comisión del codex alimentarius

ORGANIZACIÓN DE LAS NACIONES UNIDAS PARA LA AGRICULTURA Y LA ALIMENTACIÓN

ORGANIZACIÓN MUNDIAL DE LA SALUD

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Tema 3a) del programa **CX/GP 02/3**

PROGRAMA CONJUNTO FAO/OMS SOBRE NORMAS ALIMENTARIAS
COMITE DEL CODEX SOBRE PRINCIPIOS GENERALES
17ª reunión, París, Francia, 15 – 19 de abril de 2002

ANTEPROYECTO DE PRINCIPIOS DE APLICACIÓN PRÁCTICOS SOBRE ANÁLISIS DE RIESGOS

La 16ª reunión del Comité sobre Principios generales examinó los Principios de aplicación práctica sobre análisis de riesgo y aprobó varias enmiendas al texto. Sin embargo, no alcanzó un consenso sobre el ámbito de aplicación y la aplicación de la precaución en el análisis de riesgos, especialmente en la gestión de riesgos. En consecuencia, el Comité acordó pedir a la Comisión una aclaración del ámbito de aplicación, es decir, si era un texto exclusivamente para aplicación dentro del marco del Codex, o por parte de los gobiernos de los Estados Miembros o ambas cosas a la vez. El Comité acordó también pedir el asesoramiento de la Comisión sobre cómo debería reaccionar el Codex cuando los datos científicos fuesen insuficientes o incompletos y hubiera pruebas de un riesgo para la salud humana, sobre todo si debía proceder a elaborar una norma o texto afín.

La 24ª reunión de la Comisión del Codex Alimentarius confirmó su mandato inicial al Comité sobre Principios Generales de completar los principios de análisis de riesgos en el ámbito del Codex como tema de elevada prioridad, con miras a su adopción en 2003 y recomendó que el país hospedante (Francia) organizara un grupo de trabajo con considerable antelación a la reunión, con el fin de facilitar la discusión en su 17ª reunión. La Comisión convino en que el Comité debía elaborar las orientaciones a los gobiernos sucesivamente o en paralelo, según procediera conforme a su programa de trabajo. La Comisión también decidió cómo debería reaccionar cuando los datos científicos fuesen insuficientes o incompletos (ALINORM 01/41, párr. 75-83).

La Secretaría revisó el *Anteproyecto de Principios de aplicación práctica sobre análisis de riesgos* a la luz de las decisiones de la Comisión y las enmiendas de la 16ª reunión del Comité, tal como acordado anteriormente (ALINORM 01/33A, párr. 74), y distribuyó el texto para observaciones en la CL 2001/24-GP. El grupo de trabajo organizado por Francia (París, 5-7 de diciembre 2001), como recomendado por la Comisión, examinó el texto y las observaciones recibidas en respuesta a la Carta Circular.

El grupo de trabajo examinó el texto completo y aprobó varias enmiendas. El informe del grupo de trabajo presentado en el Apéndice 1 incluye las explicaciones de las enmiendas, con notas sobre las secciones que requieren un examen adicional, y el texto revisado de los *Anteproyecto de Principios de aplicación práctica sobre análisis de riesgos* con los cambios subrayados.

El texto revisado sin cambios subrayados figura en el Apéndice 2 como referencia. Las observaciones recibidas en respuesta a la CL 2001/24-GP y examinadas por el grupo de trabajo figuran en el Apéndice 3.

El texto revisado se distribuye por la presente para observaciones en el Trámite 3 y examen por la 17ª reunión del Comité. Los gobiernos y las organizaciones internacionales que deseen formular observaciones deben hacerlo por escrito preferiblemente por correo electrónico al Punto de Contacto Codex de Francia, SGCI/CODEX, Carré Austerlitz, 2 Boulevard Diderot 75703 Paris Cedex 12, Fax. 33 (0)1 44871604, Email: sgci-codex-fr@sgci.finances.gouv.fr con copia al Secretario, Comisión del Codex Alimentarius, Programa Conjunto FAO/OMS sobre Normas Alimentarias, FAO, Viale delle Terme di Caracalla, 00100 Roma, Italia, Fax: +39 (06) 5705 4593, E-mail: codex@fao.org **antes del 28 de febrero de 2002.**

APÉNDICE 1

INFORME DEL GRUPO DE TRABAJO SOBRE EL ANTEPROYECTO DE PRINCIPIOS DE APLICACIÓN PRÁCTICOS SOBRE ANÁLISIS DE RIESGOS

París, Francia, 5-7 de diciembre de 2001
COMENTARIOS GENERALES

Este texto es el fruto de los trabajos de la reunión del grupo de trabajo convocado a raíz de la petición formulada por la Comisión del Codex Alimentarius en su 24° Periodo de Sesiones. El grupo de trabajo se celebró en París (Francia) del 5 al 7 de diciembre de 2001. por amable invitación del gobierno francés. El grupo de trabajo estuvo presidido por el Dr. Chevassus-au-Louis. Asistieron a la reunión 66 participantes en representación de 22 Estados Miembros y 10 organizaciones internacionales [1].

El grupo de trabajo utilizó para su trabajó el Anteproyecto de Principios de aplicación prácticos sobre análisis de riesgos (CL 2001/24-GP) y examinó también las observaciones escritas en respuesta a la carta circular.

Este anteproyecto integra numerosas aportaciones orales y escritas de los miembros del grupo de trabajo. Durante la reunión de éste se examinaron y debatieron todas las propuestas presentadas. El grupo de trabajo alcanzó un consenso sobre muchos puntos y reconoció que se habían hecho avances importantes. Sin embargo, no se alcanzó un consenso sobre algunos párrafos. En consecuencia, los miembros del grupo de trabajo reservaron su derecho de hacer observaciones en seguido a un examen más detallado.

La Secretaría del Codex distribuirá este anteproyecto de texto al Trámite 3 para observaciones lo más pronto posible antes de la 17ª reunión del CCGP (15-19 de abril de 2002).

