codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 3a) **CX/GP 01/3-Add.3**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON GENERAL PRINCIPLES
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PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS (PRECAUTION IN RISK MANAGEMENT – paras. 34 - 35) ADDITIONAL GOVERNMENT COMMENTS AT STEP 3

ARGENTINA

Introducción

Como Resultado de la Ronda Uruguay de Negociaciones Comerciales Multilaterales se firma en 1995 el Acuerdo sobre la Aplicación de Medidas Sanitarias y Fitosanitarias de la OMC (SPS/OMC).

El mismo dispone en su art. 2.2. que "*Los Miembros se asegurarán de que cualquier medida sanitaria o fitosanitaria ....esté basada en principios científicos y de que no se mantenga sin testimonios científicos suficientes, a reserva de lo dispuesto en el párrafo 7 del artículo 5*."

El artículo 5.7. dispone: "*Cuando los testimonios científicos pertinentes sean insuficientes, un Miembro podrá adoptar provisionalmente medidas sanitarias o fitosanitarias sobre la base de la información pertinente de que se disponga, con la inclusión de la procedente de las organizaciones internacionales competentes y de las medidas sanitarias o fitosanitarias que apliquen otras partes contratantes. En tales circunstancias, los Miembros tratarán de obtener la información adicional necesaria para una evaluación más objetiva del riesgo y revisarán en consecuencia la medida sanitaria o fitosanitaria en un plazo razonable*".

La interpretación de estos dos artículos ha abierto un debate internacional que se manifiesta en diversos foros de negociación, y adquiere una relevancia significativa para los países exportadores de agroalimentos ya que, una interpretación errónea de los mismos podría habilitar la adopción de medidas restrictivas del comercio internacional.

A continuación, se acompañan algunas comentarios al respecto:

1.- CONDICIÓN JURÍDICA DE LA CAUTELA:

La misma puede considerarse como:
- un principio general del derecho o norma consuetudinaria de carácter general o,
- un principio del derecho medioambiental.

Depende de que se adopte una u otra posición, varía la implicancia de su aplicación práctica en el comercio internacional. A los efectos de aclarar el posible encuadre jurídico es importante distinguir:

Costumbre internacional: está constituida por un comportamiento constante y uniforme de los Estados, acompañada por la convicción de obligatoriedad de ese mismo comportamiento. De esta manera, son 2 los elementos necesarios para que un determinado comportamiento sea considerado como una costumbre internacional: la *praxis* (práctica generalizada) y la *opinio iuris* (con consciencia de obligatoriedad).

Principios Generales del derecho: Han sido considerados como una subcategoría dentro de las normas consuetudinarias, ya que requieren que se verifiquen los mismos requisitos: *praxis* y *opinio iuris*.

Estado de situación: Si bien es cierto que la posibilidad de aplicar medidas cautelares específicas ha sido consagrada en numerosos documentos internacionales, los mismos se refieren exclusivamente a la protección del medio ambiente [1].

Para concluir, jurídicamente no es procedente darle carácter de principio del derecho o norma de carácter consuetudinaria general, ya que su ámbito material de aplicación se encuentra acotado al derecho medioambiental. Por lo tanto, la falta de carácter generalizado, implica que no puede ser incluido en la categoría de principio general del derecho o norma consuetudinaria.

De esta manera, la cautela como un enfoque o principio [2] corresponde al marco del derecho internacional medioambiental, pero bajo ningún concepto existen fundamentos jurídicos concluyentes que permitan extenderlo al derecho general.[3]

Cabe destacar que de acuerdo a la jurisprudencia OMC (caso Hormonas) el Organo de Apelación sólo planteó la cuestión, pero prefirió no expedirse formalmente sobre la condición jurídica de la cautela. Sin embargo, en el caso Japón – Medidas que afectan a los productos agrícolas consideró al art. 5.7. como una "*exención cualificada*", con lo cual difícilmente podría resultar un principio, al menos en el marco del SPS.

De esta manera, es importante destacar el **carácter excepcional** que debe que tener la invocación del Enfoque Precautorio.

2.- ALCANCE DEL ART. 5.7.

Las dos condiciones fundamentales para establecer / mantener una medida sanitaria o fitosanitaria son: evidencia científica y análisis de riesgo, y la observancia de las mismas se encuentra receptado en los arts. 2.2. y 5.1. del SPS.

El art. 2.2. ya fue mencionado en la Introducción el art. 5.1. dispone que "*Los Miembros se asegurarán de que sus medidas sanitarias o fitosanitarias se basen en una evaluación, adecuada a las circunstancias de los riesgos...teniendo en cuenta las técnicas de evaluación de riesgo elaboradas por las organizaciones internacionales competentes.*"

OBLIGACION DE PRESENTAR EVIDENCIA CIENTIFICA "SUFICIENTE".

En primer lugar es importante considerar que el enfoque de cautela sólo libera a los Miembros de la obligación de sustentar sus medidas en testimonios científicos "suficientes". No hay ninguna disposición en el SPS que establezca que se pueden adoptar medidas precaucionales sin el correspondiente análisis de riesgo (esta interpretación fue reafirmada por el Organo de Apelación en Hormonas cuando concluye que las disposiciones del art. 5.7. no prevalecen por sobre las del 5.1. y 5.2.).

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[1] Segunda y Tercera Conferencia Internacional sobre el Mar del Norte, Conferencia de las Naciones Unidas sobre el Medio Ambiente y el Desarrollo, Convenio sobre Diversidad Biológica.

[2] De acuerdo a su amplia aceptación en numerosos instrumentos internacionales en los que se reglamenta la temática relativa a la protección del medio ambiente, se podría considerar a la cautela como un principio del derecho medioambiental

[3] Es más, el mismo Tratado de Amsterdam prevé en su art. 174 hace referencia al principio de precaución en el marco de la política medioambiental, no incluyendolo en materia de seguridad alimentaria

Por lo tanto, ¿hasta qué punto el Miembro que quiere aplicar una medida sanitaria o fitosanitaria precaucional queda liberado de la obligación de aportar evidencia científica?

En realidad, la redacción del art. 5.7. es bastante clara cuando hace referencia a que los "testimonios científicos pertinentes sean suficientes", con lo cual queda de manifiesto que los países no se encuentran totalmente liberados de la presentación de todo tipo de evidencia científica. En este sentido, la evidencia presentada por el Miembro en cuestión debería demostrar suficientemente la existencia de un riesgo, aunque no se tenga mayores precisiones sobre el alcance del mismo.

Si no se exigiese evidencia científica que apoye razonablemente la existencia de un riesgo que justifique la adopción de una medida sanitaria o fitosanitaria precaucional, se estaría violando el principio general sobre el cual está basado el Acuerdo SPS.

De esta manera, cuando se habla de que los "testimonios científicos pertinentes sean insuficientes", se hace referencia a aquella evidencia que permita determinar de manera unívoca y exacta la real magnitud o dimensión del riesgo detectado. Sin embargo, la determinación de la presencia de un riesgo para la salud debe demostrarse de manera fehaciente y con el debido sustento científico, sin el cual no podría recurrirse a una medida precaucional.

OBLIGACION DE REALIZAR UN ANALISIS DE RIESGO.

Con respecto a las exigencias establecidas en el 5.1. en materia de análisis de riesgo, tanto la redacción del SPS como las definiciones sentadas por el Organo de Apelación son claras: las disposiciones establecidas en el 5.7. no prevalecen por sobre las contenidas en el 5.1., por lo que ningún Miembro se encuentra liberado de la obligación de realizar un análisis de riesgo sobre el cual se sustente la medida que quiera aplicar, ya sea una medida ordinaria o una precaucional.

Es más, es en este análisis de riesgo donde se debe recabar la suficiente evidencia científica que permita determinar la existencia del riesgo real (y no potencial) la cual justificará la aplicación de la medida precaucional.

Establecer como obligatorio el cumplimiento de un análisis de riesgo pero relativizar el carácter de la evidencia científica resultaría contradictorio, ya que conforme a lo establecido reiteradamente por el Organo de Apelación, los artículos 2.2. y 5.1. se encuentran intrínsecamente relacionados. El rol que la ciencia cumple en el marco de los procesos de análisis de riesgo es fundamental (principalmente en la evaluación del riesgo) por lo que limitar su alcance u observancia por el gestor del riesgo implicaría desconocer uno de los pilares sobre los que deben sustentarse las medidas sanitarias.

