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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/7 AND G/SPS/N/EEC/150

(PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON TRACEABILITY AND LABELING OF GENETICALLY MODIFIED ORGANISMS AND TRACEABILITY OF GENETICALLY MODIFIED FOOD AND FEED – COM(2001) 182 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/7 and G/SPS/N/EEC/150

(Proposal for a Regulation of the European Parliament and of the Council on traceability and labeling of genetically modified organisms and traceability of genetically modified food and feed – (COM(2001) 182 final)

I. INTRODUCTION

The European Commission wishes to thank all WTO Members who submitted comments on the Proposal for a Regulation concerning traceability and labeling of genetically modified organisms (GMOs) and traceability of genetically modified (GM) food and feed COM(2001) 182 final as notified under either or both G/TBT/N/EEC/7 and G/SPS/N/EEC/150.

This document provides the response of the European Commission to comments submitted by WTO Members under either or both G/TBT/N/EEC/7 and G/SPS/N/EEC/150. For the sake of clarity and precision, comments have been grouped by subject matter. Extracts from comments by WTO Members are shown in italics for ease of reference, and the response 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. 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:

"*According to the EU's proposal, "Traceability is used to facilitate the withdrawal of products due to unforeseen adverse effects to human health, animal health or the environment…" Given the stated objective of the proposed regulation, it would be U.S. 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 notified Proposal will lay down a general, horizontal framework for traceability and *labeling* of genetically modified organisms and traceability of 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 it 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.

III. OBJECTIVE OF THE PROPOSAL

Comment by Australia:

"*Australia seeks an explanation of the substantive reasoning behind each of the stated objectives given for the for the two proposals. It is unclear to Australia how the EC's proposals would achieve the EC's stated objectives.*"

Comment by the United States:

"*Would the Commission please provide an explanation of how the objectives, as outlined in the proposal, are met through the specific requirements proposed? Are there any elements of the proposal that were not specifically intended to address one of the stated objectives? Without further description of the type of unforeseen effects anticipated, it is unclear how the proposed traceability and labeling measures would meet the stated objectives.*"

Response of the European Commission:

Background

The concept of traceability specifically for GMOs was introduced into European Community law for the first time in Directive 2001/18/EC (O.J. No L 106/1 of 17 April 2002) on the deliberate release of GMOs into the environment in so far as Article 4(6) requires that member States shall ensure traceability at all stages of the placing on the market of GMOs.

Regulation (EC) No 178/2002 (O.J. No. L 31/1 of 1 February 2002) laying down the general principles and requirements of food law (General Food Law), establishing the European Food Safety Authority and laying down procedures in matters of food safety provides in terms of traceability that all food and feed business operators must have systems in place to identify from whom they have received a food or feed and to whom they have sold a food or feed (one step back and one step forward).

This is due to the fact that experience has shown that the functioning of the market in food and feed can be jeopardised where it is impossible to trace food and feed. The European Community therefore deems it necessary to establish a comprehensive system of traceability of all food and feed within food and feed businesses so that targeted and accurate withdrawals can be undertaken or information given to consumers or control officials, thereby avoiding the potential for unnecessary wider disruption in the event of food safety problems.

However, traceability provisions in current European Community law governing food and feed and in the General Food Law do not specifically address traceability of products produced from GMOs.

Therefore, differences and overlap between national laws, regulations and administrative provisions concerning traceability of GMOs and food and feed products produced from GMOs may hinder the free movement of products, creating conditions of unequal and unfair competition.

A Community Regulation, taking as a base the requirements of Directive 2001/18/EC, laying down a harmonised framework for traceability of such products would, therefore, provide for legal certainty as well as a coherent and consistent approach that should contribute to the effective functioning of the internal market.

Objectives

The retroactive tracking of the movement of GMOs and food and feed produced from GMOs through the production and distribution chains will be facilitated by traceability requirements based on transmission and retention of relevant information for such products, at all stages of their placing on the market. Such a traceability "system" facilitates:

- withdrawal of products should an unforeseen risk to human health, animal health or the environment be established;

- monitoring of potential environmental effects;

- accurate labeling, including control and verification of labeling claims.

It should be clarified that the facilitation of accurate labeling is generally not linked to safety, but provides an improvement in the fairness and transparency of transactions. It will thereby facilitate the task of operators who must comply with regulatory or commercial requirements on the part of their customers, such as labeling of the final product.

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

The Proposal does not prejudice more specific requirements concerning traceability and labeling under other European Community law on such as batch or lot numbering for pre-packaged products. Existing traceability systems are based on paper or computerised documentation and analytical detection methods where appropriate. These systems should be easily capable of being adapted to deal with the additional traceability requirements concerning GMOs and GM food and feed.

Meeting the objectives

The Proposal lays down the following requirements to ensure a harmonised framework for traceability of GMOs at all stages of their placing on the market:

- Operators shall have in place systems and procedures to identify to whom and from whom products are made available (one step back and one step forward).

- Operators shall transmit specified information (see below) concerning the identity of a product in terms of the individual GMOs it contains or whether it is produced from GMOs.

