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Committee on Sanitary and Phytosanitary Measures
Committee on Technical Barriers to Trade

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RESPONSE FROM THE EUROPEAN COMMISSION TO COMMENTS SUBMITTED BY WTO MEMBERS UNDER EITHER OR BOTH G/TBT/N/EEC/6 AND G/SPS/N/EEC/149

(PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON GENETICALLY MODIFIED FOOD AND FEED – COM(2001) 425 FINAL)

Submission by the European Communities

Response from the European Commission to comments submitted by WTO Members under either or both G/TBT/N/EEC/6 and G/SPS/N/EEC/149

(Proposal for a Regulation of the European Parliament and of the Council on genetically modified food and feed – COM(2001) 425 final)

I. INTRODUCTION

The European Commission thanks all those who have submitted comments on Proposal COM(2001) 425 final as notified under either or both G/TBT/N/EEC/6 and G/SPS/N/EEC/149.

This document provides the comprehensive response of the European Commission to comments submitted by WTO Members under either or both G/TBT/N/EEC/6 and G/SPS/N/EEC/149.

For the sake of clarity and precision, comments have been regrouped by subject matter. Extracts from comments by WTO Members are shown in italics for ease of reference, and the answer from the European Commission is shown in regular font. The European Commission apologises for any - obviously unintended - inaccuracy or omission resulting from this way of proceeding.

II. GENERAL COMMENTS

A. NOTIFICATION UNDER SPS

Comment by Australia:

"*Like a number of other countries, Australia is concerned to ensure that GM foods do not have adverse human health effects, including in the longer term; and that consumers can make an informed choice about whether to purchase GM foods. Accordingly, Australia adopted a revised Australia and New Zealand Food Standard A18 – 'Food Produced using Gene Technology' that came into effect on 7 December 2001. However, Australia regards preventing adverse human health effects and the provision of consumer information as two separate issues and treats them separately under the revised food standard. Accordingly, Australia made separate notifications to address each of these issues – one to the Sanitary and Phytosanitary (SPS) Committee regarding food safety matters (on requirements for pre-market safety assessments); and one to the TBT Committee regarding the new Australian labeling requirements for GM foods. Australia is concerned that the EC has not made a similar distinction in its notifications*."

Comment by Canada:

"*These regulations, at least in part, appear to have a health and safety related objective. Is the EC intending to also notify these under the Agreement on the Application of Sanitary and Phytosanitary Measures? If not, why?*"

Comment by the United States:

"*Given the stated objective of the proposed regulation, it would be our understanding that the proposed regulation is therefore, in whole or in part, a measure defined as a sanitary or phytosanitary measure under the WTO, i.e., one applied, among other things, "to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs." While the United States welcomes the notification to WTO Members under the TBT Agreement, we question why a parallel notification was not also made to WTO Members under the SPS Agreement. The United States would encourage the Commission to also evaluate the proposed regulation in light of the disciplines of the SPS Agreement. Could the Commission please explain its rationale or otherwise provide a notification to the SPS Committee?*"

Response of the European Commission:

The proposed Regulation will lay down a general, horizontal framework for regulating genetically modified food and feed. As such, it pursues multiple objectives relating to consumer, health, and environmental protection and, thus, may fall potentially under either the TBT or the SPS Agreement. However, only when this framework legislation is applied to concrete cases and to specific products will be possible to state with precision which of the two WTO Agreements will be applicable. For these reasons, the European Commission did notify the proposal under both the TBT and the SPS Agreements.

B. OBJECTIVE OF THE PROPOSAL

Comment by the United States:

"*The proposed regulation fails to distinguish between considerations of health, safety and the environment on the one hand, and those of perceived consumer desires, on the other hand.*"

Response of the European Commission:

The European Commission considers that any given piece of legislation can serve a number of purposes and objectives. The objectives of the proposal in question are not contradictory; they are almost always intertwined and there is therefore no need to distinguish between clauses which primarily serve one purpose and others which primarily serve another purpose. Nor is there, in the view of the European Commission, any obligation under international treaties to operate on the basis of such distinctions.

C. GM FOODS ARE TREATED AS IF THEY WERE INHERENTLY UNSAFE

Comment by Argentina:

"*The Proposals start from the premises which, without scientific support, aim to uphold the unjustified presumption of the harmfulness of foods containing Genetically Modified Organisms (GMOs)."*

"Products containing or produced from GMOs are granted different treatment from other products, in particular taking into account that it is never possible to achieve absolute scientific certainty."

Comment by Canada:

"*The regulations attempt to respond to unidentified risks. There is no scientific or medical evidence that suggests that foods obtained through biotechnology, which have been assessed and approved under an internationally recognized approach, such as those developed by the OECD and FAO/WHO, are any less safe than their conventional counterparts. In fact, the EC's own research on GMOs has concluded that they are as safe, or safer, than foods derived through conventional means (A review of Results: EC-Sponsored Research on Safety of GMOs).*"

Response of the European Commission:

The own research of the European Community has not concluded that GM foods are safe *per se*; it has confirmed that those GM plants and derived products so far developed and marketed in the European Community, following usual risk assessment procedures, have not shown any new risks to human health or the environment, beyond the usual uncertainties of conventional plant breeding, or

risks that are likely to put in danger the chosen level of health or environmental protection in the European Community. This can certainly not be taken to mean that any other GM food to be developed in the future should not be assessed and evaluated to ensure that the European Community level of protection is also achieved.

Any country is free under the WTO law to establish pre-marketing approval and labeling requirements, if the other provisions of the relevant WTO Agreements are respected. Moreover, there is growing international consensus "that a pre-market safety assessment should be undertaken following a structured and integrated approach and be performed on a case-by-case basis" (paragraph 12 of the "Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology", at step 8 of the Elaboration Procedure of the Codex Alimentarius Commission). It is precisely this pre-market safety assessment and the ensuing risk management decision-process which the proposed Regulation purposes to establish, through a targeted reform of the current pre-market risk analysis provided for in Regulation (EC) No 258/97 (novel foods) currently in force.

D. PROPOSAL MORE TRADE RESTRICTIVE THAN NECESSARY

Comment by Australia:

"*Australia regards the proposals to be more trade restrictive than necessary to fulfil a legitimate objective and therefore raises concerns about the EC's WTO obligations under Article 2.2 of the TBT Agreement. Extensive international studies (including those conducted by the EC) show that there is no scientific evidence of GM food and feed posing any greater risk than their conventional counterparts. Given this, Australia questions how the EC assessed its proposed measures against the risk of non-fulfilment of the claimed legitimate objectives? What alternative, less trade-restrictive measures were considered by the EC and why were these alternatives discarded?*"

Response of the European Commission:

In essence, the Proposed Regulation is very similar to Australia's own provisions on 'Food Produced using Gene Technology' that came into effect on 7 December 2001, with the notable exception of: mandatory labeling of GM food in the absence of detectable DNA or protein; authorisation and mandatory labeling of GM feed; and, mandatory traceability of GM food and feed. The European Commission therefore understands the above comment from Australia to refer to those three specific aspects. Mandatory labeling of GM food in the absence of DNA or protein, on the one hand, and authorisation and labeling of GM feed, on the other hand, will be discussed below. Traceability of GM food and feed is discussed in response to comments received on Proposal COM(2001) 182 final under G/TBT/N/EEC/7 and G/SPS/N/EEC/150.[1]

In the following pages the Commission will explain the need for specific requirements of the proposed Regulation and what alternative, possibly less trade-restrictive measures were considered (see, in particular, the section on "GM-free labeling"). The European Commission contends that by clarifying the rules under which GM-food and feed can be placed on the European Community market, the proposed measure facilitates rather than restricts trade in GM-foods and feeds.

[1] Contained in document G/SPS/GEN/338 and G/TBT/W/180.

E. SEPARATION OF GM FOODS AND NOVEL FOODS

Comment by Canada:

"*In particular, Canada would ask the EC why these mandatory regulations are only applied to foods and feeds produced with certain biotechnologies and not to other novel foods and feeds which could be subject to genetic alteration via other production methods? Canada is concerned that the EC is fundamentally altering the way products are regulated by proposing a regulatory system based on non product related processing and production methods rather than product characteristics. Even within this processed-based system, the EC appears to be inconsistent in its application, e.g., by including foods produced "from" GMOs while excluding foods produced "with" GMOs.*"

Response of the European Commission:

Novel foods other than GM foods will remain subject to the provisions of Regulation (EC) No 258/97, which also provide for a pre-market risk assessment and risk management process. These provisions are themselves being reviewed and will also be adapted, in due course, to the new regulatory framework for food safety laid down in Regulation (EC) No 178/2002.

The establishment of a specific risk analysis process for genetically modified foods is entirely consistent with developments at the international level, where specific standards, guidelines or other principles are being developed for foods derived from biotechnology, notably within the *Ad Hoc* Intergovernmental Task Force on Foods derived from Biotechnology established by the Codex Alimentarius Commission.