Inclusive, la habilitación que brinda el art. 3.3. del SPS a los Miembros para apartarse de las directrices internacionales ya sea en el caso de que se disponga de evidencia científica o en caso de que responda al nivel adecuado de protección estimado por el Miembro, se encuentra limitada por la realización del correspondiente análisis de riesgo. Por lo tanto, tampoco este artículo podría servir de base jurídica realizar el análisis de riesgo "sólo cuando fuera posible" o "en los casos en que se pueda".

En este sentido, si el análisis no fuera realizado o si el mismo no se basara en evidencia científica, dejaría abierta la posibilidad de aplicar medidas basadas en apreciaciones subjetivas en lugar de la objetividad que la ciencia representa. Esto no quiere decir que el SPS no habilita el establecimiento de medidas precaucionales, el 5.7. es claro al respecto, pero su aplicación se encuentra limitada por la existencia de testimonios científicos (aunque sean insuficientes) sobre los cuales se base la medida.

En síntesis, en aquellos casos en los cuales no se disponga de evidencia científica "suficiente", en el sentido de que apoye razonablemente a una medida, pero que después del análisis de riesgo pertinente (conforme arts. 5.1. y 5.2. del SPS) se determine la existencia de un riesgo cuyo alcance aún no se puede determinar con exactitud, los Miembros pueden recurrir provisionalmente a la excepción prevista en el art. 5.7. del SPS.

3.- EXCEPCIONALIDAD DE LAS MEDIDAS ADOPTADAS.

Del informe del Organo de Apelación en el caso Japón - Medidas que afectan la importación de productos agrícolas, resulta claro que el art. 5.7. consiste en una exención cualificada de las obligaciones dimanadas del art. 2.2. de no adoptar o mantener medidas sanitarias sin evidencia científica.

Esta interpretación realizada por el Organo de Apelación refuerza la intención de los Miembros al momento de firmar el SPS de no erigir al art. 5.7. como una puerta que habilitase el incumplimiento de cualquiera de las obligaciones del Acuerdo, mas bien, su utilización se encuentra limitada a ciertos casos excepcionales.

Esto no podría ser de otra manera ya que, la adopción de medidas en el marco del enfoque precautorio implica una restricción al comercio no basada en la suficiente evidencia científica. Por lo tanto, una cláusula de éstas características debe mantener el carácter de **excepcionalidad**.

4.- PROVISIONALIDAD DE LAS MEDIDAS ADOPTADAS.

De acuerdo a lo sostenido por el Organo de Apelación en el caso de Japón, resulta claro que los 4 requisitos establecidos para aplicar medidas precaucionales son acumulativos, por lo que la revisión de la medida en un plazo razonable resulta imprescindible para el Miembro que aplica una medida al amparo de este artículo.

Por lo tanto, debe quedar muy claro que su transitoriedad no resulta objeto de debate. El punto que se encuentra en discusión consiste en cual es el elemento a tener en cuenta como parámetro para determinar la duración de la medida provisional.

Al respecto existen dos posiciones:

- Quienes sostienen que la medida debe aplicarse mientras los datos científicos sean vagos, insuficientes o no concluyentes, por lo que supeditan el mantenimiento de la medida a la evolución científica.
- Quienes sostienen que la posición anterior implicaría premiar una investigación ineficiente, y por lo tanto debe fijarse un plazo.

Si tenemos en cuenta las dificultades que tienen los países del tercer mundo para desarrollar investigaciones científicas, establecer como único límite de la aplicación de una medida provisoria la obtención de información adicional deja en manos de los países centrales el levantamiento o no de dichas medidas; sobre todo si tenemos en cuenta que los mismos son los que lideran la realización de investigaciones científicas.

Al respecto se deberían establecer límites temporales, los cuales se establecerían caso por caso teniendo en consideración, el nivel de riesgo detectado, el grado de restricción al comercio derivado de la medida precaucional y las evoluciones en el campo científico.

5.- CUMPLIMIENTO DEL RESTO DE LAS OBLIGACIONES DERIVADAS DEL SPS

De acuerdo a lo mencionado precedentemente, el art. 5.7. sólo libera a los Miembros de la obligación prevista en el 2.2. en cuanto a evidencia científica suficiente. Sin embargo, el resto de los principios sentados en el SPS deberían ser observados por los Miembros que desean aplicar medidas precaucionales.

En este sentido, el Organo de Apelación en el caso Hormonas concluyó que la cautela no fue incluida en el texto del SPS como un motivo que justifique las medidas sanitarias que fuesen incompatibles con las obligaciones de los Miembros establecidas en determinadas disposiciones del SPS.

6.- PROPORCIONALIDAD.

El art. 2.2. establece el principio de proporcionalidad al disponer que las medidas sanitarias y fitosanitarias sólo se aplicarán en cuanto sean necesarias para proteger a la salud.

De esta manera, una correcta aplicación de este principio implicaría que, dentro del abanico de medidas alternativas que se le presentan al gestor del riesgo para alcanzar su nivel de protección, debería escoger aquella que implique menor restricción al comercio.

Por lo tanto existe una doble relación, de medida con el nivel de protección y de medida con otras medidas alternativas.

7.- CARGA DE LA PRUEBA.

Tanto del texto del SPS como de la jurisprudencia derivada del Organo de Apelación (caso Hormonas) resulta claro que las medidas basadas en normas internacionales (CODEX-OIE-CIPF) se presumen compatibles con el SPS.

En caso de que un Miembro adopte una medida sanitaria que otro país estime no compatible con las obligaciones derivadas del SPS, éste asume la obligación de demostrar prima facie dicha incompatibilidad. Una vez demostrada la misma, el Miembro que adoptó la medida debe demostrar que la medida en cuestión no viola ningún precepto del SPS. Esta interpretación fue realizada por el Organo de Apelación en el caso Camarones y Gasolinas Reformuladas.

Sin embrago, en el caso de aplicación de medidas bajo el art. 5.7. y, teniendo en cuenta el carácter excepcional de las medidas precaucionales, es el Miembro que las adopta quien asume la responsabilidad de probar que se cumplen los requisitos necesarios para su aplicación. La autorización previa no puede habilitar la inversión de la carga de la prueba ya que no guarda relación alguna con el principio precautorio.

CONCLUSIONES.

Con respecto a la naturaleza jurídica, se debe hablar de un enfoque precautorio y no de un principio general del derecho.

Teniendo en cuenta que este enfoque permite a los Miembros apartarse de uno de los elementos centrales del SPS, como lo es la obligación de basar las medidas en evidencia científica suficiente, adoptando medidas que impliquen obstáculos a la libre comercialización, debe entenderse que su aplicación reviste el carácter de excepcional y limitada. Esta limitación es temporal y se relaciona con un plazo determinado, no con la evolución científica.

De acuerdo a la letra del SPS y las conclusiones arribadas por el Organo de Apelación, las medidas precaucionales deben basarse en una evaluación de riesgo (conforme arts. 5.1. y 5.2. del SPS) a través de la cual se determine la existencia de un riesgo cuyo alcance aún no se puede precisar con exactitud.

Asimismo, es el Miembro que adopta la medida provisional quien debe justificar la aplicación de la medida en cuestión.

ARGENTINA

English version

As a result of the Uruguay Round of Multilateral Trade Negotiations the Agreement on the Application of Sanitary and Phytosanitary Measures of the WTO was signed in 1995 (SPS/WTO)

The Agreement specifies in Article 2.2 that “Members shall ensure that any sanitary or phytosanitary measures …is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in para. 7 of Article 5”

According to Article 5.7: “In cases where scientific evidence is insufficient a Member may provisionally adopt sanitary or phytosanitary measures on the basis of the available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measures accordingly within a reasonable period of time”.

The interpretation of these articles has raised an international debate which appears in different negotiation fora, and is significantly relevant for agricultural and food exporter countries because an erroneous interpretation of these articles could entail the adoption of restrictive measures in international trade.

The following comments are attached in this respect.

1. LEGAL CONDITION OF PRECAUTION

Precaution may be considered as:

- A general law principle or a common law standard of a general character or
- A principle of environmental law

The implications of the practical application in international trade will depend on the approach taken. In order to clarify the possible legal framework it is important to distinguish:

International custom: this is a constant and uniform behaviour of the States, together with the conviction that this behaviour is mandatory. Consequently two elements are necessary to establish international custom: praxis (general practis) and opinio juris (with awareness of its mandatory character).

