

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
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AGENDA ITEM NO.5 b)

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD LABELLING THIRTY-THIRD SESSION KOTA KINABALU, MALAYSIA, MAY 9 – 13, 2005

#### LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING:

**Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients  
Obtained through Certain Techniques of Genetic Modification / Genetic  
Engineering : Labelling Provisions**

#### GOVERNMENT COMMENTS AT STEP 3

#### COMMENTS FROM:

ARGENTINA

BRAZIL

COSTA RICA

EUROPEAN COMMUNITY

MEXICO

INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS (IFOAM)

## **LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING:**

### **GENERAL GOVERNMENT COMMENTS:**

### **MEXICO:**

The General Standards Directorate, as contact point in Mexico for the Codex Alimentarius is grateful for the opportunity of issuing the following comments:

In addition to the specific comments that we will make to the text of Appendix VI of ALINORM 04/27/22, Mexico would like to express its general position regarding the Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods* (Draft Recommendations for Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering) and the Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering

- The policy implemented by the health authorities in Mexico, regarding the safety evaluation of foods that are or that contain genetically modified organisms (GMOs) for human consumption, has been the systematic evaluation, case by case and step by step, of the genetic events submitted by the developers, and to grant a favourable decision only when, on the basis of the scientific evidence available, the food is demonstrated to be safe.
- Mexico does not support process or production method labelling, favouring instead final product labelling based on the safety evaluation criteria approved by Codex in its July 2002 Session on General Principles, through its “Safety Principles and Guidelines for Biotechnological Products” Standard
- Mexico is in favour of labelling only when the product derived from the genetic modification is substantially different from its conventional counterpart. This means, that it will be necessary to label the product only in those cases when the GMO presents significant changes in its food composition, or its nutritional properties, or presents health risks for certain specific population groups in comparison to its conventional counterpart. In addition, the Labelling guidelines must take care that the information included in the labels be truthful, objective, clear, understandable, and useful to the consumer as well as supported by scientific and technical information.
- The agreements in other fora in which labelling and other relevant issues are being discussed will need to be considered, such as the Codex Alimentarius itself, the World Trade Organization, the Organization for Economic Cooperation and Development, and the Cartagena Biosafety Protocol.

**5b) PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING : LABELLING PROVISIONS (ALINORM 04/27/22 – APPENDIX VI)**

**GOVERNMENT COMMENTS AT STEP 3**

**ARGENTINA:**

Argentina thanks the Codex Committee on Food Labelling for the chance to comment about this document. It would also like to express its thanks for the important work done by the Chair of the Committee to allow progress in understanding this subject, in spite of which we would like to ratify and strengthen the comments we have made in previous opportunities, as well as to analyze other issues.

Argentina is not in support of dealing with the document as presented and would like to take this opportunity to present its comments.

Argentina would like to emphasize certain concepts that, given the discussions that have taken place in past years, appear not yet properly clarified.

1. When a food, of any type, is approved by the competent authorities of a country, its safety has already been fully corroborated before being placed in the market.
2. In the case of products derived from biotechnology, they are subject to strict evaluation protocols before their approval, for which purposes an exhaustive risk analysis is conducted taking into account all the stages of the food chain. Through this approach, a solid reliability support is provided through scientific knowledge, recognizing that quantifiable uncertainty limits are an inherent characteristics of data derived from scientific analysis<sup>1</sup>.
3. Historically, **non intentional effects** have always existed “potentially” when new foods or food processing techniques are introduced. These “non intentional effects” can be “harmful” or “beneficial”. Equally, conventional plant breeding also carries the possibility that non intentional effects will take place.

It should be noted once again that, in the case of products from biotechnology, these products are subjected – equally or to a higher degree than conventional products – to strict analytical controls and risk analysis along the full length of the food chain to be able to anticipate possible non intentional effects. **The presence of these effects, may they be beneficial or not, is justification for NOT approving them commercially.**

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<sup>1</sup> PRACTICAL PRINCIPLES FOR RISK ANALYSIS IN THE CODEX ALIMENTARIUS FRAMEWORK (approved by the CODEX Alimentarius Commission during its 26th Session).

4. Other issues of interest and concern are the possible relation between "*allergenic potential*" and the introduction of genetically modified organisms.

In contrast with what often takes place with conventional foods, practice indicates that, when allergenicity is determined in a product as a result of the genetic modification to which it was subjected, such product is not released in the market; therefore, such issue should not be a reason for later concerns. This is supported, as mentioned in the previous point, by extensive and strict studies made, prudently timed, before a product derived from modern biotechnology is released into the market.

In addition, the presence of allergens in a food or food ingredient has already been addressed in Section 4.2.2. of the CODEX GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS, and such standard is perfectly applicable for those foods and food ingredients that were subjected to genetic modification techniques.

5. Argentina supports labelling when it informs exclusively about the differences in the composition, nutritional value and intended use of the food in comparison to its conventional counterparts, in the manner indicated by the CODEX GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (*CODEX STAN 1-1985, Rev. 1-1991*). We consider this information to be required by consumers.

Present knowledge demonstrates that compositional changes for the same specie, within certain range, can result either from conventional crops or from crops derived from modern biotechnology.

If such information is not detailed in the label of conventional products, there is no reason either to discriminate against foods and/or food ingredients, indicating the production method in the label.

6. Argentina does not agree with the criteria that require the labelling of foods that do not present changes in composition, nutritional value or intended use but that contain, are made of, or derive from, a genetically modified organism.

This position is coherent with the fact that normally no information is given about changes that may take place as a result of modification changes not included in the definition of modern biotechnology, such as mutagenesis, somaclonal variation or protoplast fusion between sexually compatible organisms.

7. Argentina does not agree with the labelling of foods and food ingredients produced from, but that do not contain, genetically modified organisms, protein or DNA resulting from gene technology, as this is an approach that seeks the labelling of foods according to their production method, because it is impossible to verify it in the final product.

