



JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Sixth Session  
Maastricht, The Netherlands, 26 – 30 March 2012

REVISION OF THE RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON FOOD ADDITIVES AND  
THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS AS TO THEIR SEPARATION FROM THE  
CODEX COMMITTEE ON FOOD ADDITIVES AND THEIR APPLICABILITY TO FEED

(First part of the report of the electronic Working Group on the revision of the Risk Analysis Principles of the CCCF  
and the Code of Practice for Source Directed Measures)

## Background

1. The Codex Committee on Contaminants in Foods was invited by the Codex Alimentarius Commission to consider, at its 5<sup>th</sup> session, the review of the *Risk Analysis Principles Applied by the Committee on Food Additives and the Codex Committee on Contaminants in Foods* as proposed in the report of the electronic working group on future work on animal feed (Annex 1 to CX/CF 11/5/2) for further consideration by CCGP and the proposed review of the *Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals* (Annex 2 to CX/CF 11/5/2), both as to their applicability to animal feed.

2. The Committee was also requested to consider the review of its Risk Analysis Principles as proposed by CCGP (Annex 3 to CX/CF 11/5/2). In addition, the Committee was informed by the Codex secretariat that CCFA, at its 43<sup>rd</sup> session, decided to advocate separate Risk Analysis Principles on food additives and on contaminants.

3. The Committee agreed to establish an electronic Working Group (eWG) led by The Netherlands with the following terms of reference (ToR) (REP11/CF, paras. 7-9):

A- to prepare separate Risk Analysis Principles for contaminants and natural toxins in food and feed;

B- to examine whether it was necessary to further specify the applicability to feed in the Principles as well as the Code of Practice as proposed in Annexes 1 and 2 of CX/CF 11/5/2, respectively; taking into account the proposal for the amendment of the definition of contaminant as presented in CRD 18; and

C- to consider any other revisions that might be necessary to update the terminology in the Principles for consistency with the current risk assessment terminology.

4. The electronic working group was established and members included: Argentina, Australia, Austria, Brazil, Canada, Chile, Colombia, European Union, FAO, FoodDrinkEurope, Finland, France, Germany, Greece, ICBA, ICGMA, IDF, Japan, Lebanon, Spain, Thailand, United States of America and WHO (see Annex III). Comments were received from Argentina, Australia, Austria, Canada, Colombia, FAO, France, ICBA, Japan, Lebanon, USA and WHO.

Part A of the ToR is reported in the current document.

Part B of the ToR is reported in document CX/CF 12/6/4 (Agenda item 2c).

Part C of the ToR has been taken into account in Parts A and B and is not reported separately.

## Discussion

1. The Risk Analysis Principles (former Annex I to CX/CF 11/5/2) have been revised to separate the principles applying to CCCF from those applying to CCFA. As some overlap in remaining text was seen, some paragraphs have been combined in new proposed paragraphs. Also the paragraphs have been ordered in proposed separate subheadings, in order to make the different stages/tasks more clear. The Risk Analysis Principles with indicated proposed revisions are included in Annex I to this document; a 'clean' final version is included in Annex II.

2. The revisions to the Risk Analysis Principles as to their applicability to feed as proposed by the eWG on future work on animal feed have been retained in the document, as most responding members of the working group agreed to this. One member objected to the specification of feed in the Risk Analysis Principles.

3. The eWG discussed the issue of adulteration that may have occurred which could have significant food safety impact and if this issue should be dealt with in the Risk Analysis Principles. One member considered that the current mandate of CCCF already covered the possibility to deal with 'related issues'. Other members suggested amendments to either the Risk Analysis Principles, the definition of 'contaminant', the General Standard for Contaminants and Toxins in Foods and Feeds (GSCTFF, CODEX STAN 193-1995), or the Policy of the Codex Committee on Contaminants in Food for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups (as incorporated into the procedural manual). As no clear conclusion could be reached, it was proposed to recommend to CCCF to discuss this issue of adulteration further in the plenary session.

4. One member considered that addressing the issue of feeds could have two scopes according to the objective of the analysis of exposure from feeds: use of the levels of contaminants in animal (by)products resulting from transfer from feed either as input for human exposure/risk assessment or as input for determining an ML in feed. The member suggested that these issues could be further clarified in the Risk Analysis Principles. It is recommended to CCCF that this proposal is discussed in the plenary session.