Párrafo	**Comentario**
Título	Precisar con claridad el objeto y ámbito de aplicación del documento.
	ÁMBITO DE APLICACIÓN
1	Sin cambios.
2	El análisis de riesgos tiene por objetivo primordial proteger la salud y, de por sí, no garantiza las prácticas comerciales equitativas.
3	Sustitución del término “garantizar” por la expresión “proporcionar directrices” y precisión de los usuarios pertinentes.
4	Sustitución de "comités" por "órganos" porque es más general.
	ANÁLISIS DE RIESGOS - ASPECTOS GENERALES
5	Especificar más el concepto de coherencia y añadir una referencia a las dos Declaraciones de Principios pertinentes.
6	Hacer hincapié en el vínculo necesario entre las tres etapas y añadir una referencia a las definiciones del Codex.
7	Al aparecer por primera vez en este párrafo la expresión “todas las partes interesadas”, una nota a pie de página remite a la acepción de dicha expresión en el conjunto del documento.
8	Sin cambios.
9	División en dos párrafos distintos. En el primer párrafo se reitera la coherencia necesaria de las tres etapas. Se ha suprimido la referencia a “estrategias y políticas” porque éstas no incumben al Codex, sino más bien a los Gobiernos. En el párrafo 9 bis), se especifica lo que es un “riesgo de confusión” y se destaca la importancia de la interacción entre los encargados de la evaluación y los encargados de la gestión.
10	Después de un debate extenso, se propone transferir el antiguo párrafo 40 aquí, en relación con la discusión del párrafo 11, como base para una discusión complementaria.

[1] Argentina, Australia, Austria, Bolivia, Brasil, Canadá, Dinamarca, Finlandia, Francia, Alemania, Italia, Japón, Paises Bajos, Nueva Zelandia, Portugal, España, Suecia, Suiza, Tailandia, Reino Unido, Estados Unidos, CE, AEDA, BIO, CIAA, CI, CRN, IASDA, ICC, ICGMA, IFAH.

Párrafo	Comentario
11	Este párrafo refleja un esfuerzo para integrar las diferentes opiniones de los participantes del grupo de trabajo sobre esta cuestión delicada. Se debatió extensamente. Especialmente con respecto a la última frase, el grupo de trabajo decidió mantener el texto actual porque estimó que se podía utilizar como base para un debate ulterior. Se estimó que el adjetivo "inherente" era más adecuado que "esencial" para describir la precaución en la primera frase.
12	Sin cambios.
	POLÍTICA DE EVALUACIÓN DE RIESGOS
13	Sin cambios.
14	La expresión "juicio científico" se suprimió y se formuló de nuevo el objetivo de las directrices. Esta nueva definición se incluyó también en el Anexo 1.
15	Se suprimió el adverbio "preferiblemente", habida cuenta de que estaba destinado a las recomendaciones a los Países Miembros.
16	Simplificación de la redacción (supresión de la última parte de la frase).
17	Sustitución de "pueden" por "deben", habida cuenta de que la expresión "en caso de necesidad" evoca la noción de obligación.
Título	Cambio de la referencia.
18	Este párrafo es una cita textual de una Declaración de Principios.
19	Sin cambios.
20	Adición de una frase al final del párrafo para destacar la atención que merece la participación de expertos de los países en desarrollo.
21	Armonización con el párrafo 6 y modificación de la referencia a las Declaraciones de Principios pertinentes.
22	Sustitución de la expresión "las caracterizaciones de riesgos" por "los resultados de la evaluación de riesgos". Toda etapa del proceso de evaluación de riesgos debe ser fácilmente comprensible y utilizable.
23	Sin cambios.
24	Se amplía la noción de "producción" al conjunto de la cadena alimentaria. Se describe más adecuadamente el proceso de acopio y utilización de datos.
25	Sin cambios.
26	Se destaca que es necesario desplegar esfuerzos para cuantificar la estimación de los riesgos.
27	La exigencia de la última frase no tiene por qué aplicarse forzosamente en todas las situaciones.
28	Mención explícita de la necesidad de efectuar una estimación del riesgo. Se estimó pertinente transferir al final de este párrafo la segunda frase del párrafo 29. Este párrafo repite algunos elementos del párrafo 22.
29	La segunda frase se puso al final del párrafo 28.
	GESTIÓN DE RIESGOS
30	Para homogeneizar la redacción de este párrafo con la del párrafo 2, se puso la expresión "decisiones y recomendaciones del Codex". Se suprimió la noción de "nivel de riesgo aceptable" por ser un asunto que incumbe a los Países Miembros.
31	La enumeración de los componentes de la gestión de riesgos se puso al principio del párrafo. Referencia a otros factores legítimos en los textos del Codex (anteriormente figuraba en el párrafo 35). Se suprimió la noción de "aplicación de las decisiones de gestión" porque incumbe a los Países Miembros.
32	Sin cambios.
33	Armonización con el párrafo 18. Referencia a "las partes interesadas" (véase el párrafo 7)
34	Se escogió el vocablo "evaluar". Se suprimió el adjetivo "necesario" porque se consideró superfluo (véase el párrafo 30)
35	La referencia a otros factores legítimos se puso en el párrafo 31.
36	Se suprimió tal como se había pedido.
37	La adición del párrafo 37 corresponde a una síntesis de las propuestas escritas recibidas de varias delegaciones. El grupo de trabajo no la examinó en detalle. Se propone como base para un debate ulterior.

