commission du codex alimentarius

ORGANISATION DES NATIONS UNIES POUR L'ALIMENTATION ET L'AGRICULTURE

ORGANISATION MONDIALE DE LA SANTÉ

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Point 3a) de l'ordre du jour **CX/GP 02/3**

PROGRAMME MIXTE FAO/OMS SUR LES NORMES ALIMENTAIRES

COMITE DU CODEX SUR LES PRINCIPES GENERAUX
Dix-septième session
Paris, France, 15 – 19 avril 2002

AVANT-PROJET DE PRINCIPES DE TRAVAIL POUR L'ANALYSE DES RISQUES

La 16ème session du Comité sur les Principes Généraux a examiné l'Avant-projet de Principes de travail pour l'analyse des risques et est convenu d'apporter plusieurs amendements au texte. Cependant, il n'est pas parvenu à un consensus sur le champ d'application et l'utilisation de la précaution dans l'analyse des risques, en particulier dans la gestion des risques. Le Comité est donc convenu de demander à la Commission des éclaircissements sur la portée des Principes de travail, à savoir s'ils devaient être appliqués exclusivement dans le cadre du Codex, ou par les gouvernement membres, ou par les deux. Le Comité a également demandé l'avis de la Commission sur l'attitude que le Codex devrait adopter lorsque les données scientifiques étaient insuffisantes ou incomplètes et lorsqu'on avait la preuve qu'il existait un risque pour la santé humaine, et en particulier s'il devait s'engager dans l'élaboration d'une norme ou d'un texte apparenté.

La 24ème session de la Commission du Codex Alimentarius a confirmé son mandat initial au Comité, à savoir, mettre au point en priorité les principes de l'analyse des risques dans le Codex, en vue de leur adoption en 2003, et a recommandé que le pays hôte (France) organise un groupe de travail longtemps avant la session, afin de faciliter la discussion à sa dix-septième session. La Commission est convenue que le Comité devrait élaborer des directives à l'intention des gouvernements, par la suite ou en parallèle, selon les besoins, compte tenu de son programme de travail. La Commission a également décidé comment procéder lorsque les données scientifiques étaient insuffisantes ou incomplètes (ALINORM 01/41, par. 75-83).

Le Secrétariat a révisé l'*Avant-projet de Principes de travail pour l'analyse des risques* à la lumière des décisions de la Commission et des amendements apportés par la 16ème session du Comité, comme convenu précédemment (ALINORM 01/33A, para. 74), et a distribué le texte pour observations dans la CL 2001/24-GP. Le Groupe de Travail convoqué par la France (Paris, 5-7 décembre 2001), comme recommandé par la Commission, a examiné le texte et les observations reçues en réponse à la Lettre Circulaire.

Le Groupe de Travail a considéré le texte en entier et a apporté plusieurs amendements. Le rapport du Groupe de Travail à l'Annexe 1 comprend les explications des amendements, avec des notes sur les sections qui demandent une discussion ultérieure, et le texte révisé de l'*Avant-projet de Principes de travail pour l'analyse des risques* où les modifications sont soulignées.

Le texte révisé sans les modifications soulignées est présenté à l'Annexe 2 pour faciliter son utilisation. Les observations à l'étape 3 reçues en réponse à la CL 2001/24-GP et examinées par le groupe de travail figurent à l'Annexe 3.

Le texte révisé est distribué par la présente pour observations à l'étape 3 et examen par la 17ème session du Comité. Les gouvernements et organisations internationales souhaitant présenter des observations sont invités à le faire par écrit, de préférence par courrier électronique, au Point de Contact du Codex de France SGCI/CODEX, Carré Austerlitz, 2 Boulevard Diderot, 75703 Paris Cedex 12, Télécopie: 33 (0)1 4487 16 04, sgci-codex-fr@sgci.finances.gouv.fr, avec copie au Secrétaire, Commission du Codex Alimentarius, Programme mixte FAO/OMS sur les normes alimentaires, FAO, Viale delle Terme di Caracalla, 00100 Rome (Italie), Télécopie: +39 (06) 5705 4593, codex@fao.org, **avant le 28 février 2002**.

ANNEXE 1

RAPPORT DU GROUPE DE TRAVAIL SUR L' AVANT-PROJET DE PRINCIPES DE TRAVAIL POUR L'ANALYSE DES RISQUES

Paris (France), 5-7 décembre 2001

COMMENTAIRES GENERAUX

Ce texte représente le résultat de la réunion du groupe de travail convoqué à la demande de la 24ème session de la Commission du Codex Alimentarius. Le groupe de travail s'est réunit à Paris (France) du 5 au 7 décembre 2001, à l'aimable invitation du Gouvernement français. Le groupe de travail a été présidé par Dr Chevassus-au-Louis. 67 participants de 22 pays membres et de 10 organisations internationales observateurs ont participé à la réunion[1].

Le groupe de travail s'est appuyé sur l'Avant Projet de Principes de travail pour l'analyses des risques (CL 2001/24/GP) et a pris en considération les commentaires écrits établis en réponse à la lettre circulaire.

Cet avant projet combine de nombreuses contributions écrites et orales de la part des participants au groupe de travail. Toutes les propositions ont été examinés et discutés durant la réunion. Le groupe de travail est parvenu a un accord sur la plupart des points et a considéré que d'important progrès ont été faits. Cependant, le consensus n'a pu être atteint sur quelques paragraphes. Les membres du groupe de travail ont en conséquences réservés leur droit de faire ultérieurement des commentaires après un examen plus détaillé.

Cet avant projet de texte sera mis en circulation à l'étape 3 par le secrétariat du Codex, le plus tôt possible, pour commentaires avant la 17ème session du CCGP (15-19 avril 2002).

§	**Commentaire**
Titre :	Préciser clairement l'objet du document et son champ d'application.
	CHAMP D'APPLICATION
1	Pas de changement.
2	L'analyse de risque a comme objectif primaire la protection de la santé et elle n'assure pas en tant que tel des pratiques loyales.
3	Remplacement du terme « assurer » par « fournir des lignes directrices » et précision sur les utilisateurs concernés.
4	La version anglaise a été modifiée : le mot « bodies » a remplacé le mot « committees »
	ANALYSE DES RISQUES – ASPECTS GENERAUX
5	Précision sur la notion de cohérence et ajout d'une référence aux deux Déclarations de principe concernées.
6	Affirmation du lien nécessaire entre les trois étapes et ajoute une référence aux définitions du Codex.
7	Première apparition du terme « toutes les parties intéressées » et renvoi à la définition de ce terme pour l'ensemble du document.
8	Pas de changement.
9 - 9bis	Séparation en deux paragraphes. Le premier réaffirme la nécessaire cohérence des trois étapes. La référence aux « stratégies et politiques » est retirée car elle concerne plutôt les Etats membres que le Codex. 9bis précise la notion de « risque de confusion » et souligne l'intérêt d'une interaction entre évaluateurs et gestionnaires.
10	Après un long débat, il est proposé, comme base d'une discussion ultérieure, de déplacer ici le §40, en relation avec la discussion sur le §11.

[1] Argentine, Australie, Autriche, Bolivie, Brésil, Canada, Danemark, Finlande, France, Allemagne, Italie, Japon, Pays-Bas, Nouvelle Zélande, Portugal, Espagne, Suède, Suisse, Thailande, Royaume-Uni, Etats-Unis, CE, AEDA, BIO, CIAA, CI, CRN, IASDA, CCI, ICGMA, IFAH.

§	**Commentaire**
11	Ce texte reflète un effort pour rapprocher les différents point de vue des participants du groupe de travail sur cette question sensible. Il a fait l'objet d'un long débat. En particulier, en ce qui concerne la dernière phrase, le groupe de travail a décidé de retenir le présent texte comme base d'une discussion ultérieure. Dans la première phrase, le choix du terme « inhérent » pour qualifier la situation de la précaution a été jugé plus adéquat que « essentiel ».
12	Pas de changement.
	Politique d' évaluation des risques
13	Pas de changement.
14	L'expression « avis scientifique ». est remplacée par une nouvelle définition des objectifs des lignes directrices. Cette nouvelle définition de la politique d'évaluation des risques est reprise à l'annexe 1
15	Élimination du terme « préférable » qui était destiné aux recommandations pour les États membres.
16	Simplification (élimination de la fin de la phrase).
17	Remplacement de « peuvent » par « doivent ». « Lorsque c'est nécessaire » introduit une notion d'impératif.
	EVALUATION DES RISQUES
titre	Changement de la référence
18	Cette phrase est une citation de la déclaration de principe…
19	Pas de changement.
20	Addition d'une dernière phrase soulignant l'attention à porter à la participation d'experts des PED.
21	Mise en cohérence avec l'article 6 et ajout d'une modification de la référence aux principes adéquats.
22	Le « caractérisation des risques » est remplacée par « résultats de l'évaluation des risques ». Chaque étape de l'évaluation des risques est concernée par la nécessité d'être compréhensible et utile.
23	Pas de changement.
24	Élargissement de la notion de « production primaire » à l'ensemble de la chaîne alimentaire. Description plus adéquate du processus de collecte et utilisation des données.
25	Pas de changement.
26	Insistance sur un nécessaire effort de quantification des estimations du risque.
27	La dernière phrase ne peut s'appliquer systématiquement.
28	Introduction explicite de l'intérêt de fournir une estimation du risque. L'ajout de la deuxième phrase du §29 paraît appropriée ici. Ce paragraphe reprend certains éléments du § 22.
29	Deuxième phrase transférée en § 28.
	GESTION DES RISQUES
30	Précision sur les décisions et les recommandations du Codex et homogénéisation avec le texte de § 2. Élimination de la notion de risque « acceptable », qui relève plutôt des décisions des États membres.
31	Définition plus précoce des étapes de la gestion du risque. Référence de la notion de « facteurs légitimes » dans les textes du Codex (précédemment dans § 35). Retrait de la notion de « mise en œuvre des décisions », qui relève des États membres.
32	Pas de changement.
33	Homogénéité avec §18. Mention des parties intéressées (voir § 7).

§	**Commentaire**
34	Choix du terme « évaluée ». Retrait du mot « requis ». (voir §30) Terme « si nécessaire » jugé inutile.
35	Référence aux facteurs légitimes transférée en §31.
36	Supprimé comme demandé.
37	L'ajout au §37 représente une synthèse des propositions écrites reçues de plusieurs délégations. Elle n'a pas été discutée en détail par le groupe de travail. Elle est proposée comme base de discussion ultérieure.
38	La portée de la phrase n'est pas limitée aux PED.
39	Introduction d'un souhait de réexamen régulier des textes.
40	Déplacé au § 10
	COMMMUNICATION SUR LES RISQUES
41	Précision sur la définition (i) des évaluateurs et des gestionnaires dans le cadre du Codex, (ii) les parties intéressées par la communication.
41 bis	Nouvel article soulignant le caractère interactif de la communication et son importance.
42	Améliorer le libellé dans le texte anglais. Ce paragraphe reprend certains éléments du § 41bis.
43	Explication du contenu de la communication et remplacement du terme « mesures », inapproprié dans le cadre du Codex. Ajout d'une référence aux opinions minoritaires.
43 bis	Nouveau § détaillant les objectifs de la communication sur le risque.
44	Remplacement du terme « communiqué » par une formulation soulignant le caractère interactif du processus.
45	Désormais intégré dans l'article 43.
	ANNEXE 1
Annexe 1	La définition du profil de risque est issue de la consultation mixte d'experts FAO/OMS sur la gestion des risques et la sécurité des aliments

AVANT-PROJET DE PRINCIPES DE TRAVAIL POUR L'ANALYSE DES RISQUES DESTINES A ETRE APPLIQUE DANS LE CADRE DU CODEX[2].

(A l'étape 3 de la Procédure)

CHAMP D'APPLICATION

1) Les principes pour l'analyse des risques sont destinés à être appliqués dans le cadre du Codex Alimentarius

2) Le but principal de l'analyse des risques dans le cadre de la Commission du Codex Alimentarius est de protéger la santé des consommateurs, tout en tenant compte de la promotion des pratiques loyales dans le commerce des denrées alimentaires.

3) L'objectif des Principes de travail est de fournir des lignes directrices à la Commission du Codex Alimentarius ainsi qu'aux comités et aux consultations mixtes d'experts FAO/OMS de façon que les aspects sanitaires et d'innocuité des aliments dans les normes et textes apparentés du Codex soient basés sur l'analyse des risques

4) Dans le cadre de la Commission du Codex Alimentarius et de ses procédures, la responsabilité de donner des avis en matière de gestion des risques incombe à la Commission et à ses organes subsidiaires, tandis que la responsabilité de l'évaluation des risques incombe normalement aux Comités et aux Consultations mixtes d'experts FAO/OMS.

ANALYSE DES RISQUES - ASPECTS GENERAUX

5) Le processus d'analyse des risques utilisé dans le Codex doit être :

- appliqué avec cohérence
- ouvert, transparent et documenté
- conduit en accord avec, d'une part, les *Déclarations de principes concernant le rôle de la science dans la prise de décision du Codex et les autres facteurs à prendre en considération* et, d'autre part, *les Déclarations de principes sur le rôle de l'évaluation des risques en matière de salubrité des aliments*.

6) Le processus d'analyse des risques doit suivre une démarche structurée comprenant les trois volets, distincts mais intimement liés, de l'analyse des risques (l'évaluation des risques, la gestion des risques et la communication sur les risques), tels que définis par la Commission du Codex Alimentarius[3], chacun de ces volets faisant partie intégrante de l'ensemble du processus d'analyse des risques.

7) Les trois volets de l'analyse des risques doivent être complètement et systématiquement documentés de manière transparente. Tout en respectant le souci légitime de préserver le caractère confidentiel[4] des documents, la documentation doit être accessible à toutes les parties intéressées et leurs organisations représentatives[5].

8) Une communication et une consultation effectives avec toutes les parties intéressées doivent être assurées tout au long du processus d'analyse des risques.

9) Les trois volets de l'analyse des risques doivent être mis en œuvre dans un cadre global au profit de la gestion des risques pour la santé humaine liés aux aliments.

9bis) Il doit exister une séparation fonctionnelle entre l'évaluation des risques et la gestion des risques, afin de garantir l'intégrité scientifique de l'évaluation des risques, d'éviter la confusion concernant les fonctions que doivent remplir les responsables de l'évaluation des risques et de la gestion des risques et d'atténuer tout conflit d'intérêts. Cependant, il est reconnu que l'analyse des risques est un processus itératif, et l'interaction entre les responsables de la gestion des risques et les responsables de l'évaluation des risques est essentielle pour une application concrète.

[2] Ces principes sont destinés à être incorporés dans le manuel de procédure du Codex. Ces principes ne préjugent pas des principes pour l'analyse des risques destinés à être appliqués par les gouvernements qui feront l'objet de lignes directrices séparées.

[3] Définitions des termes relatifs à l'innocuité des aliments, utilisés en analyse des risques ; manuel de procédure de la Commission du Codex Alimentarius, onzième édition page 51.

[4] Une définition devrait être ajoutée ultérieurement dans le glossaire en annexe.

[5] Par parties intéressées, on entend dans ce document, les responsables de l'évaluation du risque, les responsables de la gestion du risque, les consommateurs et leurs organisations représentatives, l'industrie, les milieux universitaires et les autres parties intéressées.

10) Lorsqu'on a la preuve qu'un risque existe pour la santé humaine, mais que les données scientifiques sont insuffisantes ou incomplètes, la Commission ne devrait pas élaborer de norme, mais devrait envisager d'élaborer un texte apparenté, par exemple un code d'usages, à condition que ce texte s'appuie sur les preuves scientifiques disponibles.[6]

11) La précaution est un élément inhérent au processus d'analyse des risques. De nombreuses sources d'incertitude existent dans le processus d'évaluation et de gestion des risques, quant aux dangers pour la santé humaine liés aux aliments. Le degré d'incertitude et de variabilité dans l'information scientifique disponible doit être explicitement considéré dans le processus d'analyse des risques. Lorsqu'il y a des preuves suffisantes pour permettre au Codex de procéder à l'élaboration d'une norme ou d'un texte apparenté, les hypothèses utilisées pour l'évaluation des risques et les options de gestion des risques retenues devraient refléter le degré d'incertitude scientifique et les caractéristiques des dangers.

12) Les besoins et les situations des pays en développement doivent être spécifiquement identifiés et pris en compte par les organes responsables au cours des différentes étapes du processus d'analyse des risques.

POLITIQUE D'EVALUATION DES RISQUES

13) La détermination d'une politique d'évaluation des risques doit être un élément spécifique de la gestion des risques.

14) La politique d'évaluation des risques consiste en l'élaboration de lignes directrices documentées sur des choix d'orientations et d'avis associés ainsi que sur leur application à des points de décision appropriés au cours de l'évaluation des risques, afin que l'intégrité scientifique du processus soit maintenue.[7]

15) La politique d'évaluation des risques doit être déterminée par les responsables de la gestion des risques préalablement à l'évaluation des risques, en consultation avec les évaluateurs des risques et toutes les autres parties intéressées, de façon à ce que le processus d'évaluation des risques soit systématique, complet et transparent.

16) Le mandat donné par les responsables de la gestion des risques aux responsables de l'évaluation des risques doit être aussi clair que possible.

17) En cas de nécessité, les responsables de la gestion des risques doivent demander aux responsables de l'évaluation des risques d'évaluer les possibilités de réduction des risques découlant des différentes options de gestion des risques.

EVALUATION DES RISQUES*

18) Les aspects des décisions et recommandations du Codex liés à la santé et à l'innocuité doivent se fonder sur une évaluation des risques, en fonction des circonstances.

19) La portée et le but d'une évaluation des risques particulière en cours de réalisation doivent être clairement indiqués. La forme des analyses, conclusions et alternatives, issues de l'évaluation des risques doit être définie.

20) Les experts chargés de l'évaluation des risques doivent être choisis de manière transparente en fonction de leur compétence et de leur indépendance vis-à-vis des intérêts en jeu. Les procédures utilisées pour sélectionner ces experts doivent être documentées et impliquer notamment une déclaration publique de tout conflit d'intérêts potentiel. Cette déclaration doit aussi détailler leur expérience et leur domaine de compétence individuels. Dans la mesure du possible, les comités et consultations d'experts doivent s'assurer de la participation effective d'experts de toutes les parties du monde, notamment ceux des pays en développement.

21) L'évaluation des risques doit être conduite en accord avec *les Déclarations de principes sur le rôle de l'évaluation des risques en matière de salubrité des aliments* et intégrer les quatre étapes du processus d'évaluation des risques, c'est-à-dire l'identification des dangers, la caractérisation des dangers, l'évaluation de l'exposition et la caractérisation des risques.

22) L'évaluation des risques doit, dans la mesure la plus large possible, utiliser les données quantitatives disponibles et les résultats de l'évaluation des risques doivent être présentées sous une forme aisément

[6] Position adoptée par la 24ème session de la Commission (ALINORM 01/41, par. 81-83)

[7] Ce paragraphe est aussi inclus dans les définitions (Annexe 1) et pourrait être supprimé par la suite si les définitions sont retenues dans le texte final

* Il est fait référence aux *Déclarations de principe concernant le rôle de l'évaluation des risques en matière de salubrité des aliments*.

compréhensible et utile. L'évaluation des risques peut également prendre en compte des informations qualitatives.

23) L'évaluation des risques doit prendre en compte toutes les données scientifiques disponibles et les processus de production, d'entreposage et de manipulation concernés tout au long de la chaîne alimentaire, y compris les pratiques traditionnelles, les méthodes d'analyse, d'échantillonnage et d'inspection et la prévalence d'effets négatifs spécifiques sur la santé.

24) Reconnaissant que la production alimentaire dans les pays en développement est en grande partie réalisée par l'intermédiaire de petites et moyennes entreprises, l'évaluation des risques doit rechercher et prendre en compte des données provenant de différentes parties du monde, notamment des pays en développement. Ces données doivent comprendre en particulier des données de surveillance épidémiologique et des études d'exposition.

25) L'évaluation des risques doit tenir compte de la variabilité et des autres sources d'incertitude à chaque stade du processus d'évaluation des risques, de manière explicite.

26) Toutes les contraintes, incertitudes et hypothèses, ainsi que leur incidence sur l'évaluation des risques, doivent être documentées de façon transparente, y compris les contraintes susceptibles d'agir sur la qualité de l'estimation des risques. L'expression de l'incertitude ou de la variabilité dans le résultat de l'estimation des risques peut être qualitative ou quantitative mais doit être quantifiée dans la mesure où cela est scientifiquement réalisable.

27) Les évaluations des risques doivent s'appuyer sur des scénarios d'exposition réalistes, et l'examen des différentes situations doit être défini par la politique d'évaluation des risques. Elles doivent prendre en considération les groupes de population sensibles et à haut risque. Les effets négatifs aigus, chroniques (notamment à long terme), cumulatifs et/ou combinés sur la santé doivent être pris en compte lors de l'évaluation des risques, le cas échéant.

28) Les conclusions de l'évaluation des risques, et notamment, lorsqu'il est disponible, le résultat de l'estimation des risques, doivent être communiquées aux responsables de la gestion des risques sous une forme aisément compréhensible. Elles doivent faire état de toutes les contraintes, incertitudes et hypothèses et de leur incidence sur l'évaluation des risques, ainsi que des opinions minoritaires. La résolution du problème de l'incidence de l'incertitude sur la décision de gestion des risques est une responsabilité qui incombe au responsable de la gestion des risques, et non au responsable de leur évaluation.

29) Afin d'assurer la transparence de l'évaluation des risques, un rapport formalisé, comprenant un résumé, doit être élaboré et mis à la disposition des autres responsables de l'évaluation des risques et parties intéressées, de manière à ce qu'ils puissent examiner l'évaluation.

GESTION DES RISQUES

30) Les décisions et les recommandations du Codex en matière de gestion des risques doivent viser essentiellement à protéger la santé des consommateurs, tout en tenant compte de la promotion des pratiques loyales dans le commerce des denrées alimentaires. Des différences injustifiées quant au niveau de protection du consommateur doivent être évitées, lorsqu'elles se réfèrent à des risques similaires dans des situations différentes.

31) La gestion des risques doit suivre une démarche structurée, incluant l'appréciation des risques l'évaluation des options de gestion des risques, le suivi et le réexamen des décisions prises. Les décisions doivent être fondées sur une évaluation des risques adaptée aux circonstances et prendre en compte, le cas échéant, d'autres facteurs légitimes ayant une importance pour la protection de la santé du consommateur et la promotion de pratiques loyales dans le commerce des denrées alimentaires, conformément aux *Critères pour la prise en considération des autres facteurs mentionnés dans la deuxième Déclaration de principe*[8].

32) Pour parvenir à des objectifs souhaités, la gestion des risques doit prendre en compte les processus de production, d'entreposage et de distribution concernés, tout au long de la chaîne alimentaire, les méthodes d'analyse, d'échantillonnage et d'inspection et la prévalence des effets adverses pour la santé, spécifiques.

33) Le processus de gestion des risques doit être transparent, cohérent et parfaitement documenté. Les décisions et recommandations du Codex en matière de gestion des risques doivent être documentées et, si besoin est, clairement identifiées dans les différentes normes et textes apparentés du Codex de manière à faciliter une compréhension plus large du processus de gestion des risques par toutes les parties intéressées.