Regarding this issue, Argentina would like to remind, particularly to those Codex members which are also WHO members, what the Appeal Organism of the WTO established (case of "European Community - Measures affecting asbestos and products containing asbestos" – referred from here on as EC-Asbestos y "European Community – Commercial name of Sardines" – referred from here on as EC - Sardines). In these cases, the Appeal Organism established that there are three indispensable requisites for a disposition to be regarded as a technical regulation: that it establishes characteristics, that those characteristics are applicable to the identified or to identifiable products, and that they are compulsory in nature.

Therefore, it can be concluded that technical regulations can establish characteristics for products and production methods. However, conditions regarding production methods could only be established when the results of those methods are related to the final product. This means that if, for whatever reason, the characteristics of a specific production method are not reflected in the final product, those characteristics should not be the object of any regulations or conditions for marketing such product and, least of all, in the framework of a technical regulation compulsory for all parties.

The product characteristics must be verifiable on the product itself and, when information is transmitted through labelling to the consumer, it should be guaranteed that such information is verifiable in the final product.

8. The Technical Barriers to Trade agreement clearly stipulates that any WTO Member has the right to adopt those technical regulations it considers appropriate to pursue legitimate objectives, among which is the prevention of misleading practices and the protection of the health of consumers, under which falls the objective of providing information to consumers to satisfy their right to know.

Argentina does not question the right to know of consumers, but we consider that regulatory authorities must be responsible for the type of information offered through food labelling, to ensure it complies with the obligations established under the WTO Agreement.

Regarding this point, it is evident that, if we compare different countries or geographic regions, the interests of consumers are highly variable regarding the content of the label information, which aspects are included, which are not, its format, etc.

When addressing the need to develop this document, the Executive Committee during its 43<sup>rd</sup> Session (paragraph 29), stressed that the four Statements of Principles had to be scrupulously adhered to, and took note of the opinion that, if consumers could claim the right to know if a food had been obtained or not through biotechnological methods, this right to know was poorly defined and was variable, so it could not be used by the Codex as a key basis to adopt a decision about the appropriate labelling.

Argentina agrees with this concern expressed by the Executive Committee, and reiterates that extreme care should be exercised when working on a global standard<sup>2</sup> (considering that 171 countries are Members of the Codex) which seeks to standardize the type of information to be provided to consumers, taking into account that their demands present the above mentioned variability and, in particular, that the information it seeks to provide may be of questionable origin if it is not verifiable, and may be misleading to consumers.

We would also like to note that the Codex Alimentarius Commission, during its 24<sup>th</sup> Session (ALINORM 01/41) admitted, when making reference to the “Amendment to the Statements of Principle regarding the role of science in the decision making process of the Codex and the degree in which other factors are taken into account”, that “*some legitimate concerns expressed by the governments when establishing their national legislation, may not be generally applicable or pertinent at the international level*”; clarifying that the justification of national measures on the basis of the SPS Agreement and the TBT Agreement should not be confused with their validity at the international level. Regarding this point, it also established that “*in the Codex framework, consideration can be given only to those other*

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<sup>2</sup> Particularly taking in consideration the juridical character that national standards based on Codex have when initiating a dispute under the WTO.

*factors that can be accepted at the international level, or at the regional level when dealing with regional standards and similar texts".*

Regarding the scope of the right to know, the CODEX GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS forbids providing information that is false, deceptive or misleading or is likely to create an erroneous impression regarding the true nature of the product<sup>3</sup>.

Therefore, to label in a different way two identical or similar products, whose only difference is the production method, not even of the food but of one of its raw materials or ingredients, would be misleading to consumers, as they would perceive it as a warning about the product characteristics, qualities and even its safety.

As the goal of Codex is to promote standards that guarantee the protection of producer's health and fair trading practices, these criteria should not be underestimated in decision making.

The above mentioned reasons lead us to conclude that to offer to the consumer information of doubtful relevance may become misleading or even deceptive according to the Codex General Standard for the Labelling of Prepackaged Foods and may even stigmatize foods derived from biotechnology in spite of the fact that their safety has been extensively proven.

### **ALINORM 97/3**

#### **REPORT OF THE FORTY-THIRD SESSION OF THE EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION**

*Geneva, 4-7 June 1996*

29. In the matter of the proposal to initiate the preparation of proposed draft guidelines for the labelling of foods prepared with the aid of biotechnology, the Executive Committee stressed that the Four Statements of Principle should be closely adhered to. It noted the opinion claiming that while consumers may claim the right to know whether or not foods had been prepared by such means, it also noted that the claimed right to know was ill-defined and variable and in this respect could not be used by Codex as the primary basis of decision-making on appropriate labelling. The Executive Committee stated that there were certain elements which clearly had to be taken into account when considering the labelling of foods in relation to production processes. Foremost among these was the protection of consumers' health from any risks introduced by the production process, followed by consideration of any nutritional implications which resulted from changes to the composition of the food, by any significant technological changes in the properties of the food itself, and the prevention of deceptive trade practices. To a considerable extent such matters would have to be decided on a case-by-case basis. The Executive Committee noted that there was always the possibility of voluntary labelling.

9. Continuing with this analysis, we consider that we can not avoid making reference to the inclusion in this document of **Threshold Levels**.

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<sup>3</sup> CODEX GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS, Section 3.0 General Principles, subsection 3.1 "Prepackaged food shall not be described on any label or in any labelling or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding any aspect of its nature".

We consider, regarding this issue, that there is no science based logic to establish a fixed threshold level on a universal basis. The fact that different countries have established different levels (going from 0.9 to 5%) gives us an indication of the diversity of criteria and needs responding to different realities.

We want to stress that establishing horizontal threshold levels (for all crops, origins, etc.) is not consistent with the obligation of proportionality included in the Technical Barriers to Trade Agreement. Such Agreement indicates that: "The Members will ensure that technical regulations are not developed, adopted or implemented which have as their goal or effect the creation of unnecessary barriers to international trade. For this purpose, technical regulations will not restrict trade beyond the limits required to reach a legitimate objective, taking into account the risks that would be created if not achieved (...)" (Art. 2.2.). Regarding this point, we understand that the requisite of a general threshold would not comply with the above mentioned obligation nor would it offer the necessary flexibility to respond to the specific needs of each case.