Párrafo	Comentario
38	El ámbito de la primera frase no se refiere exclusivamente a los países en desarrollo.
39	Se tomó en consideración la demanda de una revisión periódica de los textos.
40	Se transfirió al párrafo 10.
	COMUNICACIÓN DE RIESGOS
41	Definición más precisa de: i) los encargados de la evaluación de riesgos y los encargados de la gestión de riesgos en el contexto del Codex; ii) las partes interesadas en la comunicación de riesgos.
41bis	En este nuevo párrafo se destaca la importancia de la comunicación y su carácter interactivo.
42	Mejora de la redacción. Este párrafo repite algunos elementos del párrafo 41.bis.
43	Se definió el contenido de la comunicación y se sustituyó el término “medidas” por no resultar adecuado en el marco del Codex. Se añadió además una referencia a las “opiniones minoritarias”.
43bis	Nuevo párrafo en el que se enumeran los objetivos de la comunicación de riesgos.
44	El verbo “comunicar” se ha sustituido por una expresión más prolija en la que se destaca el carácter interactivo del proceso de comunicación.
45	Se incorporó al párrafo 43.
	APÉNDICE 1
Anexo 1	La definición del perfil de los riesgos se tomó de la Consulta Conjunta de Expertos FAO/OMS sobre Evaluación de Riesgos e Inocuidad de los Alimentos.

ANTEPROYECTO DE PRINCIPIOS PRÁCTICOS SOBRE EL ANÁLISIS DE RIESGOS APLICABLES EN EL MARCO DEL CODEX[1]

(En el Trámite 3 del Procedimiento)

ÁMBITO DE APLICACIÓN

1) Estos principios sobre el análisis de riesgos están destinados a ser aplicados en el marco del Codex Alimentarius.

2) El objetivo primordial del análisis de riesgos en la Comisión del Codex Alimentarius es proteger la salud de los consumidores, teniendo en cuenta a la vez la promoción de prácticas equitativas en el comercio de alimentos.

3) El objetivo de estos Principios Prácticos es proporcionar directrices a la Comisión del Codex Alimentarius y a los comités y consultas conjuntos de expertos de la FAO y la OMS, de manera que los aspectos de inocuidad de los alimentos en las normas y textos afines del Codex se basen en el análisis de riesgos.

4) En el marco de la Comisión del Codex Alimentarius y de sus procedimientos, la responsabilidad de asesorar sobre la gestión de los riesgos incumbe a la Comisión y a sus órganos auxiliares, mientras que la responsabilidad de evaluar los 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

- aplicado coherentemente;
- abierto, transparente y documentado; y
- efectuado de conformidad 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 con las *Declaraciones de principios relativos a la función de la evaluación de riesgos respecto de la inocuidad de los alimentos.*

6) El proceso de análisis de riesgos debe ajustarse a un método estructurado que comprenda los tres componentes, distintos pero estrechamente vinculados, del análisis de riesgos (evaluación de riesgos, gestión de riesgos y comunicación de riesgos), tal como los define la Comisión del Codex Alimentarius[2]. Cada uno de estos tres componentes forma 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 legítimo interés por preservar la confidencialidad[3], la documentación debe ser accesible a todas las partes interesadas[4].

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 para la gestión de los riesgos que los alimentos entrañan para la salud humana.

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[1] Estos principios se incorporarán al Manual de Procedimiento del Codex y no prejuzgarán los principios de análisis de riesgos aplicables por parte de los Gobiernos, que serán objeto de directrices elaboradas aparte.

[2] Definiciones de los Términos del Análisis de Riesgos Relativos a la Inocuidad de los Alimentos (pág.49 del Manual de Procedimiento de la Comisión del Codex Alimentarius, 11ª edición).

[3] En una etapa ulterior se incluirá una nueva definición en el glosario que se adjunta en el Anexo 1.

[4] En el presente documento, se entiende que las "partes interesadas" son las siguientes: "las personas encargadas de la evaluación de riesgos, las encargadas de la gestión de riesgos, los consumidores, la industria, la comunidad académica y otras partes interesadas" (consúltese la definición de la comunicación de riesgos que figura en las *Definiciones*).

9bis) 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, evitar el riesgo de confusión entre las funciones que deben desempeñar los encargados de la evaluación de riesgos y las que corresponden a los encargados de su gestión, y atenuar cualquier conflicto de intereses. No obstante, se admite que el análisis de riesgos es un proceso iterativo y, para aplicarlo en la práctica, es esencial que exista una interacción entre los encargados de la gestión de riesgos y los encargados de la evaluación de riesgos.

10) Cuando hay pruebas de que existe un riesgo para la salud humana, aunque los datos científicos sean insuficientes o incompletos, la Comisión no debe elaborar una norma, sino contemplar la elaboración de un texto afín, por ejemplo un código de prácticas, a reserva de que dicho texto se base en las pruebas científicas disponibles[1].

11) La precaución es un elemento inherente al análisis de riesgos. En el proceso de evaluación y gestión de los riesgos que entrañan los alimentos para la salud humana, hay múltiples fuentes de incertidumbre. El grado de incertidumbre y variabilidad de la información científica disponible debe tomarse explícitamente en consideración en el proceso del análisis de riesgos. Cuando haya pruebas científicas suficientes para que el Codex pueda elaborar una norma o texto afín, las hipótesis utilizadas para la evaluación de riesgos y las opciones en materia de gestión de riesgos deben reflejar el grado de incertidumbre y las características del peligro.

12) Las necesidades y situaciones de los países en desarrollo deben ser objeto de una identificación específica y han de ser tomados en cuenta por los órganos responsables en las distintas fases del proceso del análisis de riesgos.

Política de evaluación de riesgos

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

14) La política de evaluación de riesgos consiste en directrices documentadas para las opciones de políticas y juicios conexos, así como para su aplicación en los centros de decisión apropiados durante la evaluación de riesgos, de manera que se mantenga la integridad científica del proceso.[2]

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

16) El mandato encomendado por los encargados de la gestión de riesgos a los encargados de la evaluación de los riesgos debe ser lo más claro posible.

17) En caso de necesidad, los encargados de la gestión de riesgos deben 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[*]

18) Los aspectos de higiene e inocuidad relativos a las decisiones y recomendaciones del Codex deben basarse en la evaluación de riesgos conforme a las circunstancias.