The European Commission is not proposing to change the scope of the regulatory framework applicable to genetically modified foods: the scope of the Proposed Regulation is identical to the scope of Regulation (EC) No 258/97 (novel foods), i.e. food produced "from" GMOs are covered, and those produced "with" GMOs are not. Again, this is consistent with the approach at international level, notably the work in progress within the Codex Alimentarius Task Force on Foods derived from Biotechnology.

F. DIFFERENCE WITH NOVEL FOOD REGULATION

Comment by Canada:

"*Canada requests that the EC explain how the proposed regulations differ from relevant existing regulations, in particular the novel food regulations. If there are differences, could the EC explain what the distinctions are based on?*"

Response of the European Commission:

The proposed Regulation differs from the current regulatory framework applicable to genetically modified food and feed mainly in the following respects.

- A centralised Community procedure would be established for the authorisation of GM food (under the current system the authorisation procedure is only partly centralised). A single scientific evaluation would be undertaken by the European Food Safety Authority (under the current system the scientific evaluation is originally carried out by one member State competent body and may have to be complemented by the relevant Scientific Committee(s) established at Community level) followed by a single authorisation decision by the Community.

- The same centralised authorisation procedure would be applied to GM feed.

- A ten year data exclusivity would be granted for some of the information submitted in support of applications.

- Detailed requirements would be introduced in respect of the particulars and documents to be supplied in support of applications (in particular lodging of reference material and methods for detection and identification).

- New transparency provisions, modeled on those laid down in Directive 2001/18/EC, would allow for public consultation after publication of the opinion of the European Food Authority.

- A threshold (maximum 1%) would be introduced for the adventitious or technically unavoidable presence of unapproved GM material in food and feed which have at least received a positive evaluation by the relevant scientific committee of the European Community (this was not foreseen in Regulation (EC) No 258/97 on novel foods).

- New labeling requirements would enable consumers to make informed choices and avoid also deceptive practices.

III. AUTHORIZATION PROCEDURE

A. SUBSTANTIAL EQUIVALENCE

Comment by the United States:

"*The United States notes that the EU is eliminating the simplified notification procedure as laid down in Regulation EC No 258/97 on novel foods and novel food ingredients for bio-engineered products which are substantially equivalent to existing foods. To date, no bio-engineered foods have completed the long novel foods and novel food ingredients approval procedures. If this is indicative of the future operation of the food and feed approval process, the United States has great concerns about its potential impact on trade.*"

Response of the European Commission:

The Proposed Regulation does not, indeed, include a notification procedure as laid down in Regulation (EC) No 258/97 on novel foods and novel food ingredients for genetically modified food which are "substantially equivalent" to existing foods. The use of this regulatory short-cut for "substantially equivalent" GM foods has been very controversial in the Community in recent years.

Recent discussions at international level have shown that demonstration of substantial equivalence is a key step in the safety assessment process of foods derived from modern biotechnology, but it is not a safety assessment in itself (see "Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology" at Step 8 of the Elaboration Procedure of the Codex Alimentarius Commission).

In proposing the Regulation on genetically modified food and feed, the Commission took this new development into account together with the need to apply the same set of transparent and vigorous assessment rules to all GM-food (and feed).

B. CHEMICAL MODIFICATION OF A GM DERIVATIVE

Comment by Switzerland:

"*Switzerland does not require authorisation of materials which have been obtained by chemical modification of a chemically defined substance derived from a GMO, e.g. modified starch products. The Swiss authorities would like to obtain information on whether such foodstuffs will require authorisation in the EU after abandonment of the notification procedure. Switzerland estimates that the control of products containing such materials is difficult as enforcement supported by analytical methods is virtually impossible. In this context the Swiss authorities are also concerned about potential trade distortions resulting from diverging regulations.*"

Response of the European Commission:

Under the proposed Regulation, the authorization of a GMO for food or feed use would, unless otherwise stated in the authorisation, encompass the authorization of all materials (food or feed) which have been obtained by chemical modification of a chemically defined substance derived from that GMO, for example: modified starch product. This is not different from the current situation under Regulation (EC) No 258/97 on novel foods and novel food ingredients. The Commission is not aware that the application of Regulation (EC) No 258/97 (novel foods) to chemically defined substances derived from GMOs has led to trade distortions.

C. PROCESSING AIDS - ENZYMES

Comment by Canada:

"*Canada would ask the EC why GM enzymes and other processing aids are not subject to the safety assessment and authorization procedure contained in these draft regulations? Is it that the safety assessment for these products is covered elsewhere in Community regulation?*"

Response of the European Commission:

Enzymes, as such, are not excluded from the scope of the authorization provisions of the proposed Regulation.

Enzymes are used in food production either as additives, or as processing aids. Additives, including enzymes used as food additives, are food ingredients, i.e. food under European Community legislation and therefore subject to the authorization provisions of the proposed Regulation. Processing aids (i.e. materials used during processing but not present in the finished food), including enzymes used as processing aids, are not food ingredients, i.e. they are not food under European Community legislation; they are therefore not subject to the authorization provisions of the proposed Regulation.

The European Commission would like to stress that the proposed Regulation is not, in this respect, in any way different from the current legal situation as it results from the application of Regulation (EC) No 258/97, which has never ledto any concern in this respect.

However, the European Commission has already announced to the European Parliament that it is considering bringing forward new legislation on enzymes.

D. SCOPE OF APPLICATION / AUTHORIZATION

Comment by the United States:

"*Could the text of regulation, rather than the Explanatory Memorandum, please clarify whether the requirement for authorization applies only to biotech events or to individual feed or food products made or derived from these events? And further, can an applicant seek approval for a biotech event for food or feed, and assume all products and derivatives have received authorization?*"

Response of the European Commission:

The text of the proposed Regulation makes it abundantly clear that the requirement for authorization applies both to genetically modified organisms for food use and to food or feed containing, consisting of or produced from a genetically organism (see Article 4(2) and 17(2)). However, authorization cannot be requested under a single application for different GMOs which contain the same manipulation event.

An applicant can seek approval for a genetically modified organism for food and/or feed use and request that all food and/or feed products and derivatives be covered by the authorization (see Article 4(4) first indent and 17(4) first indent).

However, authorization can also be sought and granted for a specific food or feed produced from or containing an ingredient produced from a genetically modified organism as well as food or feed produced from or containing that food or feed (see Article 4(4) second indent and 17(4) second indent).

E. RISK ASSESSMENT AND RISK MANAGEMENT

Comment by the United States:

"*The proposed regulation foresees that a new European Food Authority (EFA) will be required to undertake scientific risk assessments for both bio-engineered foods and feed, yet final approval decisions will be taken by member Sates in committee, rather than by the EFA itself, whose opinion appears designed to be limited to scientific and technical considerations*."

"*The United States applauds the creation of the European Food Authority and its involvement in the approval process. However, we note its limited role. Decisions will still be made through a political process. How will the EU ensure that the authorization is based on science and not politics, given that the member States will vote on the approvals by qualified majority and neither they, nor the Commission, who is responsible for drafting the proposed decision on authorization, are bound by the opinion of the EFA?*"

Response of the European Commission:

European Community food law in general (see Regulation (EC) 178/2002) and the proposed Regulation in particular, are based on the principles of risk analysis established at the international level. The European Commission draws the attention of the United States to the general decisions of the Codex Alimentarius Commission, in particular the Statements of Principle Relating to the Role of Food Safety Risk Assessment, which provide that: "There should be a functional separation of risk assessment and risk management, while recognising that some interactions are essential for a pragmatic approach".

The proposed Regulation is entirely consistent with this principle; the functional separation of risk assessment and risk management is ensured through assigning the former to the European Food Safety Authority and the latter to the European Commission assisted by a regulatory committee of member States' representatives.

In the constitutional structure of the European Community, as in many other legal systems, risk management measures are not the province of risk assessors but of the regulatory authorities which are subject to political and judicial control.

F. ENVIRONMENTAL RISK ASSESSMENT

Comment by the United States:

"*Could the EU please clarify how the risk assessments in Article 6.5 in 2001/425 and in Annex II in 2001/18 differ?*"

Response of the European Commission:

There would be no difference between the environmental risk assessment carried out under the proposed Regulation (under Article 7(3)(e) of the proposed Regulation actually, rather than Article 6(5) which concerns the application) and the environmental risk assessment foreseen in Part C Directive 2001/18/EC.

G. ROLE OF COMPETENT AUTHORITIES

Comment by the United States:

"The EFA may ask a "food assessment body" [Article 7.3 (d)] or "feed assessment body" [Article 20.3 (d)] in a member State to do a safety assessment, or a "competent authority" to carry out an environmental risk assessment. What criteria would be used by the EFA to determine if safety and/or environmental risk assessments were required beyond the initial information provided by the applicant? Could the EU provide more guidance as to the role that these bodies will play in individual regulatory decisions?"

