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.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON GENERAL PRINCIPLES
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PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS THE APPLICATION OF PRECAUTION IN RISK MANAGEMENT

GOVERNMENT COMMENTS AT STEP 3

Background

The 15th Session of the Committee on General Principles agreed that a drafting group coordinated by the French Secretariat would work by electronic mail in order to propose a revised text of paras. 34-35 in the Working Principles for consideration by the 16th Session (ALINORM 01/22, para. 60). The French Secretariat asked for comments from member countries and international organizations in June 2000. Comments were also requested by Codex Circular Letter CL 2000/12-GP (April 2000) attached to the report of the last session of the Committee (ALINORM 01/33). In the light of the comments received, the French Secretariat prepared a revised text (CX/GP 01/3) which was distributed for additional comments in January 2001.

The present document includes:

1) the comments received on the application of precaution (paras. 34-35 of the Working Principles) in reply to the CL and the letter of the French Secretariat;

2) a Table including the comments submitted on each paragraph and the relevant amendments in the text.

Notes:

1) The comments received later on the revised text (CX/GP 01/3) will be included in another Addendum.

2) The comments received on the other sections of the Proposed Draft Working Principles will be presented in a separate document (CX/GP 01/3-Add.2).

AUSTRALIA

In these comments, the first of the two alternative versions of Paragraph 34 contained in square brackets is referred to as Para 34 (A) and the second as Para 34 (B). The seven criteria under Paragraph 35, represented by dot points in the Codex document, have been referred to as Paragraph 35 (a) through (~~f~~g).

Australia accepts that risk managers sometimes need to make decisions based on incomplete information in order to protect the health of consumers. This fact was acknowledged by the International Conference on International Food Trade Beyond 2000, which called upon all parties to recognise that precaution has been and should remain an essential element of risk analysis in the formulation of national and international standards.

Such decisions must, however, be based on the available scientific evidence and be consistent with the obligations of WTO member countries as set out in the Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement) and in particular, Article 5.7 of that Agreement. In general, these obligations require measures to be based on risk assessment, to take into account available scientific evidence, to not be more trade restrictive than required to achieve the appropriate level of protection, taking into account technical and economic feasibility, and to reflect a consistent approach to risk management. Where a member adopts provisional measures in the absence of sufficient scientific evidence, the measure must be based on the available pertinent information and the member must seek to obtain the additional information necessary for a more objective assessment of risk and review the measure accordingly within a reasonable period of time.

Paragraph 34

With regard to the two proposed versions of Para 34, Australia strongly supports the position expressed in para 34 (A) that additional information to enable a more objective risk assessment should be actively sought and the interim measure reviewed within a reasonable time frame. We note that this requirement reflects Article 5.7 of the WTO SPS Agreement. However, Australia considers that para 34(B) contains additional important conditions, regarding the need for there to be evidence of rather than merely the perception of a hazard, that are not contained in Para 34 (A).

We propose that the essential components of the two versions be combined as follows:

'When there is reasonable evidence from a ~~preliminary~~ risk assessment to suggest that serious adverse effects on human health ~~may~~ are likely occur as a result of a hazard in food, but the relevant available scientific evidence is insufficient to evaluate the nature and extent of the hazard or to objectively and fully assess the associated risk, it may be appropriate for risk managers to apply precaution through interim measures to protect the health of consumers. Any such interim measures should be applied in accordance with the criteria listed in Para 35, and risk managers should seek to obtain the additional information necessary for a more objective assessment of risk and review the measures accordingly within a reasonable period of time.'

Australia considers that both footnotes to paragraph 34 can be deleted. The first serves little purpose as hazard identification is an essential step in risk assessment as defined by Codex. The second statement refers to terminology used by some member countries; this is a matter for the individual countries concerned, rather than for Codex.

Paragraph 35

Australia considers that Para 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 Paras 34 and 35 be treated as one entity, and that the criteria in Para 35 must be applied, not merely 'taken into account'. It is also necessary to clarify whether individual criteria refer to decisions, or to measures that may be implemented as a result of those decisions; in most cases the criteria apply to measures. Some of the criteria in Para 35 also need to be reworded to ensure they can be applied in a practical way.

Australia therefore proposes that paragraph 35 be amended as follows:

Chapeau - We propose this be amended to read 'In such situations the following criteria shall be applied to ensure the consistency, objectivity and transparency of the decision-making process and of any measures implemented:'

Criterion (a) (Beginning 'Following preliminary risk assessment') - We consider that the important concept expressed in this criterion should be included in Paragraph 34 (as has been done in the proposed alternative version of Paragraph 34 above). However, ~~I~~if this concept is retained in Paragraph 35, it should be strengthened by including the word 'significant' before the word 'risk' (i.e. 'specific significant risk' and 'a significant risk exists'). This is because there will always be some risk, no matter how small, and we believe the intent of this provision is to refer to a significant risk.

Criterion (b) (Beginning 'the decisions taken are proportional') - Replace 'decisions' with 'measures'. Delete 'and', and insert a comma after 'risk', in order to link assessment of the 'potential' extent of the health risk directly with the available scientific data and so seek to ensure that the measures are not based on a hypothetical worst case scenario.

Criterion (d) (Beginning 'the decisions taken are consistent') - Replace the word 'decisions' with the word 'measures'. Also, replace the word 'similar' with the word 'comparable' 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 in different situations). As this criterion deals with two separate issues, it should be divided into two criteria by inserting a full stop after 'circumstances' and inserting a new criterion reading 'The measures taken are the least trade restrictive …'.

Criterion (e) (Beginning 'the decisions are provisional') – The proposed wording of Paragraph 34 would make clear that the decisions (and any associated measures) are provisional and the words 'are provisional and' could therefore be deleted. Replace the word 'decisions' with the word 'measures'.

Criterion (f) (Beginning 'information') - Although we are proposing that a similar provision be included in the body of Para 34, it would be useful to retain this criterion because it provides guidance on what steps might be taken as the result of a review. In addition to the range of options listed, the options should include retention of the existing measures. This criterion should therefore be amended to read '…evidence. The original decisions should be reviewed, and decisions taken to retain, modify, strengthen or rescind ~~the~~ any measures as appropriate …'.

Related issues

Australia wishes to raise an issue that applies generally to the Draft Codex Working Principles for Risk Analysis of which these paragraphs are part, but is important to the application of these paragraphs. This relates to the scope and eventual application of the Working Principles, and we will be commenting further on this matters in our overall comments on the Draft Working Principles. However, we wish to make some observations in relation to Paras 34 and 35.

Under Scope in the Draft Working Principles, it is stated (in paragraph 1) that 'the principles ... are intended for application in the framework of Codex Alimentarius and are also intended to provide advice to governments where applicable' and (in paragraph 3) that 'the objective of the working principles is to ensure that Codex standards and related texts … are based on risk analysis'.

The fact that the Working Principles are intended for application in the framework of Codex limits their application to matters within the mandate of Codex – that is, matters related to food that impact on the health of consumers~~,~~ in the context of fair trade.

It is clear from this that the Working Principles are intended to apply primarily to Codex itself, and their possible use by national governments, where applicable, is a secondary function. However, the nature of the circumstances under which risk managers may need to apply precaution to the management of a foodborne hazard, through the application of interim measures, in order to protect consumers is such that the application of such measures is far more likely to be a matter for national governments than for Codex. We can see few examples of situations within the Codex system where application of precaution through

interim measures would be appropriate. Such examples might include a decision to develop a code of practice to minimise contamination of a product by a contaminant, rather than to establish a maximum level for the contaminant, in circumstances where a risk to consumers had been identified but the available scientific information on dietary intake was insufficient to enable the extent of the risk to be assessed and ~~a~~to establish a~~-~~ maximum level established for ~~the~~ a contaminant. The application of paragraphs 34 and 35 of the Working Principles therefore appears likely to be limited, in most cases, to their use by member countries as appropriate.

Conclusion

With the modifications proposed by Australia, Paragraphs 34 and 35 would read as follows:

34. When there is reasonable evidence from a ~~preliminary~~ risk assessment to suggest that serious adverse effects on human health are likely to occur as a result of a hazard in food, but the relevant available scientific evidence is insufficient to evaluate the nature and extent of the hazard or to objectively and fully assess the associated risk, it may be appropriate for risk managers to apply precaution through interim measures to protect the health of consumers. Any such interim measures should be applied in accordance with the criteria listed in Para 35, and risk managers should seek to obtain the additional information necessary for a more objective assessment of risk and review the measures accordingly within a reasonable period of time.

35. In such situations the following criteria shall be applied to ensure the consistency, objectivity and transparency of the decision-making process and of any measures implemented:'

(a) The measures taken are proportional to the potential extent of the health risk, based on the available relevant scientific data.

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

(c) The measures taken are consistent with those taken in comparable circumstances.

(d) The measures taken are the least trade restrictive necessary to achieve protection of the health of consumers.

(e) The decisions are subject to an on-going, transparent review process involving interested stakeholders.

(f) 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.

(g) Examination of the full range of management options should be undertaken. This should include an assessment of the potential advantages and disadvantages of various measures, including cost/effectiveness considerations.

MALAYSIA

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

We propose slight amendments to the criteria in paragraph 35 as follows :

i. Bullet 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.

ii. Bullet 6

We propose to amend the phrase " decisions taken should be reviewed and modified, strengthened or rescinded as appropriate in the light of such information" to " decisions taken should be reviewed and the measures retained, modified, strengthened or rescinded as appropriate in the light of such information"

iii. Bullet 7

We propose to amend the words "management options" to "management options available".

In summary, Malaysia proposes that paragraphs 34 and 35 should read as follows :

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.

35. In such situations, the following criteria should be taken into account to ensure the consistency and transparency of the decision process :

- Following preliminary risk assessment, a specific risk is identified or there is evidence to suggest that a risk exists but the cause or extent of any negative effects are unknown due to gaps or uncertainty in the available scientific data.
- The decisions taken are proportional to the potential extent of the health risk and based on the available scientific data.
- There should be a transparent explanation of the need of the measures and the procedures followed to establish them.
- The decisions taken are consistent with those taken in comparable circumstances and are the least trade restrictive necessary to achieve the protection of the health of consumers.
- The decisions taken are provisional and are subject to an on-going, transparent review process involving interested stakeholders.
- Information should continue to be gathered to strengthen the scientific evidence and decisions taken should be reviewed and the measures retained, modified, strengthened or rescinded as appropriate in the light of such information.

Examination of a full range of management options available should be undertaken. This should include an assessment of the potential advantages and disadvantages of various measures including cost/effectiveness considerations.

THAILAND

Thailand is of the opinion that the application of precaution should be consistent with provision of WTO/SPS. Risk management at international level should not be restrictive than necessary to the appropriate level of protection . The adoption of interim measure when relevant scientific evidence is insufficient must taking into account of risk assessment and evidence of serious adverse effects on human health. The additional assessment should be reviewed within the reasonable timeframe.

Paragraph 34

Thailand support the second para 34 with the addition of the following sentence. “However, additional information for a more objective risk assessment should be sought and the measures taken reviewed accordingly within a reasonable timeframe.”

Paragraph 35

The criteria in this paragraph should ensure that the decision taken to apply precaution is transparent and is rationalised with an understanding that the established measures are not intentional trade barriers. Thailand propose that the fifth bullet point be revised to provide a timeframe for transparent review process to avoid excessive trade impact .

UNITED STATES

As requested in CL 2000/12-GP, the United States has the following comments about the Proposed Draft Working Principles for Risk Analysis (Alinorm 01/33, Appendix III). While particular emphasis is placed on Paragraphs **34** and **35**, as requested, the United States would also like to emphasize at this time that precaution is an essential element of risk analysis and therefore offers the suggestion that current Paragraph **5** also be amended at this time.

Paragraphs 34 and 35

The United States believes that Paragraphs **34** and **35** should be rewritten to read as follows:

34.When available scientific information identifies a hazard in food which may present a human health risk even though the nature and extent of the risk is insufficiently known, it may be appropriate for a member government to exercise precaution by provisionally adopting measures to protect the health of consumers until additional pertinent scientific information is available and a more complete risk assessment is performed.