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

20) 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. Los procedimientos utilizados para elegir a esos especialistas se deben documentar, incluyendo una

[1] Declaración adoptada en el 24° Periodo de Sesiones de la Comisión (ALINORM 01/41, párrs. 81-83).

[2] Este párrafo está también incluido en las Definiciones (Anexo 1) y se podría suprimir después si las definiciones se mantienen en el documento final

[*] Se refiere a las *Declaraciones de principios relativos a la función de la evaluación de riesgos respecto de la inocuidad de los alimentos.*

declaración del posible conflicto de intereses. Esta declaración debe también identificar y detallar su competencia individual y experiencia. Siempre que sea posible, los comités y consultas de expertos deben velar por una participación efectiva de especialistas de las distintas regiones del mundo, incluidos los países en desarrollo.

21) La evaluación de riesgos debe efectuarse de conformidad con las *Declaraciones de principios relativos a la función de la evaluación de riesgos respecto de la inocuidad de los alimentos* y debe comprender las cuatro fases de la 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.

22) Las evaluaciones de riesgos deben utilizar, en la mayor medida posible, los datos cuantitativos disponibles y los resultados de la evaluación de riesgos deben presentarse de manera fácilmente comprensible y utilizable. Las evaluaciones de riesgos pueden también tener en cuenta datos cualitativos.

23) 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.

24) Reconociendo que la producción de alimentos en los países en desarrollo se realiza sobre todo en pequeñas y medianas empresas, para la evaluación de riesgos se debe buscar e incorporar información procedente de las distintas partes del mundo, comprendida la suministrada por los países en desarrollo. Esa información debe comprender en especial datos de control epidemiológico y estudios sobre exposiciones a los riesgos.

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

26) Cualquier limitación, incertidumbre e hipótesis, así como su repercusión en la evaluación de riesgos se deben documentar con transparencia, comprendidas las limitaciones 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, pero tendrá que cuantificarse en la medida en que ello sea científicamente posible.

27) Las evaluaciones de los riesgos deben basarse en hipótesis 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. Los efectos perjudiciales agudos, crónicos (comprendidos los efectos a largo plazo), acumulativos y/o combinados para la salud se deben tomar en cuenta en la realización de la evaluación de riesgos, cuando sea pertinente.

28) Las conclusiones de la evaluación de riesgos, incluida una estimación del riesgo, cuando se disponga de ella, se deben comunicar a los encargados de la gestión de riesgos de forma fácilmente comprensible. Deben indicar todas las limitaciones, incertidumbres e hipótesis, así como sus consecuencias sobre la evaluación de los riesgos, y también las opiniones minoritarias. La cuestión de resolver la incidencia de la incertidumbre en la decisión de gestión de riesgos no incumbe a los encargados de la evaluación de los riesgos, sino a los encargados de la gestión de riesgos.

29) Para garantizar la transparencia de la evaluación de riesgos se debe preparar un documento oficial, que incluya 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.

GESTIÓN DE RIESGOS

30) El objetivo esencial de las decisiones y recomendaciones del Codex en materia de gestión de riesgos debe ser la protección de la salud de los consumidores, teniendo en cuenta a la vez la promoción de prácticas equitativas en el comercio de alimentos. Se deben evitar diferencias injustificadas en el nivel de protección del consumidor riesgo al tratar riesgos similares en situaciones diferentes.

31) La gestión de riesgos debe ajustarse a un método estructurado, que comprenda la evaluación de los riesgos, la evaluación de las opciones de la gestión de riesgos, el seguimiento y la revisión de las decisiones adoptadas. Las decisiones se deben basar en una evaluación de riesgos que resulte adaptada a las circunstancias y tenga en cuenta, cuando corresponda, otros factores legítimos que atañen a la protección de la salud de los consumidores y a la promoción de prácticas equitativas en el

comercio de alimentos, de conformidad con los *Criterios para tomar en cuenta los otros factores mencionados en la Segunda Declaración de Principios*[1].

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

33) El proceso de gestión de riesgos debe ser transparente y coherente y estar completamente documentado. Las decisiones y recomendaciones del Codex sobre gestión de riesgos deben documentarse y, cuando proceda, deben estar claramente identificadas en las distintas normas y textos afines del Codex para facilitar que todas las partes interesadas entiendan mejor el proceso de gestión de riesgos.

34) Las opciones de gestión de riesgos se deben evaluar en función del ámbito y de la finalidad del análisis de riesgos y del grado de protección del consumidor que proporcionen. Se debe también considerar la opción de no emprender acción alguna.

35) El resultado del proceso de evaluación de riesgos debe asociarse con la evaluación de las opciones de gestión de riesgos disponibles, a fin de adoptar una decisión sobre la gestión del riesgo. Cuando se adopte 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[2].

36) Suprimido

37) Para evitar la creación de obstáculos injustificados al comercio, la evaluación de riesgos debe garantizar la transparencia y coherencia del proceso de decisión en todos los casos. El examen de todas las opciones de gestión de riesgos debe, en la mayor medida posible, tener en cuenta una evaluación de los ventajas y inconvenientes. Cuando se haga una selección entre varias opciones de gestión de riesgos, que sean igualmente eficaces para proteger la salud del consumidor, la Comisión debe seleccionar las opciones que no serían mas restrictivas al comercio que necesario, una vez adoptadas por los países miembros.

38) La gestión de riesgos debe considerar las consecuencias económicas y la viabilidad de las opciones de gestión de riesgos, especialmente 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.

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 revisados y actualizados periódicamente, cuando sea necesario, para tener en cuenta los nuevos conocimientos científicos y otra información pertinente para el análisis de riesgos.

40) Pasa a ser el párrafo 10.

COMUNICACIÓN DE RIESGOS

41) El análisis de riesgos debe comprender una comunicación clara, interactiva y documentada entre los encargados de la evaluación de riesgos (comités y consultas conjuntos de expertos) y los encargados de su gestión (Comisión del Codex Alimentarius y sus órganos auxiliares), así como una comunicación con los Países Miembros y todas las partes interesadas en todos los aspectos del proceso.