Response of the European Commission:

The role of a food (or feed) assessment body of a member State which would be asked to perform a safety assessment under either Article 7(3)(d) or Article 20(3)(d) in the case of a feed, and of a competent authority which would be asked to perform an environmental risk assessment under Article 7(3)(e) or Article 20(3)(e) would be to accomplish the preparatory work for the scientific opinion of the European Food Safety Authority. This work, which can best be compared to the role of a "rapporteur", would always be required, irrespective of the quality of the initial information provided by the applicant, but it could be entrusted to a body or an authority of a member State, or performed internally by the European Food Safety Authority.

H. "NO RISK" REQUIREMENT

Comment by Argentina:

"*Products containing or produced from GMOs are granted different treatment from other products, in particular taking into account that it is never possible to achieve absolute scientific certainty.*"

Comment by Canada:

"*Canada requests that the EC clarify the objective of the Authorization portion of the regulations. Canada finds the authorization process outlined in the proposed regulations to be unclear and is concerned that the EC appears to be trying to fundamentally alter the regulatory process by requiring products to meet a "no risk" standard, as outlined in article 4 of the Authorization and Labeling Regulation. As it is impossible to prove something has "no risk," Canada asks that the EC clarify what it considers a "risk" to be, and elaborate on how these regulations assist the risk management process?*"

Comment by the United States:

"*In addition, the legislation sets a standard of "no risk" as the basis for regulatory decision-making, which could ultimately block the authorization process since it is impossible to guarantee "no risk" for any product, biotech or conventional.*"

"*Article 4.1 establishes, among other things, a requirement that biotech foods "must not present a risk for human health or the environment." As stated previously, Article 17.1 requires that biotech feed "must not present a risk for animal health, human health or the environment." This level of assurance is wholly unobtainable for <u>any</u> food or feed product, regardless of the production method, as the absence of risk can never be proven. Virtually every food or feed carries some level of risk if not properly handled. What kind or degree of evidence does the EU envision would be necessary to demonstrate that this standard has been met? How does this relate to 2000/286's proposed food and feed safety standard, and/or existing standards established for food additives, or pesticide residues in food, and what is the basis for any difference?*"

Response of the European Commission:

The European Commission notes the concern expressed by Argentina, Canada and the United States. The proposed Regulation did not intend to impose an absolute "no risk" standard for genetically modified food and feed, but only a standard that can meet the high level of protection required by the EC Treaty (e.g. Article 95, paragraph 3). The applicants should not be required, therefore, to demonstrate the absence of any unknown risk for human health, animal health or the environment.

The Commission accepts that a clarification of Article 4(1) first indent may be desirable in that respect and will bring this issue to the attention of the European Parliament and of the Council as they consider the proposed Regulation.

I. "SHOULD NOT MISLEAD THE CONSUMER" REQUIREMENT

Comment by Switzerland:

"*According to Article 4 of the Commission's proposal (COM (2001) 425 final) it is required, in order to obtain an authorisation, that "food falling within the scope must not mislead the consumer". What is meant by this requirement? Are there any examples of food that is misleading by itself? Should this requirement not rather be treated as an aspect of labeling?*"

Comment by the United States:

"*Article 6.3 (e) requires applicants for authorization of biotech food to provide studies or otherwise demonstrate that the food satisfies the requirements of Article 4.1, i.e., that it does not,*

among other things, "mislead the consumer." Article 19.3 (e) requires applicants for authorization of biotech feed to provide studies or otherwise demonstrate that the feed satisfies the requirements of Article 17.1, i.e., that it does not, among other things, "mislead the user." Please clarify the types of information that would show that a food or feed (versus a food or feed label) does not mislead consumers or users."

Response of the European Commission:

Whilst "misleading the consumer" is indeed normally an aspect of labeling, advertising or presentation, there are instances in which the intrinsic characteristics of a food could be misleading for the consumer. For instance, the food could have been modified to suggest that it is fresh whilst it is not, or a food could have been modified to present the appearance of another food, more attractive to the consumer. Whilst such situations have not yet arisen in respect of genetically modified foods, this does not mean that the case may not arise in the future. The proposed Regulation is not meant to deal only with the type of products that went to the market over the last decade, it is also meant to deal with products that may be placed on the market in the coming decades, including products derived from genetically modified animals as the case may be.

Article 6(3)(e) should not be understood to mean that studies would be needed for the purpose of demonstrating that each and every criterion laid down in Article 4(1) has been satisfied. This, and other similar matters, will be clarified in the detailed guidance which will be published and refined over time by the European Food Safety Authority under Article 6(8) and 19(8).

Finally, the European Commission would observe that the "not mislead the consumer" criterion has been carried from Regulation (EC) No 258/97, where its application never led to any difficulty.

J. POST-MARKET MONITORING AND MONITORING PLANS

Comment by the United States:

"*Articles 6.3 (k) , 6.5 (b), 19.3 (k) and 19.5 (b) require applicants to develop proposals for post-market monitoring and monitoring plans for environmental effects. What are the criteria to be used by applicants in ascertaining whether post-market monitoring is appropriate? Without specific risks to humans, animals, and the environment identified, it will be difficult for firms to develop such plans and carry them out. Articles 10 and 23 indicate that once an authorization is granted, post-market monitoring or other restrictions may be "imposed." What criteria will guide the Commission in ascertaining whether specific restrictions and/or monitoring plans are needed? Will such monitoring requirements also apply to any conventional products?*"

Response of the European Commission:

The provisions in Articles 6(3)(k) and 19(3)(k) on the one hand, and those in Articles 6(5)(b) and 19(5)(b) on the other hand must be clearly distinguished.

Post-market monitoring for the use of the food for human consumption as foreseen in Article 6(3)(k) or for the use of the feed for animal consumption as foreseen in Article 19(3)(k) would only be required where appropriate, based on the outcome of the risk assessment. This is in line, for example, with the "Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology" at Step 8 of the Elaboration Procedure of the Codex Alimentarius Commission, which state (at paragraph 20) that "Post-market monitoring may be an appropriate risk management measure in specific circumstances. Its need and utility should be considered, on a case-by-case basis, during

risk assessment and its practicability should be considered during risk management." Therefore, it can be expected that within the context of the proposed Regulation, post-market monitoring will be undertaken for the purpose of: (a) verifying conclusions about the absence or the possible occurrence, impact and significance of potential consumer health effects; and (b) monitoring changes in nutrient intake levels, associated with the introduction of foods likely to significantly alter nutritional status, to determine their human health impact.

Post-market monitoring requirements can and have been imposed to non-GM products. In fact, under Regulation (EC) No 258/97, post-market monitoring commitments have so far only been imposed in respect of non-GM products.

The monitoring plan for environmental effects as foreseen in Articles 6(5)(b) and 19(5)(b) would always be required when the application concerns a GMO, as this is indeed a requirement of Directive 2001/18/EC.

K. DETECTION METHODS

Comment by the United States:

"*Articles 6.3 (i) and 19.3 (i) require the applicant to supply a method for sampling and detection of each event in foods and feeds. The United States is concerned that reliable methods for quantifying biotech material within the low levels established as tolerances by the EU are not yet available. Furthermore, detection methods and limits of detection vary depending on the method and degree of processing. In many cases, no trace of the event will be present in the final processed product. When the margin of error is so low, inconsistent test results will increase the level of uncertainty for shippers thereby discouraging trade for some and increasing liability for others despite best efforts.*"

Response of the European Commission:

Articles 6(3)(i) and 19(3)(i) are very clear that supplying a detection method for the identification of the transformation event is always required, whilst supplying a detection method for the detection and identification of the transformation event in the foods or feeds produced from it is only required where applicable. Thus, a method for detection and identification of the transformation will not be required where transgenic material cannot be detected in the foods or feeds produced from the GMO.

This, and other similar matters, will be clarified in the detailed guidance which will be published and refined over time by the European Food Safety Authority under Article 6(8) and 19(8).

As the United States know, the European Community has been soliciting co-operation with trading partners on the development of reliable methods for detection and quantification of biotech material.

L. ROLE OF COMMUNITY REFERENCE LABORATORY

Comment by Canada:

"*The current lack of validated testing and sampling methods for the detection of GMOs leads to the possible use, by importers in the EC and elsewhere, of inconsistent testing and sampling methods and therefore of unreliable test results. Canada understands that the newly established Community Reference Laboratory (CRL) will be responsible for validating methods for the detection of GMOs. Canada would like to ask the EC what criteria the CRL will adhere to for validation of*

methods, and if validation will be done at the member State, EC or international levels and will third countries be involved?"

Comment by the United States:

"*Please clarify the responsibilities of the Community Reference Laboratory (CRL) (Article 7.3 (f); Article 33 and Annex) and the national reference laboratories with regards to the testing for biotech events, data evaluation, and dispute settlement. How frequently will these laboratories test? Will they test only products originating within the Community as well as from third countries? Who will oversee the activities of these laboratories and ensure that their tests are carried out in a uniform and timely manner? What legal standing do tests run in one member State have in other member States? What will be the role of the CRL in dispute settlement between member States? What will be the role of the Commission? What will be the impact, if any, of testing results that may be provided from non-EC or member State sources?*"

Response of the European Commission:

Under the proposed Regulation, methods of detection, including sampling and identification of transformation events and, where applicable, for the detection and identification of the transformation events in foods and feeds would have to be proposed by the applicant. They would be tested and validated by the Community reference laboratory before authorization was granted. They would eventually form part of the authorization, and thus be published.

