

*EUROPEAN COMMUNITIES – MEASURES
AFFECTING THE APPROVAL AND
MARKETING OF BIOTECH PRODUCTS*

(WT/DS291/292/293)

Second Oral Statement of the
Argentine Republic
(First Part)

Geneva, 21-22 February, 2005

I.- INTRODUCTION

Mr. Chairman, Argentina thanks for the opportunity to address the Panel on the issues arising from the Experts' Meetings, as well as those derived from the Rebuttal and the Supplementary Rebuttals exchanged among the Parties.

Following the Panel's request, we separated our Oral Statement in two parts. However, this Introduction -put before our comments on the expert meeting- refers to the full dispute (that is scientific and legal issues), since at this stage there is a link between them.

This case appears as a complex one, and the EC worked hard trying to paper over the real situation behind the complaining parties claims. In this scenario, the Expert Meeting has helped in refocusing in the real issue, that is, the complete lack of scientific evidence supporting the EC measures.

In this sense we recall that Argentina did not request for expert advice in the case. In our view, the case is a legal one that may be adjudicated on its merits. However, we thank the EC for its request for advice, which turned out to confirm our view.

This point will be further developed in our presentation; however, we believe that it is useful to sum it up at this stage:

- The EC argued, in spite of the positive assessment of the relevant Scientific Committees that there was new "scientific information" justifying the complete stall of approvals (this new information would be provided to the Panel and would require the experts' assessment)
- The appointed experts analyzed the EC "new scientific information" in order to clarify, first whether it qualified as "scientific" information, and second, if it amounts to be construed as scientific "evidence" to justify the measures.

After written exchanges and comments on the experts' opinions, and after two days of experts' hearings, two general conclusions have arisen.

First, the documents submitted by the EC are just information which does not amount to scientific evidence -justifying the *moratorium*-

Second, the alleged "scientific uncertainty" has not been proved by the EC.

Mr. Chairman, two legal consequences arise from the above mentioned conclusion:

First, the moratorium and the stalling of approval of specific products of interest of Argentina infringe Article 5.1 of the SPS Agreement. Why? In brief, because the information provided by the EC does not constitute a risk assessment for the purpose of Article 5.1. Consequently, the delay is clearly “undue” infringing also Article 8, and additionally Annex C:1 of the SPS Agreement.

Second, neither the “de facto” *moratorium* nor the Member States bans may get justification under Article 5.7 of the SPS Agreement. Why? Because there is no scientific uncertainty, and the scientific evidence embodied in the favorable opinions issued by the European Scientific Committees remain valid. The requirement of Article 5.7 i.e.: “*relevant scientific evidence is insufficient*” is not met. In other words, if the scientific evidence is sufficient then Article 5.7 may not be used as a defense.

Moreover, the exercise with experts confirms what the EC has posited insistently in this case: the need to analyze the “de facto” moratorium and the measures affecting the specific products in a “case-by-case” basis. Why? Because the assessment of risks must be performed on a “case-by-case” basis. This sound logic was supported unanimously by the experts’ opinions; in light of this there is no scientific basis for a general suspension of the approval of biotech products. Equally, on a “case-by-case” basis, there is no support for the suspension of the approval of the specific products of interest of Argentina. This is the case for RRC1445 cotton, Bt531 cotton, NK603 maize and GA21 maize, which have been stalled or banned in spite of the positive risk assessment performed by relevant EC Scientific Committees. We will come back on this specific point with further details later.

In other words the Panel may benefit from the uncontested experts’ conclusion on the need of a “case-by-case” approach, which is not compatible with the general approach of a “de facto” moratorium.

Now I will turn specifically to my colleagues to develop in detail our presentation, addressing:

- Comments on the expert’s meeting (17-18 February)

- Related to the point of “Additional information”, this will be mentioned briefly at the end of the presentation

At a later stage, in a second intervention following Panel instructions, we will address the Written Rebuttals and the Supplementary Written Rebuttals related to:

- The “de facto” moratorium

- The “suspension and failure to consider individual applications for specific products of particular interest to Argentina”

- The “undue delay”
- The Member State bans

II.- COMMENTS ON THE EXPERT MEETING (17-18 FEBRUARY)

Mr. Chairman, the conclusions of the expert’s meetings inform all the claims put forward by the complainants. Upon the Panel’s request, Argentina has decided to address this issue first, without prejudice to making reference to the concepts linked to the legal consequence in any of the other specific claims.

Although Argentina appreciates the efforts and dedication by all the experts, we respectfully remind the Panel that we did not request this technical advice to be necessary for this case. As stated before, Argentina considers that this WTO case is of a legal nature, rather than of a scientific one.