**Recommendations to CCCF:**

- To forward the proposed revision of the Risk Analysis Principles of CCCF to the Codex Alimentarius Commission for endorsement;
- To discuss the matter of adulteration and its possible inclusion in the Risk Analysis Principles, the definition of contaminant, the GSCTFF and/or the Policy of CCCF for exposure assessment in foods or food groups;
- To discuss the matter of a possible indication for different approaches for feed as to its consideration in risk assessment for food or in setting MLs in feed.

## ANNEX I - Proposed revisions Risk Analysis Principles – track change version

### Reading note:

Proposed changes as to the applicability to feed in *italics and bold*

Proposed changes as to the separation from the Principles from CCFA and editorial amendments in track change.

Paragraphs have been reordered, original paragraph numbers are indicated in track change.

### Risk Analysis Principles Applied by the ~~Codex Committee on Food Additives and the~~ Codex Committee on Contaminants in Foods

#### 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 ~~that are not in the terms of reference of which cannot be addressed by~~ JECFA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies, or FAO/WHO ad hoc consultations as approved by the Codex Alimentarius Commission (CAC).

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

3 ~~3~~ *This document also applies to contaminants in food originating from ~~feed additives and~~ contaminants in feed<sup>9</sup> for food producing animals where it can impact food safety. This excludes feed additives, processing aids and agricultural and veterinary chemical residues that are the responsibility of other relevant Codex committees.*

#### Section 2. General principles of CCFA/CCCF and JECFA

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

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

3.6. CCFA/CCCF and JECFA recognize that communication/interaction 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 interaction communication~~ between the two ~~committees/bodies~~.

5.7. 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.

6.8. 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 should be used by CCFA/CCCF/CCCF in preparing its Priority List for JECFA. The JECFA Secretariat should consider whether these minimum requirements/quality criteria for data availability have been met when preparing the provisional draft agendas for meetings of JECFA.

#### Section 3. CCFA/CCCF/CCCF

##### Communication with JECFA

19.9. CCFA/CCCF/CCCF's risk communication with JECFA includes prioritising/prioritizing substances for JECFA review/assessment with ~~the a~~ view towards obtaining the best available/quality 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/toxins in food and feed.

20.10. CCFA/CCCF/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/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;

<sup>1</sup> 9 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). For the purposes of these principles, feed refers only to food producing animals and does not cover feed for pet animals.

- 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;

~~24~~ 11. When referring substances to JECFA, ~~CCFA/CCCF~~ shall provide a clearly defined scope for the risk assessment request, background information and ~~clearly~~ explain the reasons for the request when chemicals are nominated for evaluation;

~~22~~ 12. ~~CCFA/CCCF~~ may also ~~refer request~~ JECFA to perform an impact assessment<sup>2</sup> of 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~~ 13. ~~CCFA/CCCF~~ may 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~~ toxins. ~~CCFA/CCCF~~ would makes ~~any~~ such request with a view toward in order to obtaining JECFA's guidance on the limitations, applicability, and appropriate means for implementation of a ~~METHOD OR GUIDELINE FOR~~ particular method or guideline. ~~CCFA/CCCF'S WORK~~.

~~9~~ 14. In cases where JECFA has performed a ~~safety risk~~ assessment and ~~CCFA/CCCF~~ ~~or the~~ and ultimately 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 decision on a risk management ~~decision recommendation~~.

#### Risk management

~~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.~~

~~9~~ 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)

~~10~~ 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~~ 15. CCCF's risk management recommendations to the CAC with respect to contaminants and ~~naturally occurring toxicants~~ toxins 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 (GSCTFF);

~~12~~ 16. (Combined previous paras 8, 12, 13 and 18) ~~CCFA/CCCF~~'s risk management recommendations to the CAC that involve ~~health and safety~~ aspects of food ~~and feed~~ standards for human health shall be based on JECFA's risk assessments, and shall take into account the relevant uncertainties and safety factors in the risk assessment and recommendations described by JECFA. When establishing its standards, codes of practice, and guidelines, CCCF shall clearly state when it applies any other legitimate factors, in addition to JECFA's risk assessment, in accordance with the and other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with 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 Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles, and specify its reasons for doing so.