General law principles: they are considered as a sub-category under common law, since they require the same prerequisites: praxis (general practis) and opinio juris

Status: although the possibility to apply specific precaution measures has been endorsed in several international documents, these refer exclusively to the protection of the environment[4].

In conclusion, legally precaution should not have the status of a law principle or a standard of common law, since its scope is related to environmental law. Consequently, the lack of a general character implies that it cannot be included in a category of general law principles or common law.

As a result, precaution as an approach or principle is relevant to the area of international environmental law, but conceptually there is no conclusive legal basis to allow to extend it to general law. [5]

It should be pointed out that according to WTO jurisprudence (the hormones case) the Appellate Body only raised the issue but preferred not to express itself formally on the legal conditions of precaution. However, in the case Japan – Measures affecting agricultural commodities, it considered Article 5.7 as a "qualified extension", which it would be difficult to regard as a principle, at least in the framework of the SPS.

As a result, it is important to stress that the reference to the precautionary approach should have an **exceptional character.**

2. SCOPE OF ARTICLE 5.7

The two fundamental conditions to establish / maintain a sanitary or phytosanitary measure are: scientific evidence and risk analysis, and adherence to these is required under Article 2.2 and 5.1 of the SPS.

Article 2.2 was mentioned in the Introduction and under Article 5.1 "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, ..taking into account risk assessment techniques developed by the relevant international organizations"

Obligation to present sufficient scientific evidence

First it is important to consider that the precautionary approach only exonerates members from the obligation to support their measures with "sufficient" scientific evidence. No provision in the SPS Agreement allows to establish precautionary measures without corresponding risk analysis (this interpretation was reasserted by the Appellate Body in the Hormones when it concluded that the provisions in Art. 5.7 do not supersede those in 5.1 and 5.2)

Consequently: to what extent Members wishing to apply precautionary sanitary or phytosanitary measures are free from the obligation of providing scientific evidence ?

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4 Second and Third Intrenational Conference on the North Sea, UN Conference on Environment and Development, Convention on Biodiversity

5 In agreement with its wide acceptance in many international instruments regulating the aspects of environment protection, precaution could be consdiered as a principle of environmental law.

In fact, the wording of Art. 5.7 is clear enough when it indicates "where relevant scientific evidence is insufficient", from which it appears that countries are not totally free from the requirement to present scientific evidence. In this sense, the evidence presented by the concerned Member should demonstrate the existence of a risk, although its extent is not more precise.

If no scientific evidence were required to support the existence of a risk to justify an SPS precautionary measure, this would violate the general principle which is the basis of the SPS Agreement.

As a result, "where relevant scientific evidence is insufficient" means the evidence which allows unequivocally and precisely to measure the exact extent or importance of the risk . However, the presence of a risk should be clearly established and with the required scientific support, without which no precautionary measure could be applied.

Obligation to carry out a risk analysis

As regards the requirements in 5.1 concerning risk analysis, the wording of SPS as well as the definitions from the Appellate Body are clear: the provisions in 5.7 do not supersede those in 5.1, since no Member is free from the obligation to carry out a risk analysis as a basis for the measure it wants to apply, whether ordinary or precautionary.

In addition this risk analysis must provide sufficient scientific evidence to determine the existence of a real risk (and not a potential one), that will justify the application of the precautionary measure.

It would appear contradictory to request mandatory risk analysis but to make scientific evidence relative because in conformity with the conclusions reasserted by the Appellate Body, Articles 2.2 and 5.1 are intrinsically related. The role of science in risk analysis processes is fundamental (especially in risk assessment); to limit its scope or implementation by risk managers would amount to ignoring one of the cornerstones on which sanitary measures must be established.

The possibility under SPS Art. 3.3 to deviate from international guidelines whether on the basis of scientific evidence or adequate level of protection of the Member, is limited by the implementation of the relevant risk analysis. Consequently, this article could not be used as a legal basis to complete the risk analysis "only when possible" or "in cases where it is possible".

In view of this, if risk analysis were not completed or were not based on scientific evidence, this would allow a possibility of applying measures based on subjective evaluations instead of the objectivity pertaining to science. This does not mean that SPS does not allow precautionary measures, Art. 5.7 is clear in this respect, but its application is limited by the existence of scientific evidence (albeit insufficient) on which the measure is based.

As a summary, in those cases where relevant scientific evidence is "insufficient", insofar as it reasonably supports a measure, but the existence of a risk has been identified without determining its extent as a result of relevant risk analysis (under SPS Art. 5.1 and 5.2), Members may resort to the exception provided for in Art. 5.7 of SPS on a provisional basis.

3. EXCEPTIONAL CHARACTER OF THE MEASURES

It results from the report of the Appellate Body in the case Japan – measures affecting import of agricultural commodities, that Art. 5.7 consists in a qualified extension of the obligations arising from Art. 2.2 not to adopt or maintain sanitary measures without scientific evidence.

The interpretation of the Appellate Body strengthens the intention of members when signing the SPS Agreement not to establish Art. 5.7 as an opening to allow non-compliance with any obligation of the Agreement, but to limit its use to certain exceptional cases.

This could not be otherwise since the adoption of measures under the precautionary approach implies a restriction to trade without sufficient scientific evidence. Consequently, a clause of this type must retain an **exceptional** character.

4. PROVISIONAL CHARACTER OF THE MEASURES ADOPTED

In conformity with the conclusions of the Appellate Body in the case of Japan, it appears clear that the 4 requisites to establish precautionary measures are cumulative, since the review of the measure in a reasonable time frame is indispensable for the Member applying measures under this Article.

It must be therefore very clear that its transitory character is not for discussion. What should be discussed is the element to be taken into account as a parameter to determine the duration of the provisional measure.

In this respect two positions exist:

- Those who argue that the measure must be applied while scientific data are imprecise, insufficient or inconclusive, and therefore subordinate its continuation to scientific developments
- Those who argue that the above position would reward inefficient research, and therefore a time frame must be fixed

If we take into account the difficulties of third world countries to develop scientific research, to establish the request for additional information as the sole limit for a provisional measure leaves it in the hands of industrialized countries whether to rescind or not such measures; especially as these countries have the lead in scientific research.

In this respect temporary limits should be established, on a case by case basis taking into account the level of risk detected, the extent of restriction to trade arising from the precautionary measure and developments in the scientific field.

5. COMPLIANCE WITH THE OTHER OBLIGATIONS UNDER SPS

Following the above, Art. 5.7 exonerates Members only from the obligations of Art. 2.2 concerning sufficient scientific evidence. However, the other principles in the SPS should be followed by Members who wish to apply precautionary measures.

With this understanding, the Appellate Body concluded in the Hormones case that precaution was not integrated in the SPS text as a justification for sanitary measures which would be incompatible with the obligations of Members set out in specific SPS provisions.

6. PROPORTIONALITY

Art. 2.2 establishes the principle of proportionality in that sanitary and phytosanitary measures will apply only when necessary to protect health.

Consequently a correct application of this principle would imply that within the range of alternative measures presented to risk managers to achieve a level of protection, they should select the least trade restrictive.

7. BURDEN OF PROOF

It is clear from the SPS text as well as from jurisprudence arising from the Appellate Body (Hormones case) that measures based on international standards (Codex-OIE-IPPC) are presumed to be compatible with SPS.

In case a Member adopts a sanitary measure that another country considers incompatible with the obligations under SPS, that country has the obligation to demonstrate *prima facie* such incompatibility. Once this is demonstrated, the Member that adopted the said measure must show that it does not infringe any SPS principle. This interpretation was formulated by the Appellate Body in the case of Shrimps and Reformulated Gasoline.

Notwithstanding, when measures are applied under 5.7 and taking into account the exceptional character of precautionary measures, the Member state who adopts them is responsible to ensure that they comply with the necessary requisites for its application. Previous authorization cannot allow to reverse the burden of proof as it has no relationship with the precautionary principle.

CONCLUSIONS

As regards legal aspects, reference should be made to a precautionary approach and not to a general principle of law.

Considering that this approach allows Members to deviate from one of the central elements of SPS, as is the obligation to base measures on sufficient scientific evidence, and to adopt measures that entail barriers to free trade, it should be understood that its application is of a limited and exceptional character. This limitation is temporary and related to a specific time frame, not to scientific developments.

