countries to conform with the Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995), in particular the transparency provisions contained in paragraph 14 of the Principles.

**GENERAL CONSIDERATIONS**

4. When the food ***or feed*** control authorities in an importing country reject a consignment of food ***or feed*** presented for importation they should always provide information to the importer of the consignment giving the reasons for the rejection. Appropriate information should also be provided to the exporter if the control authorities receive such a request.

***Attention should be given to ensure that control authorities in charge of feed are properly informed when rejected food may be used as feed.***

5. When the rejection of the consignment arises from:

- evidence of a serious food ***or feed*** safety or public health problem in the exporting country; or
- evidence of serious misrepresentation or consumer fraud; or
- evidence of a serious failure in the inspection or control system in the exporting country,

***depending on the reason for rejection,*** the food ***or feed*** control authorities in the importing country should notify the food ***or feed*** control authorities in the exporting country forthwith (by telecommunication or other similar rapid means of communication) supplying the details set out in the Annex to these Guidelines.

6. Upon receipt of such a communication, the food ***or feed*** control authorities in the exporting country should undertake the necessary investigation to determine the cause of any problem that has led to the rejection of the consignment. The food control ***or feed*** authority in the exporting country, if requested, should provide the authorities in the importing country with information on the outcome of the necessary investigation, if available. Bilateral discussions should take place as necessary.

7. In other circumstances, for example:

- where there is evidence of repeated failures of a correctable nature (e.g. labelling errors, mislaying of documents); or
- where there is evidence of systematic failures in handling, storage or transport subsequent to inspection/certification by the authorities in the exporting countries,

the food ***or feed*** control authorities in the importing country should also make appropriate notification to the food ***or feed*** control authorities in the exporting country, either periodically or upon request.

8. It is also open to an importing country to supply information on rejections to an exporting country even when this is not specified in these guidelines.

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[44] ***The term "feed" refers to both "feed (feedingstuffs)" and "feed ingredients" as defined in the Code of Practice on Good Animal Feeding (CAC/RCP 054 2004).***

[45] Governments and organizations interested in receiving a List of Contacts for Food Import Control and Information Exchange in Food Control Emergency Situations should contact the Codex Contact Point for Australia, Australian Quarantine and Inspection Service, GPO Box 858, Canberra, ACT, 2601, AUSTRALIA. Telefax: 61-6-272- 3103.

9. In some countries information about the results obtained in public food ***and feed*** control is freely available, whereas in others legal constraints may prevent or restrict the dissemination to third parties of information on, for example, import rejections. In some cases information cannot be exchanged before a certain time has elapsed. So far as possible countries should minimise restrictions on the disclosure to other countries of information on rejected foods ***or feeds***.

10. To enable FAO and WHO to assist exporting countries in their efforts to meet the requirements of importing countries, information on rejections of imported food ***and feed*** should be made available to FAO and WHO on request.

**DETAILED INFORMATION**

**Identification of the food *or feed* concerned**

11. A certain amount of basic information is required in order to be able to identify the consignment or lot of food ***or feed*** that has been refused entry when presented for importation. The most important information in this respect is a description of the nature and quantity of the food ***or feed***, any lot identification or other identification stamps, marks or numbers and the name and address of the exporter and/or food ***or feed*** producer or manufacturer. Information about importers or sellers is also useful. Where a lot has been certified, the certificate number can provide an important method of identification.

**Importation details**

12. Information about importation or presentation for importation is necessary. The most important elements here are: place and date of entry, and the identity and contact details of the importer.

**Rejection decision**

13. It is important to obtain information about the decision to refuse importation, especially the name of the food ***or feed*** control authority which made the decision, when the decision was made and whether the whole or only part of the consignment was refused entry.

**Reasons for rejection**

14. The reason(s) why a consignment of food ***or feed*** has been refused entry should be clearly stated and reference should be made to the regulations or standards which have been contravened.

15. Foods may be rejected because they are found to be unacceptable when subjected to an organoleptic examination or because they have technical/physical defects, e.g. leaking cans, broken seals and damaged boxes. In circumstances where physical examination has led to rejection, a clear description of the criteria used should be provided.

16. When the level of a contaminant in a food ***or feed*** has been found to be above the maximum permitted level, the contaminant should be specified, together with the level found and the maximum permitted level. In the case of biological contamination or contamination by biological toxins, where no maximum level has been fixed, the identity of the organism or toxin concerned should be given as specifically as possible, and as appropriate, the level of contamination found. Similarly, contraventions of regulations on food additive or compositional standards should be specified. Some countries accept certain foods (e.g. fresh meat) only from specifically approved establishments in the exporting country. If such foods are refused entry because evidence that they come from such an establishment is lacking or incomplete, this should be stated.

17. Where consignments of imported food ***or feed*** are rejected on the basis of analysis performed in the importing country, the importing country authority should make available upon request details of the sampling and analytical methods employed and the results obtained.

**Action taken**

18. Information should be supplied about the action taken following the rejection or retention of a consignment of food ***or feed***. This should include information about the fate of the consignment, such as whether it was destroyed or detained for reconditioning.