- Operators shall retain specified information for a period of 5 years and make it available to competent authorities on demand.

The Proposal does not specify the means to transmit and retain this information given that existing systems to do so are already in place in many organisations.

Requirements for GMOs

The objectives for traceability of GMOs and products produced from GMOs are not identical and therefore the specified information to be transmitted and retained differs for each. This Proposal provides for the traceability of individual GMOs within a product on the basis of authorised transformation events.

Traceability to facilitate withdrawals and environmental monitoring of GMOs will, therefore, require that the specific identity of a GMO and its associated traits and characteristics can be established. This can be facilitated via a traceability system that utilises a means of unique identification for GMOs. The Proposal requires that operators shall transmit to the operator receiving products the following specified information:

- That the product contains or consists of GMOs

- A unique code(s) relating to the GMO(s) contained in the product

It is essential that the specific identity of GMOs that are to be intentionally introduced into the environment for cultivation can be established. This is because these products contain 'viable' GMOs that are capable of reproduction and dissemination. In this context, the Proposal requires that operators have to specify exactly the identity of the GMOs contained in the products and transmit this information to the operator receiving the product. Specific identity is provided for by use of unique codes assigned to individual GMOs.

The potential risk to the environment for products containing GMOs for direct use in food, feed or processing, on the other hand, is negligible or even absent as they will not be cultivated. The European Commission considers it appropriate and adequate that products, including bulk shipments, containing GMOs for food, feed and processing are accompanied by documentation stating this use with a list of unique codes for the GMOs that the product or shipment may contain.

These information requirements for the identification of individual GMOs closely align with those provided for under the Biosafety Protocol with regard to transboundary movements. The European Commission considers that this is of significant importance if a harmonised and consistent approach is to be achieved for trade with third countries, particularly where bulk shipments are concerned.

Requirements for food and feed produced from GMOs

Traceability for food and feed produced from GMOs is similarly achieved via an obligation on operators to transmit specified information that a product is produced from GMOs to the next operators in the production and distribution chain. The Proposal does not, however, require the unique code(s) assigned to GMOs to be transmitted with a produced product based on the following:

- Unforeseen environmental effects, in particular, are unlikely to arise from the placing on the market of products produced from GMOs, such as the flour produced from genetically modified maize grains, where processing results in 'non-viable' genetic material.

- The labeling requirements for GM foods do not include information concerning the transformation event of GMOs from which the product is produced.

Transmission and retention of information that a food or feed is produced from GMOs throughout the production and distribution chain would facilitate labeling of the final product for operators under the current European Community food labeling scheme. It would also provide the means for inspection and control of compliance with current labeling provisions for GM foods and reduce reliance on detection methodology.

IV. SCIENTIFIC BASIS FOR TRACEABILITY

Comment by Australia:

"*Australia is concerned that the EC's traceability proposal is not founded on a scientific basis. The traceability system proposed by the EC includes not only mechanisms for traceability of food, but also for the two more restrictive and stringent practices: identity preservation and segregation. Australia considers that traceability is a separate issue from identity preservation and segregation and has therefore addressed traceability separately. Australia already has effective provisions in place to assist recalls related to food safety and to investigate cases and outbreaks of food-borne disease. How would the EC's proposed "traceability" system for GM food/feed improve the EC's current food recall systems for non-GM foods/feed?*"

Comment by South Africa:

"*South Africa is of the opinion that a risk assessment of genetically modified organisms and food produced from them, is the most important aspect before placing the products on the market. A trace back system is an acceptable food safety system developed and used by the industry, should withdrawal of the food product be required. Should a system to trace any unforeseen risks be required for foods obtained from genetically modified organisms, the same argument and perhaps even stronger arguments could be developed for conventional food and foods that are not subject to comprehensive risk assessments.*"

Comment by the United States:

"*As the leading developer and producer of agricultural biotech products, the United States has significant interest in this proposal and its potential impact on U.S. suppliers. The United States also notes that the potential burdens imposed by the proposals would be substantial for suppliers in developing countries as well. This is particularly troublesome given it does not appear that the proposal is attempting to respond to identified risks or hazards and is being implemented on product that has already undergone a risk assessment and has been approved for use.*"

"*The U.S. continues to believe that products should be assessed for safety before release on the market. The United States understands that under Directive 90/220 and 01/18, products are not allowed on the market unless they are determined to be as safe as conventional counterparts. Unforeseen effects are not solely relegated to biotech products but are also possible for other products. The EU has acknowledged in a recent report (A Review of Reports: EC-Sponsored Research of Genetically Modified Organisms) released by DG Research that these products are as safe or even safer than conventional products. It is accordingly unclear to the U.S. why the EU would seek to impose additional traceability/monitoring requirements, and to do so only with regard to biotech products.*"

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). Canada questions the necessity of the proposed tracing and mandatory labeling requirements given that the proposed requirements will apply to biotech-derived products that have been approved for human and animal consumption, and environmental release, through well established pre-market assessments.*"

Response of the European Commission:

The European Commission notes the comments from Australia but would clearly point out that the proposed requirements do not oblige operators to engage in identity preservation and segregation systems. The need for identity preservation and segregation depends entirely on the marketplace and on consumer preferences and is not a consequence of the traceability requirements under the Proposal.