In agreement with the letter of SPS and the conclusions of the Appellate Body, precautionary measures must be based on risk assessment (under Art. 5.1 and 5.2 of SPS) to establish that a risk exists although its extent cannot be determined exactly.

Similarly the Member who adopts the provisional measure must justify the application of the said measure.

AUSTRALIA

Australia would first like to congratulate the French Secretariat for the work that has been put into redrafting paragraphs 34 and 35.

Specific Comments

Footnote 1 [It is recognised that hazard identification is a crucial step in this process]

Australia supports the deletion of this footnote; hazard identification is recognised as an essential step in risk assessment defined by Codex.

With regard to the questions posed by the Secretariat in response to the footnote; The probability of occurrence of adverse health effects is not part of hazard identification but is part of hazard characterization (ie different parts of the risk analysis process).

Footnote 2 [Some members refer to this concept as the "precautionary principle"]

Australia supports the deletion of this footnote. This is a matter for individual member countries concerned, rather than for Codex to define as an agreed term.

[risk managers/member governments]

The broader term "risk managers" is preferable in that it allows greater flexibility in the application of these guidelines.

It is the role of risk managers to take into account the uncertainty in risk assessment processes. These guidelines reiterate this in that reference is made to risk managers taking into account uncertainty (paragraph 17 "the responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessor") this is also covered in the scope of these working principles (p 4).

[within a reasonable time frame]

Australia would support the use of the wording 'within a reasonable time' or alternately 'within a reasonable period of time' which is consistent with the wording in Article 5.7 of the SPS Agreement 'Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly <u>within a reasonable period of time</u>.'

General Comments Paragraph 35

Australia considers that paragraph 35 contains the necessary criteria to ensure that the interim measures described in paragraph 34 are not used in an arbitrary way that might result in unwarranted disruption to

trade. We therefore consider it essential that paragraphs 34 and 35 be treated as one entity, and that the criteria in paragraph 35 must be applied, not merely "taken into account".

It is also necessary to clarify whether individual criteria refer to decisions or measures that may be implemented as a result of those decisions; in most cases the criteria apply to measures.

Specific comments in relation to the criteria in paragraph 35

1. Examination of the full range of management options should be undertaken with all stakeholders. This should include an assessment of the potential advantages and disadvantages of alternative measures, including where appropriate, flexibility and cost, effectiveness considerations.

Consultation "with all stakeholders" may not be a practical option in a situation where a member government needs to take precautionary action to protect consumer health; governments often have to act first and consult later (as is covered under 5).

"Flexibility" Australia would like to seek clarification as to the rationale for its inclusion and a clear explanation of its meaning.

The separation of cost and effectiveness it is unclear whether this is a grammatical error or translation problem, and should be written as "cost-effectiveness", confusion appears to be due to the use of a dash (/) rather than a hyphen in the original text. Inclusion of the words "where appropriate" seems unnecessary, because the wording is so general as to mean "inclusion of all relevant factors including cost-effectiveness."

2. There should be transparent explanation of the need for the measures and the procedures followed to establish them

3. The decisions/measures taken are proportional to the potential health risk and based on the available scientific data

Australia supports the use of "measures" rather than "decisions" to better reflect the meaning of Article 5.5 of the SPS Agreement (which requires members to avoid arbitrary or unjustifiable distinctions in the levels of protection between different situations).

4. The decisions/measures taken are consistent with those taken in similar circumstances, based on all the available pertinent information, including available scientific information. The measures taken are the least trade restrictive necessary to achieve protection of the health of consumers.

Australia supports the use of "measure" rather than "decision".

In addition Australia proposes that the word 'similar' be changed to 'comparable'. To maintain consistency with the SPS Agreement.

Australia would also suggest that as this criterion deals with two separate issues, it should be divided into separate criteria by separating the two sentences ie insert new criteria 4 bis to read

4 bis The measures taken are the least trade restrictive necessary to achieve protection of the health of consumers.

5. The decisions/measures are subject to an on-going, transparent review process involving interested stakeholders.

Australia supports the use of the word 'decisions' rather than 'measures' in this instance as the decision may have been not to implement a measure and for that reason 'decisions' is more appropriate in this context.

6. Information should continue to be gathered to strengthen the scientific evidence. The original decisions should be reviewed and decisions taken to retain, modify, strengthen or rescind any measures as appropriate in the light of such information.

Australia supports the inclusion of this point it is important as it provides guidance on what steps might be taken as a result of the review.

COSTA RICA

Spanish version
Consideramos que la aplicación del principio o enfoque de precaución depende exclusivamente de los Países Miembros y que el Codex debe elaborar normas basadas en pruebas científicas. En tal sentido el plazo de tiempo razonable para mantener un principio o enfoque precautorio es algo que deben negociar los Países Miembros.

English version
We consider that the application of the precautionary principle or approach depends exclusively from Member States and that Codex should establish standards based on scientific evidence. For this reason the reasonable time frame to maintain a precautionary principle or approach is a matter that Member States should negotiate.

MALAYSIA

Malaysia does not agree with the revised text of paragraph 34. We would like to reiterate our position on paragraph 34 as reflected in our response to CL 2000/12-GP : Proposed Draft Working Principles For Risk Analysis at Step 3 - The Application of Precaution in Risk Management :

The Application of Precaution in Risk Management (paragraph 34)

We propose to retain paragraph 34 A in line with article 5.7 of the WTO SPS Agreement. This paragraph is supported by or to be read together with the criteria listed in paragraph 35 which provides guidance on the application of precaution in risk management.

Paragraph 34
Where relevant scientific evidence is insufficient, precaution can be exercised as an interim measure to protect the health of the consumers. However, additional information for a more objective risk assessment should be sought and the measures taken reviewed accordingly within a reasonable time frame.

Regarding the revised text of paragraph 35, we propose the following amendments :

No. 1:
We propose to amend the words "management options" to "management options available", and to delete the words "where appropriate" since risk management should include flexibility and cost-effectiveness considerations. This is consistent with paragraph 32 of the Proposed Draft Codex Working Principles For Risk Analysis which states that "Risk management should take into account the economic consequences and the feasibility of risk management options 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."

No. 4 :
We propose to amend the words "similar circumstances" to "comparable circumstances" in view that similar situations may not contain sufficient common elements to render them comparable.

No. 6 :
We propose to amend the sentence "The original decisions taken should be reviewed and decisions taken to retain, modify, strengthen or rescind any measures as appropriate in the light of such information" to "The

original decisions taken should be reviewed and the measures retained, modified, strengthened or rescinded as appropriate in the light of such information".

NORWAY

Para 34: Norway considers it very important that the Codex working principles include provisions for dealing with precaution, uncertainty and insufficient data. Norway finds that the best way to ensure appropriate and consistent use of precaution is to include guidelines for its application in the working principles. These guidelines should apply to both the Codex system and member countries. Accordingly Norway favours the inclusion of the words risk managers in the first square bracket. We support the wording in the second square bracket, i.e. deletion of the bracket.

Para 35: Norway strongly supports the inclusion of criteria, as it is very important to ensure consistency and transparency in situations where precaution is appropriate, both on the national and international level.
We would suggest, however, that the words "with all the stakeholders" in 1) is somewhat modified. It is not always relevant, nor possible, to consult all stakeholders. The sentence could be amended to "…..undertaken in consultation with relevant stakeholders."

URUGUAY

Spanish version
En un sentido amplio, el resolver y obrar con precaución es inherente a la propia naturaleza humana y ha sido históricamente la forma general de actuar y reaccionar frente a lo desconocido.

La cautela o precaución han sido además, históricamente, actitudes indispensables de los buenos gobernantes, responsables en la toma de decisiones en materia de defensa y protección del bien común. Aunque modernamente hemos denominado a estos gobernantes "gestores de riesgo" y estamos avanzando sustantivamente en acordar internacionalmente un procedimiento estructurado y trasparente para mejorar el proceso de toma de sus decisiones (que hemos denominado "análisis de riesgos"), tales "decisores" han existido siempre y siempre se le ha exigido, de una u otra forma, el ejercicio de la responsabilidad y la precaución.

Y, en consecuencia, también la precaución han sido inherentes y propias del proceso de toma de decisiones del Codex en tanto organización intergubernamental y abierta a la participación universal. Esto se encuentra claramente reconocido en el párrafo 5. del punto "Generalidades del Análisis de Riesgos" del "Anteproyecto de Principios de Aplicación Prácticos del Codex para el Análisis de Riesgos".