[8] Ces critères ont été adoptés par la 24ème session de la Commission du Codex (voir annexe 2)

34) Les options de gestion des risques doivent être évaluées en fonction du champ d'application et de la finalité de l'analyse des risques et du niveau de protection du consommateur qu'elles permettent d'atteindre. L'option de ne pas agir doit aussi être examinée.

35) Le résultat du processus d'évaluation des risques doit être associé à l'évaluation des options disponibles en matière de gestion des risques afin de prendre une décision sur la gestion du risque. Lors de l'adoption de cette décision, la protection de la santé des consommateurs doit être la considération primordiale, les autres facteurs légitimes étant pris en compte comme il convient[9].

36) supprimé

37) Afin d'éviter de créer des obstacles injustifiés au commerce, la gestion des risques doit assurer la transparence et la cohérence du processus de prise de décision dans tous les cas. L'examen de toute la gamme d'options de gestion de risque prend en compte dans la mesure du possible, une évaluation de leurs avantages et inconvénients potentiels. Lors du choix parmi les différentes options de gestion de risque qui présentent la même efficacité au regard de la protection de la santé des consommateurs, la Commission doit choisir celles qui, si elles étaient adoptées par les pays membres, ne seraient pas plus restrictives que nécessaire pour le commerce.

38) La gestion des risques doit prendre en compte les conséquences économiques et la possibilité de mise en œuvre des options de gestion des risques, en particulier dans les pays en développement. La gestion des risques doit également reconnaître la nécessité de faire preuve de souplesse dans l'établissement des normes, lignes directrices et autres recommandations, de manière cohérente avec la protection de la santé des consommateurs.

39) La gestion des risques doit être un processus continu prenant en compte toutes les nouvelles données qui apparaissent dans l'évaluation et le réexamen des décisions de gestion des risques. Les normes alimentaires et textes apparentés doivent être réexaminés régulièrement et actualisés si nécessaire pour refléter les nouvelles connaissances scientifiques et autres informations afférentes à l'analyse des risques.

40) Déplacé au paragraphe 10.

COMMUNICATION SUR LES RISQUES

41)L'analyse des risques doit donner lieu à une communication claire, interactive et documentée entre les responsables de l'évaluation des risques (comités et consultations d'experts) et les responsables de la gestion des risques (Commission du Codex et ses organes subsidiaires), et à une communication avec les Etats membres et les autres parties intéressées pour tous les aspects du processus.

41bis) La communication sur les risques est plus que la diffusion de l'information. Sa fonction principale est d'assurer que toutes information et opinion essentielles à une gestion des risques effective sont prises en compte dans le processus de prise de décision. Un échange d'informations permanent entre toutes les parties intéressées est une partie intégrante du processus d'analyses des risques.

42) Une fonction majeure de la communication sur les risques consiste à établir un processus permettant l'échange, entre toutes les parties intéressées, des informations et opinions indispensables à une évaluation et à une gestion des risques effective.

43) La communication sur les risques avec les parties intéressées doit notamment expliquer de façon transparente la politique d'évaluation des risques, et l'évaluation des risques, notamment les incertitudes. Il convient aussi d'expliquer clairement la nécessité de prendre des normes ou des textes apparentés spécifiques, ainsi que les procédures suivies pour les définir, indiquant comment l'incertitude a été traitée. Elle doit faire état de toutes les contraintes, incertitudes et hypothèses et de leur incidence sur le processus d'analyse des risques, ainsi que des opinions minoritaires.

43bis) Dans ce document, les lignes directrices sur la communication sur les risques s'adressent à tous ceux impliqués dans la conduite de l'analyse des risques dans le cadre du Codex. Cependant, il est également important que ces travaux soient rendus aussi transparents et accessibles que possible aux non-spécialistes et à ceux qui ne sont pas directement engagés dans le processus, notamment les consommateurs, ceux impliqués dans la production, la transformation et la distribution d'aliments et leurs organisations représentatives et les autres parties intéressées.

Les objectifs de la communication sur les risques sont de :

[9] Consultation mixte d'experts FAO/OMS sur la gestion des risques et l'innocuité des aliments. Dans le cadre du Codex, l'élément "application" n'entre pas en ligne de compte.

i) promouvoir la prise de conscience et la compréhension des enjeux spécifiques pris en compte pendant le processus d'analyses des risques ;

ii) promouvoir la cohérence et la transparence dans la formulation des options/recommandations de gestion des risques ;

iii) fournir une base solide pour la compréhension des décisions de gestion des risques proposées ;

iv) améliorer l'efficacité et l'efficience du processus d'analyse des risques ;

v) renforcer les relations de travail entre les participants ;

vi) favoriser la compréhension du public afin de renforcer la confiance dans la sécurité de l'offre alimentaire ;

vii) promouvoir l'implication appropriée de toutes les parties intéressées et

viii) échanger des informations relatives aux préoccupations des parties intéressées sur les risques associées aux aliments.

44) Une stratégie de communication sur les risques doit être anticipative et assortie d'un programme précisant la façon dont les informations et les opinions doivent être échangées et considérées dans le processus d'analyse des risques.

45) **supprimé**

ANNEXE 1
DEFINITIONS

Définitions incluses dans le Manuel de Procédure

Sans changement

Autres définitions

Politique d'évaluation des risques : Elaboration de lignes directrices documentées sur des choix d'orientations et d'avis associés ainsi que sur leur application à des points de décision appropriés au cours de l'évaluation des risques, afin que l'intégrité scientifique du processus soit maintenue.

Appréciation des risques[10]

- identification d'un problème de sécurité alimentaire
- établissement d'un profil de risque
- classement des dangers pour définir les priorités d'évaluation des risques et de gestion des risques
- définition d'une politique d'évaluation des risques pour la conduite de l'évaluation de risques
- demande d'une évaluation des risques
- examen des résultats de l'évaluation des risques

Etablissement d'un profil de risques
Description du problème de salubrité des aliments et de son contexte[11]**.**

ANNEXE 2

Sans changement

[10] Consultation mixte d'experts FAO/OMS sur la gestion des risques et l'innocuité des aliments (section 6. Cadre de la gestion des risques)
[11] Définition proposée par la consultation mixte FAO/OMS sur la gestion des risques et l'innocuité des aliments

ANNEXE 2

AVANT-PROJET DE PRINCIPES DE TRAVAIL POUR L'ANALYSE DES RISQUES DESTINES A ETRE APPLIQUE DANS LE CADRE DU CODEX[12].

(A l'étape 3 de la Procédure)

CHAMP D'APPLICATION

1) Les principes pour l'analyse des risques sont destinés à être appliqués dans le cadre du Codex Alimentarius

2) Le but principal de l'analyse des risques dans le cadre de la Commission du Codex Alimentarius est de protéger la santé des consommateurs, tout en tenant compte de la promotion des pratiques loyales dans le commerce des denrées alimentaires.

3) L'objectif des Principes de travail est de fournir des lignes directrices à la Commission du Codex Alimentarius ainsi qu'aux comités et aux consultations mixtes d'experts FAO/OMS de façon que les aspects sanitaires et d'innocuité des aliments dans les normes et textes apparentés du Codex soient basés sur l'analyse des risques

4) Dans le cadre de la Commission du Codex Alimentarius et de ses procédures, la responsabilité de donner des avis en matière de gestion des risques incombe à la Commission et à ses organes subsidiaires, tandis que la responsabilité de l'évaluation des risques incombe normalement aux Comités et aux Consultations mixtes d'experts FAO/OMS.

ANALYSE DES RISQUES - ASPECTS GENERAUX

5) Le processus d'analyse des risques utilisé dans le Codex doit être :

- appliqué avec cohérence
- ouvert, transparent et documenté
- conduit en accord avec, d'une part, les *Déclarations de principes concernant le rôle de la science dans la prise de décision du Codex et les autres facteurs à prendre en considération* et, d'autre part, *les Déclarations de principes sur le rôle de l'évaluation des risques en matière de salubrité des aliments*.

6) Le processus d'analyse des risques doit suivre une démarche structurée comprenant les trois volets, distincts mais intimement liés, de l'analyse des risques (l'évaluation des risques, la gestion des risques et la communication sur les risques), tels que définis par la Commission du Codex Alimentarius[13], chacun de ces volets faisant partie intégrante de l'ensemble du processus d'analyse des risques.

7) Les trois volets de l'analyse des risques doivent être complètement et systématiquement documentés de manière transparente. Tout en respectant le souci légitime de préserver le caractère confidentiel[14] des documents, la documentation doit être accessible à toutes les parties intéressées et leurs organisations représentatives[15].

8) Une communication et une consultation effectives avec toutes les parties intéressées doivent être assurées tout au long du processus d'analyse des risques.

9) Les trois volets de l'analyse des risques doivent être mis en œuvre dans un cadre global au profit de la gestion des risques pour la santé humaine liés aux aliments.

10) Il doit exister une séparation fonctionnelle entre l'évaluation des risques et la gestion des risques, afin de garantir l'intégrité scientifique de l'évaluation des risques, d'éviter la confusion concernant les fonctions que doivent remplir les responsables de l'évaluation des risques et de la gestion des risques et d'atténuer tout conflit d'intérêts. Cependant, il est reconnu que l'analyse des risques est un processus itératif, et l'interaction

[12] Ces principes sont destinés à être incorporés dans le manuel de procédure du Codex. Ces principes ne préjugent pas des principes pour l'analyse des risques destinés à être appliqués par les gouvernements qui feront l'objet de lignes directrices séparées.

[13] Définitions des termes relatifs à l'innocuité des aliments, utilisés en analyse des risques ; manuel de procédure de la Commission du Codex Alimentarius, onzième édition page 51.

[14] Une définition devrait être ajoutée ultérieurement dans le glossaire en annexe.

[15] Par parties intéressées, on entend dans ce document, les responsables de l'évaluation du risque, les responsables de la gestion du risque, les consommateurs et leurs organisations représentatives, l'industrie, les milieux universitaires et les autres parties intéressées.

entre les responsables de la gestion des risques et les responsables de l'évaluation des risques est essentielle pour une application concrète.

11) Lorsqu'on a la preuve qu'un risque existe pour la santé humaine, mais que les données scientifiques sont insuffisantes ou incomplètes, la Commission ne devrait pas élaborer de norme, mais devrait envisager d'élaborer un texte apparenté, par exemple un code d'usages, à condition que ce texte s'appuie sur les preuves scientifiques disponibles.[16]

12) La précaution est un élément inhérent au processus d'analyse des risques. De nombreuses sources d'incertitude existent dans le processus d'évaluation et de gestion des risques, quant aux dangers pour la santé humaine liés aux aliments. Le degré d'incertitude et de variabilité dans l'information scientifique disponible doit être explicitement considéré dans le processus d'analyse des risques. Lorsqu'il y a des preuves suffisantes pour permettre au Codex de procéder à l'élaboration d'une norme ou d'un texte apparenté, les hypothèses utilisées pour l'évaluation des risques et les options de gestion des risques retenues devraient refléter le degré d'incertitude scientifique et les caractéristiques des dangers.

13) Les besoins et les situations des pays en développement doivent être spécifiquement identifiés et pris en compte par les organes responsables au cours des différentes étapes du processus d'analyse des risques.

POLITIQUE D'EVALUATION DES RISQUES

14) La détermination d'une politique d'évaluation des risques doit être un élément spécifique de la gestion des risques.

15) La politique d'évaluation des risques consiste en l'élaboration de lignes directrices documentées sur des choix d'orientations et d'avis associés ainsi que sur leur application à des points de décision appropriés au cours de l'évaluation des risques, afin que l'intégrité scientifique du processus soit maintenue.[17]

16) La politique d'évaluation des risques doit être déterminée par les responsables de la gestion des risques préalablement à l'évaluation des risques, en consultation avec les évaluateurs des risques et toutes les autres parties intéressées, de façon à ce que le processus d'évaluation des risques soit systématique, complet et transparent.

17) Le mandat donné par les responsables de la gestion des risques aux responsables de l'évaluation des risques doit être aussi clair que possible.

18) En cas de nécessité, les responsables de la gestion des risques doivent demander aux responsables de l'évaluation des risques d'évaluer les possibilités de réduction des risques découlant des différentes options de gestion des risques.

EVALUATION DES RISQUES*

19) Les aspects des décisions et recommandations du Codex liés à la santé et à l'innocuité doivent se fonder sur une évaluation des risques, en fonction des circonstances.

20) La portée et le but d'une évaluation des risques particulière en cours de réalisation doivent être clairement indiqués. La forme des analyses, conclusions et alternatives, issues de l'évaluation des risques doit être définie.

21) Les experts chargés de l'évaluation des risques doivent être choisis de manière transparente en fonction de leur compétence et de leur indépendance vis-à-vis des intérêts en jeu. Les procédures utilisées pour sélectionner ces experts doivent être documentées et impliquer notamment une déclaration publique de tout conflit d'intérêts potentiel. Cette déclaration doit aussi détailler leur expérience et leur domaine de compétence individuels. Dans la mesure du possible, les comités et consultations d'experts doivent s'assurer de la participation effective d'experts de toutes les parties du monde, notamment ceux des pays en développement.

22) L'évaluation des risques doit être conduite en accord avec *les Déclarations de principes sur le rôle de l'évaluation des risques en matière de salubrité des aliments* et intégrer les quatre étapes du processus d'évaluation des risques, c'est-à-dire l'identification des dangers, la caractérisation des dangers, l'évaluation de l'exposition et la caractérisation des risques.

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[16] Position adoptée par la 24ème session de la Commission (ALINORM 01/41, par. 81-83)

[17] Ce paragraphe est aussi inclus dans les définitions (Annexe 1) et pourrait être supprimé par la suite si les définitions sont retenues dans le texte final

* Il est fait référence aux *Déclarations de principe concernant le rôle de l'évaluation des risques en matière de salubrité des aliments*.

23) L'évaluation des risques doit, dans la mesure la plus large possible, utiliser les données quantitatives disponibles et les résultats de l'évaluation des risques doivent être présentées sous une forme aisément compréhensible et utile. L'évaluation des risques peut également prendre en compte des informations qualitatives.

24) L'évaluation des risques doit prendre en compte toutes les données scientifiques disponibles et les processus de production, d'entreposage et de manipulation concernés tout au long de la chaîne alimentaire, y compris les pratiques traditionnelles, les méthodes d'analyse, d'échantillonnage et d'inspection et la prévalence d'effets négatifs spécifiques sur la santé.

25) Reconnaissant que la production alimentaire dans les pays en développement est en grande partie réalisée par l'intermédiaire de petites et moyennes entreprises, l'évaluation des risques doit rechercher et prendre en compte des données provenant de différentes parties du monde, notamment des pays en développement. Ces données doivent comprendre en particulier des données de surveillance épidémiologique et des études d'exposition.

26) L'évaluation des risques doit tenir compte de la variabilité et des autres sources d'incertitude à chaque stade du processus d'évaluation des risques, de manière explicite.

27) Toutes les contraintes, incertitudes et hypothèses, ainsi que leur incidence sur l'évaluation des risques, doivent être documentées de façon transparente, y compris les contraintes susceptibles d'agir sur la qualité de l'estimation des risques. L'expression de l'incertitude ou de la variabilité dans le résultat de l'estimation des risques peut être qualitative ou quantitative mais doit être quantifiée dans la mesure où cela est scientifiquement réalisable.

28) Les évaluations des risques doivent s'appuyer sur des scénarios d'exposition réalistes, et l'examen des différentes situations doit être défini par la politique d'évaluation des risques. Elles doivent prendre en considération les groupes de population sensibles et à haut risque. Les effets négatifs aigus, chroniques (notamment à long terme), cumulatifs et/ou combinés sur la santé doivent être pris en compte lors de l'évaluation des risques, le cas échéant.

29) Les conclusions de l'évaluation des risques, et notamment, lorsqu'il est disponible, le résultat de l'estimation des risques, doivent être communiquées aux responsables de la gestion des risques sous une forme aisément compréhensible. Elles doivent faire état de toutes les contraintes, incertitudes et hypothèses et de leur incidence sur l'évaluation des risques, ainsi que des opinions minoritaires. La résolution du problème de l'incidence de l'incertitude sur la décision de gestion des risques est une responsabilité qui incombe au responsable de la gestion des risques, et non au responsable de leur évaluation.

30) Afin d'assurer la transparence de l'évaluation des risques, un rapport formalisé, comprenant un résumé, doit être élaboré et mis à la disposition des autres responsables de l'évaluation des risques et parties intéressées, de manière à ce qu'ils puissent examiner l'évaluation.

GESTION DES RISQUES

31) Les décisions et les recommandations du Codex en matière de gestion des risques doivent viser essentiellement à protéger la santé des consommateurs, tout en tenant compte de la promotion des pratiques loyales dans le commerce des denrées alimentaires. Des différences injustifiées quant au niveau de protection du consommateur doivent être évitées, lorsqu'elles se réfèrent à des risques similaires dans des situations différentes.

32) La gestion des risques doit suivre une démarche structurée, incluant l'appréciation des risques l'évaluation des options de gestion des risques, le suivi et le réexamen des décisions prises. Les décisions doivent être fondées sur une évaluation des risques adaptée aux circonstances et prendre en compte, le cas échéant, d'autres facteurs légitimes ayant une importance pour la protection de la santé du consommateur et la promotion de pratiques loyales dans le commerce des denrées alimentaires, conformément aux *Critères pour la prise en considération des autres facteurs mentionnés dans la deuxième Déclaration de principe*[18].

33) Pour parvenir à des objectifs souhaités, la gestion des risques doit prendre en compte les processus de production, d'entreposage et de distribution concernés, tout au long de la chaîne alimentaire, les méthodes d'analyse, d'échantillonnage et d'inspection et la prévalence des effets adverses pour la santé, spécifiques.

34) Le processus de gestion des risques doit être transparent, cohérent et parfaitement documenté. Les décisions et recommandations du Codex en matière de gestion des risques doivent être documentées et, si

[18] Ces critères ont été adoptés par la 24ème session de la Commission du Codex (voir annexe 2)

besoin est, clairement identifiées dans les différentes normes et textes apparentés du Codex de manière à faciliter une compréhension plus large du processus de gestion des risques par toutes les parties intéressées.

35) Les options de gestion des risques doivent être évaluées en fonction du champ d'application et de la finalité de l'analyse des risques et du niveau de protection du consommateur qu'elles permettent d'atteindre. L'option de ne pas agir doit aussi être examinée.

36) Le résultat du processus d'évaluation des risques doit être associé à l'évaluation des options disponibles en matière de gestion des risques afin de prendre une décision sur la gestion du risque. Lors de l'adoption de cette décision, la protection de la santé des consommateurs doit être la considération primordiale, les autres facteurs légitimes étant pris en compte comme il convient[19].

37) Afin d'éviter de créer des obstacles injustifiés au commerce, la gestion des risques doit assurer la transparence et la cohérence du processus de prise de décision dans tous les cas. L'examen de toute la gamme d'options de gestion de risque prend en compte dans la mesure du possible, une évaluation de leurs avantages et inconvénients potentiels. Lors du choix parmi les différentes options de gestion de risque qui présentent la même efficacité au regard de la protection de la santé des consommateurs, la Commission doit choisir celles qui, si elles étaient adoptées par les pays membres, ne seraient pas plus restrictives que nécessaire pour le commerce.

38) La gestion des risques doit prendre en compte les conséquences économiques et la possibilité de mise en œuvre des options de gestion des risques, en particulier dans les pays en développement. La gestion des risques doit également reconnaître la nécessité de faire preuve de souplesse dans l'établissement des normes, lignes directrices et autres recommandations, de manière cohérente avec la protection de la santé des consommateurs.

39) La gestion des risques doit être un processus continu prenant en compte toutes les nouvelles données qui apparaissent dans l'évaluation et le réexamen des décisions de gestion des risques. Les normes alimentaires et textes apparentés doivent être réexaminés régulièrement et actualisés si nécessaire pour refléter les nouvelles connaissances scientifiques et autres informations afférentes à l'analyse des risques.

COMMUNICATION SUR LES RISQUES

40) L'analyse des risques doit donner lieu à une communication claire, interactive et documentée entre les responsables de l'évaluation des risques (comités et consultations d'experts) et les responsables de la gestion des risques (Commission du Codex et ses organes subsidiaires), et à une communication avec les Etats membres et les autres parties intéressées pour tous les aspects du processus.

41) La communication sur les risques est plus que la diffusion de l'information. Sa fonction principale est d'assurer que toutes information et opinion essentielles à une gestion des risques effective sont prises en compte dans le processus de prise de décision. Un échange d'informations permanent entre toutes les parties intéressées est une partie intégrante du processus d'analyses des risques.

42) Une fonction majeure de la communication sur les risques consiste à établir un processus permettant l'échange, entre toutes les parties intéressées, des informations et opinions indispensables à une évaluation et à une gestion des risques effective.

43) La communication sur les risques avec les parties intéressées doit notamment expliquer de façon transparente la politique d'évaluation des risques, et l'évaluation des risques, notamment les incertitudes. Il convient aussi d'expliquer clairement la nécessité de prendre des normes ou des textes apparentés spécifiques, ainsi que les procédures suivies pour les définir, indiquant comment l'incertitude a été traitée. Elle doit faire état de toutes les contraintes, incertitudes et hypothèses et de leur incidence sur le processus d'analyse des risques, ainsi que des opinions minoritaires.

44) Dans ce document, les lignes directrices sur la communication sur les risques s'adressent à tous ceux impliqués dans la conduite de l'analyse des risques dans le cadre du Codex. Cependant, il est également important que ces travaux soient rendus aussi transparents et accessibles que possible aux non-spécialistes et à ceux qui ne sont pas directement engagés dans le processus, notamment les consommateurs, ceux impliqués dans la production, la transformation et la distribution d'aliments et leurs organisations représentatives et les autres parties intéressées.

Les objectifs de la communication sur les risques sont de :

[19] Consultation mixte d'experts FAO/OMS sur la gestion des risques et l'innocuité des aliments. Dans le cadre du Codex, l'élément "application" n'entre pas en ligne de compte.

ix) promouvoir la prise de conscience et la compréhension des enjeux spécifiques pris en compte pendant le processus d'analyses des risques ;

x) promouvoir la cohérence et la transparence dans la formulation des options/recommandations de gestion des risques ;

xi) fournir une base solide pour la compréhension des décisions de gestion des risques proposées ;

xii) améliorer l'efficacité et l'efficience du processus d'analyse des risques ;

xiii) renforcer les relations de travail entre les participants ;

xiv) favoriser la compréhension du public afin de renforcer la confiance dans la sécurité de l'offre alimentaire ;

xv) promouvoir l'implication appropriée de toutes les parties intéressées et

xvi) échanger des informations relatives aux préoccupations des parties intéressées sur les risques associées aux aliments.

45) Une stratégie de communication sur les risques doit être anticipative et assortie d'un programme précisant la façon dont les informations et les opinions doivent être échangées et considérées dans le processus d'analyse des risques.

ANNEXE 1
DEFINITIONS

Définitions incluses dans le Manuel de Procédure

Danger: Agent biologique, chimique ou physique présent dans un aliment, ou état de cet aliment pouvant avoir un effet adverse pour la santé.

Risque: Fonction de la probabilité d'un effet adverse pour la santé et de sa gravité, du fait de la présence d'un (de) danger(s) dans un aliment.

Analyse des risques: Processus comportant trois volets: évaluation des risques, gestion des risques et communication sur les risques.