The European Commission also wishes to clarify that its own research has not concluded that GM foods are safe *per se*: it has confirmed that those GM foods and GM plants and derived products so far developed and marketed, 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's level of protection is also achieved.

The European Commission would also like to refer to its response in section III concerning objectives as explaining the rationale behind the Proposal.

The objectives of the Proposal, notably facilitating withdrawals and accurate labeling of food are generally not unfamiliar to Codex Alimentarius. According to a paper (CX/FICS 02/2 of January 2002) prepared by the Australian Secretariat of the Codex Committee on Food Import and Export Inspection and Certification Systems "traceability is closely linked with product identification and it may relate to: the origin of materials and parts, the product processing history and the distribution and the location of the product after delivery. Traceability is a recognized process in adopted Codex texts and texts under elaboration, even if the word "traceability" has not been used. In most cases it is linked to product identification and recall procedures".

In document CX/FICS 02/2, the Australian Secretariat points to a number of examples, notably the Codex General Standard for the Labeling of Pre-packaged Foods (CODEX STAN 1-1985, Rev. 1-1999) Section 4.5 Country of Origin and Section 4.6 Lot Identification.

The Lot Identification requirement was introduced more than a decade ago in the Codex Standard on Food Labeling (Section 4.6). The objective of the lot or batch numbering system is understood as meeting the need for better information on the identity of products, and is therefore a useful source of information - for example when food is the subject of dispute concerning labeling claims or constitutes a health hazard to consumers. In other words, traceability is not necessarily confined to questions of product safety.

Article 4.5 of the Codex Standard for Food Labeling provides that the country of origin of the food shall be declared if its omission would mislead or deceive the consumer. Country of origin labeling is not safety related. Origin labeling can in most cases not be verified through analytical methods, but is controlled on the basis of adequate traceability based on paper documentation.

The Codex General Guidelines for use of the term "*halal*" concerns specific process-based criteria for the use of the term "*halal*" on food. As in the case with origin labeling, the only way to control that 'halal' food delivered to the final consumer complies with the necessary requirements is through an adequate paper-based traceability system.

In summary, it is clear and recognised that traceability systems can have uses other than for the purpose of safety and in certain cases there is no scientific basis whatsoever for such requirements.

V. TRACEABILITY GUARANTEES FOOD SAFETY

Comment by Argentina:

"*It is considered that traceability "per se" guarantees food safety*".

Response by the European Commission:

The European Commission does not subscribe to the view that traceability "*per se*" guarantees food safety and nowhere in the Proposal is such a statement made. When considering the objectives for traceability, it is important to recognise that traceability is not a 'safety measure' *per se*, but when appropriately implemented can be used to 'facilitate' the application of other measures, such as product withdrawals and monitoring, as a means to ensure safety. Traceability is considered to be a useful risk management tool both by companies and by control authorities.

As explained in the section concerning objectives of the Proposal, the European Commission considers that the Proposal other than facilitating withdrawals and monitoring also facilitates accurate labeling as well as effective law enforcement and thus helps in achieving the chosen level of protection.

VI. TRACEABILITY AND MONITORING

Comment by South Africa:

"*The objective to "target(ed) monitoring of specific effects" is acceptable in cases identified in the risk assessment. This is not a valid reason to trace all foods from all genetically modified organisms.*"

Comment by Switzerland:

"*The Swiss authorities are concerned about the amount of administrative work needed to meet the requirements of the proposal COM (2001) 182 final. Switzerland is not convinced that the goal of long term-monitoring which is, according to the EU commission, supported by a traceability scheme, is realistic. It is notoriously difficult to assess effects of specific food components (e.g. table salt) on populations. As for GMO-derived products, difficulties would even be enhanced as the proposed GMO-labeling rules do not contain necessary qualitative and quantitative information to trace any potential effect back to a specific GMO. While the labeling rules consider only the fact of*

genetic modification as such, detailed information on the organism and the specific genetic modifications would be essential for an effective monitoring scheme.

"*In addition, no scientific hypothesis of a negative health effect has been presented so far for GMO-derived foodstuffs authorised after a risk assessment. However, such a hypothesis would be important as a basis for an effective monitoring programme.*

"*In this respect Switzerland favours a scheme of self control where the producer that purchases raw materials or intermediate products is responsible to ensure that legal requirements are met, especially concerning the use of authorised GM material only. Switzerland considers traceability of foodstuffs to be a good manufacturing practice (GMP) measure. The responsibility for specific measures taken in the framework of GMP should lie with the manufacturer of the foodstuff in question.*."