35. In such situations, member countries should take into account the following considerations:

a) Before a provisional measure is adopted, a review of the risk management options should be undertaken, assessing the potential advantages and disadvantages of the alternative measures, including, where appropriate, feasibility and cost/effectiveness considerations.

b) Measures provisionally adopted should be appropriate to the circumstances and based on all the available pertinent information, including available scientific information.

c) Members should provide a transparent explanation of the need to protect the health of consumers and of the procedures followed to establish the measure. This would include notification and publication of such measures in a manner consistent with the member's obligations under international agreements.

d) Members should not apply provisional measures as a disguised form of trade protectionism.

e) Provisional measures should be subject to a transparent review process, involving interested stakeholders.

f) Members establishing a provisional measure should seek to obtain further, pertinent information to address gaps and uncertainties in the preliminary risk assessment, for example, by requesting additional data from those seeking to market or distribute the food in question. This information should include additional scientific evidence to determine whether a human health risk exists and, if a risk exists, the extent and severity of the risk.

g) The provisional measure established and possible risk management options should be reviewed and retained, modified, or rescinded, as appropriate, in light of a more complete risk assessment, within a reasonable period of time.

Rationale

PARAGAPH 34

Paragraph 1) under **SCOPE** in the Draft Working Principles for Risk Analysis, states that, "The principles for risk analysis are intended for application in the framework of Codex Alimentarius and are also intended to provide advice to governments where applicable." Throughout the principles there is no indication of which principles are intended for application in the framework of Codex Alimentarius, which are intended to provide advice to governments, and which are for both. When the United States submits comments on the other working principles (as requested by 15 January 2001), we will comment more fully on this issue and indicate additional changes that should be made in the draft working principles. The United States strongly believes that it is rightly within the purview of national governments to exercise precaution in risk management by establishing provisional measures when available scientific information identifies a hazard in food which may present a human health risk even though the nature and extent of the risk is insufficiently known. However, in such a situation, it would not be appropriate for Codex to set an international standard before additional pertinent scientific information becomes available that is adequate for setting an international standard or guideline. Therefore, the United States believes that paragraph **34** should refer explicitly to national governments and not include a vague reference to "risk managers".

The United States believes that it is important for the Working Principles for Risk Analysis to recognize that the mandate of Codex is food safety. Therefore, the principles should be clarified so that references to "risk" address risk to human health and references to "hazard" address hazards in food.

The United States believes that hazard identification is a crucial first step in exercising precaution by provisionally adopting measures and thus, should be specifically referenced in Paragraph **34**. Consequently, footnote [4], the first footnote associated with paragraph **34** in CL 2000/12-GP, should be deleted.

The United States believes that references to "reasonable evidence" are vague and that such statements should refer to "available scientific information"

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The United States has concerns about the undefined concept of "full" risk assessment introduced in the 2nd version of Paragraph **34** and believes that the reference should more appropriately be to "a more complete" risk assessment.

The United States supports the deletion of footnote [5], the second footnote associated with paragraph **34** in CL 2000/12-GP. It is inappropriate to reference a particular interpretation of a provision in a text that is designed to represent a consensus.

Paragraph 35

For readability and easy reference, the United States suggests that the bullet points within paragraph **35** should be designated by letters.

The United States recommends that the bullet points within paragraph **35** be reordered to reflect a more logical sequence. Before a provisional measure is adopted, risk management options should be considered (a)). The provisional measures adopted have certain characteristics (b), c), and d)). And the member adopting a provisional measure is obligated to seek additional information and review the measure (e), f) and g)).

The United States believes that:

The phrase "appropriate to the circumstances" incorporates the idea that provisional measures should be consistent, to the extent possible, with measures taken by the member country in similar situations and that the provisional measure should be rationally related to the hazard/risk identified in the preliminary risk assessment. Provisional measures must be science based.

The bullet points should recognize the member country's obligations to notify and publish food safety measures.

Measures provisionally adopted should not be used as disguised forms of trade protectionism.

Codex should acknowledge that a member country requesting additional information from a manufacturer, a distributor, or an importing country is a legitimate form of seeking information. Therefore, the United States believes that this manner of seeking additional information should be recognized in bullet point f) as being appropriate to certain circumstances.

The purpose of the information gathering is to address gaps and uncertainties in the preliminary risk assessment in order to support a more complete risk assessment; and, if possible, to affirm or disprove that a risk exists and, if a risk exists, to provide estimates of the extent and severity of that risk.

The review of the provisional measure should be based upon a more complete risk assessment.

The review of the provisional measure should include a review of risk management options, including an assessment of the feasibility and the potential advantages and disadvantages of alternative measures, including, where appropriate, cost/effectiveness considerations.

It is very important to state that the review of the measure should be accomplished within a reasonable time period.

General

The United States calls attention to, and endorses, the General Recommendations of the FAO Conference on International Trade in Food Beyond 2000, Melbourne, Australia, 11- 15 October 1999, specifically that precaution has been and should remain an essential element of risk analysis in the formulation of national and international standards. The United States believes that precaution is essential throughout risk analysis, including risk assessment, risk management, and risk communication. Therefore, the United States believes that the primary and fundamental incorporation of precaution into risk analysis is stated in Paragraph **5** in the Draft Codex Working principles for Risk Analysis (under **Risk Analysis – General Aspects**).

The United States believes that precaution is important at all steps in risk analysis and that there are numerous ways in which precaution is incorporated into the formulation of food safety standards. For example, pre-market approval is a form of precaution. To protect the health of consumers, safety data are required and reviewed before standards permitting the introduction of new food additives or establishing maximum residue limits for pesticides are promulgated. If data submitted for review are insufficient, additional information is sought. The United States recognizes that Paragraph **5** will be the subject of future comments. However, to emphasize that precaution is an essential and pervasive element of risk analysis, the United States believes that it is important that an example should be added to current Paragraph **5** at this time.

Therefore, the United States would rewrite Paragraph **5** to read:

5. 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. For example, pre-market approval is a form of precaution. To protect the health of consumers, safety data are required and reviewed before standards permitting the introduction of new food additives or establishing maximum residue limits for pesticides are promulgated. If data submitted for review are insufficient, additional information is sought before a product is introduced into a national market or a standard is set.

For further discussion of how precaution is embedded in the food safety system in the United States, we draw the Committee's attention to the paper, "Precaution in U.S. Food Safety Decision making: Annex II to the United States' National Food Safety System Paper", which can be accessed at http://www.foodsafety.gov/~fsg/fssyst4.html.

Comment

The United States takes note of incidences that have occurred since the 15th Session of the Codex Committee on General Principles, in which countries have taken actions, referring to the "precautionary principle" in a manner that appears to be only for trade protection reasons and in a manner not based on science. Additionally, the United States takes note of documents from, and statements by, officials in the European Union that appear to also underscore the potential use of the "precautionary principle" for trade protection purposes.

URUGUAY

The 22nd Session of the Codex Alimentarius Commission requested the CCGP to elaborate principles and guidelines for Risk Analysis to be applied in the work of Codex. However, the relevant Proposed Draft in its present wording extends the scope of the principles not only to Codex work but to the work of governments

Uruguay understands that this extension interferes with the coherence and usefulness of the text, especially in the Risk Management Section, since the role and responsibility of risk managers, in both cases, are different and proposes that in line with the decision of the Commission, the text should be restricted to the framework of Codex.

Consequently, paras. 34 and 35 should be deleted as they refer to situations which should be addressed with intermediate precaution measures, specifically at the national level. Such measures are presently regulated by Article 5.7 of the SPS Agreement.

The adoption of precautionary measures is not adequate for Codex as the basis of its work is sound scientific evidence. When such evidence is lacking, Codex refrains from adopting standards or elaborates other recommendations of a different nature which are intended to address the situation (as in the case of Codes of Practice). This working procedure of Codex has ensured the universality of its standards and gave it its value to be recognized as the reference organization in the WTO. Uruguay supports retaining these working procedures unchanged

The reference to precaution, as an essential element of risk analysis, is adequate and sufficiently expressed in para. 5 of the section "Risk Analysis – general aspects" and reflects the general consensus on its importance in risk management and assessment.

CONSUMERS INTERNATIONAL

Introduction

Consumers International welcomes the progress that Codex is making on this essential issue for consumer protection. We submitted detailed comments on the precautionary principle which were tabled as Conference room Document 1 at the Fifteenth Session of the Codex Committee on General Principles (CCGP). These comments supplement this paper and our earlier submissions taking into account the discussions that took place in Paris and which are continuing in various international fora.

As stated at the Fifteenth session of the CCGP, Consumers International would also welcome the opportunity to participate in the e-mail drafting group prior to the next meeting in 2001.

Precaution in risk analysis

Before we comment specifically on paragraphs 34 and 35 of the current draft relating to precaution in risk management, we would like to emphasise that we do not see precaution as purely a risk management issue. As reflected in paragraph 5 of the proposed Draft Working Principles, precaution has to be inherent throughout the risk analysis process. We therefore hope that as further progress is made developing the working principles for risk analysis practical measures can continue to be incorporated that build precaution into risk assessment, risk management and the approach taken to risk communication. Where precaution is already taken into account within some Codex decisions, this should be made explicit.

This will ensure that when risk managers are determining the appropriate course of action, they will be able to do so with a complete understanding of the state of scientific knowledge, any uncertainties or assumptions that have been made and the views of interested stakeholders.

We will be submitting more detailed comments in this respect in response to the second request for comments contained in the Circular Letter.

When considering precaution in risk management, we would also like to emphasise the importance of the risk assessment policy stage as a risk management function. This stage is crucial for framing the questions to be considered by risk assessors and in establishing the approach that they should take, including how scientific uncertainty should be dealt with and communicated.

Furthermore, as stated in paragraph 1 of these principles, we wish to emphasise that precaution in risk analysis, as for all the working principles for risk analysis, are intended for application in Codex and to provide advice to governments. Precaution throughout the risk analysis process is needed both at the national level and at the international level to ensure that sound decisions are made that protect consumers.

Paragraph 34

We support the inclusion of the second paragraph in square brackets which was proposed by the Chairman and do not support the wording proposed by the Delegation of Malaysia. We consider that the Chairman's proposal sums up the essence of the precautionary principle:

'*When relevant scientific evidence is insufficient to objectively and fully assess 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 extent, it may be appropriate for risk managers to*

apply precaution through interim measures to protect the health of consumers without awaiting additional scientific data and a full risk assessment, in accordance with the following criteria:'

We consider it essential that specific reference to the precautionary principle is made in the Working Principles as paragraphs 34 and 35 address the issue of how precaution should be applied to risk management. The text of footnote 5, currently in square brackets, should therefore be retained.

We would however, suggest the following amendment: *'from a hazard in food'* in the first-line should be changed to '*a potential food hazard*'. We are concerned that simply referring to a hazard in food could mean that other hazards that may impact on food safety, including environmental hazards or those associated with animal health could be interpreted as being excluded.

At the Fifteenth session of the CCGP, it was proposed that the first paragraph in square brackets should be included as it reflects the precautionary principle as defined within the World Trade Organisation's (WTO's) Agreement on Sanitary and Phytosanitary (SPS) Measures.

We consider that the second paragraph is much clearer, and much less open to differing interpretations than the first option. It does, for example, explain what is meant by 'when relevant scientific evidence is insufficient.' It is important that these working principles set out in more specific detail how risk analysis should be carried out in practice.

It is also our understanding that although Codex texts are recognised by the WTO, they do not have to be consistent with the wording in the WTO texts. The text of the SPS Agreement does not, therefore, need to be repeated in these working principles. The paragraph included should however be consistent with the other principles established within the Working Principles for Risk Analysis.

Paragraph 35

Our specific comments on each of the bullet points within paragraph 35 are set out below.