Evaluation des risques: Processus à base scientifique comprenant les étapes suivantes: i) identification des dangers; ii) caractérisation des dangers; iii) évaluation de l'exposition et iv) caractérisation des risques.

Identification des dangers**:** Identification des agents biologiques, chimiques et physiques susceptibles de provoquer des effets adverses pour la santé et qui peuvent être présents dans un aliment donné ou un groupe d'aliments.

Caractérisation des dangers: Evaluation qualitative et/ou quantitative de la nature des effets adverses pour la santé associés aux agents biologiques, chimiques et physiques qui peuvent être présents dans un aliment. Pour les agents chimiques, la relation dose/réponse doit être évaluée. Pour les agents biologiques ou physiques, une telle évaluation doit être effectuée si les données sont disponibles.

Evaluation de la relation dose-réponse: Détermination de la relation entre le degré d'exposition (dose) à un agent chimique, biologique ou physique et la gravité et/ou la fréquence des effets adverses qui en résultent pour la santé (réponse).

Evaluation de l'exposition: Evaluation qualitative et/ou quantitative de l'ingestion probable d'agents biologiques, chimiques et physiques par le biais des aliments, ainsi que par suite de l'exposition à d'autres sources, le cas échéant.

Caractérisation des risques: Estimation qualitative et/ou quantitative, compte tenu des incertitudes inhérentes à l'évaluation, de la probabilité de la fréquence et de la gravité des effets adverses connus ou potentiels sur la santé susceptibles de se produire dans une population donnée, sur la base de l'identification des dangers, de la caractérisation des dangers et de l'évaluation de l'exposition.

Communication sur les risque : Echange interactif, tout au long du processus d'analyse des risques, d'informations et d'opinions sur les risques, les facteurs liés aux risques et les perceptions des risques, entre les responsables de leur évaluation et de leur gestion, les consommateurs, l'industrie, les milieux universitaires et les autres parties intéressées, et notamment l'explication des résultats de l'évaluation des risques et des fondements des décisions prises en matière de gestion des risques.

Gestion des risques : Processus, distinct de l'évaluation des risques, consistant à mettre en balance les différentes politiques possibles en consultation avec toutes les parties intéressées, en tenant compte de l'évaluation des risques et d'autres facteurs ayant une importance pour la protection de la santé des consommateurs et la promotion de pratiques commerciales loyales et, au besoin, à choisir les mesures de prévention et de contrôle appropriées.

Autres définitions

Politique d'évaluation des risques : Elaboration de lignes directrices documentées sur des choix d'orientations et d'avis associés ainsi que sur leur application à des points de décision appropriés au cours de l'évaluation des risques, afin que l'intégrité scientifique du processus soit maintenue.

Appréciation des risques[20]

- identification d'un problème de sécurité alimentaire
- établissement d'un profil de risque
- classement des dangers pour définir les priorités d'évaluation des risques et de gestion des risques
- définition d'une politique d'évaluation des risques pour la conduite de l'évaluation de risques
- demande d'une évaluation des risques

[20] Consultation mixte d'experts FAO/OMS sur la gestion des risques et l'innocuité des aliments (section 6. Cadre de la gestion des risques)

– examen des résultats de l'évaluation des risques

Etablissement d'un profil de risques

Description du problème de salubrité des aliments et de son contexte[21].

[21] Définition proposée par la consultation mixte FAO/OMS sur la gestion des risques et l'innocuité des aliments

ANNEXE 2

DECLARATIONS DE PRINCIPES SUR LE ROLE DE LA SCIENCE DANS LA PRISE DE DECISIONS DU CODEX ET LES AUTRES FACTEURS À PRENDRE EN CONSIDERATION

CRITERES POUR LA PRISE EN CONSIDERATION DES AUTRES FACTEURS MENTIONNES DANS LA DEUXIEME DECLARATION DE PRINCIPE

- En ce qui concerne les questions de santé et de sécurité alimentaire, il importe de se conformer aux Déclarations de principe concernant le rôle de la science et aux Déclarations de principes sur le rôle de l'évaluation des risques en matière de salubrité des aliments;
- D'autres facteurs légitimes entrant en ligne de compte dans la protection de la santé et les pratiques commerciales loyales peuvent être recensés lors du processus de gestion des risques, et les responsables de la gestion des risques devraient indiquer dans quelle mesure ces facteurs influent sur la sélection des options de gestion des risques et sur l'élaboration des normes, directives et textes apparentés;
- L'examen des autres facteurs ne devrait pas porter atteinte aux fondements scientifiques de l'analyse des risques ; dans le cadre de ce processus, il y aurait lieu de respecter la distinction entre évaluation des risques et gestion des risques afin de garantir l'intégrité scientifique de l'évaluation des risques;
- Il faudrait admettre que certaines préoccupations légitimes des gouvernements au moment de l'élaboration de leur législation nationale ne sont pas applicables d'une manière générale, ni valables dans le monde entier [22];
- Dans le cadre du Codex, il ne faudrait tenir compte que des autres facteurs pouvant être acceptés à l'échelle mondiale ou à l'échelle régionale dans le cas des normes et des textes apparentés régionaux;
- L'examen des autres facteurs spécifiques dans l'élaboration des recommandations de la Commission du Codex Alimentarius et de ses organes subsidiaires en matière de gestion des risques devrait être clairement étayé, notamment la justification de leur prise en compte, au cas par cas;
- On peut examiner l'applicabilité des options de gestion des risques en raison de la nature et des exigences particulières des méthodes de production ou de traitement, du transport et du stockage, en particulier dans les pays en développement; les préoccupations liées aux intérêts économiques et aux questions commerciales en général devraient être étayées par des données quantifiables;
- La prise en compte des autres facteurs légitimes dans la gestion des risques ne devrait pas créer d'obstacles injustifiés au commerce[23], il faudrait accorder une attention particulière aux conséquences, pour les pays en développement, de la prise en compte de ces autres facteurs.

[22] Il conviendrait d'éviter de faire la confusion entre la justification des mesures nationales au titre des Accords SPS et OTC et leur validité au niveau international.

[23] Conformément aux principes de l'OMC, et compte tenu des dispositions particulières des accords SPS et OTC

OBSERVATIONS EN REPONSE A LA CL 2001/24-GP
(dans la langue d'origine)

ARGENTINA

ÁMBITO DE APLICACIÓN

1) Los principios para el análisis de riesgos están destinados a ser aplicados en el marco del Codex Alimentarius.
~~2)~~ **El objetivo de los Principios de Aplicación Prácticos es ~~garantizar que los aspectos de inocuidad de alimentos en las normas y textos afines del Codex se basen en el análisis de riesgos [y proporcionar una base objetiva para proteger la salud de los consumidores.]~~** garantizar el fundamento científico-técnico de las normas, directrices y recomendaciones elaboradas por el Codex .

3) El objetivo primordial del análisis de riesgos en la Comisión del Codex Alimentarius es **el de proveer la base científica para la adopción de estándares internacionales que protejan la salud humana , evitando de esta manera el establecimiento de restricciones injustificadas al comercio de alimentos**. ~~y al mismo tiempo garanticen prácticas equitativas en el comercio de alimentos~~.

4) En el marco de la Comisión del Codex Alimentarius y de sus procedimientos, la responsabilidad de dar un asesoramiento sobre la gestión de los riesgos incumbe a la Comisión y a sus órganos auxiliares, mientras que la responsabilidad de la evaluación de riesgos incumbe normalmente a los Comités y las Consultas Mixtas de Expertos de la FAO y la OMS.

ANÁLISIS DE RIESGOS – ASPECTOS GENERALES
5) El proceso de análisis de riesgos utilizado en el Codex tiene que ser
- **coherente**
- **abierto y transparente,**
- **coherente con las *Declaraciones de principios referentes a la función que desempeña la ciencia en el proceso decisorio del Codex y la medida en que se tienen en cuenta otros factores***
- Objetivo

6) El proceso de análisis de riesgos debe ajustarse a un método estructurado que comprenda los tres componentes del análisis de riesgos (evaluación de riesgos, gestión de riesgos y comunicación de riesgos); cada uno de estos tres componentes formando parte integrante del proceso de análisis de riesgos en su conjunto.
7) Los tres componentes del análisis de riesgos deben estar plena y sistemáticamente documentados de manera transparente. Sin perjuicio del respeto al legitimo interés por preservar la confidencialidad, la documentación podrá ser objeto del escrutinio de los consumidores**, los productores** y las organizaciones que los representan, así como de otras partes interesadas.

8) Se deben garantizar una comunicación y una consulta eficaces a lo largo de todo el proceso de análisis de riesgos.

9) Los tres componentes del análisis de riesgos deben aplicarse en un marco global de estrategias y políticas de gestión de riesgos. Debe existir una separación de funciones entre la evaluación de riesgos y la gestión de riesgos, a fin de garantizar la integridad científica de la evaluación de riesgos, de evitar la confusión y atenuar cualquier conflicto de intereses sobre las funciones que pertenecen a los encargados de la evaluación de riesgos y los encargados de la gestión de riesgos. No obstante, se admite que el análisis de riesgos es un proceso interactivo **y que, para una aplicación práctica, es esencial que exista una interacción entre los encargados de la gestión de riesgos y los encargados de la evaluación de riesgos.**

~~10) [La precaución es un elemento esencial del análisis de riesgos. Es especialmente importante cuando las pruebas científicas son insuficientes y los efectos perjudiciales para la salud difíciles de evaluar. La precaución debe ejercerse empleando hipótesis adecuadas en la evaluación de riesgos y la selección de opciones de gestión de riesgos que reflejen la confianza en la información científicas disponible.]~~

~~11) [En el proceso de evaluación de riesgos de peligros para la salud humana trasmitidos por los alimentos existen muchas causas de incertidumbre. En el proceso de análisis de riesgos debería tenerse en cuenta expresamente el grado de incertidumbre y variabilidad de la información científica disponible. Conforme aumenta el grado de incertidumbre científica, las hipótesis utilizadas para la evaluación de los riesgos y las opciones de gestión de riesgos seleccionadas deberían ser más cautelosas y prudentes.]~~

12) La precaución acompaña el proceso de evaluación del riesgo así como de la gestión del mismo, sin perjuicio de lo cual, tiene un alcance diferente en cada una de estas etapas del análisis.

La precaución aplicada por los científicos-técnicos encargados de la evaluación del riesgo consiste en la diligencia/cautela que todo técnico debe aplicar en su trabajo. Es un deber de diligencia que no se relaciona con la suficiencia o insuficiencia de evidencia científica, sino con el cuidado y la cautela que los técnicos deben tener en el desarrollo de sus investigaciones.

La precaución en la gestión del riesgo ha sido prevista en el Acuerdo sobre la Aplicación de Medidas Sanitarias y Fitosanitarias de la OMC (art. 5.7.) como una excepción cualificada a la obligación de basar las medidas en evidencia científica suficiente. La misma es aplicable cuando, del resultado de la evaluación del riesgo surja evidencia científica de la existencia de un riesgo para la salud y vida de las personas, pero cuyo alcance aún no puede ser precisado con exactitud.
Las medidas adoptadas al amparo del enfoque precautorio son temporarias y, corresponde al país que las aplica, jutificar las razones que motivan su adopción.

13) Las necesidades y situaciones de los países en desarrollo deben ser objeto de una **consideración especial (conforme lo establece el art. 10 SPS)** y han de ser tomados en cuenta por los organismos responsables en las distintas fases del proceso del análisis de riesgos.

política de evaluación de riesgos
14) La determinación de una política de evaluación de riesgos debe ser un componente específico de la gestión de riesgos.

15) La política de evaluación de riesgos consiste en orientaciones documentadas para el juicio científico, las cuales sirven de parámetro para guiar el desarrollo de la evaluación del riesgo. **~~y en las opciones de políticas que han de aplicarse en los centros de decisión apropiados durante la evaluación de riesgos.~~**[24]

16) Para garantizar el carácter sistemático, completo y transparente del proceso de evaluación de riesgos, los encargados de la gestión de riesgos deben establecer la política de evaluación de riesgos preferiblemente con antelación a la evaluación de riesgos, en consulta con los encargados de la evaluación de riesgos y todas las partes interesadas.

17) El mandato encomendado por los encargados de la gestión de riesgos a los encargados de la evaluación de los riesgos debe ser el más claro posible, pudiendo aportarles **~~habida cuenta de~~ las pruebas científicas** que estén a su disposición **~~disponibles~~ y todos los imperativos que influyen en el proceso de evaluación de riesgos.**

18) En caso de necesidad, los encargados de la gestión de riesgos pueden pedir a los encargados de la evaluación de los riesgos que evalúen la posible disminución de los riesgos que resulte de las distintas opciones de gestión de riesgos.

EVALUACIÓN DE RIESGOS*

19) Los aspectos relacionados con la salud y la inocuidad de las decisiones y recomendaciones del Codex deben basarse en una evaluación de riesgos **para la vida y la salud de las personas** ~~apropiada~~ **adecuada** a las circunstancias.

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[24] Este párrafo esta también incluido en las Definiciones (Anexo 1) y se podría suprimir despues si las Definiciones se mantienen en el documento final

* Se refiere a los *Declaraciones de principios referentes a la función que desempeña la ciencia en el proceso decisorio del Codex y la medida en que se tienen en cuenta otros factores*

20) El alcance y el objetivo de una evaluación de riesgos específica se deben enunciar claramente. La forma de los resultados y los otros resultados posibles de la evaluación de riesgos se deberán definir claramente.

21) La selección de los expertos encargados de la evaluación de riesgos debe ser transparente y ha de efectuarse en función de su competencia e independencia con respecto a los intereses involucrados, y los procedimientos utilizados para elegir a esos especialistas se deben documentar, comprendiendo una declaración de posible conflicto de intereses. Esta declaración debe también identificar y detallar su competencia individual y experiencia.

22) La evaluación de riesgos debe ser coherente con las *Declaraciones de principios referentes a la función que desempeña la ciencia en el proceso decisorio del Codex y la medida en que se tienen en cuenta otros factores* y debe comprender las cuatro fases de evaluación de riesgos, es decir, identificación de los peligros, caracterización de los peligros, evaluación de la exposición a los peligros y caracterización de los riesgos.

23) Las evaluaciones de riesgos deben utilizar, ~~en la mayor medida de lo posible,~~ los datos cuantitativos disponibles y las caracterizaciones de riesgos deben presentarse de manera fácilmente comprensible y utilizable. Las evaluaciones de riesgos pueden también tener en cuenta datos cualitativos.

24) La evaluación de riesgos debe tomar en cuenta todos los datos científicos disponibles y las prácticas de producción, almacenamiento y manipulación utilizadas a lo largo de toda la cadena alimentaria, comprendidas las prácticas tradicionales, así como los métodos de análisis, muestreo e inspección, y la incidencia de los efectos perjudiciales específicos para la salud.

~~25) Reconociendo que la producción primaria en los países en desarrollo es obra sobre todo de pequeñas y medianas empresas, la evaluación de riesgos se debe basar en datos procedentes de las distintas partes del mundo, comprendidos los suministrados por los países en desarrollo. Esa información debe comprender en especial datos de control epidemiológico y estudios sobre exposiciones a los riesgos.~~ A fin de garantizar la objetividad en la evaluación del riesgo, la información a ser considerada por los evaluadores deberá comprender los datos de control epidemiológico y exposición al riesgo de todas las regiones exportadoras del mundo.

26) Se deben tomar explícitamente en consideración la variabilidad y otras fuentes de incertidumbre en cada etapa del proceso de evaluación de riesgos.

27) Cualquier imperativo, incertidumbre e hipótesis, así como su repercusión en la evaluación de riesgos se deben documentar con transparencia, comprendidos los imperativos que puedan tener repercusiones en la calidad de la estimación de los riesgos. La expresión de la incertidumbre o de la variabilidad en la estimación de los riesgos podrá ser cualitativa o cuantitativa.

28) Las evaluaciones de los riesgos deben basarse en escenarios de exposición realistas y el examen de las distintas situaciones se debe definir en función de la política de evaluación de riesgos. ~~Se deben tomar en consideración los grupos de población propensos a riesgos o de alto riesgo~~. Cuando se efectúe la evaluación de los riesgos, se deben tomar en cuenta los efectos perjudiciales agudos, crónicos (comprendidos los efectos a largo plazo), acumulativos y/o combinados.

29) Las conclusiones de la evaluación de riesgos se deben comunicar a los encargados de la gestión de riesgos de forma fácilmente comprensible. La cuestión de resolver la incidencia de la incertidumbre en la decisión de gestión de riesgos no incumbe al encargado de la evaluación de los riesgos, sino al encargado de la gestión de riesgos.

30) Para garantizar la transparencia de la evaluación de riesgos, se debe preparar un documento en debida forma con un resumen, y se ha de poner a disposición de los demás encargados de la evaluación riesgos, así como de las partes interesadas, a fin de que puedan examinar la evaluación. En ese documento se deben indicar todos los imperativos, incertidumbres e hipótesis, así como su repercusión en la evaluación de los riesgos, y se deben señalar también las opiniones minoritarias.

GESTIÓN DE RIESGOS

31) El objetivo esencial de las decisiones de gestión de riesgos es la protección de la salud **humana** ~~de los consumidores~~. Las decisiones relativas a los niveles de riesgo aceptables tienen que determinarse esencialmente en función de consideraciones sobre la salud humana, y deben evitarse diferencias **arbitrarias o** injustificadas en el nivel de riesgo aceptable,[25] **si tales diferencias tienen por resultado una discriminación o una restricción encubierta al comercio internacional.**

32) La gestión de riesgos debe ajustarse a un método estructurado y basarse en una evaluación de riesgos basada en la ciencia ~~y tener en cuenta otros factores legítimos que atañen a la protección de la salud de los consumidores y al fomento de prácticas equitativas en el comercio de alimentos, cuando corresponda~~. El marco de la gestión de riesgos comprende la apreciación de los riesgos[26], la evaluación de las opciones de gestión de los riesgos, ~~la aplicación de las decisiones de gestión, así como el control~~ y la revisión.[27]

33) En el logro de los resultados acordados, la gestión de riesgos debe tomar en cuenta los procesos pertinentes de producción, almacenamiento y manipulación a lo largo de toda la cadena alimentaria, comprendidas las prácticas tradicionales, así como los métodos de análisis, muestreo e inspección, y la incidencia de los efectos perjudiciales específicos para la salud.

34) El proceso de gestión de riesgos debe ser transparente y coherente y estar completamente documentado. Las decisiones de gestión de riesgos deben documentarse y, cuando proceda, deben estar claramente identificadas en las distintas normas y textos afines del Codex para facilitar un mejor entendimiento del proceso de gestión de riesgos.

35) Las opciones de gestión de riesgos se deberán evaluar/apreciar en función del ámbito y objetivo del análisis de riesgos, la capacidad para conseguir el grado necesario de protección de la salud de la poblacion y el objetivo de no restringir el comercio internacional más de lo necesario para alcanzar dicha protección**. La opción de no tomar acción se debería también considerar, cuando proceda**

36) El resultado del proceso de evaluación de riesgos debe asociarse a la evaluación de las opciones de gestión de que se disponga, a fin de tomar una decisión sobre la gestión del riesgo. Cuando se tome esa decisión, la consideración primordial debe ser la protección de la salud de los consumidores, y los demás factores se han de tomar en consideración según proceda[28], de conformidad con los *Criterios para tomar en cuenta los otros factores mencionados en la 2ª Declaración de Principios*.

~~**37) Deben definirse directrices para incorporar al proceso de gestión de riesgos "otros factores válidos que atañen a la protección de la salud de los consumidores y al fomento de prácticas equitativas en el comercio de alimentos.**~~

38) Para evitar que se ~~pongan~~ establezcan **obstáculos injustificados al comercio, la evaluación de riesgos debe garantizar la transparencia y coherencia del proceso de decisión en todos los casos.** En este sentido, las medidas adoptadas deberán ser proporcionales a los riesgos existentes, con el objetivo de no restringir el comercio más de lo necesario.

La gestión de riesgos debe tomar en consideración las consecuencias económicas y la viabilidad de las opciones de gestión de riesgos en los países en desarrollo. La gestión de riesgos debe reconocer también que es necesaria la flexibilidad en el establecimiento de normas, directrices y otras recomendaciones, ~~en consonancia con la protección de la salud del consumidor.~~

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25 Consulta Mixta de Expertos FAO/OMS sobre la Gestión de Riesgos y la Inocuidad de los Alimentos.

26 Vease Anexo 1 *Definiciones*.

27 Consulta Mixta de Expertos FAO/OMS sobre Gestión de Riesgos y la Inocuidad de los Alimentos. En el marco del Codex, el "componente" de Aplicación no es pertinente.

28 Consulta Mixta de Expertos FAO/OMS sobre la Gestión de Riesgos y la Inocuidad de los Alimentos. La 24ª reunión de la Comisión adoptó *Criterios para tomar en cuenta los otros factores mencionados en la 2ª Declaración de Principios* (véase Anexo 2). Los Criterios tratan de la cuestión de la integración de otros factores en relación con el análisis de riesgos, incluyendo la gestión de riesgos.

39) La gestión de riesgos debe ser un proceso permanente que tenga en cuenta todos los datos nuevos que aparezcan en la evaluación y revisión de las decisiones relativas a la gestión de riesgos. Las normas alimentarias y los textos afines deben ser actualizados para tomar en cuenta los nuevos conocimientos científicos ~~y otra información pertinente~~ para el análisis de riesgos cuando proceda.

40) Cuando haya pruebas de que existe un riesgo para la salud humana pero los datos científicos son insuficientes o incompletos, la Comisión no deberá proceder a elaborar una norma sino que examinará la conveniencia de elaborar un texto afín como, por ejemplo, un código de prácticas, siempre que tal texto esté respaldado por los datos científicos disponibles.

COMUNICACIÓN DE RIESGOS

41) El análisis de riesgos debe comprender una comunicación clara, interactiva y documentada entre los encargados de la evaluación de riesgos y los encargados de su gestión, así como una comunicación con los consumidores, los productores **y otras partes interesadas en todos los aspectos del proceso.**

42) Una función esencial de la comunicación de riesgos es establecer un proceso mediante el cual se intercambian informaciones y opiniones esenciales entre todas las partes interesadas para una evaluación de riesgos y una gestión de riesgos eficaces.

43) Cuando comuniquen con el público, los encargados de la gestión de riesgos deben explicar claramente la política de evaluación de riesgos **implementada** ~~y los encargados de la evaluación de riesgos deben identificar la incertidumbre en las estimaciones de riesgos~~. También se deben explicar claramente la necesidad de adoptar medidas específicas y los procedimientos que se han seguido para determinarlas.

44) ~~Una~~ La **estrategia de comunicación de riesgos debe ser ~~anticipante~~** establecida con carácter previo, **~~incorporar~~** incorporando **un plan en el que se especifique cómo se ha de comunicar la información.**

~~45) En el proceso de comunicación con el público y las demás partes interesadas se deberá incorporar una evaluación de la incertidumbre en las estimaciones de los riesgos.~~

ANEXO 1

DEFINICIONES

Definiciones incluidas en el Manual de Procedimiento

Peligro: Agente biológico, químico o físico, o propiedad de un alimento, capaz de provocar un efecto nocivo para la salud.

Riesgo: Función de la probabilidad de un efecto nocivo para la salud y de la gravedad de dicho efecto, como consecuencia de un peligro o peligros en los alimentos.