~~8~~. ~~CCFA/CCCF shall base their risk management recommendations to the CAC on JECFA's risk assessments, including safety assessments~~ 10, of food additives, ~~naturally occurring toxicants, and contaminants in food and feed, and shall take into account the relevant uncertainties and safety factors described by JECFA.~~

~~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~~ 17. 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) meets the criteria established as a significant contributor to total dietary exposure for consumers (as per the Codex Policy for Exposure of Contaminants and Toxins in Foods) and 3) the level of the contaminant in food or feed can be determined through appropriate sampling plans and analysis-analytical methods, as adopted by Codex. CCCF should take into consideration the analytical capabilities of developing countries unless public health considerations require otherwise.

~~16~~ 18. ~~CCFA/CCCF~~ shall take into account differences in regional and national food consumption patterns and dietary exposure as assessed by JECFA when recommending maximum levels for contaminants and ~~naturally occurring toxicants~~ toxins in food ~~and feed~~.

<sup>2</sup> Such as indicated in Section 5 'Assessment of the Impact of Agricultural and Production Practices on Contaminant Levels in Foods/Food Groups' of the *Policy of the Codex Committee on Contaminants and Toxins in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups*.

~~17 19.~~ Before finalising proposals for maximum levels for contaminants and ~~naturally occurring toxicants~~toxins, 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~~toxins in foods *or feed* and about other relevant technical and scientific aspects, ~~including dietary exposure~~, as necessary to provide for a suitable scientific basis for its ~~management proposals~~advice to ~~CCFCAC~~.

~~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 Principle*, in addition to JECFA's risk assessment, and specify its reasons for doing so.

#### Section 4. JECFA

##### *Preparation of risk assessment*

~~37 20.~~ When establishing the agenda for a JECFA meeting, the JECFA Secretariat work closely with ~~CCFA/CCCF~~ and the Codex Secretariat to ensure that ~~CCFA/CCCF~~'s risk management work 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 first priority to substances that present an emergency or imminent public health risk and then to substances that are known or expected problems in international trade ~~or that present an emergency or imminent public health risk.~~

##### *Risk assessment*

~~25 21.~~ The selection of JECFA ~~JECFA's scientific~~ experts to participate in any specific meeting should be made after a careful consideration of the necessary scientific selected on the basis of their competence and experience required for the assessment of the substances on the agendaindependence, taking into account gender and geographical representation to ensure that all regions are represented.

~~26 22.~~ 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 intakedietary exposure to contaminants and toxins. Because of the lack of appropriate information, including data in humans, however, this may be possible in only a few cases on a case by case basis for the foreseeable future. For additives, JECFA should continue to use its safety assessment process for establishing ADIs.

~~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 23.~~ 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 24.~~ When evaluating intake of additives or dietary exposure to contaminants and naturally occurring toxicantstoxins during its risk assessment, JECFA should take into account regional differences in food and feed consumption patterns.

##### *Communication with CCCF*

~~27 25.~~ 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 26.~~ JECFA should provide ~~CCFA/CCCF~~ with information on the applicability and any uncertainty in 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, and the elderly).

~~33 27.~~ JECFA should provide to CCCF its scientific views on the validity and the distribution aspects of the available data regarding contaminants and toxins 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 the risk management actions or optionsrecommendations of CCCF.

~~34 28.~~ 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~~ 29. JECFA should communicate to ~~CCFA/CCCF/CCCF~~ the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties.

~~36~~ 30. JECFA's risk assessment output to ~~CCFA/CCCF/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 other than requested (such as impact assessments of MLs) by CCCF. 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~~.

## ANNEX II - Proposed revisions Risk Analysis Principles

### CLEAN VERSION

#### Risk Analysis Principles Applied by the Codex Committee on Contaminants in Foods

##### Section 1. Scope

1. This document addresses the applications of risk analysis principles by the Codex Committee on Contaminants in Foods (CCCF) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). For matters that are not in the terms of reference of JECFA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies, or FAO/WHO *ad hoc* consultations as approved by the Codex Alimentarius Commission (CAC)..
2. This document should be read in conjunction with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.
3. This document also applies to contaminants in food originating from contaminants in feed<sup>91</sup> for food producing animals where it can impact food safety. This excludes feed additives, processing aids and agricultural and veterinary chemical residues that are the responsibility of other relevant Codex committees.