Reafirmamos, por tanto, nuestro apoyo a la idea de que los criterios generales de precaución son propios del proceso de toma de decisiones humanas a nivel general. Sin embargo los párrafos 34. y 35. del citado documento, más allá de una cierta confusión en la terminolgía y de las dificultades que conlleva la carencia de definiciones apropiadas sobre precaución en el ámbito internacional, se refieren claramente a un asunto diferente del anterior.

Uruguay entiende que dichos párrafos se refieren concretamente a las posibilidades de adoptar **medidas específicas de precaución** frente a una situación determinada de ausencia de información científica suficiente para completar una evaluación de riesgos. Esta posibilidad sólo se concibe en el plano de las decisiones gubernamentales.

En consecuencia, Uruguay reafirma su opinión de que la redacción actual de los párrafos 34. y 35. no se adecua a lo que ha sido y debe seguir siendo la gestión de riesgos en el Codex, en tanto organización internacional encargada de elaborar normas **sólidamente fundamentadas en información científica relevante**. Si el Codex no trabajara sobre tales premisas no sería una organización internacional apropiada a los efectos de elaborar normas de referencia para la Organización Mundial del Comercio.

El trabajo del Codex es, en sí mismo, de naturaleza recomendatoria, La responsabilidad en la adopción de las **medidas concretas de protección** es exclusiva de los gobiernos, que resuelven soberanamente adoptar o no las recomendaciones del Codex sobre la base de su nivel de protección nacional. La adopción de **medidas concretas de precaución** no escapa a esta premisa básica y general.

En consecuencia Uruguay desea proponer la siguiente redacción del párrafo 34. del "Anteproyecto de Principios de Aplicación Prácticos del Codex para el Análisis de Riesgos":

"When relevant scientific evidence is insufficient to objectively and fully asses risk from a hazard in food, and where there is reasonable evidence to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and their extent, it may be appropriate for members governments to apply precaution through interim measures to protect the health of consumers, without awaiting additional scientific data and a full risk assessment

However, additional information for a more objective risk assessment should be sough periodically, and in the case that new relevant evidence is available, a more complete risk assessment should be performed, and the measures taken reviewed accordingly within a reasonable time frame."

English version

In a wide sense, precaution in the solution of problems and work is inherent to human nature and has been historically the general form of action and reaction in front of the unknown.

Caution or precaution have also been, historically, indispensable attitudes of good government, exercising responsibility in decision making as regards consumer protection and common welfare. Although in the modern period those who govern have been called "risk managers" and we have made substantial progress in establishing a structured and transparent process to improve the decision making process (which we called "risk analysis"), such "decisions" have always existed and have always required the exercise of responsibility and precaution.

Consequently, precaution has been inherent to the decision making process in Codex, as an intergovernmental organization open to universal participation. This is clearly recognized in para. 5 of "Risk Analysis – General Aspects" in the Proposed Draft Working Principles for Risk Analysis.

We therefore reassert our support to the idea that general precaution criteria are inherent to the human decision process in general. However, paras. 34 and 35 of the said document, besides a certain confusion in terminology and the difficulties related to the lack of appropriate definitions at the international level, are clearly referring to a different issue.

Uruguay understands that those paragraphs concretely refer to the possibility of adopting specific precautionary measures in front of a given situation in the absence of sufficient scientific data to complete risk assessment. This possibility is conceivable only at the level of government decisions.

Consequently, Uruguay reasserts its opinion that the current wording of paras. 34 and 35 does not correspond to what has been and must continue being risk management in Codex, as an international organization charged with elaborating standards **on the basis of sound relevant scientific data**. If Codex did not work on this basis it would not be an international organization entitled to elaborated reference standards for the World Trade Organization.

Codex work is in itself of an advisory nature. The responsibility for adoption of **concrete protection measures** is the exclusive responsibility of governments, who decide in sovereignty whether to adopt or not Codex recommendations on the basis of their national level of protection. The adoption of **concrete protection measures** does not detract from this basic and general rule.

Consequently Uruguay wishes to propose the following wording for para. 34 of the Proposed Draft Working Principles for Risk Analysis

"When relevant scientific evidence is insufficient to objectively and fully asses risk from a hazard in food, and where there is reasonable evidence to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and their extent, it may be appropriate for members governments to apply

precaution through interim measures to protect the health of consumers, without awaiting additional scientific data and a full risk assessment

However, additional information for a more objective risk assessment should be sough periodically, and in the case that new relevant evidence is available, a more complete risk assessment should be performed, and the measures taken reviewed accordingly within a reasonable time frame."

UNITED STATES

General Comments:

Concerning the redrafts of paragraphs 34 and 35, we continue to have concerns about these paragraphs. Indeed, in preparing for the 16th Session of the Codex Committee on General Principles (CCGP) and the planned Working Group to be held on April 21 on precaution in risk management, we have concluded that the fundamental problem is the effort to deal in a single document with the principles for risk analysis in the framework of Codex, and risk analysis as done by member governments.

We firmly believe that the CCGP should limit its work in this area to working principles for risk analysis in the framework of Codex. That is a manageable task, that is consistent with the mandate of the committee and with the urgent priority to strengthen risk analysis at the international level. The difficulty that Codex members are having in the CCGP Committee in achieving consensus on the working principles is due in large measure to the current overly broad scope of the document. Accordingly, the working principles document should be limited to risk analysis in Codex, and the more difficult and contentious issue of guidance to member governments on risk analysis in their national measures and decisions should be left to a later day. For now, the completion of the current work on risk analysis in the framework of Codex is already extremely ambitious, and the Committee needs to conclude this work in order to provide needed advice from Codex members to WHO and FAO as to the risk assessment process vital to the work of Codex and member governments.

An indicator of the current problem with the Draft Proposed Working Principles is that, throughout the document (Appendix III, ALINORM 01/33), there is no indication of which principles are intended for application in the framework of Codex Alimentarius, which principles are intended to provide advice to governments, and which are intended to address both audiences.

Summary of U.S. position:

- The document should be limited to risk analysis in the framework of Codex.
- All advice to national governments, including paragraphs 34 and 35, should be deleted from the Working Principles.
- Within Codex, precaution is important but provisional measures would not be appropriate. Where evidence is insufficient or some members are uncertain about the adequacy of evidence, Codex should not establish a standard but should seek more evidence. The matter should be put to the side until more evidence is available or members achieve consensus that evidence is adequate**.**

Rationale:

- *The fundamental problem with the Working Principles document is the effort to deal in a single document with the principles for risk analysis in the framework of* ***Codex****, and risk analysis as done by* ***national governments****.*
- *CCGP could complete the Working Principles if focused on Codex risk analysis.*
- *Focusing on risk management at the international level—Codex and its parent bodies, WHO and FAO--is consistent with the CCGP's terms of reference.*
- *WHO and FAO are responsible for convening the expert risk assessment committees that give advice to Codex's risk management committees on food hygiene, pesticides, food additives and contaminants, and veterinary drugs.*

- *Like other risk managers, Codex needs to advise its risk assessors know as to its needs in the way of risk assessments. This vital work needs to be given priority.*
- *WHO and FAO are working to strengthen their risk assessment committees, for example, to deal with microbiological hazards.*
- *Many countries, particularly developing countries, rely on WHO/FAO/Codex for risk analysis, rather than performing it at the national level.*

- *Completing work on risk analysis at the national level is not achievable as there is not consensus. The issue is not ripe. This more difficult issue should be taken up later, by Codex or its parent bodies.*
- *It is clear that governments can, under the SPS agreement, have strong national food safety systems. In particular, we would point to Article 2.1, 3.3 on level of protection and 5.7 on provisional measures. Therefore, there is no harm in waiting until more progress can be made as to advice to governments on risk analysis.*
- *At the CCGP's April 2000 meeting, there was no consensus on paragraphs 34 and 35. Delegates left the meeting expecting the Committee chair to initiate a drafting group to be conducted by e-mail and a series of workshops to continue to seek consensus. These steps were not taken. Instead we have only the working group just before the next meeting.*

- *Everyone agrees that precaution is essential when we are discussing food safety (food production practices and regulation).*
- *Precaution is part of international risk analysis under the framework of Codex.*
- *Codex members, including the U.S., have a long history of precaution as part of national food safety systems.*
- *The EU proposal of a "precautionary principle" at the risk management stage, however, is not an established principle for consideration at the international level. We would be interested in hearing about how this concept evolves within the EU, however. What is particularly of concern is the notion that politicians could overrule the findings of scientists (risk assessors) that a product or process is safe. This opens the door to arbitrary decisions and trade barriers.*
- *Precaution needs to be built, by producers and governments, into every step of the food safety production and regulatory process, "from farm to table," not "invoked" by political leaders after a food safety problem.*