Análisis de riesgos: Proceso que consta de tres componentes: evaluación de riesgos, gestión de riesgos y comunicación de riesgos.

Evaluación de riesgos: Proceso basado en conocimientos científicos, que consta de las siguientes fases: (i) determinación del peligro, (ii) caracterización del peligro, (iii) evaluación de la exposición, y (iv) caracterización del riesgo.

Determinación del peligro: Determinación de los agentes biológicos, químicos y físicos que pueden causar efectos nocivos para la salud y que pueden estar presentes en un determinado alimento o grupo de alimentos.

Caracterización del peligro: Evaluación cualitativa y/o cuantitativa de la naturaleza de los efectos nocivos para la salud relacionados con agentes biológicos, químicos y físicos que pueden estar presentes en los alimentos. En el caso de los agentes químicos, deberá realizarse una evaluación de la relación dosis-respuesta. En lo que respecta a los agentes biológicos o físicos, deberá realizarse una evaluación de la relación dosis-respuesta, si se dispone de los datos necesarios.

Evaluación de la relación dosis-respuesta: Determinación de la relación entre la magnitud de la exposición (dosis) a un agente químico, biológico o físico y de la gravedad y/o frecuencia de los efectos nocivos conexos para la salud (respuesta).

Evaluación de la exposición: Evaluación cualitativa y/o cuantitativa de la ingestión probable de agentes biológicos, químicos y físicos a través de los alimentos, así como de las exposiciones que derivan de otras fuentes, si fueran pertinentes.

Caracterización del riesgo: Estimación cualitativa y/o cuantitativa, incluidas las incertidumbres concomitantes, de la probabilidad de que se produzca un efecto nocivo, conocido o potencial, y de su gravedad para la salud de una determinada población, basada en la determinación del peligro, su caracterización y la evaluación de la exposición.

Gestión de riesgos: Proceso de ponderación de las distintas opciones normativas a la luz de los resultados de la evaluación de riesgos y, si fuera necesario, de la selección y aplicación de las posibles medidas de control apropiadas, incluidas las medidas reglamentarias.
Comunicación de riesgos: Intercambio interactivo de información y opiniones sobre los riesgos, entre las personas encargadas de la evaluación de los riesgos y de la gestión de los riesgos, los consumidores y otras partes interesadas.

Otras Definiciones

Política de evaluación de riesgos La política de evaluación de riesgos consiste en orientaciones documentadas para el juicio científico ~~y en las opciones de políticas que han de aplicarse en los centros de decisión apropiados durante la evaluación de riesgos~~

Apreciación de los riesgos[29]

- identificar un problema de inocuidad de alimentos
- establecer un perfil de riesgos
- establecer el grado del peligro para la evaluación de riesgos y la prioridad de gestión de riesgos
- establecer la política de evaluación de riesgos para el desarrollo de la evaluación de riesgos
- encargar una evaluación de riesgos
- examinar el resultado de la evaluación de riesgos

AUSTRALIA

GENERAL COMMENT

Australia gives a high priority to protecting the health of consumers, through measures based on scientific risk assessment. Australia acknowledges the important role of Codex standards, guidelines and recommendations in meeting that objective and in underpinning the effective operation of the World Trade Organization Agreement on Sanitary and Phytosanitary Measures (WTO SPS Agreement). We therefore support progress towards finalisation of the proposed Draft Working Principles for Risk Analysis for application within Codex.

We also note that the concept of risk analysis as a framework incorporating three major components (risk assessment, risk management and risk communication) was first considered by the Commission in 1993. The development of this framework has been based on the outcome of FAO/WHO Expert Consultations on food safety risk analysis in 1995[30], 1997[31] and 1998,[32] the first of which was convened at the request of the Codex Executive Committee. These Expert Consultations recognised the importance of ensuring that Codex standards, guidelines and recommendations related to food safety are based on a scientific risk assessment, in view of the status they have under the SPS Agreement.

Because of that status, Australia considers it essential that Codex risk analysis principles and the WTO Agreements be mutually-supportive so as to avoid conflict. For that reason it is important to consider very carefully both the content and the wording of the risk analysis principles to ensure they are not open to misinterpretation or to misapplication in the future, regardless of the intention at the time they are being drafted.

While Australia supports the general object and purpose of the Draft Working Principles, there are a number of important issues that need further clarification. In particular, Australia is concerned that some elements of the text create the potential for misinterpretation or misapplication and give rise to potential conflict with the existing rights and obligations of WTO members under the WTO Agreements, in particular the SPS Agreement.

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[29] Consulta Mixta de Expertos FAO/OMS sobre la Gestión de Riesgos y la Inocuidad de los Alimentos (sección 6. marco de gestión de riesgos)

[30] Application of Risk Analysis to Food Standards Issues. Report of the Joint FAO/WHO Expert Consultation. Geneva, Switzerland 13-17 March 1995.

[31] Risk Management and Food Safety. Report of a Joint FAO/WHO Expert Consultation. Rome, Italy, 27-31 January 1997.

[32] FAO/WHO Expert Consultation on the Application of Risk Communication to Food Standards and Safety Matters. Rome, 2-6 February 1998.

Australia wishes to propose alternative wording for several paragraphs for that reason. We also wish to propose some further minor amendments to other paragraphs, and some changes to the Risk Communication Section in order to make it more relevant to risk analysis within Codex.

SCOPE

Paragraph 2

Australia recognises the dual mandate of Codex in establishing standards for the protection of consumers' health and ensuring fair practices in the food trade. However, fair trade practices (such as consumer information and misleading practices) would normally fall outside the scope of Codex food safety risk analysis. Paragraph 3 moreover states that the objective of the Working Principles is "to ensure that food safety aspects of Codex standards and related texts are based on risk analysis [and to provide an objective basis for measures to protect the health of consumers]'. Australia therefore proposes that paragraph 2 be amended to read as follows:

2. The purpose of risk analysis in the Codex Alimentarius Commission is protecting the health of consumers.

Paragraph 3

This paragraph states 'to ensure food safety aspects of Codex standards etc". Australia considers that nutrition issues are not necessarily covered by the term 'food safety'. A toxic effect caused by high levels of a particular vitamin does fall under 'food safety' in terms of a risk to human health. However, setting levels of recommended vitamin intake to give optimum, or even adequate health, does not fall within the term 'food safety'. The wording in paragraph 3 should be amended to read " to ensure that health and safety aspects of Codex…" With the inclusion of 'health and safety aspects' the text in square brackets is no longer required and Australia would propose deleting the square bracketed text.

It should be noted that the Australian delegation to the 23rd Session of the Committee on Nutrition and Foods for Special Dietary Uses (Nov 2001) will be promoting the use of risk analysis in the work of that committee.

3. The objective of the Working Principles is to ensure that health and safety aspects of Codex Standards and related texts are based on risk analysis.

Australia also recalls that the guidelines are intended for application by Codex and relevant Expert Bodies and not for national governments. Australia therefore proposes the inclusion of a new paragraph in the Scope of the document to ensure that the status of the guidelines in relation to the WTO SPS Agreement (Article 5.1) is clear.

4. bis These guidelines are intended for application by Codex and relevant Expert Bodies of FAO and WHO. Note that the WTO SPS Agreement in Article 5.1 requires members to "take into account risk assessment techniques developed by the relevant international organisations". These guidelines have not been developed for that purpose.

Alternately

4. bis These guidelines are intended for application by Codex and relevant Expert Bodies of FAO and WHO, and are not intended to be regarded as risk assessment techniques for governments for the purpose of Article 5.1 of the SPS Agreement.

RISK ANALYSIS – GENERAL ASPECTS

PARAGRAPH 5

The first dash point fails to indicate what the principles should be consistent with. Australia proposes that the wording of the first dash point be amended as followed:

- applied consistently;

Secondly, there are two Statements of Principle relevant to the Draft Working Principles for Risk Analysis, but only one has been mentioned here. Dash Point 3 should be amended to read as follows (new text underlined):

> "consistent with both the *Statements of Principle Concerning the Role of Science 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.*

PARAGRAPHS 6 AND 9

Paragraph 9 is closely related to Paragraph 6 and Australia suggests the two paragraphs be combined and amended (see below). It is important to reinforce the intention of Codex that the elements of risk analysis are closely linked to ensure that the separation of risk management from risk assessment does not undermine the scientific basis for risk management decisions and lead to potential conflict with WTO rules.

Secondly, as the proposed Draft Working Principles for Risk Analysis are intended for application within the risk analysis framework already adopted by Codex and defined in the Procedural Manual, this should be clearly stated. This can be reflected by inserting after the words in parentheses, the words 'as defined by the Codex Alimentarius Commission', and inserting a footnote reference to the '*Definitions of Risk Analysis Terms Related to Food Safety* already contained in the Procedural Manual, page 48.

Australia proposes that a new Paragraph 6 would read as follows:

6. The risk analysis process 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[footnote], each component being integral to the overall risk analysis process. There should be a functional separation of risk assessment and risk management in order to ensure the scientific integrity of the risk assessment, while also ensuring that risk management measures are based on the risk assessment. It is recognised that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.

Footnote to read: Definitions of Risk Analysis Terms Related to Food Safety page 48 11th Edition Codex Alimentarius Commission Procedural Manual.

PARAGRAPHS 10 AND 11

Australia recognises that the management of scientific uncertainty and a cautious approach to consumer protection are inherent elements of food safety risk analysis. Paragraphs 10 and 11 were intended to reflect those concepts. However these concepts are now covered adequately elsewhere in the text and in particular in paragraph 25 (which we are also proposing amendments to) for documenting the treatment of uncertainty, make paragraphs 10 and 11 mostly redundant. They should therefore be deleted and replaced with one paragraph, (which conveys the intended meaning more succinctly) as follows:

> New paragraph 10: The application of precaution in the management of scientific uncertainty is inherent in the analysis of food borne risks to human health.

RISK ASSESSMENT POLICY

PARAGRAPHS 15 AND 16

Australia proposes the following amendments to paragraphs 15 and 16.

In paragraph 15 delete the words "preferably" the paragraph would then read as follows:

> 15. Risk Assessment Policy should be established by risk managers in advance of the risk assessment, in consultation with the risk assessors and all other interested parties.

In paragraph 16 Australia would suggest deleting the entire sentence after "should be as clear as possible." The remainder of the sentence is redundant. Paragraph 16 would then read as follows:

> 16. The mandate given by risk managers to risk assessors should be as clear as possible.

RISK ASSESSMENT

Footnote to heading, and paragraph 21

The footnote to the heading is meaningless as it appears. As this section of the document is dealing specifically with risk assessment, reference should be made to the *Statements of Principle Relating to the Role of Food Safety Risk Assessment.* Australia recalls that the *Statements of Principle Concerning the Role of Science and the Extent to which Other Factors are Taken into Account* provide for the consideration of other legitimate factors in the risk management process. It is therefore inappropriate to reference this in relation to risk assessment. We recommend the footnote be deleted from the sub heading and Paragraph 21 be amended to read as follows:

> 21. Risk assessment should be consistent with the *Statements of Principle Relating to the Role of Food Safety Risk Assessment* and should incorporate the four steps of the risk assessment process, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization.

Paragraph 20

As the first sentence is very long and complicated, Australia would suggest deletion of the word "and" after "to the interests involved" and start a new sentence "The procedures used to select these experts should be documented…." Paragraph 20 would then read as follows:

> 20. Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise and 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 and experience.

Paragraph 21

See above.

PARAGRAPH 24

As currently worded, this paragraph only relates to primary production, Australia would argue that this applies to all food production and would suggest changing "primary production" to read "food production". Paragraph 24 would then read as follows;

> 24. Recognizing that food production in developing countries is largely through small and medium enterprises, risk assessment should be based on data from different parts of the world, including that from developing countries. This data should particularly include epidemiological surveillance data and exposure studies.

PARAGRAPHS 25 AND 26

Essentially the points in this paragraph are covered in paragraph 29. Australia proposes deleting the first sentence of paragraph 26 and combining the last sentence of paragraph 26 with paragraph 25. Paragraph 25 would then read as follows:

> New paragraph 25: Explicit consideration should be given to variability and other sources of uncertainty at each step in the risk assessment process. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative.

PARAGRAPH 27

The last sentence of this paragraph may imply that acute, chronic, cumulative and combined assessments should all be undertaken. In practice the nature of the assessment may vary depending on the question being asked. Australia proposes that last sentence be amended to read as follows:

> 27. Acute, chronic (including long-term), cumulative and/or combined adverse health effects may be taken into account in carrying out the risk assessment, where relevant.

PARAGRAPH 31 AND 35

The 'other legitimate factors' applied to food safety risk analysis should be limited to those directly related to the protection of human health. In most cases, Codex risk analysis is dealing with human health issues. Australia therefore proposes the following amendments to paragraphs 31 and 35:

31. Risk management should follow a structured approach, that includes risk evaluation, assessment of risk management options, implementation of management decisions, and monitoring and review, and be based on the risk assessment.

35. The outcome of the risk evaluation process should be combined with the assessment of available risk management options in order to reach a decision on management of the risk. Other legitimate factors may be considered in accordance with the *Criteria for the Consideration of Other Factors Referred to in the Second Statement of Principle* where relevant, for the health protection of consumers.

Paragraph 40

Australia acknowledges that the words in this paragraph emanate directly from a decision of the 24th Session of the Codex Alimentarius Commission on how Codex should deal with lack of scientific data. Australia is concerned that while the intention of the Commission is clear in the relevant section of Alinorm 01/41 (paragraph 81), Paragraph 40 is capable of being misinterpreted as permitting Codex to take decisions in situations of the kind described in Article 5.7 of the SPS Agreement.

Risk Communication

General comment

Australia acknowledges that while the nature of risk communication within Codex is different from that at a national level, it is an important part of Codex risk analysis and needs to be covered appropriately in the Draft Working Principles. The Risk Communication section of the Draft Working Principles has received less attention than other sections and warrants careful consideration so as to provide useful guidance on risk communication within the framework of Codex.

An important element of risk communication within Codex is that between risk managers and risk assessors (generally, this is between Codex Committees and the expert bodies such as JECFA and JMPR). Although Codex does not communicate directly with members of the public, the open nature of Codex decision-making processes facilitates risk communication with a broad range of stakeholders. Risk communication is also achieved through direct participation of international non-governmental organisations (INGOs) in Codex processes and of national NGOs in the formulation of positions by member governments.

Comments on specific paragraphs
Paragraph 41

As there are differing needs for risk communication in Codex to that of member governments, this paragraph should more clearly define the roles of risk managers (Codex Committees) as opposed to risk assessors (Expert Bodies). Australia proposes that this paragraph be reworded as follows:

41. Risk Analysis should include clear, interactive and documented communication, between risk assessors (Expert Bodies), and risk managers (Codex Committees), and communication with member countries, consumers and other interested parties in all aspects of the process.

Australia proposes the addition of a new paragraph (Paragraph 41 bis) from the FAO/WHO Consultation on Risk Management in Food Safety (FAO Food and Nutrition Paper No. 65) to reinforce the importance of risk communication in the process of risk analysis. Additional paragraph as follows:

41.bis Risk communication is more than the dissemination of information, and a major function is the process by which information and opinion essential to effective risk management is incorporated into the decision. Ongoing reciprocal communication among all interested parties is an integral part of the risk management process.

Paragraph 42 bis

The conclusions of the FAO/WHO Expert Consultation on the Application of Risk Communication to Food Standards and Food Safety Matters provide a useful starting point for the further development of this section of the document. The Consultation considered that a fundamental goal of risk communication is to provide meaningful, relevant and accurate information, in clear and understandable terms, to a specific audience. Such communication promotes understanding and facilitates consensus and support for the risk management option(s) being proposed. The Consultation identified several key goals of risk communication and it would be useful to include those relevant to Codex in this document. Australia therefore proposes that a new paragraph (42 bis) be inserted as follows:

42.bis The goals of risk communication are to:

(i) promote awareness and understanding of the specific issues under consideration during the risk analysis process, by all participants;
(ii) promote consistency and transparency in arriving at and implementing risk management decisions;
(iii) provide a sound basis for understanding the risk management decisions proposed or implemented;
(iv) improve the overall effectiveness and efficiency of the risk analysis process;
(v) strengthen the working relationships and mutual respect among participants;
(vi) foster public trust and confidence in the safety of the food supply;
(vii) promote the appropriate involvement of all interested parties in the risk communication process; and
(viii) exchange information on the knowledge, attitudes, values, practices and perceptions of interested parties concerning the risks associated with food and related topics.

Paragraph 43

This paragraph as it is worded implies that it is relevant to national governments. The 34th Session of the Codex Committee on Food Hygiene (October 2001) discussed the importance of improving risk communication; including and in particular, the interaction between assessors and managers and the need to define the scope and goals of risk analysis. Australia would propose deletion of the words "In their communication with the public" and replace them with more suitable words to identify communication between Codex Committees and the Expert Bodies. Suggested alternate wording is as follows:

43. Risk Communication between risk assessors and risk managers should include a transparent explanation of the risk assessment policy and risk assessors should identify the uncertainty in risk estimates. The need for specific measures and the procedures followed to determine them should also be clearly explained.

Australia proposes that paragraph 44 be deleted because it is more relevant to dealing with specific risks at national level than as a general principle for Codex. Australia also proposes that paragraph 45 be deleted as the documentation of uncertainty is already dealt with elsewhere (para 29).

BRAZIL

1. In the "Scope" Chapter, paragraph 2, Brazil suggests a new wording, with the inclusion of the text in brackets at paragraph 3. Paragraph 2 would then read as follows:

"The primary purpose for risk analysis in the Codex Alimentarius Commission is providing an objective basis for measures to protect the health of consumers while at the same time ensuring fair practices in the food trade."

Australia presented this amendment and Brazil supported it during the 16th Session of CCGP. Such proposal did not receive clear opposition. However, the Report of the Committee situated the amendment wrongly in the text. Brazil understands that the amendment, in the proposed paragraph, improves the text.

2. In the "Scope" Chapter, paragraph 3, Brazil suggests that, according to the previous suggestion, the text in brackets should be eliminated.

3. In the "Risk Analysis – General Aspects" Chapter, Brazil suggests to eliminate paragraph 10, since the Commission has already decided over the issue. Brazil understands that the term 'precaution' should not be used in the text, given the subjectivity it carries with it.

4. In the "Risk Analysis – General Aspects" Chapter, Brazil suggests to maintain paragraph 11 without the brackets. Brazil understands that this paragraph adequately contemplates the possible situations in a risk analysis process, namely the uncertainty.

5. In the Chapter "Risk Analysis – General Aspects", Brazil suggests to eliminate the subtitle "Risk Assessment Policy", since the later is not defined as a separated element of the risk analysis process. According to the FAO/WHO Consultation on Risk Management, the Risk Assessment Policy is a component of "Risk Evaluation", which is part of Risk Management.

6. In the Chapter "Risk Analysis – General Aspects", Brazil suggests to eliminate paragraph 13, since its position would present a contradiction. Besides, the context in which the policy is inserted already appears in the definition of that Policy.

7. In the Chapter "Risk Analysis – General Aspects", Brazil suggests to eliminate paragraph 14 since a definition of the term "Risk Evaluation Policy" already exists in Annex 1.

8. In the Chapter "Risk Analysis – General Aspects", Brazil suggests to renumber paragraph 15 as paragraph 13 and to reorder the text as follows:

" ~~To ensure that the risk assessment process is systematic, complete and transparent~~ The risk assessment policy should be established by risk managers preferably in advance of risk assessment, in consultation with risk assessors and all other interested parties, in order to ensure that the risk assessment process is systematic, complete and transparent.

9. In the "Risk Analysis – General Aspects" Chapter, Brazil suggests to transfer paragraphs 16 and 17 to "Risk Management" Chapter and to locate it immediately after paragraph 39 of the current text.

CANADA

SCOPE

1) The principles for risk analysis are intended for application in the framework of the Codex Alimentarius.
2) The primary purpose of risk analysis in the Codex Alimentarius Commission is protecting the health of consumers while at the same time ensuring fair practices in the food trade.

3) The objective of the Working Principles is to ~~ensure~~ provide guidance to relevant Codex subsidiary bodies so that food safety aspects of Codex standards and related texts are based on risk analysis ~~[~~and to provide an objective basis for ~~measures~~ the elaboration of standards and related texts to protect the health of consumers~~]~~.

Rationale: Although Canada agrees with the sentiment implicit in this paragraph, we are of the view that the Working Principles in and by themselves will not "*ensure*" that the food safety aspects of Codex standards and related texts will be based on risk analysis. It is only through their application during the elaboration of standards and related texts that such standards will be based on risk analysis. Therefore Canada suggests the above revision to paragraph 3 to more realistically describe the purpose of the working principles.

4) 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, while the responsibility for risk assessment normally lies with the Joint FAO/WHO Expert Committees and Consultations.
RISK ANALYSIS - GENERAL ASPECTS

5) The risk analysis process used in Codex should be:
- consistent
- open and transparent
- ~~consistent~~ conducted in accordance with the *Statements of Principle Concerning the Role of Science and the Extent to which Other Factors are Taken into Account*

Rationale: It is Canada's view that it is the standards and related texts developed by Codex which must be consistent with the *Statements of Principle Concerning the Role of Science and the Extent to which Other Factors are Taken into Account.* The risk analysis process itself is not consistent with the Statement of Principles but rather it is the outcomes of that process which should be consistent with the Statement of Principles.

6) The risk analysis process should follow a structured approach comprising the three components of risk analysis (risk assessment, risk management and risk communication), each component being integral to the overall risk analysis process.

7) 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 ~~open~~ accessible to ~~scrutiny by~~ all interested parties including consumers and their representative organizations~~, and other interested parties~~.

Rationale: Canada concurs with this statement. However, in order to strengthen the concept that documentation should be available to all interested parties, Canada suggests that the second sentence be revised slightly as indicated above.

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

9) The three components of risk analysis should be applied within an overarching framework of strategies and policies to manage risk. 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 and to reduce any conflict of interest over the functions to be performed by risk assessors and risk managers. However it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.

~~10) [Precaution is an essential element of risk analysis. This is particularly important where scientific evidence is insufficient and negative effects on health are difficult to evaluate. Precaution should be exercised through the use of appropriate assumptions in the risk assessment and the choice of risk management options that reflect the confidence in the available scientific information.]~~

11) ~~[~~Precaution is an essential element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food borne hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis process. As the degree of scientific uncertainty increases, the assumptions used for the risk assessment and the risk management options selected should become more cautious and conservative reflecting the confidence in the available scientific information.~~]~~

Rationale: It is Canada's view that the concept expressed in paragraph 10 is similar to that expressed in paragraph 11. Paragraph 11 is a clearer and more accurate statement of the concept of precaution. However, we believe the concept of precaution in risk analysis should be clearly stated. We suggest, therefore, that the first sentence of paragraph 10 could be moved to the beginning of paragraph 11 and the rest of that paragraph deleted. Paragraph 11 is also revised slightly to indicate that not only is "precaution" exercised throughout the risk analysis process but that uncertainty also exists in risk management.

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 process.

RISK ASSESSMENT POLICY

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

~~14) Risk assessment policy consists of documented guidelines for scientific judgement and policy choices to be applied at appropriate decision points during risk assessment.[33]~~ Risk Assessment Policy consists of documented guidelines for specific factors to be considered in the risk assessment, including policy choices,

[33] This paragraph is also included in the Definitions (Annex 1) and might be deleted later if the Definitions are retained in the final text.

and their application at appropriate decision points during the risk assessment such that the scientific integrity of the process is maintained.