##### Section 2. General principles of CCCF and JECFA

4. CCCF is primarily responsible for recommending risk management proposals for adoption by the CAC.
5. JECFA is primarily responsible for performing the risk assessments upon which CCCF and ultimately the CAC base their risk management recommendations.
6. CCCF and JECFA recognize that interaction between risk assessors and risk managers is critical to the success of their risk analysis activities. CCCF and JECFA should continue to develop procedures to enhance interaction between the two bodies.
7. CCCF and JECFA should ensure that their contributions to the risk analysis process involve all interested parties, 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.
8. JECFA, in consultation with CCCF, should continue to explore developing minimum quality criteria for data requirements necessary for JECFA to perform risk assessments. These criteria should be used by CCCF in preparing its Priority List for JECFA. The JECFA Secretariat should consider whether these minimum requirements for data availability have been met when preparing the draft agendas for meetings of JECFA.

##### Section 3. CCCF

###### *Communication with JECFA*

9. CCCF's risk communication with JECFA includes prioritizing substances for JECFA assessment with a view to obtaining the best quality risk assessment for contaminants and toxins in food and feed.
10. 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;
  - 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.
11. When referring substances to JECFA, CCCF shall provide a clearly defined scope for the risk assessment request, background information and explain the reasons for the request when chemicals are nominated for evaluation.

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<sup>1</sup> 9 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). For the purposes of these principles, feed refers only to food producing animals and does not cover feed for pet animals

12. CCCF may also request JECFA to perform an impact assessment<sup>2</sup> of a range of risk management options, with a view toward obtaining JECFA's guidance on the risks and the likely reductions associated with each option.

13. CCCF may request JECFA to review any methods and guidelines being considered by CCCF for assessing maximum levels for contaminants and toxins. CCCF would make such request in order to obtain JECFA's guidance on the limitations, applicability and appropriate means for implementation of a particular method or guideline.

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

#### *Risk management*

15. CCCF's risk management recommendations to the CAC with respect to contaminants and toxins shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Contaminants and Toxins in Food and Feed (GSCTFF).

16. CCCF's risk management recommendations to the CAC that involve safety aspects of food and feed standards for human health shall be based on JECFA's risk assessments, and shall take into account the relevant uncertainties and safety factors in the risk assessment and recommendations described by JECFA. When establishing its standards, codes of practice, and guidelines, CCCF shall clearly state when it applies any other legitimate factors, in addition to JECFA's risk assessment, in accordance with 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 specify its reasons for doing so.

17. CCCF shall endorse maximum levels only for those contaminants for which 1) JECFA has performed a quantitative risk assessment, 2) meets the criteria established as a significant contributor to total dietary exposure for consumers (*as per the Codex Policy for Exposure of Contaminants and Toxins in Foods*) and 3) the level of the contaminant in food or feed can be determined through appropriate sampling plans and analytical methods, as adopted by Codex. CCCF should take into consideration the analytical capabilities of developing countries unless public health considerations require otherwise.

18. CCCF shall take into account differences in regional and national food consumption patterns and dietary exposure as assessed by JECFA when recommending maximum levels for contaminants and toxins in food and feed.

19. Before finalising proposals for maximum levels for contaminants and toxins, 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 toxins in food or feed and about other relevant technical and scientific aspects, as necessary to provide for a suitable scientific basis for its management proposals to CAC.

#### Section 4. JECFA

##### *Preparation of risk assessment*

20. When establishing the agenda for a JECFA meeting, the JECFA Secretariat work closely with CCCF and the Codex Secretariat to ensure that CCCF's work priorities are addressed in a timely manner. The JECFA Secretariat should give first priority to substances that present an emergency or imminent public health risk and then to substances that are known or expected problems in international trade.

##### *Risk assessment*

21. The selection of JECFA experts to participate in any specific meeting should be made after a careful consideration of the necessary scientific competence and experience required for the assessment of the substances on the agenda, taking into account gender and geographical representation to ensure that all regions are represented.

22. JECFA should provide CCCF with science-based risk assessments that include the four components of risk assessment as defined by CAC. JECFA should determine, to the extent possible, the risks associated with various levels of dietary exposure to contaminants and toxins. Because of the lack of appropriate information, however, this may be possible only on a case by case basis.

23. 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.

24. When evaluating dietary exposure to contaminants and toxins during its risk assessment, JECFA should take into account regional differences in food consumption patterns.