The Community reference laboratory will adhere to the validation criteria generally recognised at the international level. The European Community has long supported international co-operation in this respect, which would no doubt be more advanced if other countries had shown a similar interest.

Actual testing of products, using the validated methods laid down in the authorization, will be a matter of controls, which is essentially left in the competence of the member States. These controls are implemented without consideration of the origin of products, i.e. irrespective of whether products originate in a third country, in another member State or in the member State carrying out the controls.

Under the proposed Regulation, business operators are not required to show the results of tests at any stage of the production or distribution of the products concerned. Recognition of tests carried out in a third country or in another member State is therefore not an issue in the context of the proposed Regulation.

However, as the United States know, the European Community is soliciting co-operation with its trading partners on the development of validated detection and identification methods.

M. OTHER LEGITIMATE FACTORS

Comment by Argentina:

"*The Community regulations leave open the possibility of introducing "other factors" in risk assessment by departing from or belittling scientific evidence.*"

Comment by Canada:

"*In addition, it would be helpful to have clarification of what the EC considers, "other legitimate factors" to be, who will decide what factors are relevant in which cases, and how much weight these factors would carry in the approval process?*"

Comment by the United States:

"*The process allows the Commission to take into account unspecified "other legitimate factors" and to propose a decision regarding approval inconsistent with the outcome of the risk assessment and other safety and technical information already considered under the responsibility of the European Food Authority. This decision-making structure leaves substantial room for political interference of the type that has led to the current moratorium on agricultural biotech product approvals.*"

"*The articulation of what "other legitimate factors" may be taken into account by the Commission in developing its proposed decision should be made explicit in the regulation (Article 8.1), otherwise the lack of definition could be used to arbitrarily delay or block approvals.*"

Response of the European Commission:

The European Commission contends that the proposed Regulation is entirely consistent with the General Principles for Risk Analysis recognised at the international level, which allows risk managers to take into account not only the results of a science-based risk assessment but also other legitimate factors relevant for the matter under consideration.

Whilst acknowledging that the Proposal does not identify the "other legitimate factors" that might be considered, the European Commission would remind that member States have repeatedly requested that this matter be considered by the Codex *Ad Hoc* Intergovernmental Task Force on Foods derived from Biotechnology. The European Commission does not remember that Canada or the United States have ever supported that request, which has not been followed up so far.

N. PUBLIC INFORMATION

Comment by Switzerland:

"*In order to improve transparency of the decision-making process and the involvement of the public in the authorisation process, the proposal suggests that a summary of the application and the opinion of the European Food Authority shall be made available to the public. The public may thus submit comments to the Commission within 30 days after the publication of the opinion. What exactly is meant by "the public"? Will public opinion be sought in form of a general opinion only or are there instruments of a more formal nature envisaged?*"

Response of the European Commission:

The term "public" is used in the proposed Regulation to mean what is usually understood by it in the European Community or internationally. It refers, generally, to any natural or legal person who may be interested in the matter at stake, although it is not required to justify such an interest. All sorts of comments, whether of a general or of specific nature, can be made, the only requirements being that they be made in writing and within the specified deadline.

O. DECISIONS - TIME FRAME, APPEALS

Comment by the United States:

"*The proposed regulation indicates that the EFA will generally provide an opinion within six months of the receipt of a valid application to the Commission. The Commission then has three months to draft its proposed decision on authorization. What is the expected time frame for a final decision (by the member State) once the member State has received the Commission's proposal. If the anticipated time lines are exceeded, what recourse, if any, does the applicant have?*"

"*What is the time frame for the Commission to make its decision to modify, suspend, or revoke authorizations? What are the procedures for informing the supplier?*"

"*Once a new or existing product authorization is denied, can this decision be appealed, and if so, what is the process (including anticipated time frames)?*"

Response of the European Commission:

Under the proposed Regulation, all decisions on authorisations, including decisions to modify, suspend or revoke them would be taken at Community level, i.e. will be decisions of either the Commission or the Council as specified in Articles 8(3), 21(3) and 36 of the proposal. Moreover, Articles 8(1) and 21(1) specify the time frames within which the Commission should normally reach a decision on the application, which will initiate the subsequent steps in the authorisation procedure. Articles 8(4) and 21(4) provide that the applicant shall be informed without delay of the decision taken. As is currently the situation in nearly all areas of European Community health and environmental protection, these time frames are specified in the authorisation procedures in order to protect the interest of the applicant and allow judicial control. There is plenty of case law by the European Court of Justice on these issues.

Articles 11 and 24 of the proposal lay down the time frames on modifications, suspensions or revocations of an authorisation. In this case, the authorisation holder may still use the existing authorisation until this has been modified, suspended or revoked; consequently, specifying a time frame does not appear necessary in this respect. Final decisions to grant, refuse, modify, suspend or revoke an authorisation are decisions within the meaning of Article 249 of the EC Treaty, and can be challenged before the Court of First Instance and, eventually on appeal, the Court of Justice in conformity with and under the conditions laid down in Article 230 of the EC Treaty. In addition, an action for failure to take a decision within the specified time limits is also possible, under the conditions laid down in Article 232 EC Treaty, as well as an action for possible damages under the conditions laid down in Article 288 EC Treaty."

P. AUTONOMOUS ACTION OF MEMBER STATES

Comments by the United States:

"*In short, while the introduction of a new European Food Authority into the process could be a helpful step toward improving the predictability of the authorization process, the new proposal fails to address the core problem facing the European Union in biotechnology – individual member states will continue to be able to hold the approval process hostage to political concerns with complete disregard for science and sound regulatory decision-making. Furthermore, the United States remains concerned that individual member States will continue to flout EU regulations by maintaining their own restrictions on biotech products.*"

"*It is clear that member States' authorities apply different principles of risk management in regulating biotech products. Under this regulation, how will the Commission ensure that the risk*

management decisions of the individual member states are consistent and transparent? Will the regulation strengthen the Commission's ability to enforce EU regulations currently being flouted by several member states?"

Response of the European Commission:

The European Commission does not agree with, and cannot accept the statement that member States have been flouting the law in this area. Regulation (EC) No 258/97 on novel foods and novel food ingredients came into force in May 1997. The European Commission knows of only one instance in which one member State has suspended the authorization of genetically modified foods placed on the market in accordance with the Regulation; the measures at stake were duly notified under Article 12 of the Regulation; the matter is currently under judicial review and the European Commission would therefore refrain from any further comment on this case.

Under the proposed Regulation, granting or refusing an authorization, or a modification, suspension and revocation of an authorisation, and any refusal to renew an authorisation would become the preserve of the Community. Member States would no longer have authority to take national measures restricting the marketing of products for reasons of food or feed safety (see Article 35).

Q. 1 % THRESHOLD FOR NON-AUTHORISED GM-MATERIAL

Comment by Canada:

"*The Authorization and Labeling Regulation references a 1% threshold for the adventitious or technically unavoidable presence of approved GMOs. From a practical viewpoint, this low level is costly and unworkable, particularly from a bulk commodity perspective. To determine the adventitious presence of GMOs, particularly at very low levels, such as 1%, will require time consuming and costly tests in modern state of the art labs, and may be particularly onerous for developing countries. Therefore, given that most grain handling systems are designed to pool grains and oilseeds - a threshold of 1% could be a serious impediment to trade, affecting both GMO products and non-GMOs products.*"

Comment by the United States:

"*The United States appreciates the acknowledgment that reliably and consistently achieving 100 percent non-biotech content is not feasible, but experience has shown that a one percent threshold also cannot reliably be tested and consistently be met. To establish consumer confidence in any system, claims must be achievable and readily verifiable.*"

Response of the European Commission:

It seems that Canada has misunderstood both the purpose and the operation of the proposed 1% threshold. The 1% threshold foreseen in Articles 5, 18 and 42 concerns unauthorised GM-material which have at least received a positive scientific assessment from the European Community scientific committees. The European Commission is not aware that Canada, or indeed many other countries have legislation allowing any tolerance for unauthorised GM material.

Since most countries in the world are currently operating on the basis of a 0% threshold for unauthorised GM-material, it is difficult to understand how the introduction of a higher than 0% threshold can be "unworkable", "particularly costly" or "particularly onerous". The Commission would however welcome more precise information on feasibility problems and cost.

The introduction of a threshold, however "low", would therefore be a considerable improvement on the current situation as, in the absence of a threshold, there is no tolerance for the presence, at any level, of unauthorised GM material.