Rationale: Canada agrees that this paragraph would be redundant if there was an agreed definition for *risk assessment policy*. As risk managers establish risk assessment policy, we have a reservation with respect to the use of the term "*scientific judgement"* as this could create the perception that the risk management function is biasing the risk assessment function. This, of course, would be contradictory to the Statements of Principle Relating to the Role of Food Safety Risk Assessment in that "*There should be a functional separation of risk assessment and risk management, while recognizing that some interactions are essential for a pragmatic approach"*[34] If included in the definitions, then Canada would agree that paragraph 14 could be deleted.

15) To ensure that the risk assessment process is systematic, complete and transparent, risk assessment policy should be established by risk managers preferably in advance of risk assessment, in consultation with risk assessors and all other interested parties.

16) The mandate given by risk managers to risk assessors should be as clear as possible, taking into account available scientific evidence and any constraints affecting the risk assessment process.

17) Where necessary, risk managers ~~may~~ should ask risk assessors to evaluate the potential risk reduction resulting from different risk management options.

Rationale: In circumstances where it is necessary, Canada is of the view that risk managers should ask risk assessors to evaluate potential risk reduction recognizing that it may not always be necessary.

RISK ASSESSMENT*

~~18) Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances.~~

Rationale: Although Canada acknowledges that this paragraph serves as an introduction to the "risk assessment" section, we note that "Codex decisions and recommendations" are actually risk management decisions. It is not appropriate to address risk management issues under principles related to risk assessment. It is Canada's view, therefore, that this paragraph should be deleted and a subsequent revision made to paragraph 30 to reflect that risk management decisions should be based on a risk assessment.

19) The scope and purpose of the particular risk assessment being carried out should be clearly stated. The output form and possible alternative outputs of the risk assessment should be defined

20) Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved. ~~and~~ 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 and experience.

Rationale: Canada suggests that the first sentence in this paragraph is quite long.The need for transparency in both the selection process for experts and potential conflict of interest would be clarified and easier to understand if it was split into two sentences.

21) Risk assessment should be ~~consistent~~ conducted in accordance with the ~~*Statements of Principle Concerning the Role of Science and the Extent to which Other Factors are Taken into Account*~~ *Statements of Principle Relating to the Role of Food Safety Risk Assessment* and should incorporate the four steps of the risk assessment process, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization.

Rationale: It is Canada's view that a more appropriate reference regarding consistency would be to the *Statements of Principle Relating to the Role of Food Safety Risk Assessment.*

[34] Principle 3, AStatements of Principle Relating to the Role of Food Safety Risk Assessment@, *Codex Procedural Manual*, pg 181.

* Reference is made to the *Statements of Principle Concerning the Role of Science and the Extent to which Other Factors are Taken into Account.*

22) Risk assessment should use available quantitative information to the greatest extent possible and risk characterisations should be presented in a readily understandable and useful form. Risk assessment may also take into account qualitative information.

23) Risk assessment should take into account all available scientific data and 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.

24) Recognizing that primary production in developing countries is largely through small and medium enterprises, risk assessment should be based on data from different parts of the world, including that from developing countries. This data should particularly include epidemiological surveillance data and exposure studies.

25) Explicit consideration should be given to variability and other sources of uncertainty at each step in the risk assessment process.

26) Any constraints, uncertainties and assumptions and their impact on the risk assessment should be documented in a transparent manner, including constraints that are likely to influence the quality of the risk estimate. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative.

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.

28) The conclusions of the risk assessment should be conveyed to risk managers in a readily understandable form. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessor.

29) To ensure a transparent risk assessment, a formal record, including a summary, should be prepared and made available to other risk assessors and interested parties so that they can review the assessment. It should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and minority opinions.

RISK MANAGEMENT

30) ~~Risk management decisions~~ Codex standards and related texts should have as their primary objective the ~~protecting~~ protection of the health of consumers and should be based on a risk assessment. ~~Decisions on acceptable levels of risk should be determined primarily by human health considerations, and~~ ~~u~~Unjustified differences in the level of ~~acceptable risk~~ consumer protection to address similar risks in different situations should be avoided.

Rationale: Canada recommends the revision of "risk management decisions" to "Codex standards and related texts" to enhance the concept that these Working Principles are intended for application within the framework of Codex. Terms such as "acceptable level of risk" are recognized and defined in the WTO SPS Agreement. Furthermore, it is the sovereign right of nations to establish their own acceptable level of risk/appropriate level of protection. Canada is of the opinion that Codex should avoid using text that implies it will be attempting to establish an "international ALOP" and usurp the rights of member countries. Codex can establish standards or related text which provide a level of consumer protection but it is up to member countries to determine if such a level is suitable for application in their circumstances. There is also a need for consistency in the manner in which different Codex subsidiary bodies address similar risks. The proposed changes also reflect the need for risk management decisions to be based on a risk assessment to include the concept which was contained in the deleted paragraph 18.

31) Risk management should follow a structured approach, be grounded on science-based risk assessment and take into account other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, as appropriate. The risk management framework includes risk evaluation[35], assessment of risk management options, implementation of management decisions, and monitoring and review[36].

[35] See *Definitions* in Annex 1

[36] Joint FAO/WHO Expert Consultation on Risk Management and Food Safety. In the framework of Codex, the Implementation "component" is not relevant.

32) 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 and the prevalence of specific adverse health effects.

33) The risk management process should be transparent, consistent and fully documented. Risk management decisions 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.

34) Risk management options should be evaluated/assessed in terms of the scope and purpose of risk analysis and the ~~required~~ level of consumer protection they achieve. The option of not taking any action should also be considered~~, as required~~.

Rationale: As indicated in our comments under paragraph 30, Canada is of the view that it is not appropriate for Codex to indicate any specific level of consumer protection is "required." A "required" level of protection implies the establishment of an ALOP which is within the pervue of national governments and not within the mandate of Codex. Within Codex it is more appropriate to examine risk management options (standards and related texts) from the perspective of the level of consumer protection they provide rather than implying that such levels are "required".

35) The outcome of the risk evaluation process should be combined with the assessment of available risk management options in order to reach a decision on management of the risk. In arriving at a decision on risk management, protection of consumers' health ~~should~~ shall be the primary consideration, with other legitimate factors being considered as appropriate[37], in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*

Rationale: Recognizing that guidelines are normally meant for guidance and hence terminology such as "should" is most appropriate, Canada cannot determine circumstances where "protecting health of consumers" would not be the primary consideration in risk management decisions. Therefore, in the second sentence of this paragraph, Canada is of the opinion that "should" can be replaced with "shall".

36) ~~Guidelines should be defined for the integration in the risk management process of legitimate factors other than science relevant for the health protection of consumers and for the promotion of fair practices in food trade~~. (This paragraph was "struck out" by the Secretariat)

~~37)~~ In order to avoid unjustified trade barriers~~, risk management should ensure transparency and consistency in the decision-making process in all cases.~~ when making a choice among different risk management options which are equally effective in protecting the consumer, the Commission and its subsidiary bodies should select the "least trade-restrictive" amongst them.

Rationale: While transparency and consistency are important for avoiding unjustified trade barriers, they, by themselves, cannot fully achieve this desired objective. Canada notes that the issues of transparency and consistency are addressed in paragraph 33. Therefore, Canada suggests the focus of this paragraph should be on "least trade restrictiveness" and offers the above text as an appropriate revision.

38) Risk management should take into account the economic consequences and the feasibility of risk management options in developing countries. Risk management should also recognize the need for flexibility in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers' health.

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. Food standards and related texts should be reviewed regularly and updated as necessary to reflect new scientific knowledge and other information relevant to risk analysis.

Rationale: Canada suggests this minor modification to ensure that Codex decisions are systematically reviewed on a regular basis.

37 Joint FAO/WHO Expert Consultation on Risk Management and Food Safety. *Criteria for the Consideration of the Other Factors referred to in the Second Statement of Principles* have been adopted by the 24th Session of the Commission (see Annex 2). The *Criteria* address the question of the integration of other factors in relation to risk analysis, including risk management.

40) 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.[38]

RISK COMMUNICATION

41) Risk analysis should include clear, interactive and documented communication, ~~between~~ amongst risk assessors, ~~and~~ risk managers, and ~~communication with consumers and other~~ all interested parties, including consumers and their representative organizations, in all aspects of the process.

Rationale: This revision enhances the concept that risk communication is more than an outflow of information and also makes the text in this paragraph consistent with the text used in paragraph 7.

42) A major function of risk communication is establishing a process whereby information and opinion essential to effective risk assessment and risk management is exchanged ~~between~~ amongst all interested parties.

Rationale: Use of the term "amongst" more correctly identifies that more than just "risk assessors" and "risk managers" are engaged in the risk communication process.

43) ~~In their~~ Risk communication with ~~the public~~ interested parties ~~risk managers~~ should include a transparent explanation of the risk assessment policy ~~and risk assessors should identify the uncertainty in risk estimates~~. and an explanation of the assessment of risk, including the uncertainty. The need for specific ~~measures~~ standards or related texts and the procedures followed to determine them, including how the uncertainty was dealt with, should also be clearly explained.

Rationale: Canada suggests revising this paragraph to place the emphasis on the *content* of the risk communication rather than on *who* does the communication. It is Canada's view that the revised text more clearly identifies what should be contained in risk communication to interested parties.

44) A risk communication strategy should be proactive and include a plan specifying how information and opinion is to be ~~communicated~~ exchanged.

Rationale: Use of the term "exchanged" enhances the concept that risk communication is more than an outward flow of information but is an interactive process involving all interested parties.

~~45) An assessment of uncertainty in risk estimates should be included in the communication process with the public and other interested parties.~~

Rationale: **The revisions to paragraph 43 would make this paragraph redundant and could be deleted.**

ANNEX 1
DEFINITIONS
Definitions included in the Procedural Manual

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

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

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.

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

[38] Statement adopted by the 24th Session of the Commission (ALINORM 01/41, paras. 81-83)

Hazard Characterization: The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents that 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 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.
Risk Characterization: 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 Management: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.
Risk Communication: **The interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions**
Other Definitions
Risk Assessment policy ~~**consists of documented guidelines for scientific judgement and policy choices to be applied at appropriate decision points during risk assessment.**~~
Risk Assessment Policy **consists of documented guidelines for specific factors to be considered in the risk assessment, including policy choices, and their application at appropriate decision points during the risk assessment such that the scientific integrity of the process is maintained.**

Risk Evaluation[39]
- **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 conduct of risk assessment**
- **commissioning of risk assessment**
- **consideration of risk assessment result**

COLOMBIA

Titulo: Creemos que la concordancia con el nombre no es la mas afortunada, sugerimos como titulo del documento : "Principios practicos para el analisis de riesgos".

Ambito de aplicacion: debido a que el texto esta incluyendo tambien los objetivos, opinamos ampliar el subtitulo por "Ambito de aplicacion y objetivos", o, separar el ambito en un punto y el objetivo en otro.

Parrafo 2 y 3: ¿los temas que se traten y los documentos que se elaboren en el marco del Codex Alimentarius no deben siempre estar articulados con uno de sus objetivos principales como es "proteger la salud de los consumidores

y asegurar practicas equitativas en el comercio de los alimentos"?. En consecuencia no creemos necesario recalcar sobre el mismo en los numerales 2,3 y en el resto del documento. En resumen proponemos suprimir el parrafo 2 y el 3 y reiterar la parte que aparece entre parentesis.

Parrafo 5: Para evitar equivocos en la interpretacion de la palabra coherente, mencionada dos veces como condicion o requisito del analisis de riesgo, sugerimos cambiar en el tercer punto, e iniciarlo con la expresion ACORDE O DE ACUERDO CON LAS DECLARACIONES DE PRINCIPIOS....

Parrafo 10: Proponemos eliminar el parentesis y dejar el parrafo vigente para el documento.

Parrafo 11: Proponemos eliminar el parentesis y dejar el parrafo vigente para el documento, pero con las siguientes observaciones en el primer renglon: suprimir la palabra peligros y dejar el inicio del parrafo como sigue "En el proceso de evaluacion de riesgos para la salud humana originados por los alimentos....

[39] Joint FAO/WHO Expert Consultation on Risk Management and Food Safety (section 6. Risk Management Framework)

Parrafo 14: Estamos de acuerdo en suprimir el parrafo, dejando el concepto de politica de evaluacion de riesgo" en las definiciones, si el termino es nuevo. En caso contrario remitirse al manual de procedimientos del codex que

incluye "definiciones para los fines del Codex Alimentarius"

Parrafo 18: En nuestro concepto, la redaccion del parrafo no es la mas afortunada, proponemos para iniciar el mismo: "En los aspectos relacionados con la salud y la inocuidad, las decisiones y recomendaciones del Codex deben basarse .....

Parrafo 21: En este parrafo en el tercer renglon se menciona como una de las fases de la evaluacion del riesgo la "identificacion de los peligros", termino identificado con el cual estamos de acuerdo. Sin embargo en las definiciones del documento, como en el manual de procedimientos aparece como fase de evaluacion del riesgo la "determinacion del peligro". proponemos, para evitar diferentes interpretaciones, unificar el termino en el documento con el vocablo identificacion de los peligros.

Parrafo 30: El objetivo esencial de la gestion de riesgos, en nuestro concepto es mitigar o intervenir el riesgo y no la proteccion de la salud de los consumidores como aparece en el parrafo; concepto que podria se ridentificado como fin ultimo de la gestion, pero con cuya mencion no estamos de acuerdo, ya que la proteccion de la salud de los consumidores es uno de los objetivos centrales de todo el tema de analisis o documentos que se elabore en el marco del Codex Alimentarius.

Parrafo 31: Proponemos la siguiente estructura del parrafo con la adicion de las siguientes observaciones:

31) La gestion de riesgos debe:

- Ajustarse a un metodo estructurado

- Basarse en una evaluacion de riesgos fundamentada en la ciencia

- Tener en cuenta otros factores legitimos relacionados con la proteccion de la salud de los consumidores y el fomento de practicas equitativas en el comercio de alimentos, cuando corresponda.

El marco de la gestion de riesgo comprende la apreciacion de los riesgos, la evaluacion de las opciones de gestion de los riesgos, la aplicacion de las decisiones de gestion, el control y la revision, y la adopcion de acciones correctivas, cuando sea necesario.

Parrafo 43: Proponemos la siguiente redaccion para el primer renglon del mismo parrafo: "Cuando los encargados de la gestion de riesgo se comunique con el publico, deben explicar claramente .....

DEFINICIONES (ANEXO 1)

Sugerimos incorporar los terminos que sean nuevos en el anexo de definiciones, los otros conceptos referenciarlos al Manual de procedimientos.

COTE D'IVOIRE

(i) Concernant les 10 et 11, ils situent bien la place de la "précaution" pour son application dans le cadre du codex. Ainsi, nous sommes pour la suppression des crochets.

(ii) concernant le point 12, nous pensons qu'il ne suffit pas de faire une simple déclaration d'intention pour prendre en compte des besoins des pays en développement. Sachant que les PVD disposent de peu ou de pas du tout de données pour alimenter le processus international d'analyse des risques, comment le codex peut diligenter ou s'autosaisir de l'urgence d'une telle démarche pour des motifs sanitaires ou phytosanitaires (avec un impact sur la santé et le commerce international pour des PVD), lorsque ces derniers se trouvent face à des communautés économiques de pays développés qui leur opposent la charge de la preuve pour certains résidus, fort du principe de précaution (exemple de l'ochratoxine A dans le café vert et de certaines LMR dans les fruits tropicaux)? ce d'autant plus qu'il n'existe pas de norme codex en la matière?

Concernant ls points 24 et 27, une notion de délai doit être ajoutée pour permettre le recueil de données suffisantes des PVD.

Il faut à cet effet prévoir des mesures d'accompagnement (équipements, expertise) nécessaires à l'établissements des données dans les PVD qui n'ont pas les moyens de telles mesures.

Aussi, les organes directeurs du codex ne doivent-il pas, pour des motifs de santé publique, mettre en oeuvre des programmes prioritaires avec une mise à disposition d'assistance technique en direction des PVD en vue de leur permettre de collecter les données nécessaires à l'analyse des risques?

Il devrait exister un minimum requis de données en provenance de ces pays.

Concernant le point 38, comment le codex compte t-il prendre en compte les possibilités de mise en oeuvre des options de gestion des risques dans les PVD?

Concernant le point 40, quelle est la valeur juridique d'un code d'usage dans la procédure de règlement de différent de l'OMC?

MALAYSIA

1. SCOPE

Paragraph 3

Malaysia proposes that the text in the square brackets be deleted in view that it is rather implicit and overly prescriptive.

2. RISK MANAGEMENT

Paragraph 30

We note that there is an editorial error in the first sentence.

The sentence should real as follows:

"Risk Management decisions should have as their primary objective the protection of the health of consumers" .

NEW ZEALAND

GENERAL COMMENTS

The discussions on the draft Working Principles for Risk Analysis at the 16th Session of the CCGP, and the subsequent redrafting of the text by the Codex Secretariat, have resulted in a much clearer and more cohesive document. However, the inability of CCGP to reach a consensus on "precaution" has resulted in a text that New Zealand considers unfocused and problematic.

The limitation on the scope of the document as agreed by the 24th Session of the CAC (priority development of working principles relating to risk analysis for application by Codex rather than by national governments) should help the redrafting process. Given the revised scope, New Zealand considers that the current draft working principles incorporate too much text and this obscures their objectives. Amalgamation of a number of principles would also provide a more useful and practical document.

New Zealand supports the proposal to develop working principles for risk analysis for application by national governments as part of the future CCGP work programme.

New Zealand also supports the guidance provided by the 24th session of the CAC on the application of precaution in Codex in situations when scientific data are insufficient or incomplete. We believe that the CAC statement properly reflects the role of Codex as an international standard-setting body, compared to that of a national government where provisional (interim) and *ad hoc* sanitary measures may need to be put in place to protect public health.

Although the CCGP has overarching responsibility for developing generic risk analysis principles, current work in other Codex Committees relating to application of risk-based approaches in the development of standards, guidelines and related texts should be taken into account. New Zealand has some concerns that the current working principles are being developed without due cognisance of their likely application in the wide-ranging work of Codex. This concern particularly relates to insufficient attention to the need for systematic application of a framework for managing all food safety issues as they are brought to the attention of Codex, and recognition of differences in application of some principles when managing chemical compared with microbiological hazards. For example, discussions at the 34th Session of the CCFH (October, 2001) highlighted the imperative for systematic implementation of a risk management framework, the importance of identifying the particular Codex output required (e.g. a quantitative standard for food in trade, or a code of practice giving risk management advice to national governments), and the critical need for effective, dynamic and timely interaction between microbiological risk assessors and risk managers.

SCOPE

Paragraphs 1 and 3 appear to be addressing the same issue, and could be subsumed into a single statement, as follows: *"These principles of food safety risk analysis should be applied as appropriate in the elaboration of Codex standards, guidelines and related texts".*
It would also be useful to add a further statement at the end of the above text to state clearly that these principles are not intended for application at the national level. New Zealand would suggest adding a further sentence as follows: *"These principles are not intended for application in the development of national food safety measures."*

The text currently in square brackets in paragraph 3 is unfocused and somewhat unclear as to its intent. For example, a risk management decision on appropriate level of consumer protection, although not unfettered, is values-based rather than an objective decision. The bracketed text should be deleted.

The scope should include reference to a framework for managing risks (see discussion below under Risk Analysis – General Aspects). A suggested new paragraph is *"Application of the principles of risk analysis should be within an overarching framework for management of food-borne risks to human health". 01/11/2001 17:13*

RISK ANALYSIS – GENERAL ASPECTS

General comment

The redrafted text now recognises in part that systematic application of an overarching risk management umbrella is essential to application of "risk analysis" (this is currently mentioned in paragraphs 9 and 31). Clear and specific recognition of this is particularly important in the context of Codex. It is now well recognised that various committees prioritise and initiate risk assessment work (a risk management function), and then consider the outputs of the risk assessment process in making decisions on Codex standards (the second step in risk management). Although Codex does not implement standards (the third step in a framework for managing risks), it does have various functions in terms of monitoring and review of the effectiveness of the standards it elaborates (the last step in risk management).

Full recognition of a framework for managing risks is necessary in the draft working principles for the following reasons:

- The utility of the current document will be measured by its ability to facilitate and inform the work of Codex in terms of practical outcomes, i.e. the elaboration of Codex standards, guidelines and related texts.

- The four steps involved in a framework for managing risks are now clearly recognised in several Codex draft documents, and in regulatory policy documents emerging at the national level.

- Differences in risk management at the Codex level as compared to the national level will be best illustrated if presented in the context of the four steps of a framework for managing risks, e.g. the implementation step at the national level will involve new text on validation and verification of measures designed to achieve the appropriate level of consumer protection – issues that are not generally relevant to Codex risk management activities.

- The realities of current "risk analysis" are not sufficiently recognised. Formal quantitative risk assessments to inform Codex risk management decisions may not be available (or necessary) in many circumstances, especially in regard to microbiological hazards. Nevertheless, useful Codex standards for managing food-borne risks (e.g. codes of practice) can still be produced under systematic application of an appropriate framework

Thus New Zealand considers that the importance of application of the principles of risk analysis within an overarching framework for management of food-borne risks to human health should be considerably strengthened and needs to be made early in this document (i.e. paragraph 9). We suggest some specific text in our comments below.

Paragraph 6

This paragraph states that "The risk analysis process should follow a structured approach comprising the three components of risk analysis….", however there is no further reference to this particular "approach". New Zealand suggests that this paragraph be deleted and the identification of the three components of risk analysis be integrated elsewhere. This could be achieved by adding the text *"(risk assessment, risk management and risk communication)"* into the chapeau of paragraph 5, or following 'risk analysis' in paragraph 7.

Paragraph 7
If confidentiality refers to commercial (or other) data, then this should be clearly stated. Confidentiality in relation to other aspects of risk analysis is not necessary.

Paragraph 9
Following general comments made above, New Zealand believes that the principle in paragraph 9 reflects a core concept and should be strengthened. Suggested replacement text is: *"The principles of risk analysis should be applied within an overarching framework of strategies and policies for management of food-borne risks to human health. A framework for managing risks should include four steps: risk evaluation, assessment of risk management options, implementation of risk management decisions, and monitoring and review"*.

Paragraph 9 should only deal with this issue. A separate principle concerning functional separation of risk assessment and risk management should follow.

A further separate principle should deal with interaction between risk managers and risk assessors, either here or under the section on risk communication. This is a key activity (especially in risk analysis of microbiological hazards).

Paragraph 10
This bracketed text attempts to address several issues but is poorly directed. New Zealand suggests deletion in its current form for the following reasons:

- The statement "Precaution is an essential element of risk analysis" is misleading in that precaution is primarily a risk management function. (Expression of caution in risk assessment should be a reflection of risk assessment policy formulated by risk managers). Further, this is a statement rather than a principle.

- Reference to "appropriate assumptions in risk assessment" should be developed under risk assessment policy. Such assumptions are not necessarily predicated by caution, e.g. consistency is a key requirement

- It is not clear how a principle of choosing "risk management options that reflect the confidence in the available information" will be expressed in different types of Codex "standards".