Nevertheless, after the meetings from last Thursday 17 and Friday 18 February, we consider the following issues to be relevant for the present case:

1.- Mere information vs. scientific evidence

a.- The relevance of scientific evidence

In the current dispute, the EC has made every effort to submit more and more information, regardless of the fact whether it was relevant or not. The EC imposed the complainants and the experts the task of handling this information, sorting out what might be scientifically relevant from what was not. This led to a hard work that only confirmed that our initially submitted scientific evidence remained unrefuted.

Argentina recalls the Panel’s follow-up question 4¹, related to the distinction between what regulators “need to know” vs. what is “nice to know”, as Dr. Snow had correctly pointed out in her responses². When answering this follow-up Question 4, Dr. Squire correctly asserted that

*“If we get what we need to know, we are there”*³

¹ Follow-up Question 4 from the Panel to Experts, dated 17 February 2005, referring to “General questions”, “Safeguard measures” and “Comparison of biotech products to other type of products” (“*Dr. Snow commented that it is not always clear where to make the distinction between what regulators «need to know» vs. what is «nice to know».* (...)”)

² Dr. Allison Snow “Responses to Scientific Questions from the Panel”, “B. Scientific uncertainty during 1998-2003”, second paragraph; 5 January 2005.

³ Response by Dr. Squire to Follow-up Question 4 from the Panel, on Friday 18 February 2005.

... thus confirming the importance of identifying the necessary scientific evidence in order to make a decision.

In this respect, we believe the point has been made that not any kind of additional scientific information (regardless from its possible value for other fields) is capable of refuting solid scientific evidence. Moreover, the EC has not been able to refute any of the evidence submitted by Argentina. Our country submitted scientific evidence (arising from the EC's own Scientific Committees, by the way), while the EC submitted a huge amount of information, but not evidence capable of matching the evidence submitted by Argentina. In short, Argentina relied on the scientific evidence arising from the EC itself, with the conviction that this evidence is the one to be relevant for the EC and within the EC, since it was issued by the EC, while the EC tried to dismiss the opinions of its own Scientific Committees with mere information.

b.- Scientific evidence and hypothetical statements

This issue is closely linked to the previous one. Although Argentina sincerely appreciates the responses submitted initially by Dr. Andow, we appreciate even more the fact that he clarified his initially ambiguous answers, during the meetings of experts.

Specifically, we appreciate the clarifications referred to his use of hypothetical statements⁴. Although Argentina recognizes the value that these hypothetical statements may have in other fields, we believe that -regarding this WTO case and the existence of scientific evidence to be matched- the clarification proved to be very useful in order to make our points, that is, that there is actually no scientific evidence that can justify the EC measures towards agricultural biotech products since October 1998.

In this sense, Argentina highlights the important answer by Dr. Andow in the sense that he certainly agrees⁵ with the following statement made by Argentina

“The absence of information does not imply the presence of effects”⁶

⁴ When answering the Questions from Argentina referring to “General questions”, “Safeguard measures” and “Comparison of biotech products to other type of products” on Thursday 17 February, Dr. Andow explained that, when making his responses to the Questions from the Panel, he had taken the task “not to weigh the evidence, but to say whether it existed”.

⁵ Dr. Andow answered to this statement by Argentina submitted in Question 13 (advanced as question 10, referring to “General questions”, “Safeguard measures” and “Comparison of biotech products to other type of products”), with the words: “*Certainly. I agree.*”

⁶ Response by Dr. Andow to Question 13 from Argentina (advanced as question 10, referring to “General questions”, “Safeguard measures” and “Comparison of biotech products to other type of products”), in connection with Dr. Andow's paragraph 07.06 in his Response to Questions by the Panel.

We believe that the EC has had more than enough scientific evidence at hand (namely, the positive scientific opinions from its Scientific Committees) in order to take a valid sanitary or phytosanitary measure and approve the agricultural biotech products, but instead of that, the EC has tried to ignore this evidence in this WTO case with a huge amount of information, collected through several publications and extracted from opinions, supposed to refute solid evidence with “uncertainties”.

The EC has insofar ignored scientific evidence, and relied only on publications which address to “scientific uncertainties” but which nowhere refute consistently the scientific evidence presented by Argentina. We are fully aware that scientific uncertainties may have value in other fields, but given the present WTO case, a WTO Member cannot ignore scientific evidence simply referring to “scientific uncertainties” (which at least always will remain because science cannot provide complete assurances), or simply “hypothetical or theoretical” risks (which are unacceptable in the WTO rules, as observed by the Appellate Body)⁷.

As the experts correctly pointed out, there will always be a degree of new scientific findings that will complete or refine the previous knowledge. But this gap of knowledge cannot be used as an excuse for ignoring scientific evidence and applying a sanitary or phytosanitary measure without any supporting scientific evidence.