Comment by Canada:

"*The Traceability Regulation requires the establishment of an EC-wide system for the traceability and labeling of GM food or feed products through the production and distribution chains. The traceability requirements are aimed at facilitating "both the withdrawal of products where unforeseen adverse effects to human health, animal health or the environment are established, and the targeting of monitoring to examine potential effects, in particular, the [sic] environment*[1]

"*Canada agrees that traceability may facilitate a product's withdrawal in the event that a hazard is identified. However, risks can arise with all food products, regardless of their process and production method (e.g., bacterial contamination, accidental presence of a toxin).*

"*The Traceability Regulation also indicates that traceability is intended to assist in monitoring for long-term or unintended effects on human health or the environment. The proposal is unclear as to how the EC will accomplish this objective.*

"*The EC proposes to require post-market monitoring of GM foods "when appropriate." Canada would like to ask the EC to clarify what parameters will be used to assess the "appropriateness" of post-market monitoring for specific GM foods?*

"*Canada therefore believes that it is inappropriate to suggest that comprehensive traceability systems should be put into place to assist with measures appropriate for exceptional rather than normal circumstances. These issues are particularly important given the potentially enormous costs associated with comprehensive traceability. Particularly, the additional costs amount to discriminatory treatment as they are not borne by other like products.*"

Response of the European Commission:

The purpose of the monitoring referred to in this Proposal is to establish whether assumptions or conclusions made in the risk assessment carried out in accordance with Directive 2001/18/EC are correct and also to examine potential unforeseen effects resulting from the intentional release of GMOs into the environment. Monitoring of human health effects resulting from consumption of GM food and feed is covered by the Proposal on GM food and feed and is not addressed in the traceability Proposal.

[1] Regulation COM (2001) 128, para. 3.

According to Article 20 of Directive 2001/18/EC, post-market monitoring of GMOs is a mandatory requirement. It is foreseen that traceability will facilitate the targeting of post-market monitoring in particular with respect to the environment. Any potential effects on the environment are likely to differ according to the GMO in question and will largely depend on its inherent nature (species) and the specific genetic modification. For example, potential effects arising from transfer of genetically modified pollen to conventional crops or related wild types will, in the first instance, be dependent on pollen transfer itself. Pollen transfer is likely to be highest for genetically modified crops that are out-crossing, less for crops that are self-pollinating and absent in crops that are sterile.

Secondly, potential effects arising from the transfer of pollen will then be dependent upon the specific modification. The potential development of, for example, insect resistance to the Bt-toxin will only be linked to GMOs modified to express this specific toxin. This would not be the case for GMOs modified specifically for tolerance to herbicides, however, as these GMOs do not contain a Bt-toxin gene.

Consequently, targeted monitoring of potential environmental effects will require that the specific identity of a GMO released into the environment, with its associated traits and characteristics, can be established. This can be facilitated via a traceability system that utilises a means of unique identification for GMOs.

Post-market monitoring of GM foods is not a mandatory requirement but will be assessed on a case-by-case basis during the risk assessment carried out by the European Food Safety Authority as specified in the Proposal for a Regulation on GM food and feed. There is no requirement for mandatory post-market monitoring of genetically modified food and the traceability requirements in the Proposal are not aimed at facilitating post market monitoring of genetically modified food.

VII. TRACEABILITY OF FEED

Comment by 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).*"

Comment by the United States:

"*The United States does not believe that expanding mandatory traceability and labeling requirements to animal feed is justified nor will it enhance public health.*"

Response of the European Commission:

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

Regulation (EC) No 178/2002 also provides for traceability requirements for feed at all stages of production, processing and distribution. This is due to the fact that experience has shown that the functioning of the market in food and feed can be jeopardised where it is impossible to trace food and feed. The European Community therefore deems it necessary to establish a comprehensive system of traceability of all food and feed within food and feed businesses so that targeted and accurate withdrawals can be undertaken or information given to consumers or control officials, thereby

avoiding the potential for unnecessary wider disruption in the event of food safety problems. In accordance with this Regulation, feed business operators are required to have systems in place to identify from whom they have received a product and to whom they have sold a product.

The Proposal on traceability and labeling of GMOs and traceability of GM food and feed extends this requirement to feed that has been genetically modified.

As regards labeling of GM feed, the policy of the European Community is basically to provide the users (farmers, breeders, etc) with accurate information on the products enabling them to make a free choice. Traceability of GM feed is therefore needed to ensure labeling claims and avoid deceptive practices.

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

VIII. PRESENTATION OF THE PROPOSAL

Comment by Australia:

"*The proposal, as presented by the EC, suggests that food produced using biotechnology is inherently unsafe and therefore traceability is required. However, Australia considers that GM food should be safe before it enters the marketplace. Our system of pre-market clearances ensures that only safe food is permitted into the food supply. Australia regards current pre-market clearance processes as the best assurance that the effects on human health (including in the longer term) are addressed for foods produced using biotechnology. Moreover, based on all available scientific evidence, GM foods that have been subjected to pre-market clearances have been found to be as safe as their conventionally produced counterparts. Given these findings, why is the EC introducing a mandatory "traceability" system, which includes elements of the more stringent practices of segregation and identity preservation, for GM foods/feed, when compared with established systems used for non-GM foods/feed?*"

Comment by Argentina:

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

Response of the European Commission:

The European Commission does not agree with Australia and Argentina, and would like Australia to clarify where the Proposal suggests that food produced from biotechnology is inherently unsafe? The European Commission would like to refer to the reply concerning objectives as explaining the rationale behind the Proposal.