New Zealand suggests that the principle in paragraph 10 should be redrafted and include the relevant text from the 24th Session of the CAC: *"Precaution should be inherent to the systematic application of a framework for managing food-borne risks to human health. When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, elaboration of a quantitative standard for food in international trade should be avoided"*.

Paragraph 11
The first sentence is a statement rather than a principle, and it is unclear what the last sentence means in practical terms. To avoid confusion, this paragraph should solely address the question of uncertainty and variability in risk assessment, and the appropriate risk management response. Suggested replacement text is: *"Inherent uncertainty and variability in inputs to risk assessment and their impact on the risk estimate should be explicitly considered by risk managers when making risk management decisions"*. This text is consistent with the Principle in paragraph 28.

Paragraph 17
This should be shifted to "Risk management" section. It is not a risk assessment policy function.

RISK ASSESSMENT

Paragraph 23
The principle in paragraph 23 is virtually repeated in paragraph 32. It is suggested that this paragraph is replaced in this section with more focused text: *"Subject to available data and technical resources, exposure assessment should involve the whole food chain so as to enable evaluation of risk management options that provide optimal control of hazards".*

Paragraph 24

Ensuring appropriate representativeness of Codex risk-based standards is a universal principle and should not be predicated by specific reference to size of production units in developing countries. The need to consider developing countries is already clearly stated at the end of the first sentence. We suggest that the first part (i.e. before the first comma) of the first sentence be deleted.

Paragraph 27
The principle in this paragraph needs to be tempered with the fact that modelling of the susceptibility of different subsets of consumer populations will often be severely limited because of lack of data. Suggest adding: *"where data available".*

Paragraphs 23, 24 and 27 variously address risk assessment policy (a risk management responsibility), adequacy of exposure assessment, adequacy of hazard characterisation, human health surveillance, and representativeness of risk assessments. These principles need to be revisited so that they clearly address single objectives.

RISK MANAGEMENT

General comment

This section contains paragraphs that often repeat parts of principles set out in other paragraphs e.g. 30 and 35, 31 and 35, 33 and 37. We suggest that these paragraphs be reviewed to ensure that each sets out a single principle and duplication is removed.

The section should be introduced with a principle that reiterates the need for systematic application of a framework for managing risks. New Zealand suggests that the current paragraph 31 be replaced with the following text and should be the opening paragraph for this section: *"All aspects of risk management should be systematically applied within an established framework for managing risks (refer to Principle 9), with final decisions on risk management options being grounded on science-based risk assessment and taking into account other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in trade".*

Paragraph 30

This paragraph should be the second in this section. The term " acceptable level of risk" is used here whereas the term "required level of consumer protection" is used in paragraph 34. Use of terms should be consistent and New Zealand would prefer to see 'required level of consumer protection' used in both.

Paragraph 38

These "other legitimate factors" are not only considered by risk managers in reference to developing countries. A suggested amendment is "…feasibility of risk management options, *including those in* developing countries…."

Paragraph 40

For the purposes of the WTO SPS Agreement, all Codex texts are "standards". In respect of practical application, the objective of text from the CAC would be clarified with the following change "…should not proceed to elaborate a *quantitative* standard…"

New principles

If Codex "standards" are to be properly representative, risk managers should facilitate and pursue improved data collection and surveillance from developing countries. This should be addressed in a new principle.

RISK COMMUNICATION

Throughout the evolution of this document, risk communication has appeared to receive lesser attention than other components of risk analysis. More thought needs to be given to this Section, especially given recognition by the 34th Session of the CCFH of the fundamental importance of effective, dynamic and timely interaction between risk assessors and risk managers in the case of microbiological risk management within the Codex system. Currently, Codex has inadequate mechanisms to achieve this.

NORWAY

Recognising that the Codex Alimentarius Commission confirmed that principles should apply to the Codex system, Norway is generally supportive towards the document in its present form.

Concerning the papagraphs 10 and 11 we think it is important that there is an explicit refernce to precaution, thus supporting the text in priciple. However, we would like the text to be discussed in more detail. We look forward to discuss this and the rest of the document at the meeting of the Working Group in december.

THAILAND

First of all, we would like to express our appreciation to the secretariat on the proposed draft which forms an excellent working basis.

In general, we agree in principle with the proposed draft prepared by the secretariat. However, we wish to make a specific comment on the text of paragraph 20 as follows:

We are of the opinion that in order to support the transparent scientific evaluation process, there is a need to take into account the inputs of developing countries in the work of expert bodies. We, therefore, would like to propose to the meeting to consider the proposal of India to the 16th session of the CCGP which states as follows:

"In case the exercise of risk assessment is carried out by FAO/WHO, developing countries should also be involved in the risk assessment studies".

We would like to propose to add the following phrase after the word "involved".
"taking into account a possibility to include experts from developing countries in the composition of expert bodies".
The modified sentence, therefore, should read as follows:
"20. Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved *taking into account a possibility to include experts from developing countries in the composition of expert bodies. The* procedure used to select……"

UNITED STATES

General U.S. Comment: The United States believes that it would be useful for the Working Group meeting on the Proposed Draft Working Principles for Risk Analysis to have a general discussion on two topics before going through the draft document paragraph-by-paragraph.

First, the Working Group should have a fundamental discussion of Codex's exact role in "risk management" Codex does not do "risk management" as it is understood that national governments accomplish risk management. For example, Codex does not implement risk management options, as acknowledged in footnote 4 of this document. Further, Codex does not create risk management measures, but rather creates risk management recommendations or advice to national governments. Also, because of the status of Codex under the SPS Agreement, Codex creates reference risk management options that are useful for national governments to base their risk management measures upon. But it is national governments that establish and

implement risk management measures, thus doing risk management, in the sense that it is generally understood. We believe that there should be some discussion of the role of Codex in risk management and that the "Risk Management" section of the working principles for risk analysis as applied within the framework of Codex should be reviewed in light of this discussion.

Second, the Working Group should discuss the role of Codex in Risk Communication. This issue has not been discussed in CCGP, as yet. The U.S. believes that, within Codex, there could be two major types of communication for discussion, although it is possible that both would not be covered by the working principles. One type is that between risk assessors (e.g., expert consultations) and risk managers (e.g., Codex committees). CCGP could establish principles and processes for effective communication between these two groups. CCGP should recognize the iterative nature of risk analysis, including hazard identification and resulting risk assessment. The communication between risk assessors and risk managers must be interactive, transparent and well documented. The second major type of communication within Codex is to convey risk management options to member governments. Codex does not have a direct role in communicating with citizens; that is a role of national governments. However, if Codex carries out its risk analysis mandate in a transparent manner, Codex will be indirectly communicating with all interested parties, including individual citizens of all countries. Codex should establish principles and processes for a two-way communication with national governments, bearing in mind that this too is communication with all interested parties (consumers, food industries, academia, other international organizations, etc.). Any process should be designed to permit Codex to obtain information pertinent to risk analysis and to explain goals and reasoning behind Codex decisions. Again, this communication must be interactive and well documented. Communication should also include assessments of uncertainty, when appropriate.

PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS
(At Step 3 of the Procedure)
SCOPE

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

2. **The primary purpose of risk analysis in the Codex Alimentarius Commission is protecting the health of consumers while at the same time ensuring fair practices in the food trade.**

3. *The objective of the Working Principles is to ensure that food safety aspects of Codex standards and related texts are based on risk analysis [and to provide an objective basis for measures to protect the health of consumers].*

U.S. Comment: Paragraph 3 – The United States recommends that the text in brackets be deleted because it is redundant in that it adds little to the principles that is not contained in other paragraphs and because it refers more to countries than to Codex. Also, the U.S. believes that it is more accurate to state "that food safety aspects of Codex standards and related texts are developed in the context of risk analysis." Therefore, the U.S. would rewrite this paragraph as follows:

3. **THE OBJECTIVE OF THE WORKING PRINCIPLES IS TO ENSURE THAT FOOD SAFETY ASPECTS OF CODEX STANDARDS AND RELATED TEXTS ARE DEVELOPED IN THE CONTEXT OF RISK ANALYSIS**

4. 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, while the responsibility for risk assessment normally lies with the Joint FAO/WHO Expert Committees and Consultations.

RISK ANALYSIS - GENERAL ASPECTS

5. *The risk analysis process used in Codex should be:*

   - *consistent*
   - *open and transparent*
   - *consistent with the* Statements of Principle Concerning the Role of Science and the Extent to which Other Factors are Taken into Account

6. The risk analysis process should follow a structured approach comprising the three components of risk analysis (risk assessment, risk management and risk communication), each component being integral to the overall risk analysis process.
7. *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 open to scrutiny by consumers and their representative organizations, and other interested parties.*

U.S. Comment: Paragraph 7: The U.S. believes that specific mention of any stakeholder group is unnecessary. The phrase "all interested parties" covers consumers, industry, academics, national government agencies, international organizations, etc. Therefore, the United States would replace the words "by consumers and their representative organizations, and other" with the word "all". Therefore, the U.S. would rewrite this paragraph as follows:

7. **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 OPEN TO SCRUTINY BY ALL INTERESTED PARTIES.**

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

9. The three components of risk analysis should be applied within an overarching framework of strategies and policies to manage risk. 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 and to reduce any conflict of interest over the functions to be performed by risk assessors and risk managers. However it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.

10. [Precaution is an essential element of risk analysis. This is particularly important where scientific evidence is insufficient and negative effects on health are difficult to evaluate. Precaution should be exercised through the use of appropriate assumptions in the risk assessment and the choice of risk management options that reflect the confidence in the available scientific information.]

U.S. Comment: Paragraph 10: The United States believes that the brackets on this paragraph should be removed. The first sentence of the paragraph restates the position that was agreed to at the Melbourne Conference and should therefore be retained. However, the final two sentences discuss situations in which scientific evidence is insufficient. Because these working principles are intended only for application within the framework of Codex and because the Commission has already taken a firm stand on how Codex should act in such situations, we believe that these two sentences should be deleted. We also believe that the statement adopted by the 24th Session of the Commission *("When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the 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."*) is a general aspect of risk analysis and should be moved into this section as a new paragraph 11. Therefore, the U.S. would rewrite this paragraph as follows:

10. **PRECAUTION IS AN ESSENTIAL ELEMENT OF RISK ANALYSIS.**

11. *[Many sources of uncertainty exist in the process of risk assessment of food borne hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis process. As the degree of scientific uncertainty increases, the assumptions used for the risk assessment and the risk management options selected should become more cautious and conservative.]*

U.S. Comment: Paragraph 11: The United States believes that the information given in the first sentences of this paragraph provide a useful discussion of how uncertainty is handled in risk assessment. However, we question whether they belong in the "General Aspects" section. Also, these working principles are intended for application within the framework of Codex and the Commission has addressed the issue of uncertainty at its 24th Session. The final sentence prejudges the outcomes of the risk assessment / risk management interaction. Depending on health effects and specific uncertainties, different management options could be selected. Therefore, the U.S. believes that this paragraph should be deleted and replaced with the statement from the Commission. However, the first two sentences may be considered further if Codex develops

working principles for risk analysis that are to be advice to national governments. Therefore, the U.S. would replace paragraph 11 with current paragraph 40, as follows:

11. 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.[1]

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 process.

U.S. COMMENT: PARAGRAPH 12: The principle, as written is overly broad. While the needs and situations in developing countries should be taken into account, consumer protection cannot be compromised. Therefore, the United States believes that the principle should be modified in recognition that needs cannot always be specifically identified, nor is it always possible or appropriate to accommodate the situation in developing countries. The U.S. would delete the word "specifically" and add the phrase, "To the extent possible and as appropriate" to the beginning of the principle. Therefore, the U.S. would rewrite paragraph 12 as follows:

12. **TO THE EXTENT POSSIBLE AND AS APPROPRIATE, THE NEEDS AND SITUATIONS OF DEVELOPING COUNTRIES SHOULD BE IDENTIFIED AND TAKEN INTO ACCOUNT BY THE RESPONSIBLE BODIES IN THE DIFFERENT STAGES OF THE RISK ANALYSIS PROCESS.**

RISK ASSESSMENT POLICY

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

14. *Risk assessment policy consists of documented guidelines for scientific judgement and policy choices to be applied at appropriate decision points during risk assessment.[1]*

U.S. Comment: Paragraph 14: The United States agrees with the footnote that this principle should be deleted later if the definitions are retained in the final text. The footnote should be altered to indicate this by replacing the word "might" with "should". Therefore, the U.S. would rewrite paragraph 14 as follows:

14. **RISK ASSESSMENT POLICY CONSISTS OF DOCUMENTED GUIDELINES FOR SCIENTIFIC JUDGEMENT AND POLICY CHOICES TO BE APPLIED AT APPROPRIATE DECISION POINTS DURING RISK ASSESSMENT.[2]**

15. To ensure that the risk assessment process is systematic, complete and transparent, risk assessment policy should be established by risk managers preferably in advance of risk assessment, in consultation with risk assessors and all other interested parties.

16. The mandate given by risk managers to risk assessors should be as clear as possible, taking into account available scientific evidence and any constraints affecting the risk assessment process.

17. Where necessary, risk managers may ask risk assessors to evaluate the potential risk reduction resulting from different risk management options.

RISK ASSESSMENT*[*]*

18. Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances.

19. *The scope and purpose of the particular risk assessment being carried out should be clearly stated. The output form and possible alternative outputs of the risk assessment should be defined.*

20. EXPERTS RESPONSIBLE FOR RISK ASSESSMENT SHOULD BE SELECTED IN A TRANSPARENT MANNER ON THE BASIS OF THEIR EXPERTISE AND THEIR INDEPENDENCE WITH REGARD TO THE INTERESTS INVOLVED AND THE PROCEDURES USED TO SELECT THESE EXPERTS SHOULD BE DOCUMENTED INCLUDING A PUBLIC

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[1] Statement adopted by the 24th Session of the Commission (ALINORM 01/41, paras. 81-83)

[1] ~~*This paragraph is also included in the Definitions (Annex 1) and might be deleted later if the Definitions are retained in the final text.*~~

[2] This paragraph is also included in the Definitions (Annex 1) and should be deleted later if the Definitions are retained in the final text.

[*] Reference is made to the Statements *of Principle Concerning the Role of Science and the Extent to which Other Factors are Taken into Account.*

DECLARATION OF ANY POTENTIAL CONFLICT OF INTEREST. THIS DECLARATION SHOULD ALSO IDENTIFY AND DETAIL THEIR INDIVIDUAL EXPERTISE AND EXPERIENCE.

U.S. Comment: Paragraph 20: The U.S. suggests that for editorial clarity, the first sentence of this paragraph should be separated into two sentences by placing a period after "involved", deleting "and", and capitalizing "The". Therefore, the U.S. would rewrite paragraph 20 as follows:

20. **experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise 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 and experience.**

21. Risk assessment should be consistent with the Statements of Principle Concerning the Role of Science and the Extent to which Other Factors are Taken into Account and should incorporate the four steps of the risk assessment process, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization.

U.S. Comment: Paragraph 21:The first paragraph under "**Risk Analysis General Aspects**" (paragraph 5) already states that all risk analysis should be consistent with the Statements of Principle Concerning the Role of Science and the Extent to which Other Factors are Taken into Account. It is not necessary to repeat the same requirement in this paragraph. The U.S. recommends that reference to the Statements of Principle be deleted from this paragraph. Therefore, the U.S. would rewrite paragraph 21 as follows:

21. **RISK ASSESSMENT SHOULD INCORPORATE THE FOUR STEPS OF THE RISK ASSESSMENT PROCESS, I.E. HAZARD IDENTIFICATION, HAZARD CHARACTERIZATION, EXPOSURE ASSESSMENT AND RISK CHARACTERIZATION.**

22. Risk assessment should use available quantitative information to the greatest extent possible and risk characterisations should be presented in a readily understandable and useful form. Risk assessment may also take into account qualitative information.

U.S. Comment: Paragraph 22: All outputs from risk assessment, not just risk characterization, should be presented in readily understandable and useful form. The U.S. would modify this paragraph accordingly to refer to all outputs. Therefore, the U.S. would rewrite paragraph 22 as follows:

22. **RISK ASSESSMENT SHOULD USE AVAILABLE QUANTITATIVE INFORMATION TO THE GREATEST EXTENT POSSIBLE AND RISK ASSESSMENT OUTPUTS SHOULD BE PRESENTED IN A READILY UNDERSTANDABLE AND USEFUL FORM. RISK ASSESSMENT MAY ALSO TAKE INTO ACCOUNT QUALITATIVE INFORMATION.**

23. *Risk assessment should take into account all available scientific data and 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.*

24. Recognizing that primary production in developing countries is largely through small and medium enterprises, risk assessment should be based on data from different parts of the world, including that from developing countries. This data should particularly include epidemiological surveillance data and exposure studies.

U.S. Comment: Paragraph 24:The U.S. believes that he words "should be based" should be deleted and replaced with the words, "should seek and incorporate". This more accurately describes the handling of risk assessment data. Therefore, the U.S. would rewrite paragraph 22 as follows:

24. Recognizing that primary production in developing countries is largely through small and medium enterprises, risk assessment should seek and incorporate data from different parts of the world, including that from developing countries. This data should particularly include epidemiological surveillance data and exposure studies

25. Explicit consideration should be given to variability and other sources of uncertainty at each step in the risk assessment process.

26. Any constraints, uncertainties and assumptions and their impact on the risk assessment should be documented in a transparent manner, including constraints that are likely to influence the quality of the risk estimate. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative.

U.S. Comment: Paragraph 26:The final sentence of the paragraph is not very helpful in that it appears to give equal weight to quantitative and qualitative data. The U.S. believes that the final sentence should be deleted and replaced with a sentence reading, "Any expression of uncertainty or variability in risk estimates

should be quantified to the extent that is scientifically achievable. Therefore, the U.S. would rewrite paragraph 26 as follows:

26. Any constraints, uncertainties and assumptions and their impact on the risk assessment should be documented in a transparent manner, including constraints that are likely to influence the quality of the risk estimate. Any expression of uncertainty or variability in risk estimates 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.

28. *The conclusions of the risk assessment should be conveyed to risk managers in a readily understandable form. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessor.*

29. *To ensure a transparent risk assessment, a formal record, including a summary, should be prepared and made available to other risk assessors and interested parties so that they can review the assessment. It should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and minority opinions.*

RISK MANAGEMENT

U.S. Comment: The U.S. is concerned that there is a fundamental issue of Codex's exact role in "risk management" that has never been adequately discussed in CCGP or other Codex fora.

30. *Risk management decisions should have as their primary objective the protecting the health of consumers. Decisions on acceptable levels of risk should be determined primarily by human health considerations, and unjustified differences in the level of acceptable risk should be avoided.*[2]

U.S. Comment: Paragraph 30:The U.S. believes that this principle should recognize the dual objectives of Codex. Therefore, we add the following sentence; "Risk management decisions should also take into account the Codex mandate to ensure fair practices in the food trade." This would also require that the footnote be eliminated. Also, the concept of an "acceptable level of risk" applies to member governments and not to Codex. This paragraph should be rewritten to be applicable within Codex.

30. Risk management advice given by Codex should have as its primary objective the protecting the health of consumers. Risk management advice should also take into account the Codex mandate to ensure fair practices in the food trade. Decisions on levels of risk to be achieved by risk management options should be determined primarily by human health considerations, and unjustified differences in the levels of resultant risk should be avoided.

31. *Risk management should follow a structured approach, be grounded on science-based risk assessment and take into account other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, as appropriate. The risk management framework includes risk evaluation*[3]*, assessment of risk management options, implementation of management decisions, and monitoring and review*[4]*.*

U.S. Comment: Paragraph 31:The reference to the "*Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle"* should be made in this paragraph rather than paragraph 35. The U.S. would add the words, "according to the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle "* to the end of the first sentence and subsequently delete the reference from paragraph 35. Also, as recognized in the footnote, implementation is not relevant for Codex and should be deleted from these principles applicable within the framework of Codex. However, Codex monitoring and review role, to assure that the risk management advice being given is appropriate. Therefore, the U.S. would rewrite this principle as follows:

31. Risk management should follow a structured approach, be grounded on science-based risk assessment and take into account other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, according to the Criteria for the

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[2] ~~*Joint FAO/WHO Expert Consultation on Risk Management and Food Safety*~~

[3] ~~*See Definitions in Annex 1*~~

[4] ~~*Joint FAO/WHO Expert Consultation on Risk Management and Food Safety. In the framework of Codex the "Implementation" component is not relevant.*~~

Consideration of the Other Factors Referred to in the Second Statement of Principle.[3] In codex The risk management framework includes risk evaluation, assessment of risk management options, and monitoring and review.

32. *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 and the prevalence of specific adverse health effects.*

33. The risk management process should be transparent, consistent and fully documented. Risk management decisions 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.

34. *Risk management options should be evaluated/assessed in terms of the scope and purpose of risk analysis and the ability to achieve the required level of consumer protection. The option of not taking any action should also be considered, as required.*

U.S. Comment: Paragraph 34: The U.S. believes that risk management options should be also evaluated in terms of objective outcomes of risk assessment and would insert this phrase into the first sentence. The first sentence also contains the phrase "required level of protection", which is not appropriate to Codex. National governments would have required levels of protection. Also, to more accurately reflect the role of Codex, we would modify the final sentence to read, "The option of not establishing a standard or related text should also be considered, as appropriate."

34. Risk management options should be evaluated/assessed in terms of objective outcomes of risk assessment, the scope and purpose of risk analysis. The option of not establishing a standard or related text should also be considered, as appropriate.

35. *The outcome of the risk evaluation process should be combined with the assessment of available risk management options in order to reach a decision on management of the risk. In arriving at a decision on risk management, protection of consumers' health should be the primary consideration, with other legitimate factors being considered as appropriate[5], in accordance with the* Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles

U.S. Comment: Paragraph 35: Consistent with our comments on paragraph 31, the U.S. believes that the reference to the criteria for consideration of other factors are more appropriately referenced in paragraph 31 and such reference should be removed from this paragraph. Further, to more accurately reflect the role of Codex, rather than reaching a decision, Codex would make a recommendation. Therefore, the U.S. would rewrite this paragraph, as follows:

35. The outcome of the risk evaluation process should be combined with the assessment of available risk management options in order to make recommendations on management of the risk. In arriving at a decision on risk management, protection of consumers' health should be the primary consideration, with other legitimate factors being considered, as appropriate.

~~36. Guidelines should be defined for the integration in the risk management process of legitimate factors other than science relevant for the health protection of consumers and for the promotion of fair practices in food trade.~~

U.S. Comment: Paragraph 36: The U.S. agrees that this paragraph should be deleted and subsequent paragraphs renumbered accordingly.

37. In order to avoid unjustified trade barriers, risk management should ensure transparency and consistency in the decision-making process in all cases.

U.S. Comment: Paragraph 37: Trade barriers are established by countries and not by Codex. The U.S. believes that this paragraph should be rewritten to more clearly indicate its applicability within the framework of Codex. Therefore, the U.S. would rewrite this paragraph, as given below. (As an aside, the U.S. would like to draw attention to the amount of redundancy inherent in the current draft of the working

[3] *Criteria for the Consideration of the Other Factors referred to in the Second Statement of Principles* have been adopted by the 24th Session of the Commission. The Criteria address the question of the integration of other factors in relation to risk analysis, including risk management.

