# WORLD TRADE ORGANIZATION

**G/SPS/GEN/354**
4 November 2002

(02-6049)

**Committee on Sanitary and Phytosanitary Measures**

Original: Spanish


## RESPONSE FROM THE EUROPEAN COMMISSION TO COMMENTS SUBMITTED BY WTO MEMBERS UNDER G/SPS/N/EEC/149 AND 150[1]

Submission by Argentina

**Observance of the notification procedure**

Argentina points out that the text notified was that drawn up by the European Council, which does not include the modifications subsequently introduced by the European Parliament. According to the notification procedure laid down in Decision G/SPS/7/Rev.2 " … *a notification should be made when a draft with the complete text of a proposed regulation is available and when amendments can still be introduced and comments taken into account*". Accordingly, Argentina requests the European Communities to notify the latest version of the draft regulation so that it can be examined in detail.

**Without prejudice to the foregoing, Argentina poses the questions below. Naturally, it is be hoped that the replies given by the European Communities will be duly substantiated and not be confined to affirmations or denials.**

1. In its presentation, the European Communities recognize that, according to its risk assessment, genetically modified plants and products obtained therefrom authorized for marketing in the European Communities do not represent a higher risk than their conventional counterparts, in other words they have the same "level of safety".

In the light of this conclusion, what would be the justification for setting up a different regime for the approval, labelling and traceability of this type of product in comparison with its conventional counterparts? Do the European Communities consider that the different treatment of GMO products and their conventional counterparts is consistent with the obligation laid down in Article 5.5 of the SPS Agreement?

Following the results obtained from the risk analysis of authorized events and foods, is the obligation to "communicate the risk" reflected in these results?

Could informing the customer that a food has been modified result in partial information that could have a negative impact on consumer decisions? In this connection, should the information given not include a mention of the positive aspects of the type of food (lesser impact effect on the environment caused pesticides, reduction in the type and quantities of certain pesticides in the final product, naturally fortified food, same risk as the conventional product, etc.).

[1] G/SPS/GEN/337 and 338.

2. Why do the European Communities want labelling according to method of production rather than labelling showing the characteristics of the final product? In particular, what are the reasons for which the objectives pursued could not be reached on the basis of a declaration of the characteristics of the final product?

3. Argentina considers that, when authorizing the marketing of a food, whether or not genetically modified, the only parameters to be taken into account should be technical or scientific parameters concerning its safety. The "*should not mislead the consumer"* requirement/objective is observed if the labelling shows the specific characteristics of the final product.

4. The European Communities have replied that processing aids (i.e. materials used during processing but not present in the finished product), including enzymes used as such, are not food ingredients, in other words they are not foods according to the European Communities' legislation. Could the European Communities explain in practical terms what is the difference between a gene introduced into an event, which is not present in the final product, and processing aids (including enzymes) which are not present in the final product either?

5. Argentina considers that risk assessment is a prior and separate procedure to risk management. Nevertheless , the latter should be based on the former so as to prevent discretionary practices and ensure that the final measure is based on science. How do the European Communities interpret this obligation, in other words, how do the decision-making bodies (agencies) take into account the scientific assessment of risk?

6. In connection with the United States question on the procedures for granting or refusing an authorization, a modification, suspension or revocation of an authorization, or refusal to renew an authorization, the European Communities replied that these were the preserve of the European Communities and member States did not have authority to take national measures restricting the marketing of products for reasons of food or feed safety.

Argentina would like to know whether there are reasons other than "reasons of food or feed safety" that authorize member States to adopt national measures restricting the marketing of products covered by this draft text.

7. In the case of medicines prepared on the basis of modern biotechnology methods, does the label also inform the consumer of the production method for the raw material used? If this is not the case, how do the European Communities achieve the objective of "informing the consumer" in this case?

8. In several parts of the draft text notified it is mentioned, *inter alia*, that genetically modified food "should not present any risk to human health or the environment". As a result of the doubts expressed by several countries to the effect that such a level of security is absolutely unattainable for every type of food, the European Communities undertook to modify the text. Could the European Communities explain how the text was adjusted to these requirements so that it does not constitute discrimination against genetically modified foods in comparison with conventional foods?

9. Article 2.2 of the SPS Agreement clearly establishes the obligation to base sanitary and phytosanitary measures on sufficient scientific evidence. In this connection, various reports of the Appellate Body have recognized the close relationship between this Article and the obligation to base measures on a risk assessment.

What are the reasons for which the adoption of decisions based on so-called "other factors" are not incompatible with the aforementioned Articles of the SPS Agreement?

Could the European Communities identify what other factors are to be taken into account in risk analysis?

Do these factors differ in number and weight from those considered in the risk analysis for a conventional food?

Are the other legitimate factors taken into account by the European Communities at the risk analysis stage different from those considered for the authorization?

Could the European Communities state whether the "other legitimate factors" it is intended to take into account in the risk analysis are in conformity with Article 5.2 of the SPS Agreement?

10. On several occasions, the European Communities mention that there is "solid evidence" that the labelling requirements have been drawn up in response to the concern/needs of consumers. What do the European Communities mean by solid evidence and on what studies is this based, how is the European Commission's action in response to such concerns regulated or implemented?

11. What are the reasons for which it is considered that the various labelling requirements for genetically modified foods and their conventional counterparts would not violate the principle of not being more trade-restrictive than required (Article 5.6 of the SPS Agreement)?

12. If it is the European Communities' view that it would not be necessary to implement a system of segregation and separate identity in order to comply with the draft regulations on labelling and traceability, what are the differences between the mechanisms proposed in the draft regulations and segregation and separate identity systems?

13. What alternatives to traceability were considered and why were they rejected?

14. Bearing in mind that the European Communities have recognized that the genetically modified foods authorized have shown that they have the same level of safety as their conventional counterparts, on what basis has post-market monitoring been established? What effects on human health is it expected to find when a food has been approved for consumption by the Community authorities? If the objective pursued through post-market monitoring is to verify that the conclusions reached in the risk analysis are still valid, should the monitoring not then come within the mandatory scope of competence of community health authorities?

15. Could the European Communities give examples of cases in which it has been established that post-market monitoring of conventional foods that had been fortified had to be carried out? Who is responsible for such monitoring and what results that differed from those in the risk analysis of the product were reached?

16. Has the environmental monitoring envisaged by the European Communities also been adopted in the case of events that have occurred using techniques for obtaining seeds other than recombinant DNA?

17. The European Communities have indicated that the ethical and religious considerations to be taken into account in labelling are specially intended to cover, for example, a situation in which the gene of a bovine animal or a pig has been transferred to another animal species, because this could raise concerns on the part of those belonging to certain religions.

In the case of methods which use animal albumin to clarify wines, is this information given to consumers on the labels?

18. In response to Argentina's question regarding the cost of the system which the European Communities intend to implement, it was stated that the requirements are the same as those in Article 18(2)(a) of the Cartagena Protocol.

Firstly, Argentina wishes to point out that this Protocol has not yet entered into force, and the labelling and traceability requirements in the European Communities' draft text greatly exceed the requirements laid down in the aforementioned Article of the Protocol.

How did the European Communities take into account the special needs of developing countries when drawing up this draft regulation (Article 10.1 of the SPS Agreement)?

19. When do the European Communities think that the Unique Code system will be implemented?

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