Under the proposed Regulation, there is no obligation, on any operator, to test for the presence of GMOs. The difference that the Proposed Regulation would bring is that the discovery of unauthorised GM material in a proportion lower than 1% would no longer lead to the rejection of the consignment (provided that the other conditions were also met) as is currently the case

IV. LABELING

A. WHAT IS THE RISK BASIS FOR LABELING?

Comment by the United States:

"*Among the stated "general objectives" of the proposed regulation is that of providing "...the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumers' interest in relation to genetically modified food and feed..."(Article 1). The United States understands that Directive 2001/18, and the parallel food legislation, would achieve this objective for biotech products. Considering that any biotech foods allowed on the market will have had to be demonstrated to be safe and the EU has not articulated that bio-engineered foods are unsafe, how will mandatory labeling help the Commission achieve its objective as stated in Article 1? Specifically, what risks are the proposed labeling requirements attempting to address?*"

Response of the European Commission:

Labeling has manifold purposes, only one of which is to address risks. Admittedly, it may become necessary in the future to address labeling problems linked to health, as the StarLink situation in the United States has demonstrated.

One of the most important purposes of labeling is to provide full and accurate information to consumers and to allow them to make informed choices in relation to the foods they purchase or consume. It is to inform consumers "*as to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or production*" (Article 2(1)(a)(i) of Directive 2000/13/EC on the labeling, presentation and advertising of foodstuffs).

It is on this basis that food ingredients have to be labelled and not because there is a risk associated with them. A number of other current labeling examples, such as the mandatory obligation to label the geographic origin of certain foods or the obligation to label specific production process or production methods (e.g. fruit juice made from concentrated fruit juice, irradiated foods), clearly demonstrate that labeling goes well beyond addressing risk issues to provide information that the consumer needs in order to make informed purchasing decisions.

Since there is solid, cumulatively very strong evidence that European consumers are interested to know whether their food is derived from genetically modified organisms, it is totally justified for labeling to provide them with this information as well. In any case it is worth noting that a considerable number of countries around the world have adopted labeling rules that provide precisely this information.

B. LABELING THE METHOD OF PRODUCTION AND "LIKE PRODUCTS"

Comment by Canada:

"*The regulations establish mandatory method of production labeling for all food and feed consisting of, containing, or produced from GMOs. Canada is concerned that the labeling discriminates against like products on the basis of their method of production and believes this raises serious questions as to their consistency with the EC's WTO obligations.*"

Comment by Australia:

"*Australia queries the inclusion of foods with very little or no novel DNA and/or protein in the EC's labeling regime. It is Australia's view that GM products and their non-GM counterparts are "like products" where there are no traces of novel DNA and/or protein in the final product (e.g. GM processing aids and additives where there is no novel DNA and/or protein in the final food; very small traces of GM flavourings; and highly refined foods eg oils and sugars).*"

Comment by Switzerland:

"*Switzerland does not require labeling of GMO-derived products that are separated from the organism, purified, chemically defined and shown to be equivalent to their conventional counterpart in the framework of safety assessment. This reflects the principle of equal treatment of products.*"

Response of the European Commission:

The question whether GM food and feed products and their non-GM counterparts are "like products" for the purpose of the WTO Agreements, in particular the TBT Agreement, has to be decided on a case-by-case basis. Moreover, in the view of the European Commission, established case law suggests that the concept of "likeness" in the WTO context should be interpreted by taking into account all the relevant factors relating not only to the physical characteristics but also to other properties, composition, appearance, etc. of the products which are likely to influence the competitive relationship in the market place, not least those which have been demonstrated through empirical evidence to determine consumers' preferences, tastes and habits. Thus, the specific labeling requirements may be justified where available empirical evidence shows that consumers' choice may depend on a specific process and production method having been used or not used which may affect or modify the properties of a product, even if such DNA modification cannot be currently identified. Because there is solid evidence that for European consumers foods and food ingredients produced from GMOs are different from those produced from conventional organisms, even where the food in question has little difference from other conventional foods, it would be unacceptable to deprive consumers of the information they clearly wish to have.

The European Commission further submits that even if GM food and feed products were found to be "like" to their conventional counterparts, for the purposes of the TBT Agreement, WTO Members would still have the right to draw regulatory distinctions by imposing labeling requirements to such a category of products without, for this reason alone, being found to accord to the group of like imported products less favourable treatment than that accorded to the group of like domestic products, as long as the other provisions of the TBT Agreement are fulfilled, in particular the non-discrimination and no more trade restrictive than necessary requirements of the Agreement. In the view of the European Commission, the proposed Regulation is designed to comply with these requirements and care will be taken to continue complying with them when taking implementing legislation.

C. LABELING TERM: GENETICALLY MODIFIED OR BIO-ENGINEERED

Comment by the United States:

"*The United States would note that the term "genetically modified" applies to all breeding methods, and indeed, to all food crops. The United States continues to believe that its use by the Commission fosters the mistaken belief that only the techniques of modern biotechnology modify genes. The United States also believes that perpetuating such mistaken beliefs impedes public acceptance of bio-engineered foods and crops. The United States, therefore, once again, recommends that the Commission use a more accurate term to describe the products you want to capture under the regulation.*"

Response of the European Commission:

The term "genetically modified" has long been used in the European Community, and in many other countries around the World, to designate foods and other products derived from modern biotechnology.

The European Commission is of the opinion that terms used in labeling should be terms that consumers recognize. It is therefore difficult to understand why a term that is so well understood by the European consumers should be replaced by another one less well understood.

The European Commission is aware that in North America the term "bio-engineered" is sometimes used to designate the same category of products. The European Commission has no objection to formulate against the use of this term in other countries, if that is a term which consumers there recognize and understand.

D. PRODUCED FROM A GMO, BUT NOT CONTAINING A GMO

Comment by Switzerland:

"*Switzerland has reservations about the terminology for labeling purposes included in the two proposals as they differ from present regulations, are unduly long and are inconsistent with one another. While the wording in proposal COM (2001) 425 final reads "produced from genetically modified [name of organism], but not containing a genetically modified organism" or "genetically modified", the wording in proposal COM (2001) 182 final reads "this product contains genetically modified organisms*".

"*The Swiss authorities are also concerned that the current labeling terminology laid down in Regulation (EC) No1139/98, in which the wording "produced from genetically modified [name of organism]" is being used, will be replaced by these new proposals. Switzerland has been careful to define its own labeling rules in a way that is consistent with present EU regulations, and does not see any benefit for the consumer in the proposed changes. The differences may enhance confusions and therefore Switzerland would like to keep its current legislation with regard to labeling unchanged.*"

Response of the European Commission:

The European Commission has noted the comment of Switzerland. The European Commission attaches great value to past and on-going co-operation with Switzerland in matters of food safety in general and in matters of food labeling in particular. It also agrees that consistency in the regulatory approaches is mutually beneficial. Therefore, the Commission will bring this issue to the attention of the European Parliament and of the Council as they are currently considering the Proposal.

E. LABELING FOR PROCESSING AIDS - ENZYMES

Comment by Australia:

"*Australia seeks a scientific or other explanation behind the EC proposal to discriminate between foods produced from GMOs (including highly refined oils and sugars that have no traces of modified DNA or protein) and foods produced with GM enzymes (eg enzyme processing aids used in the production of many cheeses and wines). Such a distinction suggests that the EC's proposal is based on non-product related processing and production methods rather than product characteristics.*"

Comment by Canada:

"*Canada asks the EC what the scientific basis is for the inclusion of this type of product with no detectable genetic material when other products such as cheese and wine made from GM enzymes and other processing aids are excluded. The exclusion of certain products from the labeling requirements suggests that these requirements are not necessary.*"

Comment by the Switzerland:

"*The Swiss authorities have noted that according to the proposal processing aids derived from GMOs do not have to be labelled even if they are passed on to the consumer as such. Switzerland believes that an informed choice of the consumer wishing to purchase a processing aid should be supported by adequate labeling.*"

Comment by the United States:

"*Please explain why processing aids, such as chymosin used in cheese and processing aids available for wine production, are exempt from the labeling requirements. Since the changes to EU labeling policy laid out in this regulation are based on consumer opinion as noted the Explanatory Memorandum, has the EU undertaken similar opinion surveys to query consumers about this distinction? If yes, what were the results?*"

Response of the European Commission:

As already indicated above in relation to authorization, enzymes are not excluded as such from the scope of the proposed Regulation: where they remain in the final product, they are legally qualified as ingredients and must be labelled accordingly..

The proposed Regulation thus maintains the current legal situation as far as the labeling of enzymes is concerned.

However, the European Commission has already announced to the European Parliament that it was currently considering bringing forward new and more comprehensive legislation in respect of enzymes. The labeling of enzymes used as processing aids will be reconsidered in this context.