[5] ~~*Joint FAO/WHO Expert Consultation on Risk Management and Food Safety- Criteria for the Consideration of the Other Factors referred to in the Second Statement of Principles have been adopted by the 24th Session of the Commission (see Annex 2). The Criteria address the question of the integration of other factors in relation to risk analysis, including risk management.*~~

principles. Under "Risk Analysis – General Aspects", paragraph 5 indicates that consistency and transparency should be applied to all steps of risk analysis. Under "Risk Management" consistency and transparency are called for in paragraph 33 and again in this paragraph. The working principles would benefit from a general editorial reading.)

36. In order to avoid risk management recommendations that, if adopted by member countries, would result in unjustified trade barriers, Codex should ensure transparency and consistency in the decision-making process in all cases

38. Risk management should take into account the economic consequences and the feasibility of risk management options in developing countries. Risk management should also recognize the need for flexibility in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers' health.

U.S. Comment: Paragraph 38: The U.S. believes that consideration of economic consequences and feasibility should not be limited to developing countries. Therefore, the U.S. recommends that the phrase ", including those" be inserted before the term, "in developing countries". Also, the paragraph should be modified to make it more clearly applicable to Codex. Therefore, the U.S. would rewrite the paragraph, as follows:

37. Risk management recommendations in Codex should take into account economic consequences and feasibility of risk management options, including those in developing countries. Codex should also recognize the need for flexibility in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers' health.

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. Food standards and related texts should be updated as necessary to reflect new scientific knowledge and other information relevant to risk analysis.

U.S. Comment: This paragraph should be renumbered as 38.

40. *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.*[6]

U.S. Comment: Paragraph40: As explained in our comment to paragraph 10, the U.S. believes that this paragraph, which explains how Codex treats situations in which scientific evidence is insufficient to establish a standard, belongs more in the General Aspects section. Therefore, the U.S. would delete this paragraph:

~~**40. . 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.**~~

RISK COMMUNICATION

U.S. Comment: **RISK COMMUNICATION**: The Codex Committee on General Principles has not discussed "Risk Communication", particularly as it applies within the framework of Codex. Therefore, the U.S. recommends that this section be placed in square brackets, pending discussion. The U.S. believes that, within Codex, there are two major types of risk communication that should be discussed. One is between risk assessors (e.g., expert consultations) and risk managers (e.g., Codex committees). Codex should establish a process for effective communication between these two groups. This process should recognize the iterative nature of risk analysis, including hazard identification and resulting risk assessment. The communication between risk assessors and risk managers must be interactive, transparent and well documented. The second major type of risk communication is with all interested parties. Codex should establish a process for a two-way communication with all its stakeholders (national governments, consumers,

[6] ~~*Statement adopted by the 24th Session of the Commission (ALINORM 01/41, paras. 81-83)*~~

food industries, academia, other international organizations, etc.). This process should be designed to permit Codex to obtain information pertinent to risk analysis and to explain goals and reasoning behind Codex decisions. Again, this communication must be interactive and well documented. Communication should also include assessments of uncertainty, when appropriate. The paragraphs would have to be renumbered accordingly.

41. *[Risk analysis should include clear, interactive and documented communication, between risk assessors and risk managers, and communication with consumers and other interested parties in all aspects of the process.*

42. *A major function of risk communication is establishing a process whereby information and opinion essential to effective risk assessment and risk management is exchanged between all interested parties.*

43. *In their communication with the public, risk managers should include a transparent explanation of the risk assessment policy and risk assessors should identify the uncertainty in risk estimates. The need for specific measures and the procedures followed to determine them should also be clearly explained.*

44. *A risk communication strategy should be proactive and include a plan specifying how information and opinion is to be communicated.*

45. An assessment of uncertainty in risk estimates should be included in the communication process with the public and other interested parties.]

EUROPEAN COMMUNITY

GENERAL REMARK

The European Community supports the new proposed Draft Working Principles, which represent a real improvement and is of the opinion that the text should be adopted at step 5/8 at the next meeting of the CCGP with only some editorial modifications.

EDITORIAL REMARKS
The numbers refer to the paragraph numbering in the Codex document.

SCOPE

3) Add the word "*principles*" after "*..based on risk analysis"* and delete the text between brackets which is redundant.

4) Replace the word "Committees" by "Bodies at the end of the sentence in order to cover all the Expert Groups involved in the risk assessment: *"… Joint FAO/WHO Expert Bodies and Consultations.***"**

RISK ANALYSIS – GENERAL ASPECTS

5) "*The risk analysis process used in Codex should be:*
- *consistent in approach*
- *open, transparent and documented*
- *consistent with the Statement of Principles…*

6) Add the first sentence of paragraph 9) at the end of this paragraph.

9) Delete the first sentence.

10) and 11) The brackets should be removed and the text retained. The order of the sentences/paragraphs should be reconsidered

14) Put the definition of Risk assessment policy between brackets pending the decision to put it in the annex with the other definitions.

RISK ASSESSMENT

21) "*Risk assessment should be consistent with the "Statement of Principles relating to the Role of Food Safety Risk Assessment" and should incorporate…"*

25) and 26) could be merged as follows:

new 25): "*Any constraints, uncertainties and assumptions and their impact at each step in the risk assessment process should be documented in a transparent manner, including constraints that are likely to influence the quality and the accuracy of the risk estimate. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative."*

28) Move the last sentence of paragraph 29 to between the 1st and 2nd sentences of paragraph 28). Paragraph 28 would then read:

28 "*The conclusion of the risk assessment including a risk estimate if available, should be conveyed to risk managers in a readily understandable form. They should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and minority opinions. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors".*

We believe that the risk estimate is the most important part of the conclusion of the risk assessment. It may not always be possible to finalise the risk estimate if the data are not sufficient.

29) The second sentence: "*It should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and minority opinions."* should be deleted as this sentence has been moved to 28).
The first sentence remains unchanged.

RISK MANAGEMENT

31) We propose a redrafting of this paragraph as follows in order to put the organisation of the risk management first and the basis of the decision second:

" Risk management should follow a structured approach including risk evaluation, assessment of risk management options, monitoring and review of the decision taken. The decisions should be based on ~~[science based~~] risk assessment as appropriate to the circumstances 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.

We suggest the deletion of the wording "*science-based*" as it is already covered by the second Statement of Principles Relating to the Role of Food Safety Risk Assessment ("*Food safety risk assessment should be soundly based on science, …*").and because it is not used in the Risk Assessment Chapter and is not in line with the paragraph 23.

We propose also to add *"as appropriate to the circumstances"* to be consistent with the paragraph 18.
Finally, we believe that "*implementation of management decision"* is a task for governments, not for Codex and should be deleted.

33) We suggest adding at the end: *"..as to facilitate a wider understanding of the risk management process by consumers, industry, the academic community and other interested parties."*

37) Transparency and consistency are addressed elsewhere. We suggest the replacement of this paragraph 37 by a new one:

> New 37: *"Examination of the full range of management options should as far as possible take into account an assessment of the potential advantages and disadvantages of the alternative measures."*

38) "*Risk management should take into account the economic consequences and the feasibility of risk management options including those in developing countries. Risk management should also recognise the need for flexibility in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers' health."*

We believe that the economic consequences and the feasibility are very important for all Members of Codex, not only the developing countries.

RISK COMMUNICATION

We suggest keeping the paragraphs 41, 42 as such, and the deletion of paragraph 45.

43) We suggest to add the last sentence of 29) at the end of the paragraph:

"… to determine them should also be clearly explained. They should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and minority opinions."

We suggest also the addition of a new paragraph 44 on the improvement of the participation of NGOs in the Codex work and meetings as follows:

44) *"A risk communication strategy should be proactive and should involve the International Non Governmental Organisations which represent important sections of public opinion and are authorities in their field of professional and technical competence, concerned with matters covered by Codex Risk Analysis Process."*
(NB: This is the text of the Procedural Manual page 60)

General comment: this Chapter was not discussed in the previous CCGP meetings and should be improved.

ANNEX I
Other Definitions

The European Community supports the inclusion of the definition of the Risk Assessment Policy and proposes that the second indent of the definition of the Risk Evaluation should be completed as follows:

- establishment of a risk profile, i.e. a description of the food safety problem and its context. (Definition proposed by the Joint Expert Consultation)

As the term "Risk Estimate" is used in the Principles for Risk Analysis, the European Community suggests also to define this term.

ALA
ÁMBITO DE APLICACIÓN

Proponemos sacar los corchetes del párrafo 3) dado que el propio objetivo del CODEX es "la protección de la salud de los consumidores y al fomento de prácticas equitativas en el comercio de alimentos" por lo que el agregado estaría de más. Por lo tanto el párrafo se leería como sigue:

3) El objetivo de los Principios de Aplicación Prácticos es garantizar que los aspectos de inocuidad de alimentos en las normas y textos afines del Codex se basen en el análisis de riesgos.

ANÁLISIS DE RIESGOS – ASPECTOS GENERALES

No vemos la utilidad de integrar en el párrafo 5) el tercer ítem. El mismo aparecerá correctamente luego en el párrafo 35 del capítulo de Gestión de Riesgos, por lo que proponemos eliminarlo. El párrafo se leería como sigue:

5) El proceso de análisis de riesgos utilizado en el Codex tiene que ser
- **coherente**
- **abierto**
- **transparente.**

En tanto el uso y alcance del término "precaución" es tratado por separado, proponemos eliminar los párrafos 10 y 11. Por lo que sería necesario renumerar los párrafos subsiguientes.

EVALUACIÓN DE RIESGOS

Proponemos eliminar del párrafo 21 lo siguiente : "...debe ser coherente con las *Declaraciones de principios referentes a la función que desempeña la ciencia en el proceso decisorio del Codex y la medida en que se tienen en cuenta otros factores* y..." dado que esta referencia aparecerá correctamente luego en el párrafo 35 del capítulo de Gestión de Riesgos, por lo que proponemos eliminarlo. El párrafo se leería como sigue:

21) La evaluación de riesgos debe comprender las cuatro fases de evaluación de riesgos, es decir, identificación de los peligros, caracterización de los peligros, evaluación de la exposición a los peligros y caracterización de los riesgos.

ANEXO 2

Declaraciones De Principios Referentes A La Función Que Desempeña La Ciencia En El Proceso Decisorio Del Codex Y La Medida En Que Se Tienen En Cuenta Otros Factores - Criterios Para Tomar En Cuenta Los Otros Factores Mencionados En La 2ª Declaración De Principios

En este item, proponemos eliminar lo siguiente; "..., o en el plano regional cuando se trata de normas y textos afines regionales;....", dado que consideramos la inclusión de esta opción un factor discriminatorio y de eventual entorpecimiento del comercio. El párrafo se leería como sigue:

I.	en el marco del Codex, solamente se pueden tomar en consideración los otros factores que puedan ser aceptados en el plano mundial.

CONSUMERS INTERNATIONAL

Introduction

Consumers International (CI) welcomes this revised draft of the proposed draft working principles for risk analysis which incorporates many positive changes that we supported at the April 2001 CCGP meeting. We hope that this very important work can be taken forward and successfully resolved at the workshop to be held in December 2001 prior to the April 2002 CCGP and at the meeting itself. CI also supports the decision of the 24th Session of the Commission to have all Codex Committees and Task forces submit reports on the application of risk analysis in their work in time for the 25th Session of the Commission. CI encourages CCGP to request those committees to provide their reports to CCGP in advance of its April 2003 meeting, so that CCGP might better advise the Commission on synthesis of general principles from the empirical data provided by the Committees.

Scope

We consider it essential that Codex develops both working principles for risk analysis that are applicable to Codex, and advice to member governments that will support consistent and transparent application of risk principles in all nations, guaranteeing consumers around the world a high level of protection wherever the food product originates. We therefore welcome the decision by the Commission with respect to this. In accordance with CI's position at the 24th Session of the Commission, CI supports simultaneous work to develop working principles for risk analysis for Codex and principles which can function as guidance to governments.

At the workshop earlier this year and at the subsequent meeting of the CCGP it became clear that the application of the principles within Codex and at the member government level differed in two key ways: interim precautionary measures were unlikely to be taken in the case of Codex standards although they may be at national level; and the range of risk management options within Codex is likely to be much more limited than the range available to member governments. We have focused our comments firstly on the draft text as it is presented i.e. for use within Codex only, and have then gone on to suggest how we consider the

text could be amended so that it applies to both member governments and Codex. We hope that both aspects of this work can be progressed by the time the Committee reports to the next meeting of the Commission.

Comments that follow refer to specific numbered paragraphs in the Secretariat's draft:

(2) We strongly agree that the primary purpose of Codex should be protecting the health of consumers. Ensuring fair practices in food trade is also an important objective.

(3) We agree that the objective of the working principles is to ensure that the food safety aspects of Codex standards and related texts are based on risk analysis. Regarding the text in square brackets, we propose replacing the phrase 'an objective basis' with 'a rigorous and transparent basis'. As it is recognised later in the principles, while some aspects of risk analysis are objective, other aspects may not be. For example, they will involve a certain amount of subjectivity in determining the significance of the risk and also the appropriateness of various measures to control the risk. We consider that rigour and transparency better capture the sense of what is gained by consistent risk analysis principles.

(4) We support the clarification as to who will have responsibility for the different aspects of the risk analysis. It should also be clarified here that: '*Risk communication is an interactive process involving risk assessors, risk managers and all interested parties, including consumers, throughout all stages of the risk analysis.'*

Risk analysis – general aspects

(6) We agree that a structured approach should be followed as far as practicable, but taking into consideration the points raised in paragraph (9) – a certain amount of interaction will be required throughout the three stages of risk assessment, risk management and risk communication.

(7) We agree that the three components of risk analysis should be documented fully and systematically in a transparent manner. We also support the recognition that 'while respecting legitimate concerns to preserve confidentiality, documentation should be open to scrutiny by consumers and their representative organisations, and other interested parties.' Clarification as to what is meant by 'legitimate concerns to preserve confidentiality' should be provided in the definitions. Confidentiality claims must not impede timely and complete access to documentation of the risk analysis process and decision by all interested parties.

(8) Effective communication and consultation with all interested parties throughout the risk analysis process is essential.

(9) We strongly support the clarification provided by this paragraph – while a functional separation between risk assessment and risk management should be maintained as far as practicable, a certain amount of interaction will be inevitable.

(10) We strongly support the inclusion of this paragraph which is currently in square brackets. It is important that the working principles acknowledge that precaution is an essential element of the entire risk analysis process. This paragraph clarifies that precaution should be part of risk assessment as well as risk management. It also reflects the conclusions of the Conference on International Food Trade Beyond 2000, held in Melbourne in 1999.

(11) We also support the inclusion of this paragraph, which usefully explains the way that decisions often have to be made when faced with scientific uncertainty and how this must be explicitly acknowledged. The square brackets should therefore be deleted.

(12) It is essential that the risk analysis takes into account the needs and situations of developing countries as part of the risk analysis, as well as any other significant differences between the situations in different countries which could have a bearing on the risk analysis.

Risk assessment policy

(13) We agree – as set out in the FAO/WHO expert consultation on risk management – that risk assessment policy should be included as a specific component of risk management. This is a crucial stage of the process as it is here that the issue is first defined and the questions to be addressed by the risk assessors are framed. This can therefore have an important bearing on the approach that is taken to the risk assessment and on the outcome.

(14) We agree that it is not necessary to retain this definition of risk assessment policy here in the text if it is to be included in the definitions section.

(15) We consider that it is essential – rather than merely 'preferable' as currently stated – that the risk assessment policy is established in advance of risk assessment. We therefore suggest that 'preferably' is

deleted. We agree that it should be established by risk managers in consultation with all other interested parties including consumers.

(16) We agree that the mandate given to the risk assessors should be as clear as possible. It should also clarify the type of expertise that is needed and the approach that should be taken including how the findings should be communicated.

(17) It may be appropriate in some situations for risk managers to ask risk assessors to evaluate the potential risk reduction resulting from different risk management options. However, it is important that risk assessors are not asked to stray directly into risk management. For example, it is not appropriate for risk assessors to consider the economic impact of various measures, as this is part of the role of the risk managers.

Risk assessment

In general we agree with the guidance on risk assessment, but have the following specific comments:

(20) We strongly support the requirement for experts responsible for risk assessment to be selected in a transparent manner on the basis of their expertise and independence, and for there to be a public declaration of interests. We suggest that the last sentence is reworded as follows to clarify this: 'The declaration should also identify and detail their individual expertise and experience *and any personal interests, including financial interests.*'

(22) We agree with the intention of this paragraph, but are unclear why it refers only to risk characterisations. It is essential that all four elements of the risk assessment, including hazard identification, hazard characterisation and exposure assessment are presented in a readily understandable and usable form so that it is clear how the risk assessors reached their conclusions and what factors they took into consideration, including the weight that was given to the evidence considered.

(29) We strongly support this requirement for a formal record including a summary to be prepared and made available to other risk assessors and interested parties, which should include consumer representatives, indicating any constraints, uncertainties, assumptions and their impact on the risk assessment, and minority opinions. As these guidelines are directed at Codex, it is essential that this record is publicly available before the issue is considered by the relevant Codex committee in order to ensure full involvement by all interested parties in the discussions.

Risk management

(30) We agree that the primary purpose of risk management decisions should be protecting the health of consumers. However, we suggest that the second sentence is reworded to state that '*as far as possible* unjustified differences in the level of acceptable risk should be avoided.'

(32) We suggest that this paragraph also makes reference to 'level of compliance' and 'enforceability'. Documented level of compliance and enforcement practices should be used in evaluating the achievements of risk management policies and practices.

(33) We suggest that the following wording is added to the end of the first sentence: '*and the documentation should be readily available to all interested parties.*'

(36) We propose that this paragraph is retained rather than deleted and reworded as follows: '*General guidelines for the integration of legitimate factors other than science relevant for the health protection of consumers and for the promotion of fair practices in food trade in risk management were adopted by the Commission at its 24th Session (reference to procedural manual). Individual Codex committees and task forces should develop further detailed guidelines on the application of other legitimate factors within their specific areas of risk analysis*.'

(40) We recognise that this paragraph represents the Commission's decision reached in July. We welcome this clarification that many Codex actions have been, and will continue to be, taken without complete scientific evidence to support a thorough risk assessment. While we are cautious about suggesting any changes to this intensely debated language, we consider that the current wording could be strengthened by the addition of the following sentence at the end of the paragraph: '*In such cases, the measure would need to be reviewed in the light of new evidence.'*

Risk communication

We agree with the text as currently drafted, but suggest the following addition to paragraph (44):

(44) 'A risk communication strategy should be proactive and include a plan specifying how information and opinion is to be *incorporated and* communicated.'

Application to member governments

There are several ways CCGP could proceed to give advice on the application of risk analysis by member governments. One way would be simply to revise the current draft so that it applies both to Codex and to member governments, adding wording as necessary at various points to distinguish between the two, and clarify the applications in each case. As noted in the introduction to these comments, we believe this approach is feasible. If CCGP opts to pursue this option, we propose that the following changes would be useful:

(1) This paragraph should now broaden the scope to refer to advice to member governments.

(2) Reference specifically to the Codex Alimentarius Commission should be deleted.

(3) This should state that the objective of the working principles is to ensure that food safety aspects of Codex standards and related texts *and measures adopted by member governments* are based on risk analysis.

(5) The reference to Codex in the first-line should be removed and the third bullet point should state that '*in the case of Codex*, consistent with the Statements of Principle…..'

(12) It should state that this only applies in the case of Codex.

(21) This should state that risk assessment *within Codex* should be consistent with the Statements of Principle Concerning the Role of Science and the Extent to which Other Factors are Taken into Account.

(24) It should also state that this only applies in the case of Codex.

(35) The last sentence should state that *in the case of Codex* in accordance with the Criteria for the Consideration of the other Factors……

(40) This should also be amended to make it clear that different circumstances will apply for Codex and member governments. We suggest the following wording:

'*Where there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, it may be appropriate for risk managers to apply precaution by adopting interim measures, proportional to the risk, to protect the health of consumers while further information is gathered to strengthen the scientific evidence. In such situations the Codex Alimentarius Commission may decide not to proceed to elaborate a standard. Measures should be reviewed in the light of new evidence'*

Paragraph 27 emphasises the need for all risk management decisions to be transparent, consistent and fully documented. Paragraph 33 stresses that risk management is a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions, and that food standards and related texts must be consistent with new scientific knowledge and other information relevant to risk analysis. There is therefore no need to repeat these points in this expansion on para 40.

IACFO

We commend the Secretariat for its Proposed Draft Working Principles for Risk Analysis (Draft Principles) as applied to the work of Codex.[40] Codex's work in this area is important for two reasons:

- The existence of a Codex measure can encourage national governments to adopt a similar standard. For example, Article 4.2.1.4 of the Codex Standard for the Labelling of Prepackaged Foods says that eight groups of foods "are known to cause hypersensitivity and shall always be declared." Some national governments are now considering whether to require disclosure of known food allergens.[41]

- Under Article 3.2 of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), a national measure that complies with a Codex "standard, guideline, or recommendation" is presumed to be legal by the World Trade Organization. For example, if Codex were to accept the World Health Organization's 1997 recommendation that there should be a ban on

[40] In July 2000 the Commission directed the Committee to also "develop guidance to governments subsequently or in parallel" to completing the principles for risk analysis within Codex. ALINORM 01/41 at paragraph 75. We support this effort as well.

[41] In July 2001 Health and Consumer Protection Commissioner David Byrne said that the European Commission would propose a new directive requiring that all ingredients of foods -- including allergens -- be labeled, and on August 13, 2001 the United States Food and Drug Administration held a public meeting to consider whether to require disclosure of food allergens. The Canadian government is also considering whether to revise its food labeling regulations, which currently provide some exemptions for allergens.

accelerating the growth of livestock with human-use antibiotics,[42] then the European Union's 1999 ban of such antibiotics would be protected from a legal challenge by other countries.[43]

Thus, the Committee on General Principles (CCGP) should act quickly on the Draft Principles, as directed by the Commission, so that the Commission can adopt them in 2003.[44]

Comments on Specific Provisions

1) We support retaining the draft provision for consumer participation in paragraph 7 that was adopted at the April 2000 meeting of the CCGP following our intervention.[45]

2) We support the removal of the brackets around paragraphs 10 and 11 dealing with the important topic of how Codex should proceed in its own work "where scientific evidence is insufficient and negative effects on health are difficult to evaluate." Codex should not -- as suggested by some governments at the July 2001 Commission meeting[46] -- shy away from considering these important public health matters merely because there is disagreement among scientists about the sufficiency of the evidence. There is not an undisputed bright line between cases where the scientific evidence is sufficient and cases where it is not. Rather, there is a continuum about the weight of scientific evidence and, at any particular time, decision-makers must exercise their judgment about which inferences to draw from the available scientific evidence.[47]

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[42] The issue of antimicrobial resistant bacteria in food is currently on the agenda of four different Codex groups: the Committee on Food Hygiene, the Committee on Pesticide Residues, the Committee on Residues of Veterinary Drugs in Foods, and the Ad Hoc Task Force on Animal Feeding. In June 2001 the Executive Committee agreed to ask the World Health Organization and the Food and Agriculture Organization whether the Commission should create a new Task Force to deal with this matter. ALINORM 01/4 at paragraph 37.