In such situations the following criteria should be taken into account to ensure the consistency and transparency of the decision process:

- *Following preliminary risk assessment, a specific risk is identified, or there is evidence to suggest that a risk exists, but the cause or extent of any negative effects are unknown*

While we agree with this sentence, we consider that clarification could usefully be provided as to what is meant by a 'preliminary risk assessment'. In some situations for example, there may be so much scientific uncertainty that it is not possible to do a quantitative risk assessment and therefore the assessment may be qualitative and inconclusive. There may, for example, be some situations where the hazard is identified, but it is not possible to determine the risk that it presents.

It also raises the question about who should do the preliminary risk assessment and at what stage precautionary measures should be introduced. Where there is an emerging hazard there is likely to be the need for prompt action. The course taken will differ depending upon whether these principles are taken to apply within the Codex context or at national level. Within Codex, risk managers may decide when developing their risk assessment policy with risk assessors for example, that there is not a scientific body or committee that has the necessary skills and expertise to address the issue (precaution may need to be exercised while this body is put together) or existing committees may not be able to address the issue with the necessary urgency. In other situations, it may be that a scientific committee such as JECFA or a national body has made an assessment of the risk, but as a result of this assessment has identified a great deal of scientific uncertainty which needs to be addressed. Precautionary measures will then need to be introduced. To use the example of BSE, there was evidence of a disease in cattle and the theoretical possibility that this could present a risk to man. However, initial risk assessments determined that this was unlikely because of the enormous amount of scientific uncertainty. However, the extent of this uncertainty was not fully and openly acknowledged. Precautionary measures were therefore delayed and even when introduced were not adequately enforced as the assumption made was that the disease could not pass to humans. It is important to learn from this mistake. In some situations, therefore, the risk assessment may determine that the risk is probably minimal, but the uncertainties may be so large and the potential consequences for human health if this initial assessment is in error may be so significant that

precautionary action is still warranted. In such a scenario, it will be crucial that the uncertainties and assumptions made are clearly documented and communicated.

We consider that these concerns could be more clearly reflected if the bullet point was reworded as follows: 'Following *a* preliminary risk assessment, a specific risk *to human health* is *indicated*, or there is evidence to suggest that a risk exists, *but the evidence is insufficient to determine the precise nature* or extent of any negative effects *or to establish causal relationships* due to gaps or uncertainty in the available scientific data'.

- *The decisions taken are proportional to the potential extent of the health risk and based on the available scientific data*

We agree that precautionary action does not preclude proportionality. Precautionary action may involve a range of different measures from an outright ban on a particular product, to the introduction of labelling requirements or consumer information for example. However, it may not always be possible to quantify the long-term health costs when evaluating what is considered proportionate action. In contrast, the short-term economic implications are much easier to estimate. In some situations there may be very limited scientific data and so this cannot be used to determine possible courses of action. To use the example of BSE, assumptions were initially based on the scrapie model. However, as the state of scientific knowledge, and experience, have developed, it has become clear that the public health implications of BSE are in fact very different to scrapie. There are therefore dangers in relying on the limited scientific data that may be available, as this could be proven to be misleading as knowledge develops. Discussions taking place on the role of 'Other Legitimate Factors' will also be important in this respect. We therefore suggest that this sentence is amended as follows: 'The decisions *and measures* are proportional to the extent of the health risk, *taking into account the potential long-term health implications and resulting costs*, and *to the extent possible*, based on the available scientific data'

- *There should be a transparent explanation of the need for the measures and the procedures followed to establish them*

Transparency is crucial to ensuring the effective use of the precautionary principle. Openness and transparency have to be integral to the whole risk analysis so it is clear what uncertainties exist, what assumptions have had to be made and on what basis. It is also important that precautionary action is not taken arbitrarily and that the reasons why a particular course of action, including possible alternative approaches that have been considered, are clearly communicated and documented.

- *The decisions taken are consistent with those taken in similar circumstances and are the least trade restrictive necessary to achieve protection of the health of consumers*

We agree that this should be the case as far as is practicable. However, there will inevitably be situations which arise that are unique either in relation to the hazard itself, or to the circumstances under which a decision has to be made.

- *The decisions are provisional and are subject to an on-going, transparent review process involving interested stakeholders*

We agree that precautionary action should be provisional to the extent that efforts should be made to address the uncertainties that exist and to make a fuller assessment of the course of action that is required. However, it is essential for consumer protection that an arbitrary time limit is not set. The length of time for which precautionary measures will be required can only be determined on a case by case basis taking into account the current state of the scientific knowledge and any other legitimate factors. It may be possible that in certain situations developments will 'override' the precautionary measures, for example, safer alternatives to a particular practice may be discovered.

- *Information should continue to be gathered to strengthen the scientific evidence and decisions taken should be reviewed and modified, strengthened or rescinded as appropriate in the light of such information*

We agree that it is essential that further research is carried out with the aim of addressing the underlying uncertainties. This may result in a decision to change or even lift the precautionary measures.

- *Examination of the full range of management options should be undertaken. This should include an assessment of the potential advantages and disadvantages of various measures, including cost/effectiveness considerations.*

It is important that this is done in full consultation with relevant stakeholders which will ensure that a holistic approach is taken to the possible courses of action.

More generally, it is essential that interested stakeholders are involved throughout this process. In situations where the scientific evidence is incomplete, value judgements will need to be made by the risk assessors as well as by the risk managers about possible courses of action. It is essential that the views of all relevant stakeholders – including consumers – are taken into account. Paragraph 36 makes it clear that there should be 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. However, this should be reinforced under the criteria set out in paragraph 35. The last bullet point should therefore be amended as follows: 'Examination of the full range of management options should be undertaken. This should include an assessment of the potential advantages and disadvantages of various measures, *their risks and benefits*, including cost/effectiveness considerations *and should be carried out in consultation with consumers and other interested parties.*

CIAA

CIAA (Confederation of the Food and Drink Industries of the EU[#]) welcomes the progress made in the elaboration of the principles for risk analysis at the 15th Session of the Codex Committee on General Principles. It is very important that these principles be adopted as soon as possible. The principles are being developed for the application of risk analysis with a view to setting food safety standards by Codex Alimentarius. The same working principles and the guidelines still to be developed for their use can, however, provide a framework for all Member countries according which they should set their food safety regulations.

CIAA welcomes the opportunity to submit comments on the application of precaution in risk management (paras 34 and 35, Appendix III, Alinorm 01/33) to the French Codex secretariat.

CIAA would like to underline that the two descriptions of the application of precaution in risk management (as presented in paras 34 and 35) are complementary. The first proposed alternative is in line with the description contained in Article 5.7 of the SPS Agreement, whilst the second is more detailed and includes guidelines for application.

As stated in earlier comments, CIAA is very attentive to how such a precautionary approach will be applied in risk management, i.e. the so-called « Precautionary Principle » (see attached CIAA comments, MIN/150/00E-Final, on the European Commission Communication on Recourse to the Precautionary Principle COM (2000) 1 Final).

The « Precautionary Principle » should only be used in exceptional cases. Developing guidelines for its use is, therefore, of utmost importance. CIAA is of the opinion that the draft guidelines, contained in paragraph 35, are a step in the right direction and should be further discussed.

[#] The CIAA (Confédération des Industries Agro-Alimentaires de l'UE) membership is composed of the national federations of the 15 EU Member States. In addition, 35 European food industry branch organisations and 4 national federations (Poland, Hungary, Czech Republic and Estonia) are affiliated.

Involvement of interested stakeholders, including the food industry, is essential as well as in the application of the risk analysis process as in those exceptional cases where the « Precautionary Principle » may be used. In particular, CIAA would like to stress that interested stakeholders should not only be part of *the on-going, transparent review process of the provisional decision* (5th bullet point in paragraph 35) but should also be involved in the decision-making process leading to such a provisional decision.

CIAA looks forward to participate further in the forthcoming discussions related to the principles for risk analysis principles including the so-called « Precautionary Principle ».

COUNCIL FOR RESPONSABLE NUTRITION (CRN)

As requested in CL 2000/12-GP, the Council for Responsible Nutrition has the following comments about the application of precaution in risk management (paragraphs 34 and 35) of the Proposed Draft Working Principles for Risk Analysis (Alinorm 01/33, Appendix III).

Paragraph 34 – Definition or « chapeau » paragraph

Two alternatives for paragraph 34 are presented, both in square brackets. The first alternative was presented by the delegation of Malaysia and it closely paraphrases the Sanitary and Phytosanitary (SPS) Agreement Paragraph 5.7. The second alternative represents compromise language developed during the CCGP meeting by the delegations of the United States and the European Commission.

First alternative : The advantage of the first alternative is that it closely follows SPS Paragraph 5.7, and thus represents language already adopted by some 160 countries. By itself, this alternative for paragraph 34 is subject to the criticism that it « does not move the process forward », ie, the CCGP position on risk analysis would not provide any guidance or standards that go beyond those already present in international law through the SPS Agreement. Such criticism is invalid. It ignores the fact that Paragraph 35, the criteria for use of the precaution, accompanies this paragraph. This alternative describing precaution and the following paragraph that delineates the criteria its application, provide sufficient guidance and directions for use of precaution in risk analysis in Codex.

Second alternative : This alternative is unacceptable. The language within this paragraph itself is reasonable, and without the second footnote it would be an acceptable alternative to the Malaysian alternative described above. (First alternative).

The second footnote (#5) makes this alternative unacceptable because it states, « Some members refer to this concept as the « precautionary principle ». Use of the term « precautionary principle » for food safety policy in a Codex document is not acceptable because the term carries so much history and legal precedent that involves other meanings, applications and interpretations. These other meanings would be confuse the definition that Codex might try to give to the term. The obdurate insistence by the European Commission (EC) that the term « precautionary principle » be included in codex guidelines for risk analysis make clear its intent for the history of other meanings to impact decisions made in or influenced by codex. Otherwise, it would be sufficient to describe precaution and the criteria for its application, without a requirement to include a specific term that has previous regulatory meaning, most of which is in very different areas of application.

Although the second footnote is true, as far as it goes, it is false by being very incomplete. Also, it is a transparent move by the EC to have Codex sanction use of the « precautionary principle » without Codex providing a definition of that term or guidelines for its use.

Even with detailed, acceptable guidelines from Codex, the term « precautionary principle » has a long history of use in an environmental context that gives authority for regulatory action without waiting for conclusive evidence (that is, while there is uncertainty) related to adverse impacts of a substance or process. In contrast, the « precautionary principle » would create an impossible burden in demonstration of safety of new ingredients. Safety is the absence of ham, and conclusive proof of safety requires conclusive demonstration, of a negative – that ham does not occur- and this is impossible. Thus, application of « precautionary principle » in Codex decisions related to the safety of new products or ingredients could lead to automatic decisions that a product was not safe, because there is always some uncertainty about safety. The term « precautionary principle » is

not needed to assure adequate precaution in Codex risk analysis procedures and guidelines. Use of the term will lead to unwarranted technical barriers to trade through sanction of the imposition of politically motivated additional demands for precaution after scientific evidence has produced a high level of confidence in the safety of a product.

Paragraph 35 – Criteria for use of the precaution described in Paragraph 34

Suggested criteria are presented in seven bulleted paragraphs that are numbered here for clarity.

Bullet #1 : The major flaws of Paragraph 35 occur in the first bullet. As currently stated, this paragraph contains enough vagueness and ambiguity to render it subject to misinterpretation and a ready tool for abuse. In order :

- The term « objective » or « scientific » is needed before the word « evidence » to give a specific meaning that would be useful in risk analysis.
- The phrase « gaps or uncertainty » in relation to scientific evidence is a self-fulfilling prophecy because scientific evidence always has « gaps » and « uncertainty ». This vague criterion to allow invocation of the « precautionary principle » whenever there is a « gap » or some « uncertainty » in the scientific evidence would become an open invitation to use it to support an unjustified technical barrier to trade. In order to prevent such potential abuse, the currently final words « available scientific data » must be followed by restrictive terminology such as « when judged against established scientific risk assessment criteria and standards as used by authoritative international bodies such as the Joint Expert Committee on Food Additives ».
- Consideration should be given to the possible persistence and seventy of the specific risk identified in the identification of any precautionary measures that may be taken.