In addition, in the respective legislations (and/or implementation documents) percentage measures (i.e. 0.9%) have been proposed without specifying the **units** of this relative content. In practice, the labs (including the European *enforcement labs*), and the food industry, assume that it means a relation of mass (grams of material derived from GMOs by specie/ grams of total material derived for the specie in question).

The **analytical methods** being used are based on the detection of the protein(s) or the nucleotide sequences associated with the genetic modification. Quantitative immunological methods measure the quantity of modified protein, while those of DNA amplification (PCR) can estimate the number of modified genomes and of total genomes in the specie. None of these measurements can be "translated" to units of mass without assuming a series of parameters that would strongly affect the results and which are impossible to know for processed products.

On the other hand, the International Food Biotechnology Council (IFCB)<sup>4</sup>, when referring to labelling issues related to nutritional aspects (changes in composition) recommends that, if a food source contributes less than 5% of the daily nutrient requirement, such a source may be considered as not significant in the diet. Equally, if the variation in the content of a nutrient derived from biotechnology is less than 5%, this can be considered as not significant. Therefore, the establishment of thresholds would be related to these two indicative parameters: *daily intake* and *% of nutrient content variation*.

In the case of nutrient content, standardized measurement methodologies for each of them are available (there are many technical as well as international and regional standards documents in existence regarding this subject) and labelling criteria can be established based on the natural variations observed.

This takes us back again to the starting point, regarding what type of information it intends to provide to the consumer, and for what purpose would it be useful to him or her.

10. Another important point that Argentina wants to stress, in relation to any claim of analytical accuracy, is the one regarding **reference materials**. Up to date, no reference material adequate for food analysis has been proposed. In the case of grains and seeds, reference materials can be prepared mixing GM and non-GM grains.

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<sup>4</sup> IFCB (1990) *Biotechnologies and Food: Assuring the safety of food produced by genetic modification*. San Diego California, International Food Biotechnology Council, Academic Press. Regul. Toxicol. Pharmacool 12(3): Part II.

Although the efforts that other international organizations (i.e.: ISO, CEN, etc.) are making to develop a set of standards to cover all the aspects of **sampling and analysis** for detecting and quantifying GMOs are well known, the fact is that, from 2000 to date, no consensual and useful documents have been obtained, nor do they seem to be achievable in the short term due to:

- a) The technical difficulties derived from detection and quantification of the GMOs (some already mentioned).
- b) The political pressures to have these standards approved.
- c) The lack of global consensus regarding the need and the scope of these standards.

Argentina is of the opinion that the use of analytical methods, internationally validated and appropriate to the threshold values, with defined measurement units, is indispensable to implement a labelling standard, which is something that has not yet been achieved.

11. We must express however our concern, as a developing country that has incorporated modern biotechnology to their crops, regarding the commercial impact of the need to label the production method of products derived for modern biotechnology.

We have recently obtained the conclusions of the FAO-SAGPYA/TCP/ARG/2903 project regarding the "EVALUATION OF THE CORN AND SOY CHAINS IN ARGENTINA AND ADJUSTMENTS REQUIRED TO MAKE SEGREGATED EXPORTS OF NON LMOs" ("*Evaluación de las Cadenas de Maíz y Soja en Argentina y Ajustes Necesarios para Efectuar Exportaciones Segregadas de No OVM*") according to what has been established in the Cartagena Protocol and the standards of the main importing countries.

From this project we can determine that, at 0.9% thresholds, separate circuits or "Exclusive Infrastructure" would be needed for the reception, internal transport, and shipment of grains. At 5% threshold levels, the circuits can be for multiple use or "Shared Infrastructure".

Regarding this issue, the total costs of investment required per million tonnes (including storage infrastructure, automatic samplers at ports, training and institutional strengthening) to comply with these requisites in Argentina would be of:

- \$7'413,000 dollars for corn and \$10'206,000 dollars for soy at a 5% threshold level, and
- \$39'742,000 dollars for corn and \$40'039,000 dollars for soy at a 0.9% threshold level.

Regarding incremental costs of segregation at a 5% threshold level:

- For soy the minimum would be \$7 to \$11 dollars per tonne and for corn \$2 and \$3 dollars per tonne.

However, if we go to the 0.9% level, costs per tonne are:

- A minimum of \$12 to 17 dollars for soy and \$7 to \$9 dollars for corn.

These conclusions give us an indication of the high costs and commercial impact of the need to segregate products derived from modern biotechnology, which have demonstrated their safety, to



implement production method labelling. In addition, in the case of the 0.9% threshold, the costs are much higher.

Finally, as we all know, those costs would be reflected in the final price of the product and, therefore, the countries depending of grain imports to cover their basic food requirements will have to pay more when closing the transaction.

12. In view of the above mentioned scientific, technical and legal justifications, Argentina considers that the document being analyzed should not advance within the Codex established procedure, as we think that minimal conditions are not present to guarantee that the information it seeks to provide the consumer would be consistent with the Codex General Labelling Principles. Furthermore, we do not support those sections of the control procedures that can not be efficiently implemented due to the lack of internationally validated methods which, rather than increasing trust in control organizations, would put in question the seriousness of their decision making.

## **BRAZIL:**

Brazil is thankful for the opportunity to forward the following comments:

3.5 [Notwithstanding Section 4.2.2.2 of the General Standard<sup>6</sup>, the presence of substances that are absent in corresponding existing food and food ingredients that could be the subject of dietary restrictions, based on religious objections or cultural practices, may be labelled. Where such labelling is used, member countries should establish criteria on how labelling decisions, based on dietary restrictions, will be decided and implemented in a manner that is fair, transparent and consistent.]