##### *Communication with CCCF*

25. JECFA should strive to provide CCCF with science-based quantitative risk assessments in a transparent manner.

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<sup>2</sup> Such as indicated in Section 5 'Assessment of the Impact of Agricultural and Production Practices on Contaminant Levels in Foods/Food Groups' of the *Policy of the Codex Committee on Contaminants and Toxins in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups*.



26. JECFA should provide CCCF with information on the applicability and any uncertainty in the risk assessment to the general population, to particular subpopulations and should as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g. children, women of childbearing age and the elderly).
27. JECFA should provide to CCCF its scientific views on the validity and the distribution aspects of the available data regarding contaminants and toxins in food and feed, 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 the risk management recommendations of CCCF.
28. JECFA should communicate to CCCF the magnitude and source of uncertainties in its risk assessments. When communicating this information, JECFA should provide CCCF with a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment.
29. JECFA should communicate to CCCF the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties.
30. JECFA's risk assessment output to CCCF is limited to presenting its deliberations and the conclusions of its risk 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 other than requested (such as impact assessments of MLs) by CCCF. 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.

## ANNEX III- LIST OF PARTICIPANTS

## Chair:

## The Netherlands

Kees PLANKEN  
Policy Adviser

Ministry of Health, Welfare and Sport  
P.O. BOX 20350  
2500 EJ The Hague  
NETHERLANDS  
Tel: +31703407132  
E-mail: [k.planken@minvws.nl](mailto:k.planken@minvws.nl)

## Astrid BULDER

Senior Risk Assessor

National Institute of Public Health and the Environment  
Centre for Substances and Integrated Risk Assessment  
P.O. Box 1  
3720 BA Bilthoven  
NETHERLANDS  
Tel: +31302747048  
Fax: +31302744475  
E-mail: [astrid.bulder@rivm.nl](mailto:astrid.bulder@rivm.nl)

## MEMBER COUNTRIES

## Argentina

Punto Focal - Contact Point  
Codex Alimentarius – ARGENTINA  
Dirección de Relaciones Agroalimentarias Internacionales  
Ministerio de Agricultura, Ganadería y Pesca  
Paseo Colón 922 Planta Baja Oficina 29 -  
Buenos Aires (C1063ACW)  
Tel: (+54 11) 4349-2549/2747  
E-mail: [codex@minagri.gob.ar](mailto:codex@minagri.gob.ar)

## Australia

Dr Glenn Stanley  
Deputy Section Manager  
Product Safety Standards  
Food Standards Australia New Zealand  
E-mail: [Glenn.Stanley@foodstandards.gov.au](mailto:Glenn.Stanley@foodstandards.gov.au)  
[codex.contact@daff.gov.au](mailto:codex.contact@daff.gov.au)

## Austria

Ms DI Elke Rauscher-Gabernig  
Austrian Agency for Health and Food Safety  
Division Data, Statistics and Risk Assessment  
Spargelfeldstr. 191  
A-1220 Vienna, Austria  
E-mail: [Elke.rauscher-gabernig@ages.at](mailto:Elke.rauscher-gabernig@ages.at)

## Brazil

Ms. Lígia Lindner Schreiner  
Expert on Regulation  
Brazilian Health Surveillance Agency  
General Office of Foods  
Tel: +55 61 3462 5399  
E-mail: [ligia.schreiner@anvisa.gov.br](mailto:ligia.schreiner@anvisa.gov.br)

## Canada

Elizabeth Elliott  
Scientific Evaluator  
Health Canada  
CHEMICAL HEALTH HAZARD ASSESSMENT DIVISION  
251 Sir Frederick Banting Driveway, Tunney's Pasture  
Ottawa, Ontario K1A 0K9  
Canada  
Tel: 613-954-4599  
Fax: 613-990-1543  
E-mail: [elizabeth.elliott@hc-sc.gc.ca](mailto:elizabeth.elliott@hc-sc.gc.ca)

## Chile

Enedina Lucas Viñuela  
Sección Coordinación Laboratorios Ambientales  
Departamento Salud Ambiental  
Instituto de Salud Pública de Chile  
Marathon 1000, Ñuñoa, Santiago  
Tel: +56 (2) 5755478  
Red Minsal: 255478  
E-mail: [elucas@ispch.cl](mailto:elucas@ispch.cl)

## Colombia

Jesús Alejandro Estévez García  
Subdirección de Alimentos y Bebidas Alcohólicas  
Instituto Nacional de Vigilancia de Medicamentos y  
Alimentos INVIMA, Colombia  
E-mail: [jestevezg@invima.gov.co](mailto:jestevezg@invima.gov.co)