Bullet #2 : Greater clarity and less chance for misinterpretation would be achieved by replacing the words « and based on » with « as estimated on the basis of ».

Bullet #3 : The entire risk analysis process, including the application of precaution, should be transparent and open to participation by all interested parties. The transparency element of this bullet should be moved to an introductory statement before the bulleted items of precaution are presented. The requirement for explanation of the need for the measures taken and the procedures followed to establish them should remain in this bullet.

Bullet #4 : This statement should make it clear that the consistency is to assure non-discrimination in the decisions taken. Better language would be « the decisions taken are to be nondiscriminatory and therefore must be consistent with others taken in similar circumstances, and they are to be the least trade-restrictive that is compatible with protection of the health of consumers ».

Bullet #5 : Any regulatory measure taken must be accompanied by a timetable for review and subsequent confirmation or removal of the regulatory measure. The timetable will need to reflect the practical issues related to the development of the new evidence needed to update the risk analysis.

Bullet #6 : Information should be continue to be gathered to address gaps and uncertainties in the database and to support a more complete risk assessment.

Bullet #7 : Examination of the full range of risk management options should be undertaken. This should include an assessment of the potential advantages and disadvantages of various measures including cost/effectiveness considerations. Risk managers should weigh such information in order to review, modify, strengthen or rescind any decisions that may have been taken

Suggested new Bullet #8 : Decisions taken should be reviewed based on the results of a risk assessment including especially an estimate of the extent and severity of the risk under consideration and/or on additional scientific evidence that affirms or disproves that a significant risk exists.

Summary

The term « precautionary principle » should not be used in Paragraph 34. The terms of the SPS Agreement, or similar wording is acceptable. Such a description, together with the specific descriptions of the elements of

precaution given in Paragraph 35, make significant progress in defining and guiding the use of precaution in Codex risk analysis. With language of the SPS Agreement, or equivalent terms, in Paragraph 34 and appropriate specification for criteria for its application in Paragraph 35, there is no need for the term « precautionary principle ». The term « precautionary principle » should not be included in a Codex document because it would lead to misinterpretation that relates to the history of the term's use in environmental contexts, resulting in unwarranted technical barriers to trade.

EFLA/AEDA (European Food Law Association)

As to the Document Alinorm 01/33, Appendix III, the following comments are submitted :

-§ 34 : EFLA considers both options acceptable, but is of the opinion that the first one is preferable for the two following reasons :

- its drafting is more in line with art 5.7 of the SPS agreement
- the conditions laid down in the second option are redundant with those laid down in § 35.

Therefore, there is risk of overlap and, consequently, of difficulties of interpretation, which may lead to further debate and threaten legal certainty.

- § 35 : As to the first bullet, EFLA suggests the following amendments :

- between "there is" and "evidence", insert "objective and science based"
- after "negative effects, insert "on the health of the consumer"

GLOBAL CROP PROTECTION FEDERATION

The Global Crop Protection Federation (GCPF) represents approximately 90 % of the world's research – based crop protection industry in 73 countries. The substantial investment of GCPF member companies in agricultural research and development –more that USD 3 billion in 1999- indicates its long-term commitment to innovative science-based solutions in the context of sustainable agriculture. In this context, GCPF welcomes the opportunity to comment on the concept of a « Precautionary Principle », in response to the request of the Codex Committee on General Principles in Circular Letter CL 2000/12-GP.

In the context of Risk Assessment and risk Management policies, GCPF supports the application of a precautionary approach as defined in Principle 15 of the UNCED Rio Declaration, *viz*., « In order to protect the environment, the precautionary approach shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation ». In addition, Principle 12, dealing with the international trade context, implies that measures based on a precautionary approach should be proportionate. It specifies that trade measures for environmental purposes should not constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade. In other words, actions based on the precautionary approach must be non-discriminatory and proportionate both to the objective to be achieved and to the risk to be avoided.

The SPS Agreement of the WTO adds guidance on appropriate application of a precautionary approach. Article 5.7 of the SPS Agreement indicates that in cases where relevant scientific evidence is sufficient, there must be an on-going scientific evaluation to further clarify the actual risk, even after the measure is in place. In addition, all restrictive measures should be provisional and include a time limit for their validity and an obligation for revision within a fixed time. The SPS Agreement assumes the performance of a science-based risk assessment as a pre-condition for applying a precautionary approach.

The lack of an agreed definition and agreed criteria for « the Precautionary Principle » or a precautionary approach can give rise to abuse and undesirable results. As an example, improper use of the « Precautionary Principle » can lead to a hindrance of scientific and technological progress, which will constitute a loss for all parties. Furthermore, improper use of the « Precautionary Principle » can create disguised restrictions on trade and artificial barriers to the free movement of goods.

The crop protection industry is strongly regulated by governments. GCPF supports such regulation, providing that is based on sound science. This regulation of the industry is firmly based on the use of extensive data and a comprehensive risk assessment for its products. 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 allegedly based on the « Precautionary Principle » would have to be closely scrutinized to avoid its abuse for political or unfair trade objectives.

Criteria for application of a Precautionary Approach

GCPF firmly believes that the following elements are essential in order to apply a precautionary approach in a transparent and non-discriminatory manner :

A science-based risk assessment must be the starting point for defining policy options. Once the potential risks have been identified, independent scientists should be requested to perform an objective risk assessment, identifying at each stage the degree of scientific certainty.

The risk assessment must remain functionally separated from the risk management process.

Only if and when the risk assessment process confirms the threat of an imminent serious or irreversible damage and that the relevant science is not sufficient certain should there be consideration of a precautionary approach in the context of risk management.

The risk management process must be completed transparent and subject to input from all stakeholders. Once the results of the risk assessment are available, a wide-ranging consultation of scientists, civil associations and the business community will support decisions-makers in weighing policy alternatives and will allow the inclusion of social, political and economic factors in the decision-making process.

When the risk assessment process has concluded that the relevant science is not sufficiently certain and a precautionary approach should be considered, that approach must follow the principles of proportionality and non-discrimination.

Depending on the specific circumstances, alternative measures to prohibition could be considered, for example, the monitoring of products or the definition of provisional maximum levels.

Measures implemented on the basis of a precautionary approach should be reevaluated periodically based on the most recent scientific evidence.

Conclusion

In conclusion, the Global Crop Protection Federation (GCPF) supports the use of a precautionary approach as a preventive measure when there is a threat of imminent serious or irreversible damage and a lack of full scientific certainty. However, such application must be based on a scientific risk assessment and must be applied in a transparent, non-discriminatory and proportional manner. In addition, actions taken as a result of the application of a precautionary approach should be reviewed periodically in light of the most recent scientific evidence.

IADSA (International Alliance of Dietary/Food Supplement Associations)

General Comments

IADSA, the International Alliance of Dietary/Food Supplement Associations, believes that the introduction of a separate and additional precautionary principle is not needed as a precautionary approach is already accounted for in the risk analysis process.

IADSA's members are concerned that the precautionary principle could be easily misinterpreted or misused by regulators inviting the use of non-scientific issues to overrule scientific evidence on product safety.

Specific Comments

Paragraph	Comments	Argumentation
§34	If the precautionary principle were to be introduced in the Codex working principles, IADSA supports a version of the first alternative, which is based on article 5.7 of the WTO SPS Agreement: *Where relevant scientific evidence is insufficient, ~~precaution can~~ caution should be exercised as an interim measure to protect the health of consumers. However, additional information for a more objective risk assessment ~~should~~ must be sought and the measures taken reviewed by competent authorities accordingly within a reasonable timeframe.*	• The WTO SPS agreement has already been adopted by over 135 countries. • Consistency in language between different international organisations. • Codex standards are being used by the WTO dispute settlement mechanism.
§35	*In such situations the following criteria ~~should~~ must be taken into account to ensure the consistency ~~and~~ ,transparency, objectivity and rapidity of the decision process:*	• Replace 'should' by 'must' to make the criteria obligatory. • Insert 'objectivity' • Insert 'rapidity' because the measures are time-limited.
§35, criteria 1	*Following preliminary science-based risk assessment, a specific risk is identified, or there is scientific evidence to suggest that a risk exists, but the cause or extent of any negative effects on human health are unknown due to gaps or uncertainty in the available scientific data, when judged against established scientific risk assessment criteria.*	• Insert 'science-based' before risk assessment • Insert 'scientific' to give the word 'evidence' a better meaning in the context of risk analysis. • Insert 'on human health' for reasons of clarity (see also § 34, alternative 2) • Add 'when judged against established scientific risk assessment criteria' to prevent unjustified technical barriers to trade.
	The decisions taken are proportional to the	• Insert 'human' before health risk for reasons of

§35, criteria 2	*potential extent of the human health risk and based on the available scientific data.*	clarity.
§35, criteria 3	*There should be a transparent explanation of the need for the measures and the procedures followed to establish and implement them.*	• Insert 'and implement' as there should be transparency throughout the whole process.
§ 35, criteria 4	*The decisions taken are to be non discriminatory, ~~consistent with those taken in similar circumstances and are~~, the least trade restrictive ~~necessary to achieve~~ and compatible with consumer health protection.*	• For reasons of clarity and objectivity
§35, criteria 5	*The decisions are provisional, time-limited and ~~are~~ subject to a~~n on going~~, transparent review process involving interested stakeholders.*	• The measures are taken within a limited timeframe (see §34 and §35).
§35, criteria 6	*~~Information should~~ Scientific evidence shall continue to be gathered and reviewed ~~to strengthen the scientific evidence~~ and decisions taken ~~should~~ shall be ~~reviewed and~~ modified, ~~strengthened or rescinded as appropriate in the light of such information.~~ based on such evidence.*	• For reasons of clarity.
§35, criteria 7	*Examination of the full range of management options should be undertaken. This should include an assessment of the potential advantages and disadvantages of various measures, including cost/effectiveness considerations and proportional health risk.*	• Add 'and proportional health risk'

IACFO

We wish to make the following comments on two alternative proposals dealing with the use of precaution in risk management: (i) paragraph 34 in the Proposed Draft Codex Working Principles for Risk Analysis (Draft Principles)[1] presented by Malaysia and (ii) paragraphs 34 and 35 presented by the United States and the European Union. As indicated in paragraph 1 of the Draft Principles, they may affect both the international legality of measures taken by governments[2] and the work of Codex.

[1] ALINORM 01/33, Appendix III.

[2] 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 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. Pursuant to Article 5.1 of the Agreement on the Application of Sanitary and Phytosanitary Measures, the World Trade Organization will use the Draft Principles to help determine whether a government did a

proper risk assessment when a particular measure is challenged as an illegal trade barrier by another government.

A. Malaysian proposal

In the first sentence delete the word "interim" and in the second sentence delete the phrase "within a reasonable timeframe." The Malaysian proposal is virtually identical to Article 5.7 of the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Article 5.7 of the SPS Agreement refers to "provisionally" adopting a measure and the need to obtain additional information "within a reasonable period of time." Paragraph 34 refers to an "interim" measure and the need to obtain additional information "within a reasonable timeframe." These differences appear to be merely stylistic. The Trans Atlantic Consumer Dialogue -- comprised of consumer organizations in the United States and the European Union -- supports changes to the SPS Agreement in order to better protect consumers, such as eliminating the word "provisionally" in the first sentence of Article 5.7. Our suggested change to the Malaysian proposal is consistent with the TACD's recommendation.[3]

B. United States-European Union proposal

This proposal should be changed so that it will not limit the rights of national governments to apply precaution beyond the limitations they have agreed to in the SPS Agreement. For example,

- *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, this 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.

- *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's mandate (as indicated in paragraph 2 of the Draft Principles). 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 establishment of standards relating to genetically modified organisms.

- *In 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 about 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" of harm to human health before taking action.[4] Moreover, this provision in paragraph 34 is inconsistent with the first bullet of paragraph 35, which permits the use of precaution when "the cause or extent of any negative effects are unknown due to gaps or uncertainty in the available scientific data."