Brazil proposes:

- To renumber the section 4.2.2.2 to 4.2.3.2;
- To substitute in the text the footnote 6 by 14;
- To include in the footnote n° 14: “The Section 4.2.3.2. requires that pork fat, lard and beef fat shall always be declared by their specific names”. This sentence is part of the Spanish document.

## **[4.0 THRESHOLD LEVELS**

4.1 Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, are labeled to declare the method of production, consideration may be given to:

[Establishment of a threshold level in food and food ingredients for the presence of food and food ingredients obtained from certain techniques of genetic modification/genetic engineering, below which labelling would not apply<sup>14</sup>] and/or

Brazil proposes:

- To keep in the text the section 4.1 and the first paragraph.
- To renumber the section 4.1, the footnote 14 to 15

## **[5.0 EXEMPTIONS**

5.1. Notwithstanding the provisions of Subsection 3.1 to 3.3, consideration may be given to the exemption from labelling of specific categories (for example highly processed food ingredients, processing aids, food additives, flavours) of food and food ingredients obtained through certain techniques of genetic modification / genetic engineering.]

Brazil proposes:

- To exclude the examples of foods/ highly processed foods and to include in the text the expression: **“according to national legislation”**, like the following:

Notwithstanding the provisions of Subsection 3.1 to 3.3, consideration may be given to the exemption from labelling of specific categories (~~for example highly processed food ingredients, processing aids, food additives, flavours~~) **according to national legislation** of food and food ingredients obtained through certain techniques of genetic modification / genetic engineering].

Justification:

- Brazil understands that this section must not indicate products to be excluded. These exclusions will be established by the national legislation.

## 6.0 LABEL DECLARATIONS

6.2 In accordance with Section 6.0 and in addition to the provisions in Subsection 6.1, food labels should be meaningful to the [intended] consumer. Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labelled to declare the method of production, examples of label declaration(s) include but are not limited to:

(...) Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labelled to declare the method of production, examples of label declarations(s), **“which may be adopted in accordance to national legislation”**, include but are not limited to: (...)

Brazil suggests:

- To exclude the expression "intended".  
- To include after examples of label declarations the expression: "which may be adopted in accordance to national legislation", as indicated to follow:

Justification:

Brazil's proposal is based on the section 4.2.3.3 of the “Codex General Standard for the Labelling of Prepackaged Foods”, CODEX STAN 1-1985 (Rev. 1-1991). This section has already adopted this expression, and it has aimed to give more clarity to the item, since countries will have to adopt for the labelling the expressions that are more understandable to consumers.

## [7.0 IMPLEMENTATION

Consistent with the approach(es) adopted under Section 3, additional consideration should be given to procedures and methodologies for the identification of food and food ingredients produced using certain

techniques of genetic modification/genetic engineering and verification of label declarations. These include, but are not limited to: development of validated detection methods; establishment of verification (for example, documentation) systems; and efforts for the development of supporting capacity and infrastructure. ]

Brazil proposes to remove the square brackets from the section, keeping the Section in the document.

## **COSTA RICA:**

As a result of the 32<sup>nd</sup> Session of the Codex Committee on Food Labelling (CCFL) that took place May 2004, in Montreal, Canada, (paragraphs 79 – 93 of ALINORM 04/27/22), Costa Rica is pleased to accept the consensus achieved regarding the Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/ Genetic Engineering, when that type of products has an impact on the health of consumers and on safety; we declare there is a mandate for compulsory labelling in those cases when it has been scientifically corroborated that there are significant changes in the composition, the characteristics, the nutritional value, or the use for which the food is intended

Notwithstanding the aforesaid, our country is following with great concern and responsibility the discussions that are taking place, and the lack of consensus, regarding a directive to indicate in the label the production method of foods and ingredients obtained through certain techniques of genetic modification/genetic engineering.

Given the analysis and discussions that took place in our country regarding this project, during a national forum that took place in April 2002, Costa Rica decided to support the compulsory labelling of genetically modified foods in those cases when it has been scientifically corroborated that there are significant changes in the composition, the characteristics, the nutritional value or the use for which the food is intended making it different from their conventional counterparts, but was not in agreement with method of production labelling. In those circumstances the Labelling should indicate the composition change and not the method through which it was obtained.

Another issue of concern for our country, against accepting this type of labelling, and which is probably also a major question mark for a large number of developing countries is that, if there were no proven risks to human health, in which case we would support compulsory labelling, the implementation of this type of labelling combined with other supplementary actions to demonstrate the presence or absence of these foods and ingredients, would have an impact not only in increasing costs for producers, importers, exporters, distributors, and particularly consumers, but would also limit the increase of international marketing of our foods. These actions, regarding which we need to consider the technological and economical capacity of developing countries, could generate competitive and commercial disadvantages in comparison to other countries with better economic opportunities. In view of this possibility a clear technical barrier to food trade could be created, as costs of production and marketing are increased in our countries as we would have to label food and ingredients without any significant compositional changes and about which no potential risk to human health has yet been scientifically demonstrated. In addition, we consider that if the product has not been modified in its composition it could mislead consumers and interfere with their purchasing decisions, having an impact on the economy of countries. Regarding this point it should be clear that, when doubts exist regarding the safety of a food due to its nature, processing, etc., the way of ensuring an impact on the health of consumers is not through its

labelling but through scientific studies about it. Thus the responsibility of governments to allow the marketing of products on the basis of their own criteria, established within a food control framework.

From this point of view, we would like once more to recall the debates that have taken place in Codex about the need of a higher participation of developing and less advanced countries to allow their opinions be taken into account regarding their participation in decision making in those on issues of health protection, consumer rights, and fair trading practices in the international food trade. Note should be taken of the needs and of the implementation capacity of directives in developing countries, with the labelling of foods and food ingredients obtained through certain techniques of genetic modification to indicate the method of production creating situations that would have a profound impact in the economy of our countries for some of the above mentioned reasons.