Diana Ximena Correa Lizarazu  
Coordinator Unit Risk Assessment For Food Safety  
Affiliation: Instituto Nacional de Salud  
E-mail: [dcorrea@ins.gov.co](mailto:dcorrea@ins.gov.co)

**European Union**

Ms Almut BITTERHOF  
 European Commission  
 Health and Consumers Directorate-General  
 Tel: ++32 - 2 - 298 67 58  
 E-mail: [almut.bitterhof@ec.europa.eu](mailto:almut.bitterhof@ec.europa.eu)  
[codex@ec.europa.eu](mailto:codex@ec.europa.eu)

**Finland**

Ms Liisa Rajakangas  
 Senior Officer, Food Policy  
 Ministry of Agriculture and Forestry  
 Department of Food and Health  
 PO Box 30, 00023 Government, FINLAND  
 Tel: +358-9-1605 3384  
 Fax: +358-9-1605 3338  
 E-mail: [liisa.rajakangas@mmm.fi](mailto:liisa.rajakangas@mmm.fi)

**France**

Mr Jeremy Pinte  
 Ministère de l'Agriculture  
 Direction Générale de l'Alimentation  
 251 rue de Vaugirard  
 75 732 Paris Cedex 15  
 Tel: + 33 1 49 55 81 46  
 Fax: + 33 1 49 55 59 48  
 E-mail: [jeremy.pinte@agriculture.gouv.fr](mailto:jeremy.pinte@agriculture.gouv.fr)

Mr David Brouque  
 Ministère de l'Agriculture  
 Direction Générale de l'alimentation  
 251 rue de Vaugirard  
 75732 Paris Cedex 15  
 E-mail: [david.brouque@agriculture.gouv.fr](mailto:david.brouque@agriculture.gouv.fr)

**Germany**

Ms. Angelika Preiss-Weigert  
 Head of Unit Contaminants  
 Federal Institute for Risk Assessment  
 Safety in the Food Chain  
 Thielallee 88-92  
 D-14195 Berlin  
 Tel: + 49 – 30 – 18412 – 3352  
 Fax: + 49 – 30 – 18412 – 3457  
 E-mail: [angelika.preiss-weigert@bfr.bund.de](mailto:angelika.preiss-weigert@bfr.bund.de)

**Greece**

Dr Dimitra Kardassi  
 Hellenic Food Authority  
 Directorate of Training, Communication and IT Technologies  
 124 Kifissias Ave & 2 Iatridou str.  
 P.O. 11526 Athens, Greece  
 Tel: +30 2106971592  
 Fax: +30 2106971501  
 E-mail: [dkardassi@efet.gr](mailto:dkardassi@efet.gr)

**Japan**

Dr Takashi SUZUKI  
 Deputy Director  
 Standards and Evaluation Division, Department of Food  
 Safety, Ministry of  
 Health, Labour and Welfare  
 1-2-2 Kasumigaseki, Chiyoda-ku Tokyo 100-8916, Japan  
 E-mail: [codexj@mhlw.go.jp](mailto:codexj@mhlw.go.jp)

Dr Takanori UKENA  
 Associate Director  
 Food Safety and Consumer Policy Division, Ministry of  
 Agriculture,  
 Forestry and Fisheries  
 1-2-1 Kasumigaseki, Chiyoda-ku, Tokyo  
 100-8950 Japan  
 E-mail: [takanori\\_ukena@nm.maff.go.jp](mailto:takanori_ukena@nm.maff.go.jp)

Mr Wataru IIZUKA  
 Assistant Director  
 Standards and Evaluation Division, Department of Food  
 Safety, Ministry of  
 Health, Labour and Welfare  
 1-2-2 Kasumigaseki Chiyoda-ku, Tokyo 100-8916, Japan  
 E-mail: [codexj@mhlw.go.jp](mailto:codexj@mhlw.go.jp)

Dr Akihiko HIROSE  
 Director  
 Division of Risk Assessment, Biological Safety Research  
 Center, National  
 Institute of Health Sciences  
 1-18-1 Kamiyoga, Setagaya-ku, Tokyo 158-8501, Japan  
 E-mail: [hirose@nihs.go.jp](mailto:hirose@nihs.go.jp)