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[3] While Article 5.7 of the SPS Agreement puts the burden of proof on the importing country to obtain additional evidence, the Malaysian proposal is silent on the issue of burden of proof. The TACD supports a reconsideration of the SPS rules related to burden of proof.

[4] 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 a 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.

- *In paragraph 34, delete the word "interim", and in bullet 5 of paragraph 35, delete the phrase "are provisional."* The need for these changes is explained above in our discussion of the need for a similar change to the Malaysian proposal.
- *In bullet 2 of paragraph 35, after the phrase "health risk" add the phrase "(if its extent is known)".* This change will make this provision consistent with the first bullet in paragraph 35, which says that precaution may be used when the "extent of any negative effects are unknown."

- *In bullet 4 of paragraph 35, delete the phrase "and the least trade restrictive necessary to achieve protection of the health of consumers."* Codex has no special competence is making such assessments. Moreover, Article 5.4 of the SPS Agreement merely requires that Members "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).
- *In bullet 5 of paragraph 35, replace "interested stakeholders" with "all interested parties."* This change makes this provision consistent with paragraphs 2 and 3 of the Draft Principles and thus make it clear that consumers are to be consulted.[5]
- *In bullet 7 of paragraph 35, delete the phrase "including cost/effectiveness considerations."* While such considerations may be appropriate for those specific Codex decisions where all relevant costs and benefits can be measured in financial terms, there is no similar provision in the SPS Agreement, and governments -- especially legislatures -- may decide to adopt a precautionary measure without doing any explicit "cost/effectiveness" calculation.

ICGMA (International Council of Grocery Manufacturers Associations)

The international Council of Grocery Manufacturers Associations (ICGMA) is an international non-governmental organization (NGO) officially recognized by the Codex Alimentarius. ICGMA represents the interests of national and regional associations representing all sectors of the grocery industry and serves to facilitate harmonization of standards and policies concerned with health, safety, packaging , labelling, advertising and marketing of foods, beverages and other grocery products.

As requested by the French Secretariat of the Codex Alimentarius, ICGMA is pleased to present its comments to ALINORM 01/33 APPENDIX III Proposed Draft Codex Working Principles for Risk Analysis, and appreciate the opportunity to do so.

Paragraph 34 puts forward two alternative proposals for Committee consideration :

- Proposal introduced by the delegation of Malaysia

- Proposal introduced by the delegations of the United States, European Union and others.

PARAGRAPH 34

ICGMA offers the following paragraph, which incorporates elements of both texts and provides for common ground between the two, and is consistent with the summary statement of the EU Commission's Communication on the Precautionary Principle (COM 2000 1 of 02/02/2000). We suggest the following language based on Articles 2.2 and 5.7 of the WTO SPS Agreement as a reasonable conciliation between the two proposals :

« Where relevant scientific evidence suggests that a specific adverse consumer health risk may exist, then precautionary measures can be exercised as an interim measure to protect the health of consumers.

[5] See summary of discussion at the 2000 meeting of the Codex Committee on General Principles at paragraph 16 of ALINORM 01/33.

However, additional information for an objective risk assessment shall be sought and the measures taken reviewed accordingly within a reasonable timeframe. Moreover, Interim measures should be applied only to the extent necessary to protect consumer health, and those interim measures reviewed within a reasonable timeframe ».

PARAGRAPH 35

Paragraph 35 puts forth criteria, which should be taken into account when applying precaution under paragraph 34. Our comments to those criteria are as follows :

For readability ,and reference, we suggest that the « bullets » under paragraph 35 be lettered.

Bullet One : « Objective scientific » is needed before the word « evidence » to give a specific meaning useful in risk analysis. After the word « effects » insert the words « on consumers health ». The phrase « gaps or uncertainty » in relation to scientific evidence is vague criterion which may allow for an open invitation to use it to support an unjustified technical barrier to trade. Additionally, hazard identification is crucial for the application of precaution. We therefore suggest the following amended text under bullet one :

« A thorough risk assessment is performed in which a specific consumer health risk is identified, or ,there is reliable, objective scientific evidence to suggest that such a risk exists »

Bullet two : Greater clarity and less chance for misinterpretation would be achieved by replacing the words « and based on » with « supported and consistent with ». We therefore suggest the following amended text under bullet two :

« The interim measures are proportional to the extent of the potential health risk, as estimated on the basis of the available scientific data, and to the level of uncertainty in the scientific data ».

Bullet three : The entire risk analysis process, including the application of precaution, should be transparent and open to participation by all interested parties. This bullet provides for the basic tenet of the application of precaution and should be moved to introductory statement in paragraph 35.

Bullet four : Suggest the following language for clarity :

« The interim measure taken is consistent with others taken by the member country in

similar circumstances, and is no more trade-restrictive than required to achieve the

level of human health protection ».

Bullets five, six and seven : No changes suggested.

IGCMA appreciates the opportunity to provide you with our input and looks forward to collaborating with the Secretariat as a member of the *Draft Codex Working Principles for Risk Analysis* Drafting Group.

Table of the comments

Present draft	**Comments**	**New draft**
Paragraph 34	**US**	Revised Paragraph
34.B[When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food [4], 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, it may be appropriate for risk managers to apply precaution through interim measures to protect the health of consumers without awaiting additional scientific data and a full risk assessment, in accordance with the following criteria [5] :]	Paragraph 1) under SCOPE in the Draft Working Principles for Risk Analysis, states that, "The principles for risk analysis are intended for application in the framework of Codex Alimentarius and are also intended to provide advice to governments where applicable." Throughout the principles there is no indication of which principles are intended for application in the framework of Codex Alimentarius, which are intended to provide advice to governments, and which are for both. When the United States submits comments on the other working principles (as requested by 15 January 2001), we will comment more Fully on this issue and indicate additional changes that should be made in the draft working principles. The United States strongly believes that it is rightly within the purview of national governments to exercise precaution in risk management by establishing provisional measures when available scientific information identifies a hazard in food which may present a human health risk even though the nature and extent of the risk is insufficiently known. However, in such situations Codex should seek The required additional scientific information before establishing an international standard or guideline. Therefore, the United States believes that paragraph 34 should refer explicitly to national governments and not include a vague reference to "risk managers". The United States believes that it is important for the Working Principles for Risk Analysis to recognize that the mandate of Codex is food safety. Therefore, the principles should be clarified so that references to "risk" address risk to human health and references to "hazard" address hazards in food. The United States believes that hazard identification is a crucial first step in exercising precaution by provisionally adopting measures and thus, should be specifically referenced in Paragraph 34. Consequently, footnote [4], the first footnote associated	When available scientific information identifies a hazard in food which may present a human health risk even though the nature and extent of the risk is insufficiently known, it may be appropriate for a member government to exercise precaution by provisionally adopting measures to protect the health of consumers until additional pertinent scientific information is available and a more complete risk assessment is performed.

Present draft	**Comments**	**New draft**
[4] [It is recognized that hazard identification is a crucial step in this process.] [5] [Some Members refer to this concept as the "precautionary principle".]	with paragraph 34 in CL 2000/12-GP, should be deleted. The United States believes that references to "reasonable evidence" are vague and that such statements should refer to "available scientific information". The United States has concerns about the undefined concept of "full" risk assessment introduced in the 2nd version of Paragraph 34 and believes that the reference should more appropriately be to "a more complete" risk assessment. The United States supports the deletion of footnote [5], the second footnote associated with paragraph 34 in CL 2000/12-GP. It is inappropriate to reference a particular interpretation of a provision in a text that is designed to represent a consensus.	

Paragraph 34	**Australia**	Revised Paragraph
34.A[When relevant scientific evidence is insufficient, precaution can be exercised as an interim measure to protect the health of consumers. However, additional information for a more objective risk assessment should be sought and the measures taken reviewed accordingly within a reasonable timeframe.]	With regard to the two proposed versions of Para 34, Australia strongly supports the position expressed in para 34 (A) that additional information to enable a more objective risk assessment should be actively sought and the interim measure reviewed within a reasonable time frame. We note that this requirement reflects Article 5.7 of the WTO SPS Agreement. However, Australia considers that para 34(B) contains additional important conditions, regarding the need for there to be evidence of rather than merely the perception of a hazard, that are not contained in Para 34 (A).	**B**.When there is reasonable evidence from a risk assessment to suggest that <u>serious</u> adverse effects on human health <u>are likely</u> occur as a result of a hazard in food, but the relevant <u>available</u> scientific evidence is insufficient to evaluate the nature and extent of the hazard or to objectively and fully assess the <u>associated risk</u>, it may be appropriate for risk managers to apply precaution through interim measures to protect the health of consumers. Any such

Present draft	Comments	New draft
34.B	We propose that the essential components of the two versions be combined. Australia considers that both footnotes to paragraph 34 can be deleted. The first serves little purpose as hazard identification is an essential step in risk assessment as defined by Codex. The second statement refers to terminology used by some member countries; this is a matter for the individual countries concerned, rather than for Codex.	interim measures should be applied in accordance with the criteria listed in Para 35, and **A**.risk managers should seek to obtain the additional information necessary for a more objective assessment of risk and review the measures accordingly within a reasonable period of time.
	CONFEDERATION OF THE FOOD AND DRINK INDUSTRIE OF THE EU	
	The "Precautionary Principle" is described, without however defining the concept, as the use of precaution, under specific conditions, during risk management. CIAA would propose to describe the "Precautionary Principle".	The precautionary principle is an approach in risk management for consumer health protection that is applied in the case of an unknown risk of a potentially significant hazard while awaiting further results of scientific research.
Paragraph 34	**ICGMA**	Revised Paragraph
34.A 34.B	ICGMA offers the following paragraph, which incorporates elements of both texts and provides for common ground between the two, and is consistent with the summary statement of the EU Commission's Communication on the Precautionary Principle (COM (2000) 1 of 02/02/2000). We suggest the following language based on articles 2.2 and 5.7 of the WTO SPS Agreement as a reasonable conciliation between the two proposals.	**B.**When relevant scientific evidence <u>suggests that a specific adverse consumer health risk may exist</u>, then <u>precautionary measures</u> can be exercised as an interim measure to protect the heath of consumers. **A.**However, additional information for an objective risk assessment <u>shall</u> be sought and the measures taken reviewed accordingly within a reasonable timeframe. <u>Moreover, interim measures should be applied only to the extent necessary to protect consumer health, and those interim measures reviewed within a reasonable timeframe</u>.