Specific Comments on CX/GP 01/03

The United States submits that paragraphs 33. through 35. in the Working Principles are not appropriate principles for the application of risk analysis within the framework of Codex. The criteria contained in these paragraphs may be appropriate for consideration by national governments, but not Codex. The U.S. therefore recommends that the paragraphs be deleted as inappropriate in a document focused on risk analysis under Codex. Set forth below is the text that the United States recommends for deletion (from CX/GP 01/3):

> ~~**34. [When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food [1], and where there is reasonable evidence to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and their extent, it may be appropriate for [risk managers/members governments] to apply precaution [2] through interim measures to protect the health of consumers, without awaiting additional scientific data and a full risk assessment.]**~~
>
> ~~**[However, additional information for a more objective assessment should be sought and the measures taken reviewed accordingly [within a reaonsable time frame/until a more complete risk assessment is performed]**~~
>
> ~~**[[1]It is recognized that hazard identification is a crucial step in this process.]**~~
>
> ~~**[[2] Some Members refer to this concept as the "precautionary principle."]**~~

Rationale: The United States submits that it is properly within the purview of national governments, rather than Codex, to exercise precaution in risk management by establishing interim measures. The way Codex

should deal with situations where there is insufficient data, or there is not consensus as to adequacy of data, is to seek the required additional scientific information before establishing an international standard or guideline. Therefore, the United States believes that paragraph 34. should be deleted.

35. [In such situations the following criteria should be taken into account:

1) **Examination of the full range of management options should be undertaken with all the stakeholders. This should include an assessment of the potential advantages and disadvantages of alternative measures, including, where appropriate, flexibility and cost, effectiveness considerations.**
2) **There should be a transparent explanation of the need for the measures and the procedures followed to establish them.**
3) **the decisions/measures taken are proportional to the potential extent of the health risk and based on the available scientific data**
4) **the decisions/measures taken are consistent with those taken in similar circumstances, based on all the available pertinent information, including available scientific information. The measures taken are the least trade restrictive necessary to achieve protection of the health of consumers.**
5) **The decisions/measures are subject to an on-going, transparent review process involving interested stakeholders.**
6) **Information should continue to be gathered to strengthen the scientific evidence. The original decisions should be reviewed and decisions taken to retain, modify, strengthen or rescind any measures as appropriate in the light of such information**

Rationale: This paragraph should be deleted for the same reasons that paragraph 34 should be deleted. See above discussion.

CONSUMERS INTERNATIONAL

Consumers' International welcomes this opportunity to submit further comments on the application of precaution in risk management (CX/GP 01/3). These comments complement our more detailed comments submitted on this topic and earlier comments on the other working principles.

We consider it essential for consumer protection that the precautionary principle is incorporated into Codex's procedures. Paragraphs 34 and 35 of the document focus on the application of precaution in risk management, but we consider it is essential that precaution is integral to the entire risk analysis process. This is now reflected in paragraph 5 of the working principles (risk analysis – general aspects) and it is important that it remains so.

Paragraph 34

We consider that substantial progress has been made on the wording of this paragraph. We are however concerned that in some situations precaution may need to be applied when there is insufficient evidence to objectively and fully assess the hazard, let alone the risk that the hazard presents. We discuss this further below in relation to hazard identification.

In response to the questions raised in the discussion section of the document:

Should both footnotes be retained?

[1] It is recognised that hazard identification is a crucial step in this process

As stated, the Codex Procedural manual defines hazard identification, an element of risk assessment, as '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.'

While this step is clearly essential, so are the other elements of risk assessment: hazard characterisation, exposure assessment and risk characterisation. We therefore do not consider that particular emphasis needs to be given to hazard identification. There may also be certain circumstances where the precautionary principle/ a precautionary approach will have to be applied when the hazard cannot be identified. For example, measures have been introduced on a precautionary basis to protect against BSE. Although further measures have since been introduced

as knowledge about the disease and possible routes of infectivity have developed, initial measures had to be introduced before the precise nature of the agent responsible had been identified. We would therefore be concerned if measures for public health protection were delayed on the basis that the agent had not been identified, while the hazard characterisation suggested that the effects could be severe, and the exposure assessment indicated that a large number of consumers could be affected.

[2] Some members refer to this concept as the precautionary principle

It is essential that this footnote is retained.

Terms retained in square brackets

Risk managers/member governments

The precautionary principle/approach is very relevant to Codex work. For example, precaution is already exercised in the establishment of Maximum Residue Limits. To assume that Codex should refrain from developing standards where scientific evidence is insufficient would leave Codex with very little work to do. There is always going to be some uncertainty. This is why we have emphasised that precaution is made integral to the entire risk analysis process so that decisions can be made with much greater awareness of the underlying uncertainties. Applying precaution can involve a range of measures, from a complete ban through to labelling requirements, for example. It is therefore just as relevant to Codex standards as it is to member governments. We therefore suggest that the text reads: '…it may be appropriate for risk managers *as well as* member governments to apply precaution'.

Within a reasonable time frame

It is not going to ever be possible to specify the time frame by which the decision taken on the basis of the precautionary principle/approach should be revised. This can only ever be decided on a case-by-case basis taking into account the particular circumstances, for example, the extent of the uncertainty and the type of research that is needed to gain a clearer understanding of the unresolved issues. We therefore consider that it is appropriate for measures to be reviewed '*within a reasonable time frame and when a more complete risk assessment can be performed'*. Therefore we propose that the two options in square brackets be combined.

Paragraph 35

We agree that the reorganisation of the paragraph has helped to improve the clarity and logic of the text. We have the following comments:

1) Examination of the full range of management options should be undertaken with all the stakeholders. This should include an assessment of the potential advantages and disadvantages of the alternative measures, including, where appropriate, flexibility and cost, effectiveness considerations.

We very much welcome the recognition that all stakeholders must be involved in the examination of management options. The meaning behind the new reference to 'flexibility' in the new text is not clear at the moment and should therefore be clarified.

2) There should be a transparent explanation of the need for the measures and the procedures followed to establish them.

Transparency is essential throughout the entire risk analysis process. It is vital that the reason why a particular measure was introduced, including possible alternative approaches that have been considered, are clearly communicated and documented.

3) The decisions/ measures taken are proportional to the potential extent of the health risk and based on the available scientific data.

We are pleased that reference is now made to measures, as well as to decisions. We agree that precautionary measures should also be proportionate. It will however always be easier to quantify the economic impact of introducing a measure, compared with the long-term public health and economic costs of not taking action. This needs to be borne in mind when determining the type of measures that are required. While decisions and measures should be based on the available scientific data, care should be taken in over-reliance on limited data in the face of scientific uncertainty. To again refer to the example we have previously highlighted, reliance on the scrapie model when BSE was first discovered in the UK, led to many incorrect assumptions being made about the nature of the

risk posed. It is clear with hindsight that this resulted in essential public health measures being delayed and when they were introduced, poorly enforced.

4) The decisions/ measures taken are consistent with those taken in similar circumstances, based on all the available pertinent information, including available scientific information. The measures taken are the least trade restrictive to achieve protection of the health of consumers.

Again, we welcome the reference to measures as well as decisions. Our caution about over-reliance on limited scientific information, raised above, also applies here.

5) The decisions/measures are subject to an on-going, transparent review process involving interested stakeholders.

We fully agree that the measures should be reviewed on an on-going basis as scientific understanding develops or as circumstances change and that this should be a transparent process that involves interested stakeholders.

6) Information should continue to be gathered to strengthen the scientific evidence. The original decisions should be reviewed and decisions taken to retain, modify, strengthen and rescind any measures as appropriate in the light of such information.

We agree with the proposed amendments.

COMISA

Introduction

COMISA is the acronym for Confédération Mondiale de l'Industrie de la Sante Animale representing the Global Animal Health Industry. COMISA members are committed to the provision of safe, high quality and effective veterinary drugs to achieve optimum animal health standards which are the prerequisite for the provision of safe, healthy food for consumers.