41bis) La comunicación de riesgos no se limita a la mera difusión de la información. Su función principal consiste en garantizar que en el proceso de elaboración de las decisiones se tiene en cuenta toda información o dictamen que sean esenciales para la gestión eficaz de los riesgos. La comunicación recíproca permanente entre todas las partes interesadas forma parte integrante del proceso de análisis de riesgos.

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1 Estos criterios se adoptaron en el 24° Periodo de Sesiones de la Comisión (véase el Anexo 2).

2 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.

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

43) La comunicación de riesgos con las partes interesadas debe comprender una exposición transparente de la política de evaluación de riesgos y de la evaluación del riesgo, incluida la incertidumbre. También se deben explicar claramente la necesidad de adoptar normas o textos afines específicos y los procedimientos que se han seguido para determinarlos, comprendida la manera en que se ha tratado la incertidumbre. Se deben indicar asimismo todas las limitaciones, incertidumbres e hipótesis y sus correspondientes repercusiones en el proceso del análisis de riesgos, así como las opiniones minoritarias.

43bis) En el presente documento, las directrices sobre la comunicación de riesgos están destinadas a todos los que participan en la realización del análisis de riesgos en el marco del Codex Alimentarius. No obstante, es importante que esta labor tenga la mayor transparencia y accesibilidad posibles para los que no son especialistas o no participan directamente en el proceso, comprendidos los consumidores y sus organizaciones representativas, así como los que intervienen en la producción, transformación y distribución de alimentos, y otras partes interesadas.

Los objetivos de la comunicación de riesgos son:

i) promover la concienciación sobre las cuestiones específicas que se toman en consideración a lo largo del proceso del análisis de riesgos, así como la comprensión de las mismas;

ii) promover la coherencia y la transparencia en la formulación de las opciones y recomendaciones relativas a la gestión de riesgos;

iii) suministrar una base sólida para el entendimiento de las decisiones que se proponen en materia de gestión de riesgos;

iv) mejorar la eficacia y eficiencia globales del proceso del análisis de riesgos;

v) reforzar las relaciones de trabajo entre los participantes;

vi) promover el entendimiento del proceso por parte del publico, a fin de consolidar la confianza en la seguridad de los abastecimientos de alimentos;

vii) promover la adecuada participación de todas las partes interesadas;

viii) intercambiar información sobre las cuestiones que preocupan a las partes interesadas en relación con los riesgos relativos a los alimentos.

44) Una estrategia de comunicación de riesgos debe ser anticipante y comprender un plan en el que se especifique cómo se han de intercambiar y considerar las informaciones y las opiniones en el proceso del análisis de riesgos.

45) Suprimido

ANEXO 1

DEFINICIONES

Definiciones incluidas en el Manual de Procedimiento

Sin cambios

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[1]

- 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

Perfil de los riesgos
La descripción del problema de la inocuidad de los alimentos y su contexto[2].

ANEXO 2

Sin cambios

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

[2] Definición propuesta por la Consulta Conjunta de Expertos FAO/OMS sobre Gestión de Riesgos e Inocuidad de los Alimentos

APÉNDICE 2

ANTEPROYECTO DE PRINCIPIOS PRÁCTICOS SOBRE EL ANÁLISIS DE RIESGOS APLICABLES EN EL MARCO DEL CODEX[1]

(En el Trámite 3 del Procedimiento)

ÁMBITO DE APLICACIÓN

1) Estos principios sobre el análisis de riesgos están destinados a ser aplicados en el marco del Codex Alimentarius.

2) El objetivo primordial del análisis de riesgos en la Comisión del Codex Alimentarius es proteger la salud de los consumidores, teniendo en cuenta a la vez la promoción de prácticas equitativas en el comercio de alimentos.

3) El objetivo de estos Principios Prácticos es proporcionar directrices a la Comisión del Codex Alimentarius y a los comités y consultas conjuntos de expertos de la FAO y la OMS, de manera que los aspectos de inocuidad de los alimentos en las normas y textos afines del Codex se basen en el análisis de riesgos.

4) En el marco de la Comisión del Codex Alimentarius y de sus procedimientos, la responsabilidad de asesorar sobre la gestión de los riesgos incumbe a la Comisión y a sus órganos auxiliares, mientras que la responsabilidad de evaluar los 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

- aplicado coherentemente;
- abierto, transparente y documentado; y
- efectuado de conformidad 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 con las *Declaraciones de principios relativos a la función de la evaluación de riesgos respecto de la inocuidad de los alimentos.*

6) El proceso de análisis de riesgos debe ajustarse a un método estructurado que comprenda los tres componentes, distintos pero estrechamente vinculados, del análisis de riesgos (evaluación de riesgos, gestión de riesgos y comunicación de riesgos), tal como los define la Comisión del Codex Alimentarius[2]. Cada uno de estos tres componentes forma 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 legítimo interés por preservar la confidencialidad[3], la documentación debe ser accesible a todas las partes interesadas[4].

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 para la gestión de los riesgos que los alimentos entrañan para la salud humana.

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[1] Estos principios se incorporarán al Manual de Procedimiento del Codex y no prejuzgarán los principios de análisis de riesgos aplicables por parte de los Gobiernos, que serán objeto de directrices elaboradas aparte.

[2] Definiciones de los Términos del Análisis de Riesgos Relativos a la Inocuidad de los Alimentos (pág.49 del Manual de Procedimiento de la Comisión del Codex Alimentarius, 11ª edición).

[3] En una etapa ulterior se incluirá una nueva definición en el glosario que se adjunta en el Anexo 1.

[4] En el presente documento, se entiende que las "partes interesadas" son las siguientes: "las personas encargadas de la evaluación de riesgos, las encargadas de la gestión de riesgos, los consumidores, la industria, la comunidad académica y otras partes interesadas" (consúltese la definición de la comunicación de riesgos que figura en las *Definiciones*).