Present draft	**Comments**	**New draft**
Paragraph 34	**International Alliance of Dietary/Food Supplement Association (IADSA)**	Revised Paragraph
34.A	The WTO SPS agreement has already been adopted by over 135 countries. Consistency in language between different international organisations. Codex standards are being used by the WTO dispute settlement mechanism.	When relevant scientific evidence is insufficient, caution should be exercised as an interim measure to protect the health of consumers. However, additional information for a more objective risk assessment must be sought and the measures taken reviewed by competent authorities accordingly within a reasonable timeframe.
Paragraph 34	**Confederation Mondiale de l'Industrie de la Sante Animale (COMISA)**	Revised Paragraph
34.A[When relevant scientific evidence is insufficient, precaution can be exercised as an interim measure to protect the health of consumers. However, additional information for a more objective risk assessment should b sought and the measures taken reviewed accordingly within a reasonable timeframe.]	COMISA recommends the A version of paragraph 34 rewritten.	When relevant scientific evidence is insufficient, interim measures can be exercised to protect the health of consumers. However, additional information for a more objective risk assessment should be sought and the measures taken reviewed accordingly within a reasonable timeframe.
34.B[When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food (4) , 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, it may be appropriate for risk managers to apply precaution through interim measures to protect the health of consumers without awaiting additional scientific data and a full risk assessment, in accordance with the following criteria (5) :]	If the second version of Paragraph 34 is preferred by the majority then COMISA would delete the word "precaution" in the sentence.	When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food (4) , 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, it may be appropriate for national authorities to apply interim measures to protect the health of consumers without awaiting additional scientific data and a full risk assessment, in accordance with the following criteria (5) :

Present draft	**Comments**	**New draft**
Paragraph 34	**Consumers International**	Revised Paragraph
34.B	We support the inclusion of the second paragraph in square brackets which was proposed by the Chairman and do not support the wording proposed by the Delegation of Malaysia. We consider that the Chairman's proposal sums up the essence of the precautionary principle. We are concerned that simply referring to a hazard in food could mean that other hazards that may impact on food safety, including environmental hazards or those associated with animal health could be interpreted as being excluded.	When relevant scientific evidence is insufficient to objectively and fully assess risk from <u>a potential food hazard</u>, 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, it may be appropriate for risk managers to apply precaution through interim measures to protect the health of consumers without awaiting additional scientific data and a full risk assessment, in accordance with the following criteria :
Paragraph 34	**International Association of Consumer Food Organisations (IACFO)**	Revised Paragraph
34.B [When relevant scientific evidence is insufficient to objectively and fully assess risk	This proposal should be changed so that it will not limit the rights of national governments to apply precaution beyond the limitations they have agreed to in the SPS Agreement. The 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, this 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. The phrase is broader and is Codex's mandate (as indicated in paragraph 2 of the Draft Principles). For example, certain food production	<u>In cases where relevant scientific evidence is insufficient to assess the risks</u>

Present draft	Comments	New draft
	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 establishment of standards relating to genetically modified organisms.	
from a hazard in food (4)	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 about 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" of harm to human health before taking action. Moreover, this provision in paragraph 34 is inconsistent with the first bullet of paragraph 35, which permits the use of precaution when "the cause or extent of any negative effects are unknown due to gaps or uncertainty in the available scientific data.	<u>to the Health of consumers while at the same time ensuring fair practices in the food trade</u>,
(~~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~~),		
	The need for these changes is explained above in our discussion of the	

Present draft	Comments	New draft
it may be appropriate for risk managers to apply precaution through (~~interim~~) measures to protect the health of consumers without awaiting additional scientific data and a full risk assessment, in accordance with the following criteria 5 :]	need for a similar change to the Malaysian proposal	it may be appropriate for risk managers to apply precaution through measures to protect the health of consumers without awaiting additional scientific data and a full risk assessment, in accordance with the following criteria :
Paragraph 34	**EFLA**	
34.A	EFLA considers both options acceptable, but is of the Opinion that the first one is preferable for the two following reasons - its drafting is more in line with art 5.7 of the SPS agreement - the conditions laid down in the second option are redundant with those laid down in § 35. Therefore, there is risk of overlap and, consequently, of difficulties of interpretation, which may lead to further debate and threaten legal certainty.	
Paragraph 34	**Council for Responsible Nutrition**	
34.A	34.A The advantage of the first alternative is that it closely follows SPS Paragraph 5.7, and thus represents language already adopted by some 160 countries. By itself, this alternative for paragraph 34 is subject to the criticism that it « does not move the process forward », ie, the CCGP position on risk analysis would not provide any guidance or standards that go beyond those already present in international law through the SPS Agreement. Such criticism is invalid. It ignores the fact that Paragrap 35, the criteria for use of the precaution, accompanies this paragraph. **This alternative describing precaution and the following paragraph that delineates the criteria its**	

Present draft	Comments	New draft
34.B	**application, provide sufficient guidance and directions for use of precaution in risk analysis in Codex.** 34.B The language within this paragraph itself is reasonable, and without the second footnote it would be an acceptable alternative to the Malaysian alternative described above. (First alternative). **The second footnote (#5) makes this alternative unacceptable** because it states, « Some members refer to this concept as the « precautionary principle ». Use of the term « precautionary principle » for food safety policy in a Codex document is not acceptable because the term carries so much history and legal precedent that involves other meanings, applications and interpretations. These other meanings would be confuse the definition that Codex might try to give to the term. The obdurate insistence by the European Commission (EC) that the term « precautionary principle » be included in codex guidelines for risk analysis make clear its intent for the history of other meanings to impact decisions made in or influenced by codex. Otherwise, it would be sufficient to describe precaution and the criteria for its applicatio without a requirement to include a specific term that has previous regulatory meaning, most of which is in very different areas of application. Although the second footnote is true, as far as it goes, it is false by being very incomplete. Also, it is a transparent move by the EC to have Codex sanction use of the « precautionary principle » without Codex providing a definition of that term or guidelines for its use. Even with detailed, acceptable guidelines from Codex, the term « precautionary principle » has a long history of use in an environmental context that gives authority fo regulatory action without waiting for conclusive evidence (that is, while there is uncertainty) related to adverse impacts of a substance or process. In contrast, the « precautionary principle » would create an impossible burden in demonstration of safety of new ingredients. Safety is the absence of ham, and conclusive proof of safety requires conclusive demonstration, of a negative –that ham does not occur- and this is impossible. Thus, application of « precautionary principle » in Codex decisions related to the safety of new products or ingredients could lead to automatic decisions that a product was not safe, because there is always some uncertainty about safety. **The term « precautionary principle » is not needed to assure adequate precaution in Codex risk analysis procedures and guidelines. Use of the term will lea to unwarranted technical barriers to trade through sanction of the imposition of politically motivated additional demands for precaution after scientific evidence has produced a high level of confidence in the safety of a product.**	

Paragraph 34	**Global Crop Protection Federation**	UNCED Rio Declaration
	In the context of Risk Assessment and risk Management policies, GCPF supports the application of a precautionary approach as defined in Principle 15 of the UNCED Rio Declaration, *viz*., « In order to protect the environment, the precautionary approach shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation ». In addition, Principle 12, dealing with the international trade context, implies that measures based on a precautionary	In order to protect the environment, the precautionary approach shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a

Present draft	Comments	New draft
34.A	approach should be proportionate. It specifies that trade measures for environmental purposes should not constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade. In other words, actions based on the precautionary approach must be non-discriminatory and proportionate both to the objective to be achieved and to the risk to be avoided. The SPS Agreement of the WTO adds guidance on appropriate application of a precautionary approach. Article 5.7 of the SPS Agreement indicates that in cases where relevant scientific evidence is sufficient, there must be an on-going scientific evaluation to further clarify the actual risk, even after the measure is in place. In addition, all restrictive measures should be provisional and include a time limit for their validity and an obligation for revision within a fixed time. The SPS Agreement assumes the performance of a science-based risk assessment as a pre-condition for applying a precautionary approach.	reason for postponing cost-effective measures to prevent environmental degradation.
Paragraph 34	**Thailand**	
	Thailand is of the opinion that the application of precaution should be consistent with provision of WTO/SPS . Risk management at international level should not be restrictive than necessary to the appropriate level of protection . The adoption of interim measure when relevant scientific evidence is insufficient must taking into account of risk assessment and evidence of serious adverse effects on human health. The additional assessment should be reviewed within the reasonable timeframe. Thailand support the second para 34 with the addition of the following sentence. “However, additional information for a more objective risk assessment should be sought and the measures taken reviewed accordingly within a reasonable timeframe.”	
Paragraph 34	**Uruguay**	
	Consecuentemente, los párrafos 34 y 35 deberían ser eliminados puesto que se refieren a situaciones que se deben resolver mediante medidas de precaución provisionales, específicamente a nivel nacional. Tales medidas están actualmente disciplinadas por el artículo 5.7 del Acuerdo sobre la Aplicación de Medidas Sanitarias y Fitosanitarias (MSF).	

Present draft	Comments	New draft
	La adopción de **medidas de precaución** no es propia del Codex, puesto que la base de su trabajo es la evidencia científica fehaciente. A falta de tal evidencia, el Codex se abstiene de adoptar normas o elabora recomendaciones de otra naturaleza que apunten a mitigar la situación (como es el caso de los Códigos de Práctica). La referencia a **la precaución**, como elemento esencial en el Análisis de Riesgo en el Codex, está adecuada y suficientemente expresada en el párrafo 5 de la Sección "Análisis de Riesgos - Generalidades" y refleja el consenso general sobre su importancia en la gestión y en la evaluación de riesgos.	

Table of comments- Paragraph 35

Present draft	Comments	New draft
Paragraph 35	**US**	**Revised Paragraph**
[In such situations the following criteria should be taken into account to ensure the consistency and transparency of the decision process : 7/Examination of the full range of management options should be undertaken. This should include an assessment of the potential advantages and disadvantages of various measures, including cost/effectiveness considerations.	**For readability and easy reference, the United States suggests that the bullet points within paragraph 35 should be** designated by letters. The United States recommends that the bullet points within paragraph 35 be reordered to reflect a more logical sequence. Before a provisional measure is adopted, risk management options should be considered (a)). The provisional measures adopted have certain characteristics (b), c), and d)). And the member adopting a	In such situations, member countries should take into account the following considerations: a.Before a provisional measure is adopted, a review of the risk management options should be undertaken, assessing the potential advantages and disadvantages of the alternative measures, including, where appropriate, feasibility and cost/effectiveness considerations.

	provisional measure is obligated to seek additional information and review the measure (e), f) and g)).	b.Measures provisionally adopted should be appropriate the circumstances and based on all the available pertinent information, including available scientific information.
4/The decisions taken are consistent with those taken in similar circumstances and are the least trade restrictive necessary to achieve protection of the health of consumers.	The United States believes that: The phrase "appropriate to the circumstances" incorporates the idea that provisional measures should be consistent, to the extent possible, with measures taken by the member country in similar situations and that the provisional measure should be rationally related to the hazard/risk identified in the preliminary risk assessment.	
2/The decisions taken are proportional to the potential extent of the health risk and based on the available scientific data.	Provisional measures must be science based.	c.Members should provide a transparent explanation of th need to protect the health of consumers and of the procedures followed to establish the measure. This would include
3/There should be a transparent explanation of the need for the measures and the procedures followed to establish them.	The bullet points should recognize the member country's obligations to notify and publish food safety measures.	notification and publication of such measures in a manner consistent with the member's obligations under international agreements.
		d.Members should not apply provisional measures as a disguised form of trade protectionism.
		e.Provisional measures should be subject to a transparent review process, involving interested stakeholders.
4/	Measures provisionally adopted should not be used as disguised forms of trade protectionism.	f.Members establishing a provisional measure should seek t obtain further, pertinent information to address gaps and uncertainties in the preliminary risk assessment, for example by requesting additional data from those seeking to market distribute the food in question. This information should include additional scientific evidence to determine whether human health risk exists and, if a risk exists, the extent and
5/The decisions are provisional and are subject to an on-going, transparent review	Codex should acknowledge that a member country requesting additional information from a manufacturer, a distributor, or an importing country is a legitimate form of seeking information. Therefore, the United States believes that this manner of seeking additional information should be recognized in bullet point f) as being	

process involving interested stakeholders. 1/Following preliminary risk assessment, a specific risk is identified, or there is evidence to suggest that a risk exists, but the cause or extent of any negative effects are unknown due to gaps or uncertainty in the available scientific data. 6/Information should continue to be gathered to strengthen the scientific evidence and decisions taken should be reviewed and modified, strengthened or rescinded as appropriate in the light of such information.]	appropriate to certain circumstances. The purpose of the information gathering is to address gaps and uncertainties in the preliminary risk assessment in order to support a more complete risk assessment; and, if possible, to affirm or disprove that a risk exists and, if a risk exists, to provide estimates of the extent and severity of that risk. The review of the provisional measure should be based upon a more complete risk assessment. The review of the provisional measure should include a review of risk management options, including an assessment of the feasibility and the potential advantages and disadvantages of alternative measures, including, where appropriate, cost/effectiveness considerations. It is very important to state that the review of the measure should be accomplished within a reasonable time period.	severity of the risk. g.The provisional measure established and possible risk management options should be reviewed and retained, modified, or rescinded, as appropriate in light, of a more complete risk assessment, within a reasonable period of time
Paragraph 35	**Australia**	Revised Paragraph
	We propose this be amended to read 'In such situations the following criteria shall be applied to ensure the consistency, objectivity and transparency of the decision-making process and of any measures implemented : 1/(Beginning 'Following preliminary risk assessment') - We consider that the important concept expressed in this criterion should be included in Paragraph 34 (as has been done in the proposed alternative version of Paragraph 34 above). However, if this concept is retained in Paragraph 35, it should be strengthened by including the word 'significant' before the word 'risk' (ie 'specific significant risk' and 'a significant risk	In such situations the following criteria shall be applied to ensure the consistency, objectivity and transparency of the decision-making process and of any measures implemented :