[43] There may be such a challenge. In October 1999 a coalition of United States agricultural organizations and pharmaceutical companies wrote to the United States Trade Representative (USTR) supporting its August 1999 letter to the European Union that asserted that the European Union's ban on the use of human-use antibiotics to stimulate the growth of livestock "appears to have been taken without proper risk assessment being done." The coalition argued that the European Union had "invoked the so-called precautionary principle" in adopting its ban and said that "the continued application of such a policy would effectively negate the disciplines of the SPS Agreement." In February 2000 the USTR said that "the United States will continue to call for the EC to comply with the provisions of the SPS Agreement in implementing" its ban. A United States government official was more blunt in a subsequent article, stating "the European Union took the decision to ban [antimicrobial use in animal feed] on an emergency basis and then studied [sic] to see if there was enough scientific evidence to sustain the ban, that is backwards." Alejandro B. Thiermann, "Protecting Health, Facilitating Trade, or Both," 916 *Annals New York Academy of Sciences* 24 (December 2000) at 28. In July 2001 the United States told the WTO's Committee on Sanitary and Phytosantiary Measures that it still considers the European Union's ban to be an "unresolved" trade dispute. G/SPS/GEN/265 (July 10, 2001) at paragraph 46.

[44] ALINORM 01/41 at paragraph 75.

[45] ALINORM 01/33A at paragraph 31 of agenda item 3. For editorial consistency, the phrase used in paragraph 7 -- "consumers and their representative organizations, and other interested parties" -- should also be used in paragraph 8 (which now uses the phrase "all interested parties"), paragraph 29 (which now uses the phrase "interested parties"), paragraph 42 (which now uses the phrase "all interested parties"), and paragraph 45 (which now uses the phrase "the public and other interested parties").

[46] ALINORM 01/41 at paragraph 80 and draft United States position (June 25, 2001).

[47] Such a judgment includes an assessment of the consequences of two different types of incorrect decisions: banning a product as unsafe when (unknown to the decision-maker) it is in fact safe or permitting the sale of a product as safe when (unknown to the decision-maker) it is unsafe. "These two types of errors are sometimes called producers' and consumers' risks," as in the former case the producers suffer an unjustified loss and in the latter case consumers suffer an unjustified risk of harm. W. J. Dixon and F. J. Massey, Jr., *Introduction to Statistical Analysis* (1957) at 245. [These two types of errors are sometimes called either a Type I error (rejecting a null hypothesis when it is true) and a Type II error (accepting a null hypothesis when it is false), G. R. Norman and D. L. Streiner, *Biostatistics, The Bare Essentials* (1998) at 43-44, or a false positive error (showing a health problem when in fact there is no problem) and a false negative error (showing no health problem when in fact there is a problem). D. L. Streiner and G. R. Norman, *PDQ Epidemiology* (1996) at 101-103.] In some cases it may be prudent to seek to minimize consumers' risks when there is little evidence. For example, the United States Environmental Protection Agency (USEPA) is currently considering whether to exempt certain plant-incorporated protections from its regulations dealing with genetically engineered plants. While acknowledging that current knowledge does not indicate that the proposed exemptions would

The probability of disagreement among scientists is frequently proportional to the commercial importance of the product being considered.[48] The Commission decided, by a majority vote, that in such situations it will develop a "code of practice" for national governments to follow.[49]

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pose an unreasonable risk, the Center for Science in the Public Interest (in September 2001) urged the USEPA to reject the proposed exemptions because they have the potential to cause unreasonable harm and, sufficient experience to predict such harmful cases, has not yet been acquired.

[48]Consider, for example, antibiotics used in livestock. The World Health Organization estimates that in North America and Europe about 50 percent in tonnage of all antimicrobial production is used in food-producing animals and poultry. World Health Organization, *WHO Global Strategy for Containment of Antimicrobial Resistance* (2001) at 38. Codex should promptly consider restricting the use for poultry of one class of antibiotics, fluoroquinolones, even though there is disagreement among scientists about whether such use jeopardizes human health. On the one hand, in October 2000 the United States Food and Drug Administration (USFDA) asked the two producers of fluoroquinolones used in poultry -- Abbott Laboratories and Bayer Corporation -- to withdraw them from the United States market because the USFDA had determined that the use of fluoroquinolones in poultry causes the development of fluoroquinolone-resistant *Campylobacter*, which is transferred to humans, and is a significant cause of resistant *Campylobacter* infections in people. USFDA estimated that over 9,000 people per year will have more severe and prolonged food poisoning because of fluoroquinolone-resistant *Campylobacter*. Abbott agreed to stop its sales. On the other hand, Bayer refused and exercised its legal right to a hearing (which could last for many years). Bayer says that its review of the scientific evidence indicates that the continued use of its fluoroquinolones in poultry poses no public health threat.

[49] ALINORM 01/41 at paragraphs 81-84.

3) It appears that some experts, who are members of recent WHO/FAO expert advisory bodies, have received funding from the food industry.[50] Thus, we support retaining the draft provision on the transparent selection of experts (paragraph 20) approved in April 2000 by the CCGP.[51] This provision would help the public to assess the possible conflict of interest of both private and public experts used by FAO/WHO Expert Committees. We urge the CCGP to continue its work in this area to ensure even greater transparency in the future.

IADSA

IADSA, the International Alliance of Dietary/Food Supplement Associations, would like to make the following comments on the new proposed Draft Working Principles:

§25

IADSA questions the lack of clarity of this point and recommends that the entire bracketed point be deleted as redundant to the points made in §23 and §24.

§38

Strictly speaking, economic considerations should not be part of risk management whose purpose is only to control risk. However, in choosing the appropriate risk management option, account should be taken of the economic consequences and feasibility of the option. These aspects should be considered regardless of whether the country is a developing or developed one. This paragraph should therefore be replaced by:

"In selecting risk management options, account should be taken of the economic consequences. The risk management options should take into account economic costs and feasibility in relation to the intended benefit of the risk management option"

§40

IADSA does not consider it logical to propose the development of a code of practice if there is insufficient evidence to elaborate a standard. What would be the value of a code of practice based on insufficient evidence? The
Codex Alimentarius Commission would more logically elaborate text summarizing the conclusions of risk assessment at that given time.

Annex 1

As has been recognized during previous discussions, the scientific data is rarely complete. The risk assessor must therefore judge whether the data available is sufficient or insufficient. If this judgement were to be challenged by any Codex member, the development of Codex Standards may be severely hindered. Further elaboration of what constitutes "insufficient scientific evidence" is therefore required. IADSA proposes that this issue is addressed either among the definitions set out in Annex 1 or within the Working Principles for Risk Analysis themselves.

Annex 2

The 4th bullet point should be clarified by adding at the end of the sentence: ".but such concerns nevertheless must not be used as unjustified barriers to trade."

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[50] We examined four expert committees -- Expert Joint FAO/WHO Consultation on Human Vitamin and Mineral Requirements, Roster of Experts for JECFA Discussions on Food Additives and Contaminants, Joint FAO/WHO Meeting on Pesticide Residues, and Roster of Experts for FAO/WHO Joint Consultations on Foods Derived from Biotechnology -- and found eleven persons who had received money from business. www.cspinet.org/integrity (last checked October 25, 2001). Receipt of such funds does not imply that these persons had improper motives or acted unethically and does not necessarily invalidate their advice to these committees.

[51] ALINORM 01/33A at paragraph 39 of agenda item 3.

IFAH (INTERNATIONAL FEDERATION FOR ANIMAL HEALTH)

SPECIFIC COMMENTS

Point 7: while referring to "respecting legitimate concerns to preserve confidentiality", it is stated that " documentation should be open to scrutiny by consumers ...".

This is contradictory and Companies can not submit proprietary information to Codex without a firm understanding that such information will be kept confidential.

Points 10 and 11: 10 still contains reference to "precaution". Precaution is embedded in the risk assessment process by the use of large safety factors, which account for uncertainty in the available data.

This is acknowledged in 11 and this might be why both points 10 and 11 are in brackets meaning that one or the other could be deleted. We believe that point 10 should be deleted.

Point 28: The responsibility for judging the impact of uncertainty should be with the scientific experts who review the data and carry out the assessment. How can the risk manager resolve the uncertainty in the data?

This is implicitly acknowledged in point 17 which advises risk managers to "ask risk assessors to evaluate the potential risk reduction resulting from different risk management options".

Point 31: We do not agree with adding " other legitimate factors". Factors "relevant for the health protection of consumers and for the promotion of fair practices in food trade" will have been considered within the context of the risk assessment. "Other legitimate factors" might be applicable to risk management by a national government but as stated in the introduction "the text should refer only to risk management in Codex".

49TH PARALLEL BIOTECHNOLOGY CONSORTIUM

INTRODUCTION

Although we understand that the 24th Session of the Codex Alimentarius Commission confirmed the mandate of the Committee on General Principles to work on Principles of Risk Analysis, we are also participating in the Codex Task Force on Foods Derived from Biotechnology which has spent considerable time working on a document on the same topic. It is our belief that the CGP draft is superior, and we are pleased that it will apparently become the operative Codex statement. Also open is the question of how risk assessment required under the Cartagena Biosafety Protocol (for genetically engineered food shipped across transnational borders) will relate to the CGP document.

At the threshold, 49th Parallel feels compelled to point out that the currently fashionable schema of risk analysis/risk management/risk assessment, while appearing logical, is not representative of real-world activities and has a history of serving certain political ends.

The modern era of risk assessment can be traced back to Chauncey Starr's 1969 article in *Science*, but it was not perhaps until 1976, with the publication of William Lowrence's *Of Acceptable Risk*, that the subjective elements of the process began to get a forthright treatment. While Lowrence tried to maintain that "risk" was scientifically objective, his discussion of "safety"—as socially acceptable risk—acknowledged the political nature of the overall context of the evaluation. But it is obvious that even a rigid determination of a clear risk—say of injury from skydiving or of winning the lottery jackpot—cannot, in itself, tell us why only some people will accept the risk and jump from an airplane or buy a ticket. Nor can it tell us the fractional portion of the population willing to undergo such an action.

Therefore, we must recognize that risk itself (defined as the probability of a hazard) has subjective elements. And when we affirm this characteristic of risk—that assessing risk *inherently* involves judgment--the Precautionary Principle can be seen as a natural aspect of risk assessment, not something alien.

Thus, the proposition is the subjective nature of risk itself, and perforce of its assessment.
Subjective aspects include:

- The choice of phenomena to research;
- The definition of what is a "hazard" (ie, undesirable);

- How to actually measure a hazard, especially if it combines different aspects not subject to a single metric ;
- How to account for incomplete knowledge, uncertainty, etc. in the nature/consequences of the hazard as well as its probability;
- Who has the burden of proof of developing the necessary data—the proponent of the technology, the regulatory agency, or consumer/environmental citizen organizations?;
- How to account for the social distribution of risk, since hazards impact different sectors/classes in society differently;
- How to discount future events in light of present actions ;
- How to monitor a risk, and how much surveillance is "worth" in both monetary and non-monetary terms;
- How to balance risks against "benefits", since benefits involve all the above factors as well; and
- How to account for the interests/commitments/goals of decision-makers and the effects of these factors on the conduct and conclusions of the assessment.

Despite this reality, the current dominant paradigm still claims that risk assessment is a matter for "sound science" rather than politics or social values; these other messy factors must wait until after risk is assessed when they can come into play as part of "risk management." This bifurcation is historically traceable to William Ruckelshaus' second tenure as head of the US EPA.

Ruckelshaus was brought back into that role as part of the larger agenda under Ronald Reagan to roll back the "democratic paradigm" of public policy and install a "technocratic" one (in the terminology of David Dickson, a report/editor with *Science, Nature, New Scientist*). This maneuver helped that Administration (and subsequent ones) deflect popular environmental and consumer concerns while calling for endless technical studies, thus delaying substantially any constraints on industry practices (and simultaneously enabling citizen groups to be discredited as anti-rational and selfish, and alienating liberal scientists from those movements to which they otherwise might have given pro bono advice.) "Sound science" thus became a mantra to obscure the exercise of partisan political power.

Of course, 49th Parallel recognizes that there is an important role for science in decision-making; but it is equally important to recognize the social and political aspects of science, and how these bear on conclusions. There is no such thing as a single, universally "sound" science; scientific standards and practices are, by definition, negotiated within (and sometimes beyond) the scientific community.

The reference to "other factors" legitimate to an analysis of food risks is a welcome recognition that handling risk under Codex is not like doing traditional "science" because there are *explicit* policy concerns mandated to be considered.

The remainder of this document offers comments on the CCGP Working Principles for Risk Analysis, under the context of the above discussion.

SCOPE

We urge the elimination of the material in the brackets in para (3); as indicated above, risk analysis is not "objective" in the sense of being value-free. It is far more important for the principles of transparency that the values which contribute to the analysis are clearly evident, rather than falsel;y implying that they are non-existent.

RISK ANALYSIS - GENERAL ASPECTS

In para (6), as noted above, the tripartite distinction is artificial and inaccurate. It should be eliminated.

The 49th Parallel organization strongly supports the emphasis in para (7) that claims of "confidential business information" should not trump democratic needs for informed public oversight of government regulatory decisions and participation in policy formation.

The inconsistencies in para (9) result from the false model of para (6). The second sentence should be eliminated, since there is no "functional separation" (as the third sentence clearly indicates), and risk assessment is not accurately described as "scientific," where that term is defined as being wholly objective. Perhaps risk assessment should be more aptly labeled as a form of "regulatory science" which is understood to encompass many of the factors noted in our general discussion at the beginning of this document. In any

event, the initial word "However" should be eliminated from the third sentence, and the next word should begin with a capital letter.

The brackets should be eliminated in paras (10) and (11), in our view. Precaution is an inescapable element of responsible risk assessment, where information will often be limited and/or uncertain, as recognized by the Cartagena Biosafety Protocol. Throughout the negotiations over the Protocol, the United States delegation always challenged those who promoted the Precautionary Principle as being emotional and attacking sound science. Yet, as a lengthy paper sponsored by Consumers International documented over a year ago, US law is full of precautionary provisions. There is no evidence whatsoever that they have hindered the application of the best *possible* science to assessing various risks while also taking due account of uncertainties and searching for appropriate and feasible alternatives. The responsibilities of national and international bureaucracies to respond to a democratic public's political and social desires should not be sloughed off onto unaccountable scientists in the guise that some mysterious "sound science" itself can tell us the *right* choices to make without considering these factors.

In para (15), we urge that the phrase "complete and transparent" be replaced by "as complete and transparent as possible, since completeness and transparency are not discrete states but relative evaluations of a regulatory process.

Risk Assessment

The 49th Parallel Biotechnology Consortium strongly supports para (20); as activist citizens we are sorely aware of the many abuses which have occurred in the past when conflicts of interest have not been clearly identified and supposedly neutral experts render opinions inevitably shaped by biases.

In para (21), the reference to "the four steps" is misleading. This is only one model of assessment of the several in the relevant literature. In addition, characterizing them as "steps' implies that they are sequential, when in fact these activities must be conducted in iterative fashion.

Para (22) acknowledges that risk assessment is not "objective" nor "science" by recognizing that "qualitative information"—which can include objective, as well as subjective and impressionistic, elements-- may also be taken into account in the process. We would like to see a small amendment, however--the replacement of the word "may" in the last sentence by "should, to the greatest extent possible" so that it urges that *all* relevant information, qualitative and quantitative, be considered. We cannot see why *any* information should be excluded a priori.

We strongly support the concepts in paras (25)-(27).

Paras (28) and (29) are confusing and not conducive to either transparency or an informed citizenry. We urge amending (28) by inserting in the first sentence "and the public". The second sentence should be recast to recognize that *both* risk assessors and managers must deal with uncertainty, but that the latter are politically responsible to the citizenry and so must take ultimate responsibility for how this aspect of the process is handled. Thus, in (29) the "formal record" should not be understood to be an abbreviated summary of the process (and it should include the "conclusions") which might reduce transparency.

Risk Management

In para (30) the term "unjustified risk" is unclear and undefined.

We are very supportive of the second sentence of para (35). However, the term "risk evaluation" in the first sentence appears to be an error; shouldn't it be "risk analysis"?

In para (37) the vague modifier "unjustified" appears again, this time regarding trade barriers. This term should be replaced by one with a clearer meaning, or it should be clearly defined itself.

Risk Communication

The 5 paras under this section (41-45) need to be amended to clearly state that communication is a 2-way street, and that the assessors and managers must provide clear procedures for the public to participate by receiving communications from the public. The current language implies that the term "communication" is (or ought to be) one-way only—from the bureaucrats to the public.

CRN

Comments are provided to specific paragraphs as numbered:

Scope:

1. This statement is appropriate and does not need to be changed. It accurately reflects the decision of the Commission that principles of risk analysis are to be applied to the framework of Codex.

3. To avoid ambiguity, the word "scientific" should be inserted after the second "objective."

Risk Analysis- General Aspects:

10. The bracketed text should be deleted. Precaution is build into standard procedures should be used when negative effects on health are identified. The phrase "are difficult to evaluate" will lead to misinterpretation because complex problems are always difficult to evaluate.

11. The bracketed text should be deleted.

12. We agree with the concept, but question the process—how will needs and situations for developing countries be identified? We suggest the description in paragraph 38 be employed here.

16. See Paragraph 17 comment. Combine the two.

17. We suggest the following, "The mandate given by risk managers to risk assessors should be as clear as possible, taking into account available scientific evidence and any constraints affecting the risk assessment process. Risk managers should evaluate human health and safety risk reductions resulting from different risk management options."

Risk Assessment:

18. We recommend combining this paragraph with paragraph 19 as follows, "Science based risk assessments should form the basis of Codex standards, guidelines and recommendations. The scope and purpose of each risk assessment should be clearly stated and the outputs of the risk assessment should be defined."

26. A second sentence should be added that reads, "Any expression of uncertainty or variability in risk estimates should be quantified to the extent it is scientifically achievable."

Risk Management: These principles are "intended for application in the framework of the Codex Alimentarius." The role of Codex Alimentarius in risk management needs to be appropriately clarified.

30. We suggest using language in paragraph. 2, "The basis of risk management decisions should be to protect the health of consumers while not unjustly hinder fair practices in food trade."

31. This should be changed. We suggest, "…as identified in *Criteria for the Consideration of Other Factors Referred to in the Second Statement of Principles."* after OLF.

34. This should be changed. We suggest, "Risk management options should be evaluated/assessed in terms of the objective outcomes of risk assessment and risk characterization, as well as the overall scope and purpose of risk analysis considering the risk of taking no action.

35. This should be changed. We suggest, "The outcome of the risk evaluation process should derive from the appropriate exercise of objective and scientific standards, weighing risks against benefits, with protection of consumer health and safety the primary consideration, and the standard of proof based on that articulated in Article 5.7 of the Sanitary and Phytosanitary (SPS) Agreements.

36. No comment.

37. This should be changed. We suggest, "Risk management should ensure transparency in the decision making process. Decisions should ensure consistency in similar circumstances to avoid unjustified trade barriers.

Risk Communication: Since these principles are "intended for application in the framework of the Codex Alimentarius," we request clarification as to the role of Codex Alimentarius in risk communication.

ICGMA

Scope

1. This statement accurately reflects the decision of the Commission that principles of risk analysis be applied to the framework of Codex

3. Insert the word "scientific" after second "objective"

7. Replace "consumers and their representative organizations, and other interested parties" with 'all interested parties" for consistency with para. 8

Risk Analysis – General Aspects

10. Delete bracketed text. Precaution should be used when negative effects on health are identified – not when those effects are "difficult to evaluate".

11. Delete the bracketed text.

12. We agree with this premise, but questions how all needs and situations for developing countries can be identified. We suggest paragraph 38 verbiage.

16. Delete this paragraph and combine the concept with paragraph as indicated in our suggested new para. 17.

17. We suggest "The mandate given by risk managers to risk assessors should be as clear as possible, taking into account available scientific evidence and any constraints affecting the risk assessment process. Risk managers should evaluate human health and safety risk reductions resulting from different risk management options."

Risk Assessment

18. Suggest combining this paragraph with para. 19 as follows, "Science based risk assessments should form the basis of Codex standards, guidelines and recommendations. The scope and purpose of each risk assessment should be clearly stated and the outputs of the risk assessment should be defined."

20. For clarity, suggest, "Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved. The procedures used to select these experts should be documented, including details of their expertise and experience and a declaration of any potential conflict of interest."

26. Suggest second sentence. "Any expression of uncertainty or variability in risk estimates should be quantified to the extend it is scientifically achievable."

Risk Management: As these principles are "intended for application in the framework of the Codex Alimentarius", we request clarification as to the role of Codex Alimentarius in risk management.

30. In accordance with the scope of the document and for consistency we suggest using language in para. 2, "The basis of risk management decisions should be to protect the health of consumers while not unjustly hinder fair practices in food trade."

31. We suggest, "..as identified in *Criteria for the Consideration of Other Factors Referred to in the Second Statement of Principle*" after OLF.

34. Suggest, "Risk Management options should be evaluated/assessed in terms of the objective outcomes of risk assessment and risk characterization, as well as the overall scope and purpose of risk analysis considering the risk of taking no action"

35. Suggest, "The outcome of the risk evaluation process should derive from the appropriate exercise of objective and scientific standards, weighing risks against benefits, with protection of consumer health and safety the primary consideration, and the standard of proof based on that articulated in Article 5.7 of the Sanitary and Phytosanitary (SPS) Agreement.

36. Agree with deletion

37. Suggest, "Risk management should ensure transparency for application in the framework of the Codex Alimentarius," we request clarification as to the role of Codex Alimentarius in risk communication.

AEDA/EFLA

The scope of the present Codex document

Considering the orientations taken at the 24th Session of the Codex Alimentarius Commission held in Geneva (2-7 July 2001), EFLA acknowledges that the scope of the present document is limited to the principles for Risk Analysis for application at Codex, and not for governments.

However, EFLA is of the view that, in order to prevent misuse of precaution which may generate barriers to trade, Codex should define the circumstances under which Article 5.7 of the SPS agreement may be applied, and particularly

- when "relevant scientific information" is considered "insufficient"
- what is "pertinent information"
- where and how the "additional information" is to be sought by the Member States

Specific comments

As long as the present document is restricted to guidelines in the framework of the Codex Alimentarius, EFLA submits the following comments:

§ 10

A majority considers that precaution, if introduced, must apply at the risk management level and not at the risk assessment level. This position is based on the principle that the scientists must remain free to give fully

independent statements, whereas the decisions taken on the basis of these statements incorporate political factors. This is clear since risk managers can also take into account "other legitimate factors".

Therefore, EFLA suggests that "the use of appropriate assumptions in the risk assessment and" at § 10 should be deleted.

§ 11

It is not clear whether the uncertainty referred to at this paragraph is about the risk or about the hazard (both as defined in Annex 1). Therefore, the practical meaning of the last sentence of § 11 is not clear. This sentence should be deleted if the whole paragraph remains as it stands,

§ 37

Considering the scope of the present document, this paragraph does not seem to be necessary and, consequently, it should be deleted to avoid confusion.

Annex 1 : Definitions

The following concepts, referred to in § 40, should be defined

- insufficient scientific data
- incomplete scientific data
- available scientific evidence

Annex 2 : Other legitimate factors

For reasons explained at § 37, EFLA does not understand why the 4th and the last "bullet points" are still present in the present document, if such document deals only with guidelines for Codex Alimentarius and not for member states.