We would like to add that, lacking scientific proof that a food derived from biotechnology presents potential risks to human health, there is no justification for the label to indicate the method of production, as conventional food production does not presently do so either, with this information not being of help to consumers in their purchasing decisions nor affecting their health nor the safety of the food.

When the product has not been modified in its composition, nutritional value, or intended use making it different from its corresponding conventional counterpart, it should not be necessary to declare it in the label as genetically modified, as in reality the product is not different from the already existing product. It could rather confuse the consumer. We reiterate that it has not been demonstrated that genetically modified products represent a risk to consumer health; therefore the product is still the same – there is no difference.

Regarding the above mentioned document, Costa Rica would like to thank the Working Group for their great information and consensus seeking efforts regarding this issue and for their valuable contributions to facilitate its discussion.

Costa Rica's position is as follows:

1. Regarding Section 1.0 SCOPE, we propose the following changes:
  - 1.1.1 when it is demonstrated **through scientific evidence**, ~~through an appropriate analysis of data~~, that the composition, nutritional value, or intended use of the food or food ingredient differ in comparison to that of corresponding conventional counterparts, having regard to accepted limits of natural<sup>22</sup>; and/or
2. Add the following to point 1.1.2: **“when they are composed of or contain a genetically modified/engineered organism or contain protein or DNA resulting from gene technology; and/or<sup>23</sup>; in those cases when the presence of genes of genetically modified foods is proven; and/or...”**
3. We propose eliminating point 1.1.3 “when they are produced from, but do not contain, genetically modified/ engineered organisms, protein or DNA resulting from gene technology”, as it would not make any sense to label foods and ingredients that do not contain, genetically modified/ engineered organisms, protein or DNA resulting from gene technology.

It is difficult for our economies to demonstrate the presence of genetically modified organisms, and this sentence could create confusion and mislead consumers by including a type of labelling for a food or ingredient that does not contain genetically modified material.

4. Costa Rica supports the inclusion of a new point as 1.1.3, as the text of the previous point is deleted, to indicate: **when they are specifically indicated in the appropriate Codex standards or in the national legislation of the countries...** Given the aforesaid, and the fact we are discussing such a controversial subject, it is necessary for countries to have clear guidance that would allow us to decide, through an appropriate national legislation, orientation, the implementation of these measures, taking into account our technical and economical capacity.
5. In paragraph 3.1 we propose eliminating the brackets and the term “differ significantly from” and to add the term “metabolizing”, to read as follows:

3.1 When food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, as defined in Section 2, are no longer equivalent to the corresponding existing food and food ingredients, regarding their:

- composition; and/or
- nutritional value; and/or
- **metabolizing**
- intended use;

The characteristics or properties which make it different from the corresponding existing food and food ingredients should be clearly identified on the label, as described in Subsection 6.1 about label declarations.

6. We propose eliminating all 3.3, as to inform the consumer through labelling of the “presence of substances with health implications” is already covered in point 3.1 of these directives and in section 4.2.2 of the General Standard for the Labelling of Prepackaged Foods.
  7. We would like to point out that, if the previous point being proposed is approved, there would be a need to renumber 3.4 regarding references to Subsections 3.1 to 3.3. On the other hand, we want to indicate we do not agree to keep point 3.4 b) as it is in contradiction to point 3.1 of the proposed draft, and also because we do not agree with the goal of the labelling foods and food ingredients obtained through certain techniques of genetic modification that do not contain genetically modified material.
  8. We agree to eliminate the brackets form point 3.5, as we believe it is the right of every country to legislate for the protection of the health of its consumers; however, to assist in clarifying the paragraph, we propose to add the following:
- 3.5 [Notwithstanding Section 4.2.2.2 of the General Standard<sup>28</sup>], the presence of substances **in foods modified through certain techniques of genetic modification but** that are absent in corresponding existing food and food ingredients that could be the subject of dietary restrictions, based on religious objections or cultural practices, may be labelled.

Where such labelling is used, member countries ~~may should~~ establish criteria on how labelling decisions, based on dietary considerations, will be decided and implemented in a manner that is fair, transparent and consistent.}

9. Eliminate Section 4.0 THRESHOLD LEVELS, as we consider that if the purpose of labelling is to provide truthful, verifiable, understandable and not misleading information relevant for the protection of consumers' health, there should not be a threshold level above which the presence or absence of foods and food ingredients obtained through certain techniques of genetic modification should be notified. Furthermore, there is still no clear evidence or scientific justification to demonstrate a minimum threshold level to consider declaring this information. Another reason for eliminating this section is that with our scientific and technological capacity, as in many developing countries, it is difficult to establish scientific criteria to determine the threshold level due to the diversity of foods and the complexity of their composition, which would allow us to determine the percentage of error that the contamination may contain. From another point of view, our country does not have the economic viability to certify the presence or absence of genetically modified organisms, due to the cost of implementing certification laboratories.
10. In point 6.1 a) we propose eliminating the brackets and the sentence **“is significantly different from”**. The same in 6.1 b).
11. In point 6.2 we propose eliminating the brackets from a) to i) if in Section 1.0 SCOPE the decision is taken to label these foods.
12. Regarding Section 7. IMPLEMENTATION, Costa Rica considers that this section is not subject to discussion to include it in a labelling document and, therefore, we suggest that it should be eliminated for this as being discussed in the Codex Committee for Analysis and Sampling Methods (CCMAS), specifically in the discussions regarding a document of Certain Criteria Regarding the Detection and Identification Methods for Foods Obtained through Biotechnology: General Approach and Criteria Regarding Methods. Regarding this point, it is not necessary to specify this issue under these Proposed Draft Guidelines and the CCMAS should provide the appropriate indications. We would also like to note that in this section some aspects related to the Traceability of products are being included, and although there is already an established definition approved by the Commission regarding this issue (paragraph 20 of the English version of ALINORM 04/27/41), the Codex Committee for Inspection and Certification Systems of Food Imports and Exports (CCFICS) was also instructed to present a new work about the Principles for the Application of Product Traceability. We suggest therefore analyzing those recommendations once the CCFICS finishes its work regarding this subject.