COMISA would like to reiterate the position that it took in April 2000 whereby it supports the validity of a risk analysis procedure comprising a recognised iterative process which must incorporate precautionary measures in the evaluation steps.

This process is an integral component of the regulatory requirements for the approval of animal health products and is the basis of the evaluations performed by JECFA for the establishment of MRL and ADI values.

COMISA supports the commentary of GCPF referencing the SPS Agreement of WTO providing guidance under Article 5.7. that where relevant scientific evidence is insufficient an ongoing scientific evaluation is a requirement.

Paragraph 34

Under these circumstances, COMISA would propose that the text for paragraph 34 should read:

"… it may be appropriate to apply interim measures to protect the health of consumers, …"

There is no requirement to reference precaution and therefore COMISA continues to maintain the position that Footnote [2] "Some Members refer to the concept as the "precautionary principle" is superfluous and should be deleted.

Paragraph 35

COMISA has no objections to the revised paragraph 35 as identified in CX/GP 01/3. It is proposed to agree to a final detail of the text at the Working Group to be held on 21 April 2001.

CRN (Council for Responsible Nutrition)

The revised draft of Paragraphs 34 and 35, prepared by the French Secretariat after consideration of comments submitted by the Working Group members, including CRN, in June 2000 makes some progress and will serve as a topic for discussion at the Working Group meeting on April 21, 2001.

In general, it must be recognized that ***precaution*** is a necessary and already accepted component of risk analysis. As such, it is appropriate for Codex to describe how precaution should be used in risk analysis. Concurrently, it must be recognized that Codex standards must be based on scientific principles and evidence, rather than cultural or national preferences or desires to achieve trade protectionism.

Consequently, these comments are directed toward modifying Paragraphs 34 and 35 to provide a rational scientific basis, while avoiding language that reflects cultural or national preferences that could be misused to support unjustified trade barriers.

Proposed Redrafting of Paragraphs 34 And 35

Revised Paragraph 34

- Footnote 1:This footnote should be rewritten as follows (with non-grammatical changes underlined): "It is recognized that hazard definition and the criteria for its identification are crucial steps in this process."
  Footnote 2: This footnote is not acceptable and should be deleted.
- Text of Paragraph 34:
  - The word "fully" should be replaced with "adequately" or a synonym. No amount of scientific evidence can ever logically claim to allow risk to be "fully" assessed. The word "fully" allows misinterpretation that a risk is not "fully" assessed because there is "some uncertainty." Science can provide a high level of confidence, but never certainty.
  - At the end of the sentence, the following phrase should be inserted: ", in a manner consistent with obligations under international agreements such as the World Trade Organization's Sanitary and Phytosanitary (SPS) Agreement."
  - The square brackets should be dropped and the wording changes from "risk managers/member governments" to read "risk managers of member governments."

The rationale for each recommendation is given later under Discussion.

Revised Paragraph 35

Item 1: In the first sentence, "all the stakeholders" should be changed to read "all interested stakeholders." In the second sentence, there seems to be a typographical error. The part "cost, effectiveness" should be changed to "cost-effectiveness."
Item 2: The phrase "transparent explanation" should be changed to "transparent and sufficient explanation."
Item 3: No changes are recommended.
Item 4: The emphasis is the reverse of what it should be, i.e., the primary emphasis should be on scientific evidence. The first sentence should be changed to read: "The decisions/measures taken are consistent with those taken by Codex in similar circumstances, based primarily on all available and pertinent scientific information and secondarily, as appropriate, on other legitimate factors that are pertinent to food safety and fair trade."
Item 5: The word "all" should be inserted before "interested stakeholders."
Item 6: No changes are recommended.

Discussion
Discussion of Revised Paragraph 34

Footnote 1:

- The sentence in square brackets should be changed to read: *[It is recognized that hazard definition and the criteria for its identification are crucial steps in this process.]*
- After the first paragraph of discussion, this paragraph should be added:

  - It must be recognized that some food substances, ingredients, and components have beneficial or even essential effects. For these substances, high levels and their effects may qualify as a "hazard," whereas lower levels of the same substance would not be a "hazard" but instead would be useful or essential to human health. Also, the mere presence of some substances, such as the element lead that have no known beneficial effects, do not necessarily qualify as "hazard" but instead are simply unavoidable. The mere presence of any amount of a hazardous substance must not be construed to necessarily mean that it is a "hazard" in the food.

- The second paragraph (as currently drafted) is overly broad and completely misses the point that even essential substances can have adverse effects, i.e., constitute a "hazard" at some high level of intake. This problem could be solved by changing "which may be present in a particular food" to read "which may be present at a hazardous level in a particular food."
- The third paragraph which addresses hazard identification and probability of occurrence should take into account the following:

  - The term "hazard" must not be used to always describe a specific substance. For example, extremely high levels of iron could be a hazard, but it is the high level, not iron itself at any level, that generates the hazard. Some substances with no known beneficial effects, such a lead, are not completely avoidable. The term 'hazard" must not be used in relation to any detectable amount of lead. It is the effect that creates the "hazard," not the chemical identity of the agent.
  - The probability of an adverse effect that must be related to the identification or non-identification of a "hazard" should correspond to the severity, permanence, and cost of the adverse effect. In any case, the alternative risk related to not using the substance must be taken into account. For example, the probability, severity, permanence, and cost of adverse effects related to use of a food additive must be compared to those characteristics of the effects of a failure to use the food additive. This is alternative risk analysis, or risk/risk analysis.
  - The concept of precaution is addressed below, under Footnote 2.

Footnote 2:
Yes, Footnote 2 should be deleted for two important reasons: (1) the specific term "precautionary principle" (PP) is inappropriate for use as an overall, basic principle in food safety because it generates an impossible burden of proof for the safety of deliberate ingredients, especially new ones; and (2) the term PP originated from the Rio Declaration on the Environment and Development (Principle 15 of 27) statement on a "precautionary approach" while there was still uncertainty about harm, and as such has so much history in association with environmental toxicology issues and meanings that those precedents will prevent widespread recognition and acceptance of any more appropriate definition and guidelines that Codex might adopt.

This Footnote is wrong to point out that some Members refer to this concept as the "precautionary principle" without telling the rest of the story. The rest of the story is that other Members refer to this as a "precautionary approach," others refer to is as the "application of precaution," and still others simply apply precaution without giving it any collective description. Footnote 2 should be deleted but if it is kept these additional descriptions should be added.

First square brackets
The phrase in square brackets *[Risk managers/member governments]* leaves much uncertainty about the identity of the "risk managers." The phrase should be replace with *[Risk managers of member governments]*.

Relevance of precautionary principle/approach
Precaution is an inherent and essential element of risk analysis. Evaluation of uncertainty and the scientific rationale for risk management options are proper parts of risk analysis. The exercise of precaution at a political decision level, after Codex has adopted a standard, or decided not to do so, is the option of individual countries. The countries must, of course, meet their obligations under the SPS Agreement and other relevant agreements. The specific term "precautionary principle" should not be used by Codex or other global organizations for the reasons given above.

Second square brackets
The phrase *[within a reasonable time frame]* requires additional explanation to specify what steps are being taken and why the timeframe suggested is appropriate. This could be done by additional wording as follows: *[within a reasonable timeframe, with specific steps and the time needed to accomplish them described in the decision to take the measure]*.

The terms "reasonable timeframe" and "more complete risk assessment" are compatible and this may be shown by the following wording: "reasonable time frame to obtain the needed information and perform a more complete risk assessment."

Discussion of Revised Paragraph 35
The discussion of revised Paragraph 35 is quite simple, but sufficient, as long as it is not further revised.

EUROPEAN COMMUNITY

Paragraph 34 of the Draft Working Principles for Risk Analysis

The European Community generally agrees with the proposal made by the working group, but would like to make the following comments.

Concerning the two expressions in brackets the European Community is of the opinion that **risk managers** is the correct expression, since the guidelines would provide guidance for the risk mangers in Codex Committees and in governments. For the second bracketed wording we would propose the following compromise "*within a reasonable timeframe which allows for the collection of sufficient data*".

Furthermore, the European Community considers the **precautionary principle** to be part of a general policy approach that applies in risk management. We have observed that sometimes the term "precautionary principle" is replaced be the expression "precautionary approach". In the European Community, however, we use term "precautionary principle", as it reflects more accurately current thinking. Consequently we would prefer to use this term in paragraph 34. However, in order to reach a compromise, we can accept to mention the precautionary principle in a footnote as indicated.