The Proposal does not impose segregation and identity preservation on operators who are trading in GMOs and GM foods/feed approved in the European Community. However, it remains illegal to import into the European Union GMOs or genetically modified food that have not received authorisation in accordance with current European Community law. Operators are, therefore, already obliged to ensure that unauthorised GMOs or genetically modified foods are not imported into the European Community.

IX. IMPLEMENTATION OF TRACEABILITY

1. Implementation is difficult

Comment by Argentina:

"*Some of the rules contained in the Proposals for regulations are very difficult to implement and extremely burdensome for developing countries.*"

Response of the European Commission:

The obligatory information requirements foreseen by the European Commission's Proposal are requirements that are in most cases required either under European Community law or normal commercial transactions. The only additional element is that this information will have to be transmitted to all operators in the commercial chain within the European Community.

The European Commission would also like to refer to Article 18 of the Biosafety Protocol concerning transboundary movements of living modified organisms (LMOs), which provides that:

- GMOs for intentional introduction into the environment have to be accompanied by documentation that specifies their identity and relevant traits and characteristics. This clearly requires some form of unique identification for individual GMOs.

- GMOs intended for direct use as food or feed, or for processing, shall be accompanied by documentation which clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment. A decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, shall be taken no later than two years after the date of entry into force of this Protocol

To date, more than 120 countries, many of which are developing countries, have signed up to the Biosafety Protocol and this, as a matter of course, includes the requirements of Article 18.

Work on detection and sampling methodology, including guidance from the European Commission, is described in further detail below.

The European Commission is ready to consider requests from developing countries for technical co-operation and assistance to address identified priorities and needs.

2. The proposal is not workable, enforceable and would be very costly to implement

Comment by United States:

"*The United States believes that this proposal is not workable or enforceable, would be very expensive to implement, and would not achieve the stated objectives. The proposal is not workable or enforceable because it would require products (for food, feed, or processing) containing or consisting of biotech events to be accompanied by a listing of the biotech events that they may contain along with their unique codes. Absent expensive identity preservation systems, suppliers will be forced to list all biotech events approved by the EU. The difficulty and complexities in accurately identifying*

all of the biotechnology events that could possibly be in a shipment creates enormous liability and risk for the shipper/trader."

Response by the European Commission:

The Proposal does not require operators to identify all individual events present in a shipment of GMOs intended for food, feed or processing. In fact, Article 4, paragraph 2 of the Proposal specifies that the operator is only obliged to provide a list of the unique codes for the GMOs that the shipment may contain together with a declaration that the product shall only be used as food or feed, or for processing. A system for attributing unique codes to GMOs has already been agreed by the OECD and it is foreseen that this will be accounted for in developing the system under the Proposal.

The European Commission would also like to point out that it remains illegal to import GMOs or genetically modified food into the European Union that have not received authorisation in accordance with current European Community law. Operators are, therefore, already obliged to ensure that unauthorised GMOs or genetically modified foods are not imported into the European Community.

3. The use of batch numbering systems

Comment by the United States:

"*U.S. experience shows that traceback systems for human health or food safety, and traceability systems for consumer information, lead to significantly different approaches and policy decisions. The traceback system used in the United States is part of a food safety system. The U.S. traceback system was developed largely by the private sector to recall food in response to a public health or food safety concern. In the United States, lot numbers, batch codes and/or processing plant indicators appear on virtually all processed food packages to satisfy the various business needs of food producers and for traceback purposes. Such measures are also widespread in Europe. This less burdensome and less costly system has worked effectively for years and enjoys a high level of public confidence*."

Response of the European Commission:

As pointed out in the Proposal, European Community law also includes specific requirements as regards batch or lot numbering systems. However, and as already pointed out, due to the fact that experience has shown that the functioning of the market in food and feed can be jeopardised where it is impossible to trace food and feed, the European Community deemed it necessary to establish a comprehensive system of traceability within food and feed businesses so that targeted and accurate withdrawals can be undertaken or information given to consumers or control officials, thereby avoiding the potential for unnecessary wider disruption in the event of food or feed safety problems.

The European Commission would like to point out that Article 6 paragraph 1 of the Proposal provides that in cases where European Community law provides for specific identification systems, such as lot or batch numbering, operators shall not be obliged to retain the information concerning the genetic modification as specified in Articles 4(2), 4(3) and 5(1), provided that this information and the lot or batch number is clearly marked on the package. Thus, the Proposal foresees that existing systems concerning lot and batch numbering can continue to be used.