19. If the rejected food ***or feed*** is re-exported, the conditions attached to such re-export should be stated. For example, some countries permit re-export only to the country of origin or to countries which have stated in advance that they are prepared to accept the consignment knowing that it has been refused entry elsewhere.

20. In addition to the exchange of information between the food ***or feed*** control authorities of exporting and importing countries it may also be valuable to inform the embassy or other representative body of the exporting country of the situation so that the country concerned can take action to rectify the deficiencies found and thus avoid rejection of future shipments.

**ANNEX**

**STANDARD FORMAT FOR EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOOD *OR FEED***

The following information should be provided by countries in relation to rejections of imported food as available and appropriate to the circumstances.

**Identification of the food *or feed* concerned**

- Description and quantity of product
- Type and size of package
- Lot identification (number, production date, etc.)
- Container number, bill of loading or similar transportation details
- Other identification stamps, marks or numbers
- Certificate number
- Name and address of manufacturer, producer, seller and/or exporter, establishment number, as appropriate

**Importation details**

- Port or other point of entry
- Name and address of importer
- Date presented for entry

**Details of rejection decision**

- Whole/part of (specify) consignment rejected
- Name and address of food ***or feed*** control authority making decision to reject
- Date of decision
- Name and address of food ***or feed*** control authority which can provide more information on reason for rejection

**Reason(s) for rejection**

- Biological/microbiological contamination
- Chemical contamination (pesticide or veterinary drug residues, heavy metals, etc.)
- Radionuclide contamination
- Incorrect or misleading labelling
- Compositional defect
- Non-conformity with food additive requirements ***(or feed requirements in the case of feed)***
- Organoleptic quality unacceptable
- Technical or physical defects (e.g., packaging damage)
- Incomplete or incorrect certification
- Does not come from an approved country, region or establishment
- Other reasons

Note: Where imported food ***or feed*** has been rejected on the basis of sampling and/or analysis in the importing country, details should be made available on request as to sampling and analytical methods and test results and the identity of the testing laboratory.

**Action taken**

- Food ***or feed*** destroyed
- Food ***or feed*** held pending reconditioning/rectification of deficiencies in documentation

- Food ***or feed*** held pending final judgement
- Place where food ***or feed*** is held
- Import granted for use other than human ***or animal*** consumption
- Re-export granted under certain conditions, e.g. to specified informed countries
- Importer notified
- Embassy/food ***or feed*** control authorities of exporting country notified
- Authorities in other likely destination countries notified
- Other

**Annex III**

**Codex Electronic Working Group on Animal Feed 2009/2010**

**Proposed Changes to the Codex *Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals* (CAC/RCP 49-2001) as to their applicability to animal feed**

**Proposal**

**CODE OF PRACTICE FOR SOURCE DIRECTED MEASURES TO REDUCE CONTAMINATION OF FOOD *AND FEED*[46] WITH CHEMICALS**

**CAC/RCP 49-2001**

Proposed changes in ***italics and bold***

1. This document deals with the major sources of environmental chemicals which may contaminate food~~s~~ ***or feed for food producing animals*** and constitute a hazard to human health and therefore, have been considered for regulation by CCCF~~***AC***~~/CAC. Apart from environmental contaminants ***and residues of feed additives,*** foods may contain chemicals used as pesticides, veterinary drugs, food additives or processing aids. However, since such substances are dealt with elsewhere in the Codex system, they are not included here, neither are mycotoxins or natural toxins.

2. The main objective of this document is to increase awareness of sources of chemical contamination of food and feed, and of source-directed measures to prevent such contamination. This means that measures recommended in the document may lie outside the direct responsibility of the food ***or feed*** control authorities and Codex.

3. National food ***or feed*** control authorities should inform relevant national authorities and international organizations of potential or actual food ***or feed*** contamination problems and encourage them to take appropriate preventive action. This should result in decreased levels of chemical contamination and, in the long term, could result in a decreasing need to establish and maintain Codex Maximum Levels for chemicals in food ***or feed.***

4. Different approaches may be used to try and ensure that the levels of chemical contaminants in Foodstuffs ***and feed*** are as low as reasonably achievable and never above the maximum levels considered acceptable/tolerable from the health point of view. Essentially, these approaches consist of

a. measures to eliminate or control the source of contamination,

b. processing to reduce contaminant levels and,

c. measures to identify and separate contaminated food ***or feed*** from food fit for human consumption ***or feed fit for food producing animals***.