As examples, Argentina welcomes that, during the meetings of experts, two important matters have been finally clarified for us all, disregarding the EC’s arguments:

On one hand, we solved the alleged problem of the possibility of horizontal gene transfer. In this regard, we thank the clarification made by Dr. Squire, which confirmed Argentina’s point⁸. Being so, we cannot accept the EC assertion⁹ as a valid scientific statement.

On the other, we appreciate that the experts did confirm that, compared to the impact of agricultural practice, the known impact of agricultural biotech products is marginal. In this sense, Argentina highlights the fact that even the EC had to finally admit this¹⁰.

⁷ First Written Submission of the Argentine Republic, dated 21 April 2004, paragraph 93.

⁸ Question 32 from Argentina to Dr. Squire, dated 18 February 2005, referring to “Product Specific Questions”. In his response, Dr. Squire stated: “*The issue of unlikely refers to the frequency... considering frequency, it is extremely low, time-dependant... whether evolution or agricultural practice is uncertain... There are studies in place... I am not qualified... In general, I agree with the tone of this question.*”

⁹ See Comments by the European Communities on the Scientific and Technical Advice to the Panel, 28 January 2005, paragraph 95, in which the EC refers to “*circumstantial evidence... during evolution and confirms the likelihood of the scenario.*” Besides, the EC immediately says “*However, in terms of risk analysis, the risk has not been properly quantified and is probably very low.*”

c.- The excuse of waiting for more information to appear

Another issue Argentina is satisfied with is that it has been made clear that there is no sense in neither approving nor rejecting the approval of agricultural biotech products, just because the EC claims that it is waiting for new information to appear, for new technologies to develop, or for new methods and techniques to be discovered, when there is solid scientific evidence at hand, arisen from the EC's own Scientific Committees, and favoring approvals.

Argentina has (just as the Panel, Canada and the United States, and the experts also have) carefully read the information submitted by the EC, and has found no matching evidence that could refute the positive scientific opinions by the EC Scientific Committees. The EC has maintained an attitude of neither approving nor rejecting any new agricultural biotech product since October 1998, and the EC has certainly demonstrated that it has done so not because of a valid scientific reason, but for the alleged need of changing its legislation, or the need of a new legislation of traceability and labeling, or finishing the legislation of coexistence of biotech and "non-biotech" products¹¹, or even waiting for never appearing "negative" evidence. The alleged "uncertainties" or "hypothetical risks" (which the EC intends to use as a possible scientific excuse), do not refute the scientific evidence, and thus cannot justify what the EC did towards its WTO obligations.

Furthermore, Argentina points out the fact that since the EC stopped the approvals of agricultural biotech products, the EC did not mention any scientific reason for its measures, but tried to justify these measures at that time on the alleged need of changing its legislation¹².

Argentina states that the EC did not submit valid scientific evidence for not approving or rejecting agricultural biotech products since 1998. Additionally, the EC has tried to shift the burden of proof on the shoulders of the Panel and of the experts, in order to find the scientific evidence within the information.

d.- The twisted view of the biotechnology – Relevance of science

¹⁰ Comments by the European Communities on the Scientific and Technical Advice to the Panel, 28 January 2005, paragraph 238.

¹¹ See First Written Submission of the Argentine Republic, dated 21 April 2004, paragraphs 30-31. See also Written Rebuttal of the Republic of Argentina, dated 19 July 2004, title II.A.4 "The EC implements and maintains a «de facto» moratorium". In the same sense, see Supplementary Rebuttal of the Republic of Argentina, dated 15 November 2004, title II.A.1 "Introduction. The existence of the «de facto» moratorium."

¹² Ibid.

In this regard, Argentina also welcomes the appropriate clarifications by the experts in their responses and during the meetings, for example the use of the concept “contamination” (which should not be intended to be understood as negative, but in the same neutral sense as the concept “adventitious presence”).

The malicious use of terms, when referring to agricultural biotech products, has distorted the view in which these products are considered and the way in which they should be treated.

Particularly, we would appreciate if the EC would restrain itself from using concepts like, “cancer”¹³, “may induce dramatic unintended changes”¹⁴, “infestation ... to cause contamination”¹⁵, or others, which are truly misleading and intended to frighten instead of convincing.

The Experts’ conclusion is contrary to EC assumption that all agricultural biotech products should be treated as a whole (“in baskets”, as Argentina proved previously¹⁶), regardless from the “case-by-case” analysis which Argentina firmly believes should be strictly applied for deciding upon approvals or rejections of agricultural biotech products. The EC has continuously invoked this approach as well, but it actually does not apply it since October 1998. Even at these later stages of this WTO proceeding, the EC states that agricultural biotech products deserve to be considered as a whole¹⁷, in spite of the fact that some of them received a positive scientific opinion within the EC.