	exists'). This is because there will always be some risk, no matter how small, and we believe the intent of this provision is to refer to a significant risk.	
	2/(Beginning 'the decisions taken are proportional') - Replace 'decisions' with 'measures'. Delete 'and', and insert a comma after 'risk', in order to link assessment of the 'potential' extent of the health risk directly with the available scientific data and so seek to ensure that the measures are not based on a hypothetical worst case scenario.	2/The measures taken are proportional to the potential extent of the health risk, based on the available relevant scientific data.
	4/(Beginning 'the decisions taken are consistent') – Replace the word 'decisions' with the word 'measures'. Also, replace the word 'similar' with the word 'comparable' 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 in <u>different</u> situations). As this criterion deals with two separate issues, it should be divided into two criteria by inserting a full stop after 'circumstances' and inserting a new criterion reading 'The measures taken are the least trade restrictive …'.	3/There should be a transparent explanation of the need for the measures and the procedures followed to establish them.
	5/(Beginning 'the decisions are provisional') – The proposed wording of Paragraph 34 would make clear that the decisions (and any associated measures) are provisional and the ~~words 'are provisional and~~' could therefore be deleted. Replace the word 'decisions' with the word 'measures'.	4/The measures taken are consistent with those taken in comparable circumstances. 4bis/The measures taken are the least trade restrictive necessary to achieve protection of the health of consumers.
	6/(Beginning 'information') - Although we are proposing that a similar provision be included in the body of Para 34, it would be useful to retain this criterion because it provides guidance on what steps might be taken as the result of a review. In addition to the range of options listed, the options should include retention of the existing measures. This criterion should therefore be amended to read '…evidence. The original decisions should be reviewed, and decisions taken to retain, modify, strengthen or rescind any measures as appropriate.	5/The <u>measures</u> are subject to an on-going, transparent review process involving interested stakeholders. 6/Information should continue to be gathered to strengthen the scientific evidence. <u>The original</u>

	7/No changes suggested.	decisions should be reviewed and decisions taken to retain, modify, strengthen or rescind any measures as appropriate in the light of such information. 7/Examination of the full range of management options should be undertaken. This should include an assessment of the potential advantages and disadvantages of various measures, including cost/effectiveness considerations.
Paragraph 35	**CONFEDERATION OF THE FOOD AND DRINK INDUSTRIE OF THE EU (CIAA)**	
	CIAA seeks clarification on the specific procedures for the handling of the risk analysis process within the current European regulatory decision-making process and the place of the "Precautionary Principle" in this context. Such clarification should also address the interaction between the EU Institutions involved and the organisation of the involvement of the stakeholders. B/It is essential that all relevant factors affecting risk analysis are identified and debated in a transparent and objective manner. The food industry has a role to play in the process. Industry's technical expertise is essential for bodies involved in the process to help set the risk assessment conditions and to understand performance characteristics of various food processing systems. It is also important in the evaluation of the various risk management options. It is particularly important that the business community is consulted during the implementation process that should also be objective and transparent. C/CIAA fully supports the principle that food safety measures should be proportionate to the food safety problem to be limited or eliminated. Restrictive measures are to be taken only if established that other measures less restrictive cannot achieve a similar result for the protection of health. Measures taken should be the least restrictive that are needed to achieve the objective.	A/The process must start with an **objective risk assessment, identifying at each stage the degree of scientific uncertainty**. B/All the **stakeholders must be involved** in the study of the various management options that may be envisaged once the results of the risk assessment are available and the procedure be as transparent as possible. C/Measures taken must be **proportionate** to the risk and the hazard which is to be limited or eliminated.

	Public perception should be explicitly addressed as part of risk communication and is therefore excluded from the risk management process.	D/Measures taken must include a **cost/benefit assessment** (advantages/disadvantages) with the intention to reducing the risk to a level that is acceptable to all the stakeholders. E/Measures taken must always be of **temporary nature**, pending the results of scientific research performed to furnish the missing data and perform a more objective risk assessment.

Paragraph 35	**International COUNCIL of GROCERY Manufacturers Associations (ICGMA)**	Revised Paragraph
[In such situations the following criteria should be taken into account to ensure the consistency and transparency of the decision process : 1/Following preliminary risk assessment, a specific risk is identified, or there is evidence to suggest that a risk exists, but the cause or extent of any negative effects are unknown due to gaps or uncertainty in the available scientific data. 2/The decisions taken are proportional to the potential extent of the health risk and based on the available scientific data.	1/“Objective scientific” is needed before the word “evidence” to give a specific meaning useful in risk analysis. After the word “effects” insert the words “on consumers health”. The phrase “gaps or uncertainly” in relation to scientific evidence is vague criterion which may allow for an open invitation to use it to support an unjustified technical barrier to trade. Additionally, hazard identification is crucial for the application of precaution. 2/Greater clarity and less chance for misinterpretation would be achieved by replacing the words “and base on” with “support and consistent with”.	1/A thorough risk assessment is performed in which a specific consumer health risk is identified, or there is reliable, objective scientific evidence to suggest that such a risk exists. 2/The interim measures are proportional to the extent of the potential health risk, as estimated on the basis of the available scientific data, and to the level of uncertainty in the scientific data.

3/There should be a transparent explanation of the need for the measures and the procedures followed to establish them. 4/The decisions taken are consistent with those taken in similar circumstances and are the least trade restrictive necessary to achieve protection of the health of consumers. 5/6/7/	3/The entire risk analysis process, including the application of precaution, should be transparent and open to participation by all interested parties. This bullet provides for the basis tenet of the application of precaution and should be moved to introductory statement in paragraph 35. For clarity 5/6/7/No changes suggested.	4/<u>The interim measures taken by the member country in</u> similar circumstances, and is no more trade-restrictive than required to achieve <u>the level of human heath protection</u>.

Paragraph 35	**International Alliance of Dietary/Food Supplement Association (IADSA)**	Revised Paragraph
[In such situations the following criteria should be taken into account to ensure the consistency and transparency of the decision process : 1/Following preliminary risk assessment, a specific risk is identified, or there is evidence to suggest that a risk exists, but the cause or extent of any negative effects are unknown due to gaps or uncertainty in the available scientific data.	Replace “should” by “must” to make the criteria obligatory. Insert “objectivity”. Insert “rapidity” because the measures are time-limited. 1/Insert “science-based” before risk assessment. Insert “scientific” to give the word “evidence” a better meaning in the context of risk analysis.	In such situations the following criteria <u>must</u> be taken into account to ensure the consistency, transparency <u>objectivity and rapidity</u> of the decision process : 1/Following preliminary <u>science-based</u> risk assessment, a specific risk is identified, or there is <u>scientific</u> evidence to suggest that a risk exists, but the cause or extent of any negative effects on <u>human health</u> are unknown due to gaps or uncertainty in the available scientific data, w<u>hen judged against established scientific risk assessment criteria</u>.

	Insert “on human heath” for reasons of clarity. Add “when judged against established scientific risk assessment criteria” to prevent unjustified technical barriers to trade. 2/Insert “human” before health risk for reasons of clarity.	2/The decisions taken are proportional to the potential extent of human health risk and based on the available scientific data. 3/There should be a transparent explanation of the need for the measures and the procedures followed to establish and implement them. 4/The decisions taken are to be non discriminatory, the least trade restrictive and compatible with consumer health protection.
2/The decisions taken are proportional to the potential extent of the health risk and based on the available scientific data.		
3/There should be a transparent explanation of the need for the measures and the procedures followed to establish them.	3/Insert “and implement” as there should be transparency throughout the whole process.	5/The decisions are provisional, time-limited and subject to transparent review process involving interested stakeholders. 6/Scientific evidence shall continue to be gathered and reviewed and decisions taken shall be modified based on such evidence.
4/The decisions taken are consistent with those taken in similar circumstances and are the least trade restrictive necessary to achieve protection of the health of consumers.	4/For reasons of clarity and objectivity.	7/Examination of the full range of management options should be undertaken. This should include an assessment of the potential advantages and disadvantages of various measures, including cost/effectiveness considerations and proportional health risk.
5/The decisions are provisional and are subject to an on-going, transparent review process involving interested stakeholders.	5/The measures are taken within a limited timeframe.	
6/Information should continue to be gathered to strengthen the scientific evidence and decisions taken should be reviewed and modified, strengthened or rescinded as appropriate in the light of such information.	6/For reason of clarity.	

7/Examination of the full range of management options should be undertaken. This should include an assessment of the potential advantages and disadvantages of various measures, including cost/effectiveness considerations.]	7/Add “and proportional health risk”	

Paragraph 35	**Confederation Mondiale de l’Industrie de la Sante Animale (COMISA)**	
	The full version of paragraph 35	

Paragraph 35	**Consumers International**	Revised Paragraph
[In such situations the following criteria should be taken into account to ensure the consistency and transparency of the decision process : 1/Following preliminary risk assessment, a specific risk is identified, or there is evidence to suggest that a risk exists, but the cause or extent of any negative effects are unknown due to gaps or uncertainty in the available scientific data.	1/While we agree with this sentence, we consider that clarification could usefully be provided as to what is meant by a ‘preliminary risk assessment’. In some situations for example, there may be so much scientific uncertainty that it is not possible to do a quantitative risk assessment and therefore the assessment may be qualitative and inconclusive. There may, for example, be some situations where the hazard is identified but it is not possible to determine the risk that it presents. It also raises the question about who should do the preliminary risk assessment and at what stage precautionary measures should be introduced. Where there is an emerging hazard there is likely to be the need for prompt action. The course taken will differ depending upon whether these principles are taken to apply within the Codex context or at national level. Within Codex, risk managers may decide when developing their risk assessment policy with risk assessors for example, that there is not a scientific body or committee that has the necessary skills and expertise to address the issue (precaution may need to be exercised while this body is put together) or existing committees may not be able to address the issue with the necessary urgency. In other situations, it may be that a scientific committee such as JECFA or a national body has made an assessment of the risk, but as a result of this assessment has identified a great deal of scientific uncertainty which needs to be addressed. Precautionary measures will then need to be introduced. To use the example of BSE, there was evidence of a disease in cattle and the theoretical possibility that this could present a risk to man. However, initial risk assessments determined that this was unlikely because of the enormous	1/Following <u>a</u> preliminary risk assessment, a specific risk <u>to human health</u> is <u>indicated</u>, or there is evidence to suggest that a risk exists, <u>but the evidence is insufficient to determine the precise nature</u> or extent of any negative effects <u>or to establish causal relationships</u> due to gaps or uncertainty in the available scientific data.

	amount of scientific uncertainty. However, the extent of this uncertainty was not fully and openly acknowledged. Precautionary measures were therefore delayed and even when introduced were not adequately enforced as the assumption made was that the disease could not pass to humans. It is important to learn from this mistake. In some situations, therefore, the risk assessment may determine that the risk is probably minimal, but the uncertainties may be so large and the potential consequences for human health if this initial assessment is in error may be so significant that precautionary action is still warranted. In such a scenario, it will be crucial that the uncertainties and assumptions made are clearly documented and communicated.	
2/The decisions taken are proportional to the potential extent of the health risk and based on the available scientific data.	2/ We agree that precautionary action does not preclude proportionality. Precautionary action may involve a range of different measures from an outright ban on a particular product, to the introduction of labelling requirements or consumer information for example. However, it may not always be possible to quantify the long-term health costs when evaluating what is considered proportionate action. In contrast, the short-term economic implications are much easier to estimate. In some situations there may be very limited scientific data and so this cannot be used to determine possible courses of action. To use the example of BSE, assumptions were initially based on the scrapie model. However, as the state of scientific knowledge, and experience, have developed, it has become clear that the public health implications of BSE are in fact very different to scrapie. There are therefore dangers in relying on the limited scientific data that may be available, as this could be proven to be misleading as knowledge develops. Discussions taking place on the role of 'Other Legitimate Factors' will also be important in this respect. 3/ Transparency is crucial to ensuring the effective use of the precautionary principle. Openness and transparency have to be integral to the whole risk analysis so it is clear what uncertainties exist, what assumptions have had to be made and on what basis. It is also important that precautionary action is not taken arbitrarily and that the reasons why a particular course of action, including possible alternative approaches that have been considered, are clearly communicated and documented. 4/ We agree that this should be the case as far as is practicable. However, there will	2/ The decisions and measures are proportional to the extent of the health risk, taking into account the potential long-term health implications and resulting costs, and to the extent possible, based on the available scientific data.