## EUROPEAN COMMUNITY:

The European Community is in favour of the clear identification of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering in view of transparency for the consumers and in accordance with the mandate given in 1991 to the CCFL by the Codex Alimentarius Commission (ALINORM 91/40, Para. 90).

The European Community wishes to suggest that two levels of labelling be included in the proposed guidelines, which should remain as a single document: first mandatory labelling provisions in relation to

health and consumer protection, and second optional provisions linked to the mode of production. This approach is in line with the conclusions of the Working Group which met in Calgary in October 2003.

The European Community wishes to propose the attached amended version of the draft proposed Guidelines for the Labelling of Food and Food Ingredients obtained through certain techniques of genetic modification/genetic engineering which includes the two levels of labelling in line with the format of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985, Rev.1-1991). The paragraph drafted by the Calgary Working Group is placed as an introduction to the new section on optional labelling. In addition to these amendments, a new section 3.6 has been included in order to cover foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering which do not correspond to existing foods or food ingredients (this point has been discussed in Calgary).

In addition, the European Community is of the view that from the consumers' point of view, it is important that label declarations concerning genetically modified/Genetically engineered food should be simple, easy to understand, meaningful and non-misleading. Experience shows that this often depends on regional or cultural differences and may differ from country to country. The European Community thinks that there is a need for some kind of guidance for member countries on label declarations within the document and therefore suggests amendments of the Proposed Draft Guidelines accordingly.

Alternatively to the proposed amendments, the European Community could be open to other options mentioned in the Calgary Working Group:

- Possibility to place the list of label declarations currently in subsection 6.2 in an Annex to the Draft Guidelines, which would allow different wordings according to the cultural and societal differences. As long as there is a consensus on what has to be included on the label, the way each country addresses its consumers could be in the remit of the national competence.
- Section 7 'Implementation' could be deleted as the implementation of the labelling requirements decided in the framework of the Codex Alimentarius are under the responsibility of each country.

**PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOOD AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING**

(At Step 3 of the Procedure)

**European Community suggestions of amendments****PURPOSE OF THE GUIDELINES**

To provide guidelines to ensure that the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering provides factual, verifiable, understandable and nonmisleading information to protect consumer's health and to ensure fair practices in food trade. Food labelling plays an important role in providing information to consumers and thereby facilitating consumer choice.

These guidelines set out a number of approaches and related information that could be used for the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

**1.0 SCOPE**

These guidelines recommend procedures for the **mandatory and optional** labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

1.1 These guidelines apply to the labelling of such food and food ingredients:

- 1.1.1 when it is demonstrated, through an appropriate analysis of data, that the composition, nutritional value, or intended use of the food or food ingredient differ in comparison to that of corresponding conventional counterparts, having regard to accepted limits of natural variation<sup>8</sup>; and /or
- 1.1.2 when they are composed of or contain a genetically modified / engineered organism or contain protein or DNA resulting from gene technology<sup>9</sup>; and/or
- 1.1.3 when they are produced from, but do not contain, genetically modified / engineered organisms, protein or DNA resulting from gene technology.

**2.0 DEFINITION OF TERMS<sup>10</sup>**

(At Step 7 of the Procedure)

For the purpose of these Guidelines:

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<sup>8</sup> This would include products such as oils with altered fatty acid levels, but would not include products such as those with agronomic modifications which contain recombinant DNA and/or protein but no further overall change to composition, nutritional value or intended use.

<sup>9</sup> [Gene Technology: Means a collection of techniques which are used to alter the heritable genetic material of living cell or organisms in a way that does not occur naturally by multiplication an/or recombination]

<sup>10</sup> The terminology used in this section on definitions should not determine the terminology which is appropriate for use on food labels



“Food and food ingredients obtained through certain techniques of genetic modification / genetic engineering” means food and food ingredients composed of or containing genetically modified / engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified / engineered organisms obtained through modern biotechnology.

“Organism” means any biological entity capable of replication, reproduction or of transferring genetic material.

“Genetically modified / engineered organism” means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.

“Modern biotechnology” means the application of:

- a. In vitro nucleic acid techniques<sup>11</sup>, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- b. Fusion of cells<sup>12</sup> beyond the taxonomic family,

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

### **3.0 LABELLING—PROVISIONS MANDATORY LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING**

In adopting a specific approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering the following provisions could be used:

3.1 When food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, as defined in Section 2 are [no longer equivalent to / differ significantly] from the corresponding existing food and food ingredients, as regards:

- composition; and/or
- nutritional value; and/or
- intended use;

the characteristics or properties which make it different from the corresponding existing food and food ingredients should be clearly identified on the label as described in Subsection 6.1 on label declarations.

3.2 The presence in any food or food ingredients obtained through certain techniques of genetic modification/genetic engineering of an allergen transferred from any of the products listed in Section 4.2.1.4 of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev.1-1991) shall be declared<sup>13</sup>

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<sup>11</sup> These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism such as micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion

<sup>12</sup> Fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family

<sup>13</sup> This provision was adopted at Step 8 by the Codex Alimentarius Commission at its 24rd Session (July, 2001)

3.3 [The presence of substances which may result in physiological or metabolic disorders for certain sections of the population and that are absent in corresponding existing foods[should][shall] be labelled].

~~3.4 In addition to the provisions of Subsection 3.1 to 3.3, when food and food ingredients obtained through certain techniques of genetic modification/genetic engineering as defined in Section 2, are labelled to indicate method of production, labelling declarations should apply (some examples of which are described in Subsection 6.2):~~

~~(a) When they are composed of or contain a genetically modified / engineered organism or contain protein or DNA resulting from gene technology; and/or~~

~~(b) When they are produced from, but do not contain, genetically modified /engineered organisms, protein or DNA resulting from gene technology even when they do not differ in composition, nutritional value and, intended use.~~

3.5 [Notwithstanding Section 4.2.2.2 of the General Standard<sup>6</sup>, the presence of substances that are absent in corresponding existing food and food ingredients that could be the subject of dietary restrictions, based on religious objections or cultural practices, may be labelled. Where such labelling is used, member countries should establish criteria on how labelling decisions, based on dietary restrictions, will be decided and implemented in a manner that is fair, transparent and consistent.]