4. Costs of traceability

Comment by Australia:

"*Australia seeks an estimate of the costs involved in developing, maintaining and enforcing the proposed system.*

"*In Australia's experience, food recalls are rarely associated with failure of pre-market safety clearances. Given this experience and assuming that current recall systems are effective, the costs involved in a mandatory traceability system for GM foods/feed would not justify the extra cost and questionable benefits to all producers and consumers. Australia notes that such a system would be particularly burdensome for developing countries.*

"*While the EC argues that 'no credible estimate' of the cost of such a system has been determined, studies have been undertaken of the potential impact of such systems. An Australian study (Genetically Modified Grains - Market implications for Australian grain growers by ABARE, August 2001) assessed that "for every 1% [increase in] grain export transaction costs above that required under normal commercial disciplines, the welfare of the world's consumers of grain products would be lowered by an estimated US$330 million a year*."

Response of the European Commission:

In the explanatory memorandum to the Proposal the European Commission stated that it is difficult to estimate the costs of introducing traceability specifically for GMOs and products produced from GMOs. This view is shared by the United States Department of Agriculture (USDA) who in a recent article stated that "estimating the magnitude of the costs of identity preservation, tracing, and labeling is complex and subject to varying assumptions" (see Agricultural Outlook/January-February 2002).

The European Commission considers that the transmission and retention of information can largely be incorporated into existing (documentary) systems for transactions and as such should not imply significant extra costs for operators and consumers. Information with respect to the supplier, customer, price, and transaction date as well as the nature, source, contents and amount of the product already accompanies the majority of transactions.

For operators supplying food derived from GMOs to the market, traceability only implies that operators must inform the next operator in the chain that the food, feed or food/feed ingredient is derived from GMOs and retain that document. This is neither particularly burdensome nor costly and it does not entail segregation.

Aggregated costs, if any, will be passed on to the consumer and the labeling of GM foods ensures that consumer demands will ultimately drive the market in the direction of their preferences also taking into account the price of the food.

Traceability and systematic labeling will promote transparency in the market place and the freedom of choice for consumers, as well as, leaving it to the market forces to decide the fate of the different products.

A non-harmonised approach resulting in the establishment of different traceability requirements in member States may hinder the free movement of products, creating conditions of unequal and unfair competition. The costs of such an approach are also difficult to estimate but would most likely result in much higher costs for all operators.

The Proposal foresees that transmission and retention of information as a means to facilitate traceability will even limit the need for sampling and testing of products to confirm their identity at every stage of the placing on the market. This would result in a reduction in the costs for companies to meet the current *labeling* criteria in European Community law particularly for retailers.

Sampling and testing would, however, still be required for verification whenever reliable documentation is not available from exporting countries and for control and inspection purposes. A degree of cost must, therefore, be considered in this respect. The Proposal foresees that the European Commission shall develop guidance on sampling and detection. This will minimise legal uncertainty and alleviate the burden in terms of testing and sampling for operators. Current experience with detection methods demonstrates that testing raw ingredients is much more simple and cost-effective than testing the final products on the supermarket shelves.

It should be emphasised that the potential costs of traceability should also be weighed against the potential costs of no traceability system. The establishment of effective traceability requirements could prevent excessive economic losses or brand damage in case an unforeseen risk to human health or the environment arises. The recent case in the United States, where a genetically modified maize variety approved only for use in animal feed entered the food chain and the subsequent need for urgent recall of products from the market, has clearly demonstrated the usefulness of a traceability system. Although voluntary traceability systems can also be useful, mandatory ones are more likely to be followed in a consistent way by all operators in the production and distribution chain, which can also be instrumental in helping prevent such problems arising in the first place, thereby avoiding potential huge costs for the companies involved and for public authorities.

5. Discrimination of processing aids

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*"

Response of the European Commission:

Enzymes, as such, are not excluded from the scope of the provisions of the Proposal.

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 law and therefore subject to the provisions of the Proposal. Processing aids (i.e. materials used during processing but not present in the finished product), including enzymes used as processing aids, are not food ingredients, i.e. they are not food under European Community law; they are therefore not subject to the provisions of the Proposal.

The European Commission would like to stress that the Proposal 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 led to 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.

6. Unique codes

Comment by the United States:

"*What is the system for the development and assignment of unique codes to "genetically modified organisms?*"

Comment by Switzerland:

"*Switzerland welcomes the proposal of the introduction of a unique identifier code system in the EU. However, the Swiss authorities would like to emphasize the importance of an internationally agreed / harmonised system, such as the one under development in the frame of OECD work.*"

Response of the European Commission:

The Proposal takes, as its point of departure, the authorised transformation events from which genetically modified organisms are developed. It is foreseen that the system will determine the alphanumeric make-up of codes to provide unique identification for these events. This will take account of ongoing work in international organisations and it is notable that the OECD has recently adopted a document detailing a format for this purpose (ENV/JM/MONO(2002)7). It is also foreseen under the system that the appropriate unique code would be provided as part of the notification or automatically prescribed as part of the consent on the basis of information provided in the notification.