The contaminated food is then rejected for food use, unless it can be reconditioned and made fit for human consumption. ***By analogy in the case of feed, the contaminated feed is also then rejected for feed use unless the feed is reconditioned and made fit for animal consumption.*** In some cases, a combination of the above approaches must be used, for example, if emissions from a previously uncontrolled source have resulted in environmental pollution with a persistent substance, such as PCBs or mercury. When fishing waters or agricultural land become heavily polluted due to local emissions, it may be necessary to blacklist the areas concerned, i.e. to prohibit the sale of foods ***and feeds*** derived from these polluted areas and to advise against the consumption of such foods ***or feeds.***

5. Control of final products can never be extensive enough to guarantee contaminant levels below established Maximum Levels. In most cases, chemical contaminants cannot be removed from foodstuffs ***or feed*** and there is no feasible way in which a contaminated batch can be made fit for human consumption ***or a contaminated feed batch can be made fit for animal consumption.*** The advantages of eliminating or controlling food ***or feed*** contamination at source, i.e. the preventive approach, are that this approach is usually more effective in reducing or eliminating the risk of untoward health effects, requires smaller resources for food ***or feed*** control and avoids the rejection of foodstuffs ***or feedstuffs.***

6. Food ***and feed*** production, processing and preparation operations should be analysed with a view to identifying hazards and assessing the associated risks. This should lead to a determination of critical control points and the establishment of a system to monitor production at these points (i.e. the Hazard Analysis Critical Control Point or "HACCP" approach). It is important that care is exercised throughout the whole production-processing and distribution chain, since food safety and quality in other respects cannot be "inspected into" the product at the end of the chain.

7. Pollution of air, water and arable land can result in the contamination of crops grown for food or feed, food producing animals and surface and ground waters used as sources of water for drinking and food production and processing. The

[46] ***The term "feed" refers to both "feed (feedingstuffs)" and "feed ingredients" as defined in the Code of Practice on Good Animal Feeding (CAC/RCP 054 2004).***

relevant national authorities and international organisations should be informed about actual and potential food ***or feed*** contamination problems and encouraged to take measures to:

- control emissions of pollutants from industry, e.g. the chemical, mining, metal and paper industries, and also from weapons testing.
- control emissions from energy generation (including nuclear plants) and means of transportation.
- control the disposal of solid and liquid domestic and industrial waste, including its deposition on land, disposal of sewage sludge and incineration of municipal waste.
- control the production, sale, use and disposal of certain toxic, environmentally-persistent substances, e.g. organohalogen compounds (PCBs, brominated flame retardants, etc.), lead, cadmium and mercury compounds.
- ensure that before new chemicals are introduced onto the market, and especially if they may eventually be released into the environment in significant amounts, they have undergone appropriate testing to show their acceptability from the health and environmental points of view.
- replace toxic environmentally-persistent substances by products which are more acceptable from the health and environmental points of view.

**8.** ***This Code should be read in connection with the Code of Practice for Good Animal Feeding (CAC/RCP 54-2004).***

**Annex IV**

**Codex Electronic Working Group on Animal Feed 2009/2010**

**Proposed Changes and additions to the Definitions for the Purposes of the Codex Alimentarius[47] and proposed changes to the Definitions of Risk Analysis Terms related to Food Safety[48]**
**(Task not included in the Terms of Reference for the E-WG)**

**DEFINITIONS FOR THE PURPOSES OF THE CODEX ALIMENTARIUS**:

(Proposed changes in ***italics and bold***)

Contaminant means any substance not intentionally added to food ***or feed***, which is present in such food ***or feed*** as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food ***or feed***, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter.

Traceability/Product Tracing: the ability to follow the movement of a food ***or feed*** through specified stage(s) of production, processing and distribution.

**To be added to the definitions for the Purposes of the Codex Alimentarius:**

Feed (Feedingstuff)[49]: Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food producing animals.

Undesirable Substances[50]: Contaminants and other substances which are present in and/or on feed and feed ingredients and which constitute a risk to consumers' health, including food safety-related animal health issues.

**Definitions of Risk Analysis Terms related to Food Safety**

(Proposed changes in ***italics and bold***)

Hazard: A biological, chemical or physical agent in, or condition of, food ***or feed***, with the potential to cause an adverse ***human*** health effect.

Risk: A function of the probability of an adverse ***human*** health effect and the severity of that effect, consequential to a hazard(s) in food ***or feed***.

Risk Profile: The description of the food ***or feed*** safety problem and its context.

Hazard Identification: The identification of biological, chemical, and physical agents capable of causing adverse ***human*** health effects and which may be present in a particular food ***or feed*** or group of foods ***or feeds***.

Hazard Characterization: The qualitative and/or quantitative evaluation of the nature of the adverse ***human*** health effects associated with biological, chemical and physical agents which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

Dose-Response Assessment: The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse ***human*** health effects (response).

[47] Definitions for the Purpose of the Codex Alimentarius, Section I Foundation Texts and Definitions, Procedural Manual, 18th Edition, Rome 2009
[48] Definitions of Risk Analysis Terms related to Food Safety, Section V Working Principles for Risk Analysis, Procedural Manual 18th Edition, Rome, 2009.
[49] Section 3, Para 6 of the Code of Practice on Good Animal Feeding, (CAC/RCP 54-2004) that also includes other feed related definitions.
[50] Section 3, Para 6 of the Code of Practice on Good Animal Feeding, (CAC/RCP 54-2004) that also includes other feed related definitions.

**Annex V**

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