10) 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, evitar el riesgo de confusión entre las funciones que deben desempeñar los encargados de la evaluación de riesgos y las que corresponden a los encargados de su gestión, y atenuar cualquier conflicto de intereses. No obstante, se admite que el análisis de riesgos es un proceso iterativo y, para aplicarlo en la práctica, es esencial que exista una interacción entre los encargados de la gestión de riesgos y los encargados de la evaluación de riesgos.

11) Cuando hay pruebas de que existe un riesgo para la salud humana, aunque los datos científicos sean insuficientes o incompletos, la Comisión no debe elaborar una norma, sino contemplar la elaboración de un texto afín, por ejemplo un código de prácticas, a reserva de que dicho texto se base en las pruebas científicas disponibles[1].

12) La precaución es un elemento inherente al análisis de riesgos. En el proceso de evaluación y gestión de los riesgos que entrañan los alimentos para la salud humana, hay múltiples fuentes de incertidumbre. El grado de incertidumbre y variabilidad de la información científica disponible debe tomarse explícitamente en consideración en el proceso del análisis de riesgos. Cuando haya pruebas científicas suficientes para que el Codex pueda elaborar una norma o texto afín, las hipótesis utilizadas para la evaluación de riesgos y las opciones en materia de gestión de riesgos deben reflejar el grado de incertidumbre y las características del peligro.

13) Las necesidades y situaciones de los países en desarrollo deben ser objeto de una identificación específica y han de ser tomados en cuenta por los órganos 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 directrices documentadas para las opciones de políticas y juicios conexos, así como para su aplicación en los centros de decisión apropiados durante la evaluación de riesgos, de manera que se mantenga la integridad científica del proceso.[2]

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

17) El mandato encomendado por los encargados de la gestión de riesgos a los encargados de la evaluación de los riesgos debe ser lo más claro posible.

18) En caso de necesidad, los encargados de la gestión de riesgos deben 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 de higiene e inocuidad relativos a las decisiones y recomendaciones del Codex deben basarse en la evaluación de riesgos conforme a las circunstancias.

20) El alcance y el objetivo de una evaluación de riesgos específica se deben enunciar claramente. La expresión de los resultados y 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. Los procedimientos utilizados para elegir a esos especialistas se deben documentar, incluyendo una declaración del posible conflicto de intereses. Esta declaración debe también identificar y detallar su competencia

[1] Declaración adoptada en el 24° Periodo de Sesiones de la Comisión (ALINORM 01/41, párrs. 81-83).

[2] Este párrafo está también incluido en las Definiciones (Anexo 1) y se podría suprimir después si las definiciones se mantienen en el documento final

* Se refiere a las *Declaraciones de principios relativos a la función de la evaluación de riesgos respecto de la inocuidad de los alimentos s.*

individual y experiencia. Siempre que sea posible, los comités y consultas de expertos deben velar por una participación efectiva de especialistas de las distintas regiones del mundo, incluidos los países en desarrollo.

22) La evaluación de riesgos debe efectuarse de conformidad con las *Declaraciones de principios relativos a la función de la evaluación de riesgos respecto de la inocuidad de los alimentos* y debe comprender las cuatro fases de la 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 posible, los datos cuantitativos disponibles y los resultados de la evaluación 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 de alimentos en los países en desarrollo se realiza sobre todo en pequeñas y medianas empresas, para la evaluación de riesgos se debe buscar e incorporar información procedente de las distintas partes del mundo, comprendida la suministrada por los países en desarrollo. Esa información debe comprender en especial datos de control epidemiológico y estudios sobre exposiciones a los riesgos.

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 limitación, incertidumbre e hipótesis, así como su repercusión en la evaluación de riesgos se deben documentar con transparencia, comprendidas las limitaciones 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, pero tendrá que cuantificarse en la medida en que ello sea científicamente posible.

28) Las evaluaciones de los riesgos deben basarse en hipótesis 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. Los efectos perjudiciales agudos, crónicos (comprendidos los efectos a largo plazo), acumulativos y/o combinados para la salud se deben tomar en cuenta en la realización de la evaluación de riesgos, cuando sea pertinente.

29) Las conclusiones de la evaluación de riesgos, incluida una estimación del riesgo, cuando se disponga de ella, se deben comunicar a los encargados de la gestión de riesgos de forma fácilmente comprensible. Deben indicar todas las limitaciones, incertidumbres e hipótesis, así como sus consecuencias sobre la evaluación de los riesgos, y también las opiniones minoritarias. La cuestión de resolver la incidencia de la incertidumbre en la decisión de gestión de riesgos no incumbe a los encargados de la evaluación de los riesgos, sino a los encargados de la gestión de riesgos.

30) Para garantizar la transparencia de la evaluación de riesgos se debe preparar un documento oficial, que incluya 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.

GESTIÓN DE RIESGOS

31) El objetivo esencial de las decisiones y recomendaciones del Codex en materia de gestión de riesgos debe ser la protección de la salud de los consumidores, teniendo en cuenta a la vez la promoción de prácticas equitativas en el comercio de alimentos. Se deben evitar diferencias injustificadas en el nivel de protección del consumidor riesgo al tratar riesgos similares en situaciones diferentes.

32) La gestión de riesgos debe ajustarse a un método estructurado, que comprenda la evaluación de los riesgos, la evaluación de las opciones de la gestión de riesgos, el seguimiento y la revisión de las decisiones adoptadas. Las decisiones se deben basar en una evaluación de riesgos que resulte adaptada a las circunstancias y tenga en cuenta, cuando corresponda, otros factores legítimos que atañen a la protección de la salud de los consumidores y a la promoción de prácticas equitativas en el comercio de alimentos, de conformidad con los *Criterios para tomar en cuenta los otros factores mencionados en la Segunda Declaración de Principios*[1].