Paragraph 35 of the Draft Working Principles for Risk Analysis

In principle the European Community agrees with the proposal made by the Working Group. In our opinion, nothing in these proposals is innovative or relates solely to the application of precaution - the procedures described in paragraph 35 are elements of general risk management practice. Nevertheless, we would propose the following modifications.

In paragraph 1 the first sentence should be modified as follows:

"*Examination of the full range of management options should be undertaken in consultation with consumers, industry, the academic community and other interested parties, as early as possible ~~all the stakeholders~~*."

Paragraph 5 should be modified accordingly:

"*The decisions/measures are subject to an on-going, transparent review process involving consumers, industry, the academic community and other interested parties ~~interested stakeholders~~*."

These changes bring these paragraphs in line with the language used in the Codex Manual, 11th edition, page 49 in the definition of risk communication.

Paragraph 6 should be modified as follows:

"*Information should continue to be gathered to strengthen the scientific evidence. The original decisions should be reviewed in order to retain, modify or abolish ~~and decisions taken to retain, modify, strengthen or rescind~~ any measures taken as appropriate in the light of such information*."

GLOBAL CROP PROTECTION FEDERATION

As GCPF stated in its previous comments, the crop protection industry is strongly regulated by governments. GCPF supports such regulation, providing that is based on sound science. Precaution has already been incorporated into the risk assessments conducted as a normal part of the registration process. As a result, any further action on crop protection products as a result of an alleged « Precautionary Principle » would have to be closely scrutinized to avoid its abuse for political or unfair trade objectives.

For this reason, GCPF strongly recommends the delegation of Footnote 2 under para. 34. GCPF strongly believes that the lack of an agreed definition and agreed criteria for a « Precautionary Principle » can give rise to abuse and undesirable results. In addition, use of such an arbitrary standard can create disguised restrictions on trade and artificial barriers to the free movement of goods.

GCPF recommends the deletion of the brackets in the third line of paragraph 34, and the rephrasing of the wording to state : « risk managers of member governments ». GCPF believes that this application of precaution is a national prerogative and should be clearly indicated to be such.

Regarding the second set of brackets in para. 34, GCPF recommends that the preferred wording is « reviewed accordingly within a fixed period of time ». This wording is in agreement with Article 5.7 of the SPS Agreement of WTO, and is appropriate for inclusion in this paragraph.

The proposal for redrafting para. 35 is acceptable as written.

IACFO (International Association Of Consumer Food Organizations)

We wish to make the following comments on the revised text of paragraphs 34 and 35 prepared by the French Secretariat. We strongly support the text referring to the procedural involvement of consumers and other interested parties[6] and the need for "a transparent" explanation and review[7] of the precautionary measures taken.

However, as indicated in paragraph 1 of the scope of the Proposed Draft Codex Working Principles for Risk Analysis,[8] the substantive aspects of paragraphs 34 and 35 may affect both the international legality of measures taken by governments[9] and the work of Codex. Thus, this proposal should be changed so that

[6] However, the Secretariat's draft uses the phrase "all the stakeholders" in paragraph 35.1 and the phrase "interested stakeholders" in paragraph 35.5. The Committee should use the phrase "consumers and other interested parties" in both paragraphs in order to be consistent with the phrase in paragraph 36 in the Proposed Draft Working Principles for Risk Analysis that the Committee agreed upon in April 2000. ALINORM 01/33, APPENDIX III.

[7] In paragraphs 35.2 and 35.5.

[8] ALINORM 01/33, APPENDIX III.

[9] For example, in October 1999 a coalition of United States agricultural organizations and pharmaceutical companies wrote to the United States Trade Representative (USTR) supporting its letter to the European Union that asserted that the European Union=s ban on the use of antibiotics to stimulate the growth of livestock when they are also used to treat humans Aappears to have been taken without proper risk assessment being done.≅ The coalition argued that the European Union had Ainvoked the so-called precautionary principle≅ in adopting its ban and said that Athe continued application of such a policy would effectively negate the disciplines of the SPS Agreement.≅ In February 2000 USTR informed the Center for Science in the Public Interest -- which had criticized USTR=s letter for ignoring the findings of the United States Centers for Disease Control, the United States National Academy for Sciences, the United States General Accounting Office, and the World Health Organization -- that Athe United States will continue to call for the EC to comply with the provisions of the SPS Agreement in implementing≅ its ban. In May 2000 the Trans Atlantic Consumer Dialogue (TACD) -- comprised of consumer organizations in the United States and the European Union -- wrote to President Clinton and European Commission President Prodi urging that this matter be resolved on the basis of

it will not limit the substantive rights of national governments to apply precaution beyond the limitations they have agreed to in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). For example,

X *In paragraph 34, replace the phrase "When relevant scientific evidence is insufficient to objectively and fully assess risk"with the phrase "In cases where relevant scientific evidence is insufficient to assess the risks."* The latter phrase is used in the first sentence of Article 5.7 of the SPS Agreement to define the circumstance in which a Member may "provisionally adopt"a measure. While the second sentence of Article 5.7 says that the "more objective assessment of risk"is only made *after* the Member invokes the precautionary measure, the current version of paragraph 34 requires that the "objective"assessment must be made *before* the precautionary measure is invoked, Thus, the current version of paragraph 34 raises the important issues of who would make this initial "objective"assessment of the evidence and what it means to "fully"assess risk when a government decides it wants to exercise precaution.

X In paragraph 34, replace the phrase "from a hazard in food"with the phrase "to the health of consumers while at the same time ensuring fair practices in the food trade". The latter phrase is broader and is Codex" mandate. For example, certain food production techniques -- such as the use of genetically modified seeds -- could lead to unfair trade practices, and such matters should be considered by both Codex and governments in the precautionary establishment of standards relating to genetically modified organisms.

X I*n paragraph 34, delete the phrase "and where there is reasonable evidence to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and extent".* This additional requirement, which is not contained in Article 5.7 of the SPS Agreement, appears to mean that neither Codex nor a government could apply precaution when there is no evidence on the impact on human health. While it may be reasonable for Codex to decide not to issue a standard until there is an international consensus on the evidence, a national government need not wait for "reasonable evidence" -- however and by whom that would be determined -- of harm to human health before taking action.[10]

X *In the last sentence of paragraph 34, remove the brackets and delete the phrase "within a reasonable time frame," thus leaving the phrase "until a more complete risk assessment is performed."* The Transatlantic Consumer Dialogue -- comprised of consumer organizations in the United States and the European Union -- supports eliminating the word "provisionally" in the first sentence of Article 5.7 of the SPS Agreement, and this suggested change in the current version of paragraph 34 is consistent with the TACD's

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the precautionary principle. On October 31, 2000 the United States Food and Drug Administration announced that it is proposing to withdraw its approval for any use in poultry of two fluoroquinolones that it had approved in the mid-1990s because such use is a significant cause of the development of resistant *Campylobacter* infections in humans. 65 Fed. Reg. 64954 (October 31, 2000).

[10] For example, Codex and the United States took different approaches to the pesticide methyl parathion in the summer of 1999. In the Food Quality Protection Act of 1996 the United States Congress established an extra tenfold safety margin for pesticide chemical residues for infants and children. Pursuant to that law, on August 2, 1999 the United States Environmental Protection Agency announced a ban on the use of methyl parathion for some fruits and vegetables. Meanwhile, six weeks earlier the Commission (without objection by the United States) adopted a maximum residue level for methyl parathion, noting that the Committee on Pesticide Residues had agreed in 1998 that there was no internationally agreed methodology for assessing the potential adverse effects on infants and children. While the Food Quality Protection Act is an example of a precautionary approach by the United States government, there are other examples (as discussed in the Appendix to this comment) where the United States -- contrary to the views it expressed to the Organization for Economic Cooperation and Development in the paper *Precaution in U.S. Food Safety Decisionmaking: Annex II to the United States= National Food Safety System Paper* -- has not followed a precautionary approach in the food area.

recommendation.

X I*n paragraph 35.4, delete the second sentence*. Codex has no special competence is assessing whether a measure is the least trade restrictive to achieve protection of the health of consumers. Moreover, Article 5.4 of the SPS Agreement merely requires Members "to "take into account the objective of minimizing negative trade effects", and Article 5.6 of the SPS Agreement provides that the "measures are not more-trade restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility" (footnote omitted). Paragraph 35.4 omits this SPS reference to "technical and economic feasibility."