F. LABELING: RISK OF FRAUD

Comment by Australia:

"*Australia is concerned that there may be practical problems caused by the inability to detect traces of novel DNA and/or protein in highly refined foods, opening the way for fraud and difficulties in enforcing compliance. How does the EC intend to address these issues?*"

Comment by Canada:

"*Canada is concerned that the proposed mandatory labeling requirements will apply to highly refined products such as oils, where there is no detectable DNA or protein. The inability to verify labels through testing raises serious concerns about the effectiveness of the regulations and increases the risk of fraud and misrepresentation of products. How does the EC propose to enforce compliance and control fraud?*"

Comment by Switzerland:

"*Switzerland is worried that a scheme asking for product labeling based exclusively on information provided by documents accompanying product ingredients along non-segregated food chains, would be susceptible to fraud and error. It has to be feared that mislabeling of products could not be detected in many cases, which may damage the credibility of the authorities in charge of food safety control and subsequently the credibility of the labeling regime itself.*"

Comment by the United States:

"*This proposed regulation would expand mandatory labeling of biotech food and feed to require the labeling of all food and feed products according to the biotech content of each ingredient whether or not those ingredients are detectable in the end product and even when test methods do not exist to confirm their presence. In these cases it will be impossible to verify, by testing, a claim that product ingredients are non-biotech. The United States is greatly concerned that this regulation will, therefore, invite fraud and a further weakening of consumer confidence in EU food safety delivery systems.*"

Response of the European Commission:

The European Commission would certainly acknowledge that enforcement of labeling provisions is more difficult when it is not possible to verify the truthfulness of claims through analytical methods.

This, however, is hardly a new problem and certainly not one that cannot be solved. The same can be said of "origin labeling", "organic labeling" and a host of other labeling situations where the characteristic which is being labelled, irrespective of whether labeling of the said characteristic is required or offered voluntarily, is one that cannot be controlled through analytical methods. In all such cases, the truthfulness of claims is normally controlled by the accompanying certification and documentation (i.e. traceability).

This is precisely why the European Commission has proposed that the traceability of GM food and feed become mandatory, through the production and distribution chain (see the Proposal notified under G/TBT/N/EEC/7 and G/SPS/N/EEC/150).

There is no objective grounds, none at all, for claiming that GM labeling, backed by compulsory traceability of GM ingredients, would "invite fraud" any more than, say, origin labeling, where it is mandatory and backed by compulsory traceability.

It is worth noting that the Commission has received positive comments on the feasibility of the proposed labeling system. For example, *EuroCommerce*, the Retail, Wholesale and International Trade Representation to the EU, stated that:

> "In spite of the sensitivity of the available methods of analysis, it is no longer possible for retailers, as the last placers of products on the market, to provide analytical proof of transgenic ingredients in final products due to the multiple processing stages involved in many foodstuffs. Thus, frequently, retailers can only rely on contractual assurances or paper documentation and supplier audits, even though in theory, they could even be held liable for an erroneous labeling of products. Therefore, already today, they are dependent on correct and complete information from their suppliers as well as on appropriate documentation." (EuroCommerce, Position Paper on COM(2001) 425 final and COM (2001) 182 final, March 2002).

G. GM-FREE LABELING

Comment by Canada:

"*It appears that consumer information is the primary objective of the labeling requirements. Canada believes that if consumers demand non-health and safety related information on approved GM food or feed, market pressures will lead producers to respond. Therefore, a better and less trade restrictive approach is a voluntary scheme which would appear sufficient to provide consumers with a "choice." As the Commission is aware, Canada is developing a voluntary standard for the labeling of foods derived from gene technology. This voluntary standard will provide a clear basis for the market to respond, as appropriate, to consumer demands.*"

"*In addition, Canada is very concerned by the EC's apparent failure to consider alternative measures to those outlined in the regulations, which meet the stated objectives, and are less trade restrictive. Canada asks the EC if any other measures were explored? If so, what led the EC to recommend mandatory labeling and traceability measures over a less restrictive, market driven approach, such as voluntary labels? For example, Canada is developing a voluntary standard for the labeling of foods derived from gene technology. This voluntary standard will provide a clear basis for the market to respond, as appropriate, to consumer demands.*"

Comment by South Africa:

"*South Africa is of the opinion that the choice that consumers want, are between: (a) 'Foods that contain or are derived from genetically modified organisms' versus (b) 'Foods that do not contain or are not obtained from genetically modified organisms'. A situation where an increasing quantity of foods could contain or are derived from genetically modified organisms, as a future scenario, should be kept in mind. This would result in a decreasing choice for those consumers that prefer (b). Therefore, establishing a system to provide a food chain for NON-Genetically Modified Foods, having as little adventitious commingling with GMOs, is essential. Paper trailing complemented with laboratory analysis of samples taken in a statistically acceptable method seems to be a way of verifying claims, although deficiencies of such a system would have to be acknowledged. South Africa therefore, regards labeling of all foods that contain or are derived from genetically modified organisms as a short-sighted approach."*

Comment by Switzerland:

"*Switzerland regrets that the EU Commission proposal does not include a legal basis for labeling of foodstuffs which have been produced without the use of genetic engineering. Many consumers wish to purchase foodstuffs that have been produced without the use of genetically modified organisms at any stage of the production process. This includes for example the use of GMO derived animal feedingstuffs in the production of meat, eggs, dairy products, etc. Due to the absence of a respective*

legal basis the Swiss authorities are concerned that "GM-free" labels, which may not be true and therefore misleading to the consumer, might be tolerated and used in EU countries. In Switzerland, "GM-free" labels are unlawful (if printed in French, German or Italian), as the complete absence of GMO-derived material in foodstuffs cannot be guaranteed, a fact that is documented by the proposal for a threshold value. Switzerland would thus welcome a EU-wide regulation of "negative" labeling relating to the non-use of GE technologies in the production of the particular foodstuff. Therefore, Switzerland proposes that a negative label refer to the fact that the foodstuff has been produced without the application / use of genetic engineering at any stage of the production process. (For such a negative label, Switzerland proposes the wording "ohne Gentechnik hergestellt", "produit sans recours au génie génétique", and "ottenuto senza ricorso alla tecnologia genetica", respectively.).

In this context the Swiss authorities would like to obtain further information on what the EU rules on these "negative declarations" will be. Of particular interest is also the question whether products carrying a "negative" declaration as outlined above can still be placed on the EU markets."

Comment by the United States:

"*The proposal indicates the objective of the "comprehensive" labeling requirements are to respond to an overwhelming need for consumers to make individual choices, thereby fostering increased public confidence and acceptance of products of biotechnology. If consumer choice is truly the objective of the proposal, the United States would argue that a more crucial element would be to give guidance as to what would constitute a food that has not been produced through biotechnology. Would it not be more informative to publish guidance or impose requirements that would assure that products labelled, "non-GMO" are in fact, non-biotech?*"

Response of the European Commission:

In preparation of its Proposal, the Commission examined the merits and disadvantages of a number of different labeling approaches, including the one that would complement the current mandatory labeling provisions (based on the presence of DNA or protein resulting from the genetic modification) with a Community-wide voluntary "GMO-free" (or similarly phrased) scheme.

The Commission's preparatory work, including experiences in some member States, revealed that voluntary "GMO-free" (or similarly phrased) schemes were beset by a number of technical, commercial and other difficulties. It also became evident that consumers in the European Community were primarily interested in knowing whether their food was produced from GMOs or contained ingredients produced from GMOs. Consumers clearly prefer to be informed what is in products and not what is not in products. For instance irradiated food has to be labelled as such and not non-irradiated. European Community legislation allows for "Free of" labeling claims provided the claim is truthful and not misleading. "GMO-free" products are already supplied by the Organic Production scheme, which excludes the use of GMOs in the whole production chain on a very strict basis. A second "GMO-free" production scheme is therefore also considered to be confusing for consumers and potentially misleading.

H. LABELING THRESHOLD

Comment by Canada:

"*In addition, the proposed regulations reference a 1% threshold for the adventitious or technically unavoidable presence of approved GMOs. Is labeling and traceability required for those situations where the presence of GMOs is intentional, but less than 1%? Can the EC clarify what would be considered "appropriate steps" to avoiding adventitious GMOs, as outlined in paragraph 24 of the Authorization and Labeling Regulation.*"

"*Given that modern, competitive grain handling systems are designed to pool grains and oilseeds in farm storage, country grain elevators, railway cars, and export bulk shipments - a tolerance level of 1% could be expected to be a serious impediment to trade.*"

Response of the European Commission:

Canada appears to have misunderstood the operation of the 1% thresholds as these relate to the adventitious or technically unavoidable presence of unauthorized GM-material (Articles 5, 18 and 42) which have been found not to present a risk for human health or the environment under a scientific assessment carried out by the relevant European Community scientific body.

The proposed labeling thresholds in Articles 13(2) and 26(2) are for the combined adventitious presence of both authorised and unauthorised material, but no figure is specified.

Labeling and traceability would indeed be required whenever the presence of GMOs or GM-material is intentional.

The comment that a tolerance level of 1% could be expected to be a serious impediment to trade is difficult to understand. If it refers to the tolerance for the adventitious presence of unauthorised material, certainly 1% is better than 0% which is the current situation in the European Union and, indeed, in most countries including Canada. If it refers to the labeling threshold for the combined presence of authorised and unauthorised material (for which no figure is specified in the proposed Regulation), it is difficult to understand how this can be a serious impediment to trade, as products would be allowed to the market provided that they are appropriately labelled.