[1] Estos criterios se adoptaron en el 24° Periodo de Sesiones de la Comisión (véase el Anexo 2).

33) En el logro de los resultados acordados, la gestión de riesgos debe tener en cuenta los procesos pertinentes de producción, almacenamiento y manipulación a lo largo de toda la cadena alimentaria, incluidas 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 y recomendaciones del Codex sobre gestión de riesgos deben documentarse y, cuando proceda, deben estar claramente identificadas en las distintas normas y textos afines del Codex para facilitar que todas las partes interesadas entiendan mejor el proceso de gestión de riesgos.

35) Las opciones de gestión de riesgos se deben evaluar en función del ámbito y de la finalidad del análisis de riesgos y del grado de protección del consumidor que proporcionen. Se debe también considerar la opción de no emprender acción alguna.

36) El resultado del proceso de evaluación de riesgos debe asociarse con la evaluación de las opciones de gestión de riesgos disponibles, a fin de adoptar una decisión sobre la gestión del riesgo. Cuando se adopte 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[1].

37) Para evitar la creación de obstáculos injustificados al comercio, la evaluación de riesgos debe garantizar la transparencia y coherencia del proceso de decisión en todos los casos. El examen de todas las opciones de gestión de riesgos debe, en la mayor medida posible, tener en cuenta una evaluación de los ventajas y inconvenientes. Cuando se haga una selección entre varias opciones de gestión de riesgos, que sean igualmente eficaces para proteger la salud del consumidor, la Comisión debe seleccionar las opciones que no serían más restrictivas al comercio que necesario, una vez adoptadas por los países miembros.

38) La gestión de riesgos debe considerar las consecuencias económicas y la viabilidad de las opciones de gestión de riesgos, especialmente 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.

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 revisados y actualizados periódicamente, cuando sea necesario, para tener en cuenta los nuevos conocimientos científicos y otra información pertinente para el análisis de riesgos.

COMUNICACIÓN DE RIESGOS

40) El análisis de riesgos debe comprender una comunicación clara, interactiva y documentada entre los encargados de la evaluación de riesgos (comités y consultas conjuntos de expertos) y los encargados de su gestión (Comisión del Codex Alimentarius y sus órganos auxiliares), así como una comunicación con los Países Miembros y todas las partes interesadas en todos los aspectos del proceso.

41) La comunicación de riesgos no se limita a la mera difusión de la información. Su función principal consiste en garantizar que en el proceso de elaboración de las decisiones se tiene en cuenta toda información o dictamen que sean esenciales para la gestión eficaz de los riesgos. La comunicación recíproca permanente entre todas las partes interesadas forma parte integrante del proceso de análisis de riesgos.

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

43) La comunicación de riesgos con las partes interesadas debe comprender una exposición transparente de la política de evaluación de riesgos y de la evaluación del riesgo, incluida la incertidumbre. También se deben explicar claramente la necesidad de adoptar normas o textos afines específicos y los procedimientos que se han seguido para determinarlos, comprendida la manera en que se ha tratado la incertidumbre. Se deben indicar asimismo todas las limitaciones, incertidumbres e hipótesis y sus correspondientes repercusiones en el proceso del análisis de riesgos, así como las opiniones minoritarias.

44) En el presente documento, las directrices sobre la comunicación de riesgos están destinadas a todos los que participan en la realización del análisis de riesgos en el marco del Codex Alimentarius. No obstante, es

[1] 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.

importante que esta labor tenga la mayor transparencia y accesibilidad posibles para los que no son especialistas o no participan directamente en el proceso, comprendidos los consumidores y sus organizaciones representativas, así como los que intervienen en la producción, transformación y distribución de alimentos, y otras partes interesadas.

Los objetivos de la comunicación de riesgos son:

(i) promover la concienciación sobre las cuestiones específicas que se toman en consideración a lo largo del proceso del análisis de riesgos, así como la comprensión de las mismas;

(ii) promover la coherencia y la transparencia en la formulación de las opciones y recomendaciones relativas a la gestión de riesgos;

(iii) suministrar una base sólida para el entendimiento de las decisiones que se proponen en materia de gestión de riesgos;

(iv) mejorar la eficacia y eficiencia globales del proceso del análisis de riesgos;

(v) reforzar las relaciones de trabajo entre los participantes;

(vi) promover el entendimiento del proceso por parte del publico, a fin de consolidar la confianza en la seguridad de los abastecimientos de alimentos;

(vii) promover la adecuada participación de todas las partes interesadas;

(viii) intercambiar información sobre las cuestiones que preocupan a las partes interesadas en relación con los riesgos relativos a los alimentos.

45) Una estrategia de comunicación de riesgos debe ser anticipante y comprender un plan en el que se especifique cómo se han de intercambiar y considerar las informaciones y las opiniones en el proceso del análisis de 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[1]

- 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

[1] Consulta Mixta de Expertos FAO/OMS sobre la Gestión de Riesgos y la Inocuidad de los Alimentos (sección 6. marco de gestión de riesgos). En el marco del Codex, el "componente" de Aplicación no es pertinente.

Perfil de los riesgos
La descripción del problema de la inocuidad de los alimentos y su contexto[1].