7. Technical guidance on sampling

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 South Africa:

"*South Africa is of the opinion that there would be many shortcomings in a traceability system as a way to verify labeling claims as described by the EU documents COM(2001)182 and COM(2001)425. This could be even more so in the circumstances of developing countries.*"

Comment by the United States:

"*The traceability requirements may be problematic for developing countries, particularly for those importing from many sources for further processing and re-export to third countries. When will the EU provide importers with guidance on sampling and testing for bulk commodities so that they can determine the identity of the biotech events in products where this information is not available?*

"*According to Article 9.1, member States shall ensure compliance. Article 9.2 indicates the Commission will, in the future, develop technical guidance on sampling and testing to facilitate a coordinated approach for implementation. The United States is concerned with potential*

discrepancies in testing and enforcement across the Community and would welcome the opportunity to review and comment on the proposed technical guidance as it is developed."

Response of the European Commission:

According to Article 9 of the Proposal, the European Commission will provide guidance on sampling and testing prior to the application of the traceability provisions to facilitate implementation.

The Joint Research Centre of the European Commission is currently working on the development of sampling and testing methodology and has established a network of member States laboratories for this purpose. Third country laboratories, governmental organisations and competent authorities are welcome to participate in the work.

The Codex Alimentarius Task Force on Foods Derived from Modern Biotechnology has identified a number of methods for the identification or detection of genetic modification in foods and agreed to transmit these methods for the consideration of the Codex Committee on Methods of Analysis and Sampling. The European Commission would encourage all countries to engage in the work on sampling and detection.

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

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

The European Commission is ready to consider requests from developing countries for technical co-operation and assistance to address identified priorities and needs.

X. OTHER CONCERNS

1. Labeling requirements

Comment by United States:

"*The proposed regulation would impose labeling requirements on products that have already been approved for use and for which no specific handling, usage, safety, or compositional distinctions have been identified. The result of the foregoing could be a further erosion of consumer confidence in the EU's regulatory system, because the consumer is left without truly accurate information about the product.*"

Response of the European Commission:

Under current European Community law genetically modified foods have to be labelled even in cases where there are no specific handling, usage, safety, or compositional distinctions. The objective is to inform the consumer about the fact that the food or food ingredient is genetically modified.

The European Commission is not aware of any studies indicating that the current rules for providing information to the consumer about genetically modified foods has or will erode consumer confidence in the European Community's regulatory system. On the contrary, the

Eurobarometer 2000 and various other surveys throughout Europe show that European consumers are demanding clear labeling whether food contain or are produced from a GMO(s) in order to make an individual choice.

The European Commission believes that providing accurate information by labeling all food or food ingredients containing or produced from GMOs will foster confidence in the regulatory system and social acceptance of the application of biotechnology in agri-food production, and ultimately facilitates trade in such products.

2. EU food producers have shifted away from GM sources

Comment by the United States:

"*As more biotech events and products are approved and used worldwide, tracking these products through the distribution system and/or testing will become more complex, if not impossible. The result is added expense and liability risk for shipping products without any corresponding increase in consumer and environmental protection. Already, EU food processors have shifted away from foreign sources of food ingredients to meet the extremely low one percent threshold for labeling. This is only possible because the approval process in the EU is blocked and planted acreage of biotech crops is minimal.*"

Response of the European Commission:

The European Community is not the only region in the world that operates with a 1% labeling threshold for the adventitious presence of GM-material in food products. The comments by the United States indicate that other reasons than those mentioned by the United States determine business decisions of European Community food processors and other economic operators, notably market signals such as perceived consumer preferences in the European Community. If the consumer preferred GM food, business operators would not have to avoid GM sources in their products. Such business decisions and their motivation do not concern TBT issues.

3. Legal uncertainty and non-compliance costs

Comment by the United States:

"*The legal uncertainty and non-compliance risks compounded at each step of the food chain by the documentation requirements will discourage trade and increase delays and liability costs for exporters, EU importers, and processors.*"

Response of the European Commission:

According to Regulation (EC) No 178/2002 each food and feed business operator is responsible for ensuring that products comply with European Community law. In the majority of cases, operators further down the production and distribution chain may rely on documentation received from suppliers as, in the absence of reason to believe that the supplied data is false or misleading, there would be no benefit in re-testing products for compliance with European Community law concerning contaminants, additives, flavourings, pesticides etc. at each stage of the placing on the market.

The European Commission also notes that according to a recent article by USDA, "both USDA and FDA rely ultimately on documentation maintained by private firms to trace the flow of inputs into the final food products" (see Agricultural Outlook, January-February 2002, page 24).

Concerning genetically modified foods, the European Commission would like to refer to a statement by EuroCommerce, the Retail, Wholesale and International Trade Representation to the EU, 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).

European retailers continue to place products on the market and to rely on correct information from their suppliers. The traceability requirements will reduce liability risk and enhance the legal certainty for operators, notably operators at the end of the chain who are responsible for the accurate labeling of a food. The requirements also alleviate the burden of testing for operators.

4. Fraudulent claims in documentation

Comment by the United States:

"*Imposing such traceability requirements without the means for testing the veracity of documentation can lead to fraudulent practices and fuel consumer distrust in the regulatory regime. How does the EU intend to detect fraudulent claims in documentation?*"

Response of the European Commission:

All legislation can potentially lead to fraudulent practices, however fraudulent practices do not necessarily lead to distrust in regulatory regimes, but rather in the operators who commit fraud.