I. THRESHOLD FOR AUTHORISED AND UNAUTHORISED MATERIAL

Comment by Switzerland:

"*Adventitious traces (below 1%) of GMOs in products are suggested to be exempted from the labeling requirement. Switzerland supports this tolerance level and believes it to be necessary. However, this provision also includes non authorised GMO varieties. Will there be a possibility for third parties to obtain information on whether a risk assessment for an unauthorised GMO has been carried out?*"

"*Starting from the idea that the overall goal of the labeling provisions is consumer information, Switzerland feels that there is a certain incoherence between the requirement to label food that is produced from GMOs but does not contain GMOs and the exemption of products containing GMOs in an amount below the tolerance level of 1% from the labeling requirement.*"

Response of the European Commission:

The proposed Regulation foresees that the labeling thresholds (Article 13 and 26), which concern the adventitious or technically unavoidable presence of authorised or unauthorised genetically modified material, would be laid down by the European Commission through the standard (comitology) procedures. The regime currently applicable in the European Community, where the labeling threshold is in force under Regulation (EC) 49/2000, only concerns authorised GM material and is indeed fixed at 1%. However, once a level will have been set in accordance with the established procedures, this will be published and third parties will have access to this information.

The Commission does not see any inconsistency in its labeling approach. Foods and feeds intentionally produced from GMOs or containing ingredients intentionally produced from GMOs are not exempted and will have to be labelled. However, in order for the system to be feasible and operational, the problem of adventitious presence had to be addressed and this is why the Commission has foreseen the adoption of a tolerance level for the labeling of such adventitious presence. In other terms, compliance with the set threshold will not be sufficient for exemption from the labeling requirement. Operators will also have to supply evidence that they have taken appropriate steps to avoid the use of GMOs or products thereof (see articles 13 and 26)

J. ETHICAL OR RELIGIOUS CONCERNS

Comment by Australia:

"*Australia seeks clarification of the requirement for labeling to inform of "any characteristic or property which gives rise to ethical or religious concern*"."

"*What does the EC regard as an ethical or religious concern? Furthermore, in the EC's view, what is the relevance of such concerns for TBT provisions? Without such clarification, Australia is concerned about the potential for free interpretation and further barriers to trade particularly if similar requirements are not also extended to conventional foods.*"

Comment by Canada:

"*We would further note that the inclusion of non-science based factors, such as ethical and religious concerns, without adequate definitions, is of particular concern to Canada.*"

Comment by the United States:

"*Articles 6.3(g) and 19.3 (g) call for the applicant to provide either a reasoned statement that the food or feed, respectively, "... does not give rise to ethical or religious concerns, or a proposal for labeling it...". Who determines what the ethical or religious concerns are? These vague requirements give no guidance to food or feed manufacturers regarding what those concerns, which will vary exceedingly from one consumer to the next in a multi-cultural society like the EU, might be. By what standards are potential ethical or religious concerns weighed? Such concerns, if used for regulatory decision making, should be detailed in the proposed regulation so that comments can be provided and to facilitate compliance.*"

"*Please clarify how the additional labeling requirements for undefined ethical and religious issues in Article 14.2 will inform a consumer that may prefer to avoid a biotech derived product. Why are these issues specific to foods produced through biotechnology and not foods produced through other means? Is this information also required for conventional products? If not, why not?" "Who determines when a biotech food "may give rise to ethical or religious concerns" as foreseen in Articles 14.2 (b) and 27.3 (c)? Who determines what additional labeling requirements will be and on what basis? Clarification of these questions should be made explicit in the proposed regulation to afford a meaningful opportunity for comment and to provide information to U.S. exporters on the specific requirements.*"

Response of the European Commission:

The requirement that the labeling should contain appropriate information where a GM food may give rise to ethical concerns was also used in Regulation (EC) No 258/97, where its application does not seem to have raised any concerns. A similar requirement is thus applicable to novel foods

produced through other means than biotechnology, to signal the presence of material which is not present in an existing equivalent foodstuff and thus may give rise to ethical concerns.

The proposed Regulation adds "religious" concerns to the "ethical" concerns already mentioned in Regulation (EC) No 258/97. This is specifically meant to address the situation where a gene from a bovine animal or from a pig would have been transferred into another animal species, as this may give rise to concerns for the followers of some religions.

Under the proposed Regulation, it would be for the applicant to indicate, at the time of application, either that the food does not give rise to ethical or religious concerns, or, on the contrary, how it is proposed to address through labeling any ethical or religious concerns that may have been identified. The European Food Safety Authority will not consider this matter in the opinion it is to submit to the Commission, as ethical and religious concerns should not be considered in the context of the risk assessment of the food. It will therefore be for the European Commission, when it shall consider other legitimate factors, to determine whether the proposal made by the applicant is acceptable or not in this respect.

Detailed rules for the implementation of these provisions can be adopted through the standard procedures applicable in such cases (see Articles 15 and 28 of the proposed Regulation).

K. RISK OF UNEVEN APPLICATION OF LABELING REQUIREMENTS

Comment by the United States:

"*The U.S. understands that operators will be required to demonstrate that they have taken appropriate steps to avoid the adventitious presence of biotech material. Given difficulties encountered with the implementation of similar documentation requirements in other circumstances in the EU (such as in the case of organic products), the United States is concerned about the potential for uneven application and enforcement of this requirement across member States or even local governments. For example, in the case of organic products, the absence of a harmonized EU procedure for issuing import authorizations and the lack of EU-wide oversight of the approval and enforcement process has resulted in varying member State procedures, policies, and approval rates causing a great deal of uncertainty and administrative burden on organic exporters and certifers, thereby blocking trade*."

Response of the European Commission:

The obligation for operators to demonstrate that they have taken appropriate steps to avoid the adventitious presence of GM material is already in force in the European Community, under Regulation (EC) No 1139/98, as amended by Regulation (EC) No 49/2000, and does appear to have resulted in uneven application and enforcement.

Furthermore, the Proposal foresees the possibility to adopt detailed rules for the implementation of the labeling provisions (see Articles 15 and 28), and this should allow to deal with difficulties in enforcement, should they occur.

L. LINKAGE TO BIOSAFETY PROTOCOL

Comment by Australia:

"*Noting that the Biosafety Protocol does not provide any linkage to domestic labeling regimes, Australia would appreciate advice as to how the proposed regulations contained in*

Notification G/TBT/N/EEC/6 takes account of the requirements of the Protocol "as regards importer obligations and notification"."

Response of the European Commission:

The proposed Regulation has taken into account Article 11.4 of the Biosafety Protocol which determines that " a Party may take a decision on the import of living modified organisms intended for direct use as food or feed or processing under its domestic regulatory framework that is consistent with the objective of this Protocol".

As regards labeling, the Biosafety Protocol covers the issue of advanced information agreement between parties to protect biological diversity, but does not address labeling of products containing or produced from GMOs or LMOs for the purpose of informing the consumer or facilitating *consumer choice.*

This matter is being given further consideration in the European Commission response to comments submitted by WTO Members under either or both G/TBT/EEC/7 and G/SPS/N/EEC/150.[2]

M. GM FEED - AUTHORISATION AND LABELING

Comment by the Australia:

"*Australia queries why GM feed is included in the EC's proposed regulations given the EC's views that animals that consume GM feed are not considered to be genetically modified (nor are any products from these animals, such as meat, milk or eggs, genetically modified).*"

Response of the European Commission:

The European Commission would like to stress that the fact that the current proposals do not include products derived from animals fed with GMOs, does not imply that GM feed should not be regulated. The objective of the proposed Regulation in this field is not only a high level of protection of human health, covering the entire food chain, but also the protection of animal health and of the environment.

As part of the framework to improve and bring coherence to Community legislation from "farm to table", the Commission already highlighted in the White Paper on Food Safety of 12 January 2000 the need for legislation for the evaluation, authorisation and labeling of novel feed, in particular GM feed.

In other words, no feed shall be placed on the market or fed to animals if it is considered to have an adverse effect on human, animal health or the environment.

Also, experience has shown that authorisation should not be granted for a single use when a product is likely to be used both for food and feed purposes: such products should fulfil the authorisation criteria specific to food and feed.

As regards labeling of GM feed, the EU policy is basically to provide the users (farmers, breeders, etc.) with accurate information on the products enabling them to make a free choice.

[2] See footnote 1 above.

The European Commission believes that the proposed requirements will enhance transparency and safety throughout the feed chain, contributing also to restore users and consumer confidence in the application of gene technology in the agro-food sector.