3/There should be a transparent explanation of the need for the measures and the procedures followed to establish them. 4/The decisions taken are consistent with those taken in similar circumstances and are the least trade restrictive necessary to achieve protection of the health of consumers. 5/The decisions are provisional and are subject to an on-going, transparent review process involving interested stakeholders. 6/Information should continue to be gathered to strengthen the scientific evidence and decisions taken should be reviewed and modified, strengthened or rescinded as appropriate in the light of such information. 7/Examination of the full range of management options should be undertaken. This should include an assessment of the potential advantages and disadvantages of various measures, including cost/effectiveness considerations.]	inevitably be situations which arise that are unique either in relation to the hazard itself, or to the circumstances under which a decision has to be made. 5/We agree that precautionary action should be provisional to the extent that efforts should be made to address the uncertainties that exist and to make a fuller assessment of the course of action that is required. However, it is essential for consumer protection that an arbitrary time limit is not set. The length of time for which precautionary measures will be required can only be determined on a case by case basis taking into account the current state of the scientific knowledge and any other legitimate factors. It may be possible that in certain situations developments will 'override' the precautionary measures, for example, safer alternatives to a particular practice may be discovered. 6/We agree that it is essential that further research is carried out with the aim of addressing the underlying uncertainties. This may result in a decision to change or even lift the precautionary measures. 7/ It is important that this is done in full consultation with relevant stakeholders which will ensure that a holistic approach is taken to the possible courses of action.	

Paragraph 35	**International Association of Consumer Food Organisations (IACFO)**	Revised Paragraph
[In such situations the following criteria should be taken into account to ensure the consistency and transparency of the decision process :		

1/Following preliminary risk assessment, a specific risk is identified, or there is evidence to suggest that a risk exists, but the cause or extent of any negative effects are unknown due to gaps or uncertainty in the available scientific data. 2/The decisions taken are proportional to the potential extent of the health risk and based on the available scientific data. 3/There should be a transparent explanation of the need for the measures and the procedures followed to establish them. 4/The decisions taken are consistent with those taken in similar circumstances ~~and are the least trade restrictive necessary to achieve protection of the health of consumers~~. 5/The decisions are provisional and are subject to an on-going, transparent review process	1/No changes suggested 2/After the phrase "health risk" add the phrase "(if its extent is known)". This change will make this provision consistent with the first bullet in paragraph 35, which says that precaution may be used when the "extent of any negative effects are unknown." 3/No changes suggested 4/Delete the phrase "and the least trade restrictive necessary to achieve protection of the health of consumers." Codex has no special competence is making such assessments. Moreover, Article 5.4 of the SPS Agreement merely requires that Members "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). 5/Replace "interested stakeholders" with "all interested	2/The decisions taken are proportional to the potential extent of the health risk <u>if its extent is known</u> and based on the available scientific data. 4/The decisions taken are consistent with those taken in similar circumstances.

involving interested stakeholders. 6/Information should continue to be gathered to strengthen the scientific evidence and decisions taken should be reviewed and modified, strengthened or rescinded as appropriate in the light of such information. 7/Examination of the full range of management options should be undertaken. This should include an assessment of the potential advantages and disadvantages of various measures, including cost/effectiveness considerations.]	parties." This change makes this provision consistent with paragraphs 2 and 3 of the Draft Principles and thus make it clear that consumers are to be consulted. 6/ No changes suggested 7/Delete the phrase "including cost/effectiveness considerations." While such considerations may be appropriate for those specific Codex decisions where all relevant costs and benefits can be measured in financial terms, there is no similar provision in the SPS Agreement, and governments -- especially legislatures -- may decide to adopt a precautionary measure without doing any explicit "cost/effectiveness" calculation.	5/The decisions are provisional and are subject to an on-going, transparent review process involving <u>all interested parties</u>. 7/Examination of the full range of management options should be undertaken. This should include an assessment of the potential advantages and disadvantages of various measures.
Paragraph 35	**EFLA**	Revised Paragraph
[In such situations the following criteria should be taken into account to ensure the consistency and transparency of the decision process : 1/Following preliminary risk assessment, a specific risk is identified, or there is evidence to suggest that a risk exists, but the cause or extent of any negative effects are unknown due to gaps or	1/ Between "there is" and "evidence", insert "objective and	1/Following preliminary risk assessment, a specific risk is identified, or

uncertainty in the available scientific data. 2/3/4/5/6/7/	science based. After “negative effects, insert “on the health of consumer”. 2/3/4/5/6/7/ No changes suggested	there is objective and science based evidence to suggest that a risk exists, but the cause or extent of any negative effects on the health of the consumer are unknown due to gaps or uncertainty in the available scientific data.
Paragraph 35	**Council for Responsible Nutrition**	
[In such situations the following criteria should be taken into account to ensure the consistency and transparency of the decision process : 1/Following preliminary risk assessment, a specific risk is identified, or there is evidence to suggest that a risk exists, but the cause or extent of any negative effects are unknown due to gaps or uncertainty in the available scientific data.	1/The major flaws of Paragraph 35 occur in the first bullet. As currently stated, this paragraph contains enough vagueness and ambiguity to render it subject to misinterpretation and already tool fo abuse. In order : -The term « objective » or « scientific » is needed before the word « evidence » to give a specific meaning that would be useful in risk analysis. -The phrase « gaps or uncertainty » in relation to scientific evidence is a self-fulfilling prophecy because scientific evidence always has « gaps » and « uncertainty ». This vague criterion to allow invocation of the « precautionary principle » whenever there is a « gap » or some « uncertainty » in the scientific evidence would become an open invitation to use it to support an unjustified technical barrier to trade. **In order to prevent such potential abuse, th currently final words « available scientific data » must be followed by**	1/Following preliminary risk assessment, a specific risk is identified, or there is objective or scientific evidence to suggest that a risk exists, but the cause or extent of any negative effects are unknown due to gaps or uncertainty in the available scientific data when judged against established scientific risk assessment criteria and standards as used by authoritative international bodies such as the Joint Expert Committee on Food Additives .

	restrictive terminology such as « when judged against established scientific risk assessment criteria and standards as used by authoritative international bodies such as the Joint Expert Committe on Food Additives ». -Consideration should be given to the possible persistence and seventy of the specific risk identified in the identification of any precautionary measures that may be taken. 2/Greater clarity and less chance for misinterpretation would be achieved by replacing the words « and based on » with « as estimate on the basis of ».	
2/The decisions taken are proportional to the potential extent of the health risk and based on the available scientific data. 3/There should be a transparent explanation of the need for the measures and the procedures followed to establish them.	3/The entire risk analysis process, including the application of precaution, should be transparent and open to participation by all interested parties. **The transparency element of this bullet should be moved to an introductory statement before the bulleted items of precaution are presented**. The requirement for explanation of the nee for the measures taken and the procedures followed to establish ther should remain in this bullet. 4/This statement should make it clear that the consistency is to assu non-discrimination in the decisions taken. Better language would be « the decisions taken are to be nondiscriminatory and therefore mus be consistent with others taken in similar circumstances, and they ar to be the least trade-restrictive that is compatible with protection of the health of consumers ».	2/The decisions taken are proportional to the potential extent of the health risk <u>as estimated on the basis of</u> the available scientific data. 4/The decisions taken are <u>to be nondiscriminatory and therefore must be</u> consistent with <u>others</u> taken in similar circumstances, and <u>they</u> are <u>to be</u>

4/The decisions taken are consistent with those taken in similar circumstances and are the least trade restrictive necessary to achieve protection of the health of consumers. 5/The decisions are provisional and are subject to an on-going, transparent review process involving interested stakeholders. 6/Information should continue to be gathered to strengthen the scientific evidence and decisions taken should be reviewed and modified, strengthened or rescinded as appropriate in the light of such information. 7/Examination of the full range of management options should be undertaken. This should include an assessment of the potential advantages and disadvantages of various measures, including cost/effectiveness considerations.]		the least trade-restrictive that is compatible with protection of the health of consumers. 5/Any regulatory measure taken must be accompanied by a timetable for review and subsequent confirmation or removal of the regulatory measure. The timetable will need to reflect the practical issues related to the development of the new evidence needed to update the risk analysis . 6/Information should be continue to be gathered to address gaps and uncertainties in the database and to support a more complete risk assessment. 7/Examination of the full range of risk management options should be undertaken. This should include an assessment of the potential advantag and disadvantages of various measures including cost/effectiveness considerations. Risk managers should weigh such information in order to review, modify, strengthen or rescind any decisions that may have been taken. new 8/Decisions taken should be reviewed based on the results of a risk assessment including especially an estimate of the extent and severity of the risk under consideration and/or on additional scientific evidence that affirms or disproves that a significant risk exists.

Paragraph 35	**Global Crop Protection Federation**	Revised Paragraph
	The lack of an agreed definition and agreed criteria for « the Precautionary Principle » or a precautionary approach can give rise to abuse and undesirable results. As an example, improper use of the	GCPF firmly believes that the following elements are essential in order to apply a precautionary approach in a transparent and non-discriminatory manner :

	« Precautionary Principle » can lead to a hindrance of scientific and technological progress, which will constitute a loss for all parties. Furthermore, improper use of the « Precautionary Principle » can create disguised restrictions on trade and artificial barriers to the free movement of goods. The crop protection industry is strongly regulated by governments. GCPF supports such regulation, providing that is based on sound science. This regulation of the industry is firmly based on the use o extensive data and a comprehensive risk assessment f its products. Precaution has already been incorporate into the risk assessments conducted as a normal part the registration process. As a result, any further actio on crop protection products allegedly based on the « Precautionary Principle » would have to be closely scrutinized to avoid its abuse for political or unfair tra objectives.	A/A science-based risk assessment must be the starting point for defining policy options. Once the potential risks have been identified, independent scientists should be requested to perform an objective risk assessment, identifying at each stage the degree of scientific certainty. B/The risk assessment must remain functionally separated from the risk management process. C/Only if and when the risk assessment process confirms the threat of an imminent serious or irreversible damage and that the relevant science is not sufficient certain should there be consideration of a precautionary approach in the context of risk management. D/The risk management process must be completed transparent and subject to input from all stakeholders. Once the results of the risk assessment are available, a wide-ranging consultation of scientists, civil associations and the business community will support decisions-makers in weighing policy alternatives and will allow the inclusion of social, political and economic factors in the decision-making process. E/When the risk assessment process has concluded that the relevant science is not sufficiently certain and a precautionary approach should be considered, that approach must follow the principles of proportionality and non-discrimination. F/Depending on the specific circumstances, alternative measures to prohibition could be considered, for example, the monitoring of products or the definition of provisional maximum levels. G/Measures implemented on the basis of a precautionary approach should be reevaluated periodically based on the most recent scientific evidence.
Paragraph 35	**Thailand**	
	The criteria in this paragraph should ensure that the decision taken to apply precaution is transparent and is rationalized with an understanding that the established measures are not intentional trade barriers. Thailand propose that the fifth bullet point be revised to provide a timeframe for transparent review process to avoid excessive trade impact .	