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

Control based on paper documentation is not new, but has existed for many years. For instance Article 4.5 of the Codex Standard for Food Labeling provides that the country of origin of the food shall be declared if its omission would mislead or deceive the consumer. Country of origin labeling claims can in most cases not be verified through analytical methods, but is verified through paper-based traceability.

According to a paper (CX/FICS 02/2 of January 2002) prepared by the Australian Secretariat of the Codex Committee on Food Import and Export Inspection and Certification Systems "the application of traceability "to ensure fair practices in the food trade" is probably most directly linked to the first of the General Principles set down in the General Standard for Labeling of Pre-packaged Foods which reads: "Pre-packaged food shall not be described or presented on any label or in any labeling in a manner that is false, misleading or is likely to create an erroneous impression regarding its character in any respect". This application is also expressed in the *Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods*, the aims of which include "to

protect consumers against deception and fraud in the market place and unsubstantiated product claims"".

In other words paper-based traceability can be and is applied to ensure fair practices in the food trade**,** to provide relevant information and to protect consumers against deception and fraud.

For instance, origin labeling and dolphin safe tuna labeling are implemented and controlled on the basis of paper-based traceability.

5. Specific concerns of the United States

Comment by the United States:

"*The U.S. is concerned that the proposal will continue to undermine the EU's efforts to establish a credible food safety regulatory regime. The proposal will weaken European consumer confidence in the safety of its food supply. The proposal does nothing to ensure food safety and it encourages fraudulent labeling claims. This outcome is not in any country's interest.*"

Response of the European Commission:

The European Commission does not agree with the United States and as previously mentioned considers that the proposed requirements will enhance transparency and safety throughout the food and feed chain, contributing also to restore users and consumers confidence in the application of gene technology in the agro-food sector. The statement by the United States does nothing to ensure or enhance the confidence of the European consumer in the safety of food and cannot be considered relevant in the context of the TBT Agreement.

6. Link to the bio-safety protocol

Comment by Australia:

"*Australia seeks clarification of Notification G/TBT/N/EEC/7, which states that the proposed regulation on traceability and labeling of GMOs would take account of the requirements of the Biosafety Protocol "as regards specification of the identity of GMOs". The detail contained in Box 6 of the Notification states that for GMOs intended for food, feed or processing (FFP), operators may transmit a declaration that the product shall be only used for FFP, "together with the identity (unique) codes of all GMOs the product may contain". Australia considers that the EC's explanation is not justified as requirements under Article 18.2 (a) have yet to be fully negotiated.*"

Response by the European Commission:

It is correct that requirements under Article 18.2 (a) concerning the specification of the identity of GMOs are under negotiation. However, this does not prevent the European Commission from proposing what information it considers should accompany transboundary movements of GMOs intended for food, feed or for processing. The European Commission maintains that its Proposal, in terms of the traceability requirements for GMOs intended for food, feed or, for processing, is consistent with Article 18.2 (a) of the Protocol.

Moreover, the European Commission continues to closely monitor developments in international fora, for example, concerning the system for unique codes as developed by the OECD, with the objective of establishing a system for unique codes in the European Community which is consistent with international agreements.

7. 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 Proposal is identical to the scope of the Novel Food Regulation, 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.

8. Linkages between the two proposals

Comment by Canada:

"*The linkages between the two proposed regulations are not clear. For example, it is unclear if the threshold for adventitious presence of approved GMOs is the same in the Traceability Regulation, as the threshold outlined in the Authorization and Labeling Regulation. In addition, although it is clear that products made "with" GM enzymes and processing aids are excluded from the scope of the Authorization and Labeling Regulation, it is not clear that these products are excluded from the scope of the Traceability Regulations.*"

Response of the Commission:

Article 6 paragraph 3 and 4 of the Proposal explicitly exempts products intended for food and feed and for processing from traceability provided the conditions and thresholds established in accordance with Articles 5, 18 and 42 of the Proposal for a Regulation on GM food and feed are met.

Nowhere is it stated that processing aids are included in the scope of the traceability Proposal, however it is clear from the scope of the Proposal that products containing GMOs are covered, which includes of course the deliberate release of processing aids containing a GMO(s).

There is a clear link between the two Proposals in so far as the traceability requirements for food and feed produced from GMOs will facilitate that such products are accurately labelled in accordance with Article 13 and 26 of the Proposal for a GM food and feed Regulation.

9. Alternative measures

Comment by Canada:

"*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 the United States:

"*What other less trade distorting options were considered? Why were these rejected?*"

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 preparation of its Proposal, the European 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 European 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. European Community law allows for "free of" *labeling* claims provided the claim is truthful and not misleading. It would be considered misleading to label a food "GMO-free" or "non-GM" if there is no corresponding GM food on the market. "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.

The European Commission would like to point out that the Proposal together with the Proposal for a Regulation on GM food and feed facilitates consumer choice and a demand driven approach.