N. GM FEED LABELING – UNIQUE CODES

Comment by the United States:

"*Please clarify the requirements of Article 27 of EEC/6 on genetically modified food and feed and Articles 4 and 5 of EEC/7 on traceability and labeling. Article 27 appears to require the operator to carry all relevant unique codes for feed on the accompanying document, packaging, container, or label throughout the entire labeling system. Whereas, for products that include ingredients produced from biotech events, Article 5 requires the operator to transmit information on which ingredients are biotech derived to the recipient of the product, although the unique codes do not need to be transmitted.*"

Response of the European Commission:

The requirement laid down in Article 27(3)(b) of the proposed Regulation applies only to feed containing or consisting of GMOs and not to feed produced from GMOs, due to the fact that the unique codes do not need to be transmitted for feed produced from GMOs according to the proposal on traceability and labeling (G/TBT/N/EEC/7 and G/SPS/N/EEC/150).

Just as in the basic Community legislation in the field of feed labeling and in accordance with the proposal on traceability and labeling, the provisions of Article 27 of the proposal on genetically modified food and feed concerns each stage of placing on the market. This implies that the particulars may be mentioned on an accompanying document, as there is not always a label attached to the product.

This is also in line with Article 4(2) last indent of the proposal on traceability and labeling, as the unique codes for all the GMOs potentially present in the feed have to be declared (for example on an accompanying document) at the time of the transmission of the product to the subsequent operator.

V. MISCELLANEOUS

A. LACK OF ADDITIONAL GUIDANCE

Comment by Canada:

"*Canada notes that in some aspects of the regulations there is a lack of sufficient detail or additional guidance is foreseen. The absence of such information limits our ability to provide comments. When does the EC anticipate that these proposals will be developed? Canada looks forward to the opportunity to comment on these proposals.*"

Comment by the United States:

"*Finally, the United States would note that there are a number of areas which lack sufficient detail and/or for which additional guidance is possible or explicitly foreseen in the proposal. The absence of such information in the proposed regulation itself limits our ability to provide meaningful comment on a number of aspects at this juncture.*"

"*Articles 4.5 and 17.5 state that authorization is based on procedures set out in this proposed regulation. However, the proposal itself identifies a number of areas where additional guidance and*

criteria will be developed. The United States looks forward to commenting on these procedures when they are completed."

"*The final provisions of Articles 6 and 19 indicate the Commission "may establish" implementing rules for the application of those Articles; and, the EFA "shall publish" detailed guidance concerning the preparation and the presentation of the application. The United States looks forward to the opportunity to comment on these proposals as they are developed.*"

"*Articles 7.8 and 20.8 state that "before the entry into application of this Regulation, the Commission shall publish a recommendation on the nature of the risk assessment to be undertaken by the Authority for the purpose of preparing its opinion." The United States believe this recommendation should be published in the proposed regulation to afford a meaningful opportunity for comment and we look forward to commenting as it is developed.*"

"*Article 12.5 (Renewal of food authorizations) indicates the implementing rules for the application of this Article shall be established by the Commission, and 12.6 indicates the EFA will publish detailed guidance concerning the preparation and presentation of the application (with parallel provisions for feed). The United States looks forward to the opportunity to comment on these proposals as they are developed.*"

"*Articles 15 and 28 indicate implementing measures containing detailed rules for labeling requirements may be adopted to address food safety concerns. The United States looks forward to the opportunity to provide comment on these proposals as they are developed.*"

Response of the European Commission:

The EC Treaty provides, in Article 202, that in the instruments which it adopts, the Council has to confer on the Commission powers for the implementation of the rules which the Council lays down. The implementing powers conferred on the Commission under the proposed Regulation are in conformity with that principle.

Where appropriate, the measures adopted by the Commission under these implementing powers are notified under the TBT and/or the SPS Agreements.

Recommendations from the European Commission and detailed guidance to be published by the European Food Safety Authority are of a non-binding character and would normally not be notified under the TBT and/or the SPS Agreements.

B. EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES

Comment by the United States:

"*Article 34 states that the Commission or member States can consult the European Group on Ethics in Science and New Technologies. There is no time limit given for this group to deliver an opinion. The United States is concerned that this group could delay or block the approval of a product by not issuing timely opinions. An anticipated time frame for the delivery of its opinion should be published in the proposed regulation, along with procedures for addressing situations where an opinion of this Group is not forthcoming. How will consultations be conducted? Will they involve all interested parties? Under what circumstances would such consultations take place?*"

Response of the European Commission:

The United States seems to have misunderstood the role of the European Group on Ethics in Science and New Technologies. It is not foreseen, in the proposed Regulation, that the Group on Ethics will be consulted on individual applications for authorization.

This of course, does not mean that the Commission may not, on its own initiative or at the request of a member State, consult the Group on Ethics before reaching a specific decision. As has been indicated above, the Commission will not receive advise from the European Food Safety Authority on the ethical concerns that a particular application may give rise to. In such case, the Commission may therefore wish to obtain the advice of the Group on Ethics on the matter. In such case, an opinion would be sought in time for the Commission to prepare its draft decision within the three-months deadline, but in exceptionally complex cases this deadline would be extended.

C. REGISTER OF AUTHORISED GM FOODS AND FEEDS

Comment by the United States:

"*Article 30 proposes the establishment of a register of "authorized genetically modified foods and feeds." Could the text of the regulation, rather than the Explanatory Memorandum, please clarify whether, if an event is approved, all food and feed derivatives will automatically be included in the registry? Which DG will be responsible for maintaining the registry? Will it be available to the public and if so, where? The United States looks forward to commenting on this information.*"

Response of the European Commission:

Entries in the Register will reflect the scope of the decision, which will itself depend on the scope of the application. Thus where authorization will have been requested for and granted in respect of a GMO and foods produced from or containing ingredients produced from that GMO, this will be specified in the Register.

It is an internal matter for the Commission to decide which of its services is responsible for carrying tasks assigned to it by European Community legislation.

The Register shall be made available to the public, as expressly laid down in Article 30(2), presumably through on-line electronic access.

The European Commission has noted that the United States intends to comment on this information, although this is not information on which the European Commission would normally expect comments from third countries.

D. EMERGENCY MEASURES: CRITERIA – ROLE OF EFSA

Comment by the United States:

"*What criteria are required for adopting emergency measures under Article 35 (Emergency Measures)? What is the role of the EFA in evaluating such information and the merits of taking emergency action? Please clarify the criteria which will underpin such emergency decisions and the role of the EFA in the proposed regulation.*"

Response of the European Commission:

Emergency measures may be adopted where it is evident that the use of a food or a feed authorised in accordance with the proposed Regulation is likely to constitute a serious risk to human health, animal health or the environment. The European Food Safety Authority may be consulted before emergency measures are taken, but this is not a prerequisite for the adoption of such measures.

E. EMERGENCY MEASURES: INTERNATIONAL CO-OPERATION

Comment by Switzerland:

"*As regards possible threats to human health, animal health or the environment the Commission suggests provisions for emergency measures. Will there be any consultation, collaboration or information exchange with the competent authorities in foreign countries? Will other countries have the possibility to participate in the rapid alert system?*"

Response of the European Commission:

Consultation, collaboration or information exchange with the competent authorities in foreign countries in the context of emergency measures being considered or adopted within the Community is not foreseen under the proposed Regulation. However, the proposed Regulation does certainly not preclude international co-operation where the circumstances of a case makes this useful.

Under Article 50 of Regulation (EC) No 178/2002, participation in the rapid alert system may be opened up to third countries on the basis of agreements between the Community and those countries and in accordance with the procedures defined in those agreements, which must be based on reciprocity and must include confidentiality measures equivalent to those applicable in the Community.

F. MONITORING AND CONTROL: INTERNATIONAL COLLABORATION

Comment by the Switzerland:

"*With respect to implementation, monitoring and control does the Commission's proposal provide for any collaboration with foreign laboratories? Will foreign test results be accepted and if so what are the modalities for their acceptance?*"

Response of the European Commission:

The proposed Regulation does not require that tests be carried out and, therefore, does not deal with the issue of modalities for the acceptance of foreign tests.

Implementation of the Regulation, monitoring and control will be the responsibility of member States and their control authorities. Monitoring and control will be carried out on Community territory and therefore there was no need for the Proposal to foresee provisions for collaboration with foreign authorities/laboratories. This does not exclude technical collaboration between the European Community and foreign laboratories. The European Community has been soliciting co-operation with other countries on the development of reliable detection and identification methods.

G. STANDARDIZED TESTING METHODOLOGIES

Comment by the United States:

"*Article 44 allows each member State to establish rules for penalties on infringement. In the absence of available, accessible and standardized testing methodology, the United States is concerned that the member States, who will be responsible for enforcing the legislation, will not be able to do so consistently, raising uncertainty for operators throughout the chain.*"

Response of the European Commission:

The proposed Regulation does provide for available, accessible and standardized methods. Indeed, under the proposed Regulation, no GM food or feed will be placed on the market in the European Union without a valid authorization first being granted by the Community and no authorization will be granted by the Community unless a method for detection, including sampling and identification of the transformation event has been tested and validated by the Community reference laboratory. As indicated, these methods will form part of the authorizations granted and will be made available in the Register.