~~3.6 In addition to the provisions of Subsections 3.1 to 3.5, the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering as defined in Section 2 which do not have a corresponding existing food and food ingredients shall contain appropriate information about the nature and the characteristics of the food and food ingredients concerned.~~

#### ~~[4.0 OPTIONAL LABELLING THRESHOLD LEVELS~~

~~Without prejudice to the acceptance of the approach to method of production labelling as a “legitimate concern<sup>13 bis</sup>” of governments in establishing their national legislation, the following is provided to be considered as optional labelling provisions.~~

~~4.1 In addition to the provisions of Section 3, when food and food ingredients obtained through certain techniques of genetic modification/genetic engineering as defined in Section 2, are labelled to indicate method of production, labelling declarations shall apply (some examples of which are described in Subsection 6.2):~~

~~(a) When they are composed of or contain a genetically modified / engineered organism or contain protein or DNA resulting from gene technology; and/or~~

~~(b) When they are produced from, but do not contain, genetically modified /engineered organisms, protein or DNA resulting from gene technology even when they do not differ in composition, nutritional value and, intended use.~~

4.12 Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, are labelled to declare the method of production, consideration may be given to:

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<sup>13 bis</sup> Statements of principle concerning the role of science and the extent to which other factors are taken into account in the Codex decision making process

[Establishment of a threshold level in food and food ingredients for the presence of food and food ingredients obtained from certain techniques of genetic modification/genetic engineering, below which labelling would not apply<sup>14</sup>] and/or

[Establishment of a de minimis threshold level for adventitious or accidental inclusion in food and food ingredients, of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, below which labelling would not apply]]

## **5.0 EXEMPTIONS FROM MANDATORY LABELLING REQUIREMENTS**

5.1 Notwithstanding the provisions of Subsection 3.1 to 3.3, consideration may be given to the exemption from labelling of specific categories (for example highly processed food ingredients, processing aids, food additives, flavours) of food and food ingredients obtained through certain techniques of genetic modification / genetic engineering.]

## **6.0 LABEL DECLARATIONS**

In accordance with the General Principles section of the Codex General Standard for the Labelling of Prepackaged Foods and the Codex General Guidelines on Claims, prepackaged food shall not be described on any label or in any labelling or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character or safety in any respect.

6.1 Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labelled to indicate final product characteristics, the following requirements should apply:

- (a) if the composition or nutritional value of food and food ingredients is [no longer equivalent to/ differs significantly] from the corresponding existing food and food ingredients, the label should provide, in conjunction with, or in close proximity to, the name of the food and food ingredients, such additional words or phrases as necessary to inform the consumer as to its changed composition or nutrient content in conformity with Sections 4.1 and 4.2.2 of the General Standard. In addition, nutrient declaration should be provided in conformity with the Codex Guidelines on Nutrition Labelling.
- (b) **if the food and food ingredients obtained through certain techniques of genetic modification/genetic engineering do not have a corresponding existing food and food ingredients, the label should provide, in conjunction with, or in close proximity to, the name of the food and food ingredients, such additional words or phrases as necessary to inform the consumer as to its specificity.**

(~~b~~c) if the mode of storage, preparation or cooking is [no longer equivalent to / differs significantly] from the corresponding existing food and food ingredients, clear instructions for use should be provided.

6.2 In accordance with Section 6.0 and in addition to the provisions in Subsection 6.1, food labels should be meaningful to the [intended] consumer. Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labelled to declare the method of production, ~~examples of the~~ label declaration(s) **should** include ~~but are not limited to an indication or a reference to genetic modification/genetic engineering~~. **A product will be regarded as bearing**

<sup>14</sup> Consideration of a threshold must address existing provisions of the *Codex General Standard for the Labelling of Prepackaged Foods*, e.g. Section 4.2.1.3 (Compound Ingredients)

indications referring to genetic modification/genetic engineering where in the labelling or claims, including advertising material or commercial documents, the product or its ingredients is defined by the terms “*genetically engineered*”, “*genetically modified*”, “*modern biotechnology*”, “*plant/animal biotechnology*”, “*gene technology*”, “*recombinant DNA technology*” or words of similar intent including diminutives which, in the country where the product is placed on the market, suggests to the purchaser that the product or its ingredients were obtained through certain techniques of genetic modification/genetic engineering.

Any national additional existing mandatory rules regarding GM labelling in the country where the food or food ingredients obtained through certain techniques of genetic modification/genetic engineering are placed on the market must be fulfilled.

- (a) [~~“Produced from genetically modified (naming the source)”~~] e.g. ~~“produced from genetically modified soya”~~
- (b) ~~If the ingredient is already listed as produced from the source, [“genetically engineered (naming the food)”], e.g. “genetically engineered maize flour”~~
- (c) [~~“Grown from seeds obtained through [modern] plant biotechnology”~~]
- (d) ~~If the ingredient is designated by the name of a category, [“contains (name of the ingredient) produced from genetically modified (source)”], e.g. starch (“contains starch produced from genetically modified maize”)~~
- (e) [~~“Genetically engineered (naming the characteristic) (naming the food)”~~] e.g. ~~“genetically engineered high oleic soybean oil”~~
- (f) [~~“Product of plant / animal biotechnology”~~]
- (g) [~~“Naming the food/food ingredient (genetically modified)”~~] e.g. ~~“soybean (genetically modified)”~~
- (h) [~~“Naming the food/food ingredient (genetically modified food/food ingredient (not segregated)”~~] e.g. ~~“soybean (genetically modified soybean not segregated)”~~
- (i) [~~“Product of gene technology”~~]

6.3 Where the presence of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering is declared on the label, the following would apply:

- (a) In the case of single-ingredient foods, or where there is no list of ingredients, the information should appear clearly on the label of the food; or
- (b) In the case of a food ingredient(s) in a multi-ingredient food, the information should be shown in the list of ingredients or in parentheses immediately following the ingredient(s). Alternately, the ingredient(s) may be identified by an asterisk and the required wording should appear in a statement immediately following the list of ingredients.