**Lebanon**

Rania ELHAYEK BOUSTANY  
 Agriculture Engineer  
 Ministry of Agriculture Lebanon  
 Department Agriculture Process  
 Tel: 00961 03 3196 71  
 00961 01 824 100 (ext 104)  
 E-mail: [boustany1@yahoo.com](mailto:boustany1@yahoo.com); [rhayek@agriculture.gov.lb](mailto:rhayek@agriculture.gov.lb)

**Spain**

Jorge Muñoz Palencia  
 Jefe Departamento Análisis Especiales  
 Laboratorio Arbitral Agroalimentario. Madrid  
 Email: [jmunozp@marm.es](mailto:jmunozp@marm.es)

**Thailand**

Mr. Pisan Pongsapitch  
 Director, Office of Commodity and System Standard  
 National Bureau of Agricultural Commodity and Food  
 Standards  
 50 Phaholyothin Road, Ladyao, Chatuchak  
 Bangkok 10900 Thailand  
 Tel: (+662) 561 2277 ext. 1401  
 Fax: (+662) 561 3357, (+662) 561 3373  
 E-mail: [codex@acfs.go.th](mailto:codex@acfs.go.th)

**United States of America**

Henry Kim  
 On behalf of Nega Beru, U.S. Delegate to CCCF  
 U.S. Food and Drug Administration  
 Center for Food Safety and Applied Nutrition  
 5100 Paint Branch Parkway  
 College Park, MD 20740  
[henry.kim@fda.hhs.gov](mailto:henry.kim@fda.hhs.gov)

**INTERNATIONAL GOVERNMENTAL AND NON-GOVERNMENTAL ORGANISATIONS****FoodDrinkEurope**

Lorcan O'FLAHERTY  
 Junior Manager Food Policy, Science and R&D  
 Avenue des Arts 43  
 1040 Bruxelles – BELGIUM  
 Tel: 02 5008756  
 Fax: 02 5081021  
 E-mail: [l.oflaherty@fooddrinkeurope.eu](mailto:l.oflaherty@fooddrinkeurope.eu)

**ICBA**

Ms. Päivi Julkunen  
 Chair, ICBA Committee for Codex  
 International Council of Beverages Associations  
 E-mail: [pjulkunen@na.ko.com](mailto:pjulkunen@na.ko.com)

**ICGMA**

Peggy S. Rochette  
 Senior Director, International Affairs  
 Grocery Manufacturers Association (GMA)  
 Secretariat ICGMA  
 1350 I St NW  
 Washington, DC 20005  
 (202) 639-5921  
 E-mail: [prochette@gmaonline.org](mailto:prochette@gmaonline.org)

**IDF**

Mr. Koenraad Duhem  
 R&D Director  
 CNIEL  
 42, rue de Châteaudun  
 F-75314 Paris Cedex 09 France  
 Tel: +33 1 49 70 71 19  
 Fax: +33 1 42 80 63 45  
 E-mail: [kduhem@cniel.com](mailto:kduhem@cniel.com)

Ms. Aurélie Dubois  
 IDF Standards Officer  
 International Dairy Federation (FIL-IDF)  
 Silver Building  
 Bd. Auguste Reyers 70/B  
 1030 Brussels  
 Tel: +32 2 706 86 45  
 Fax: +32 2 733 04 13  
 E-mail: [adubois@fil-idf.org](mailto:adubois@fil-idf.org)

**FAO**

Dr Annika Wennberg  
 Senior officer, FAO JECFA Secretary  
 Nutrition and Consumer Protection Division  
 Food and Agriculture Organization of the United Nations  
 Viale delle Terme di Caracalla  
 00153 Rome, Italy  
 Tel: + 39 06 5705 3283  
 Facsimile: + 39 06 5705 4593  
 E-mail: [Annika.Wennberg@fao.org](mailto:Annika.Wennberg@fao.org)

**WHO**

Dr Angelika Tritscher  
 WHO Joint Secretary to JECFA and JMPR  
 Department of Food Safety and Zoonoses  
 World Health Organization  
 20, Avenue Appia, CH-1211 Geneva 27  
 Switzerland  
 Tel. direct: +41 22 791 3569  
 Fax direct: +41 22 791 4807  
 Mobile: +41 79 633 9995  
 E-mail: [tritschera@who.int](mailto:tritschera@who.int)