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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

- cuando se trata de cuestiones relacionadas con la salud y la inocuidad, se deben seguir las *Declaraciones de principios referentes a la función que desempeña la ciencia* y las *Declaraciones de Principios relativos a la función de la evaluación de riesgos respecto de la inocuidad de los alimentos*;
- se pueden determinar otros factores legítimos pertinentes en materia de salud y de prácticas comerciales leales en el proceso de gestión de riesgos, y los encargados de la gestión de riesgos deben indicar de qué manera influye esto en la selección de opciones de gestión de riesgos y en la elaboración de normas, directrices y textos afines;
- la consideración de otros factores no debe afectar al fundamento científico del análisis de riesgos; en este proceso se debe respetar la separación entre la evaluación de riesgos y la gestión de riesgos con miras a garantizar la integridad científica de la evaluación de riesgos;
- se debe admitir que algunas preocupaciones legítimas manifestadas por los gobiernos cuando establecen sus legislaciones nacionales no son en general aplicables o pertinentes en el plano internacional[2];
- en el marco del Codex, solamente se pueden tomar en consideración los otros factores que puedan ser aceptados en el plano mundial, o en el plano regional cuando se trata de normas y textos afines regionales;
- debe estar claramente documentada la consideración de otros factores específicos en la elaboración de las recomendaciones de gestión de riesgos formuladas por la Comisión del Codex Alimentarius y sus órganos auxiliares, comprendida la justificación para incorporarlos, caso por caso;
- se tiene que examinar la viabilidad de las opciones en materia de gestión de riesgos en función de la índole e imperativos particulares de los métodos de producción, procesamiento, transporte y almacenamiento, especialmente en los países en desarrollo, habida cuenta de que los problemas relacionados con intereses económicos y cuestiones comerciales en general se confirman con datos cuantificables;
- la integración de otros factores legítimos en la gestión de riesgos no debe crear trabas injustificadas al comercio[3]; se debe prestar una atención especial a las repercusiones que podría tener en los países en desarrollo la incorporación de esos otros factores

[1] Definición propuesta por la Consulta Conjunta de Expertos FAO/OMS sobre Gestión de Riesgos e Inocuidad de los Alimentos.

[2] La justificación de medidas nacionales en virtud del Acuerdo MSF y del Acuerdo OTC no se debe confundir con su validez en el plano internacional.

[3] Con arreglo a los principios de la OMC y teniendo en cuenta las disposiciones específicas de los Acuerdos MSF y OTC.

APÉNDICE 3

OBSERVACIONES EN RESPUESTA A LA CL 2001/24-GP
(idioma original)

ARGENTINA

ÁMBITO DE APLICACIÓN

46) Los principios para el análisis de riesgos están destinados a ser aplicados en el marco del Codex Alimentarius.

~~**47)**~~ 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 .**

48) 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~~.

49) 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

50) 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**

51) 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.

52) 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.

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

54) 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.

~~55) [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.]~~

~~56) [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.]~~

57) 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, justificar las razones que motivan su adopción.

58) 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

59) La determinación de una política de evaluación de riesgos debe ser un componente específico de la gestión de riesgos.
60) 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.~~[1]

61) 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.
62) 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.

63) 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[*]

64) 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.
65) 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.

66) 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.

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[1] 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*

67) 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.
68) 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.

69) 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.

~~70) 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.**

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

72) 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.

73) 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.

74) 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.

75) 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

76) 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,[1] **si tales diferencias tienen por resultado una discriminación o una restricción encubierta al comercio internacional.**

77) 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

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

marco de la gestión de riesgos comprende la apreciación de los riesgos[1], la evaluación de las opciones de gestión de los riesgos, ~~la aplicación de las decisiones de gestión, así como el control~~ y la revisión.[2]

78) 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.

79) 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.

80) 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 población 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

81) 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[3], de conformidad con los *Criterios para tomar en cuenta los otros factores mencionados en la 2ª Declaración de Principios*.

~~82) 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.~~

83) 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.~~

84) 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.

85) 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

86) 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.

87) 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.

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1 Vease Anexo 1 *Definiciones*.

2 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.

3 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.

88) 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.

89) ~~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.

~~90) 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[1]

- 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

[1] Consulta Mixta de Expertos FAO/OMS sobre la Gestión de Riesgos y la Inocuidad de los Alimentos (sección 6. marco de gestión 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[1], 1997[2] and 1998,[3] 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.

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

[1] Application of Risk Analysis to Food Standards Issues. Report of the Joint FAO/WHO Expert Consultation. Geneva, Switzerland 13-17 March 1995.
[2] Risk Management and Food Safety. Report of a Joint FAO/WHO Expert Consultation. Rome, Italy, 27-31 January 1997.
[3] FAO/WHO Expert Consultation on the Application of Risk Communication to Food Standards and Safety Matters. Rome, 2-6 February 1998.

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 <u>both</u> the *Statements of Principle Concerning the Role of Science and the Extent to Which Other Factors are Taken into Account* <u>and the *Statements of Principle Relating to the Role of Food Safety Risk Assessment.*</u>

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 '<u>as defined by the Codex Alimentarius Commission</u>', 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* <u>where relevant, for the health protection of consumers</u>.

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.[1]~~ 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.

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*"[2] 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.

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

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.*

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.

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

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[1], assessment of risk management options, implementation of management decisions, and monitoring and review[2].

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

[1] See *Definitions* in Annex 1

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

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[1], 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.

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.[2]

1 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.

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

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.
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[1]

- 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....

Parrafo 14: Estamos de acuerdo en suprimir el parrafo, dejando el concepto de politica de evaluacion de

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

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*

[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.*

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.

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

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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.*~~

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 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.

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[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.*~~

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 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.**~~

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

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, 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.[1] 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

[1] 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.

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.[1]

- 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 accelerating the growth of livestock with human-use antibiotics,[2] then the European Union's 1999 ban of such antibiotics would be protected from a legal challenge by other countries.[3]

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.[4]

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.[5]

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[6] -- 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-

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[1] 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.

[2] 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.

[3] 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.

[4] ALINORM 01/41 at paragraph 75.

[5] 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").

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

makers must exercise their judgment about which inferences to draw from the available scientific evidence.[1] The probability of disagreement among scientists is frequently proportional to the commercial importance of the product being considered.[2] The Commission decided, by a majority vote, that in such situations it will develop a "code of practice" for national governments to follow.[3]

3) It appears that some experts, who are members of recent WHO/FAO expert advisory bodies, have received funding from the food industry.[4] Thus, we support retaining the draft provision on the transparent selection of experts (paragraph 20) approved in April 2000 by the CCGP.[5] 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

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[1] 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 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.

[2]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.

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

[4] 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.

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

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."

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.