## [7.0 IMPLEMENTATION

Consistent with the approach(es) adopted under Section 3, additional consideration should be given to procedures and methodologies for the identification of food and food ingredients produced using certain techniques of genetic modification/genetic engineering and verification of label declarations. These include, but are not limited to: development of validated detection methods; establishment of verification (for example, documentation) systems; and efforts for the development of supporting capacity and infrastructure. ]

## **INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS (IFOAM):**

IFOAM – has already communicated at the last meeting in Canada in May 2004 - is against splitting between “method of production” labelling of GMO-derived foods derived and “health and safety related” labelling (defined as when the food is significantly different/or no longer equivalent in composition “Codex has acknowledged the legitimacy of the labelling for process and production method other than for health and safety as it has dedicated considerable efforts to the Guidelines for the production, processing, marketing and labelling of organically produced food. Consumers of organic products have emphatically spoken that no GMOs are used in the production of organic food. The CCFL organic guidelines reflect this and prohibit all use of GMOs in organic production and processing. Therefore IFOAM has the opinion that CCFL should develop labelling guidelines that are inclusive for all uses of GMO in all stages of the production of food, regardless of the final composition or other characteristics of the product. Without such labelling it will continue to be difficult to verify that GMOs have not been added within the organic food system. Furthermore, the audit and tracing systems developed to meet organic certification requirement demonstrate the feasibility of implementing similar traceability systems for GMOs through the supply chain.”

With respect to the details of Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering, IFOAM offers the following comments.

### ***1.0 Scope***

In the organic production method the process of production is as important as the result, the organic product. In the IFOAM Basic Standards the use of gmo's is forbidden. The EU regulation 2092/91 and the US National Organic Program (NOP) Standards and JAS (Japan) Organic Standards, as well as organic standards of all other nations, prohibit any use of GMOs or product thereof in the production and processing of food labelled as organic. Reflecting this, the Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods also prohibit the use and products GMOs. In order not to introduce food ingredients obtained through genetic engineering into organic products, these ingredients must be recognizable as such.

IFOAM urges the introduction of mandatory and comprehensive labelling for genetically engineered agricultural products for two main reasons:

1. A rapidly growing number of consumers throughout the world do not want to consume genetically engineered agricultural products. Mandatory and comprehensive labelling is necessary in order to secure the right of consumer choice.
2. The labelling of genetically modified/engineered food is of particular importance to producers and consumers of organic food, as well to organic inspection and certification bodies. This is because certain products from conventional agriculture or of non-agricultural origin are still permitted in organic production. In order to ensure that genetic engineering does not enter the organic production chain through such compounds, reliable and comprehensive labelling is needed.

Labelling should not be limited to those agricultural products, which contain or consist of genetically modified organisms; it should also cover agricultural products, which are produced by using genetically engineered products.

The scope of the guidelines, as articulated in the draft, fulfill the needs of producers in the organic sector, producing organic products according to regulations and guidelines from governments and Codex.

## **2.0 Definition of Terms**

IFOAM is opposed to the use of the term ‘modern biotechnology’ to explain ‘genetically modified / engineered organism’. The notion of ‘biotechnology’ refers to a lot of techniques, e.g. used for making yogurt or beer. The term ‘modern biotechnology’ suggests that it deals here with e.g. modern yogurt making, however the techniques used here are completely different, crossing natural borders. IFOAM does not see why another notion ‘modern biotechnology’ that again needs explanation is used to explain the issue concerned. In defining ‘genetically modified / engineered organisms’ the term ‘modern biotechnology’ should be deleted. The terms in use here should be recognizable not just by an elite group of government and industry representatives and lobbyists, but should be easily recognized by citizens/consumers. This latter group is much more likely to be familiar with the terms “genetically engineered” or “genetically modified” than with the term “derived from modern biotechnology.”

## **3.0 Labelling Provisions**

Organic production methods are recognized in the market by means of labelling the end product. Therefore provision 3.4 b is of great importance and we strongly support it.

## **4.0 Threshold Levels**

If a threshold level is to be established, the process approach should prevail in this, meaning that it is not about the sole presence of food and food ingredients obtained through certain techniques of genetic modification / genetic engineering, but about the adventitious or accidental inclusion in food and food ingredients of substances obtained through certain techniques of genetic modification / genetic engineering. The latter would prevent mixing of batches resulting in an end product just staying under a certain threshold level. If a threshold level is to be established, it should be a de minimis threshold level for adventitious or accidental inclusion.

## **5.0 Exemptions**

For reasons of clear consumer information, clear and transparent information for organic producers and processing and others who want to stay free from (influences of) genetic engineering, IFOAM is opposed to any exemptions for labelling of food and food ingredients obtained through certain techniques of genetic modification / genetic engineering.

**6.0 Label declarations**

Consequent to our reasoning above, we support and highly encourage the inclusion of provision 6.2 for labelling of products , as it refers to the method of production.

**7.0 Implementation**

It is IFOAM's position that the responsibility for GE gene contamination lies with the polluters. The producers and the users of GMOs must be held fully responsible for preventing the spread of the GMOs and their properties. Organic producers should not have to prove their crops are uncontaminated. The genetic industry could be forced to deliver the methods to detect their (unwanted) product.

Seen from the perspective of production method (as apposed to looking at only the end product) testing is a tool available to certification bodies to utilize in certain specified situations, such as when negligence or fraud is suspected or to assess if established safeguards are sufficient.

Main instrumentation however should be verification methods by documentation throughout the whole production chain.