In this sense, we quote Dr. Snow:

“... Furthermore, it is not logical to group all GM crops into a single category and conclude that they are either inherently safe or inherently dangerous (see

¹³ Ibid.

¹⁴ Comments by the European Communities on the Scientific and Technical Advice to the Panel, 28 January 2005, paragraph 55.

¹⁵ Comments by the European Communities on the Scientific and Technical Advice to the Panel, 28 January 2005, paragraph 191.

¹⁶ See Written Rebuttal of the Republic of Argentina, dated 19 July 2004, title II.A. “The «de facto» moratorium”, especially paragraphs 52 and 54. In the same sense, see Supplementary Rebuttal of the Republic of Argentina, dated 15 November 2004, title II.A “The «de facto» moratorium”, especially paragraphs 17, 19 and 24, and title II.B “The suspension and failure to consider individual applications for specific products of particular interest of Argentina”, especially paragraph 59.

¹⁷ Comments by the European Communities on the Scientific and Technical Advice to the Panel, 28 January 2005, paragraph 45, last sentence, in which the EC refers to the products in general (not “case-by-case”), regarding possible effects on human health.

*Question 103 below). It is important to evaluate new GM crops on a case-by-case basis in each country where the crop will be grown, ...*¹⁸

This quotation led to the response to Panel question 103 by Dr. Snow, which was also raised by Argentina in the meetings with the experts and made an important clarification towards the proper treatment of agricultural biotech products as compared to the “conventional” agricultural products.

2.- Agricultural biotech products and “non-biotech” products

Considering the food safety assessment, it has been proved continuously and to the end that agricultural biotech products with a positive scientific opinion by the EC Scientific Committees have shown no differences with their “non-biotech” counterparts. Dr. Nutti has been very clear in this matter and has always remained within her field of expertise and referring to the Codex guidelines. However, we also recall the point made clear on Friday 18th February, regarding the feed safety, in the sense that the given products -crops- proven to be safe for humans, are expected to be safe for animals as well.

Considering the no lesser important environmental issue, Argentina had the three experts on this matter -Dr. Andow, Dr. Snow and Dr. Squire- to confront their opinions¹⁹, and the result was that they agreed in two decisive statements.

Both Dr. Snow²⁰ and Dr. Andow²¹ agreed with the following statement by Dr. Squire, when referring to whether “contamination” risk is greater than for non-GM varieties:

“... there is no reason to suppose that biotech crops confer different degrees of impurity compared with crops produced from, say, induced mutagenesis”²²

¹⁸ Dr. Allison Snow “Responses to Scientific Questions from the Panel”, “A. Which environmental concerns about GM crops are really «science-based»”, second paragraph; 5 January 2005.

¹⁹ Questions from Argentina to Experts, dated 17 February 2005, referring to “Comparison of biotech products to other type of products”.

²⁰ When asked to clarify by Dr. Snow, Dr. Squire stated “A lot of crops have impurities; some can be ignored, some can be managed.” Consequently, Dr. Snow answered: “Being so, I agree, because it is related to gene flow, and that is common to GMOs and to non-GMOs.”

²¹ After the answer of Dr. Snow, Dr. Andow replied: “If it refers to gene flow, I agree. It will depend on the goal, on the impurity management.”

²² Dr. Squire “Measures affecting the approval and marketing of biotech products”, “Notes on ecological and environmental standards”, Issue 3, response to Panel Question 103.

Additionally, both Dr. Squire²³ and Dr. Andow²⁴ did agree with the following statement of Dr. Snow, when referring to whether any of the biotech products at issue in this dispute poses a substantially greater risk as regards the direct or indirect consequences of unintentional “contamination”:

*“Another way to answer this question is to focus on the characteristics of biotech crops -their phenotypes- rather than the mere presence of transgenes. This is more appropriate if the goal is to avoid direct or indirect harms to human, plant or animal health, or the environment. (...)”*²⁵

Argentina observes as well that Dr. Andow agreed with two important statements by Dr. Snow, used by the Panel to put follow-up questions 6 and 7 to the experts:

On one hand, Dr. Andow did agree when he was asked

*“Dr. Snow indicated that the process of inserting genes can have unintended consequences such as abnormal growth or development, but it is unlikely that these effects will be ecologically significant in commercially-produced biotech crops or that they would be more risky than the types of side-effects that arise routinely from conventional breeding”.*²⁶

On the other hand, he did also agree when asked

*“Dr. Snow stated that there is no reason to expect different effects on the genetic diversity of wild relatives to arise from the gene flow from biotech as compared to non-biotech crops.”*²⁷

²³ Dr. Squire answered: *“In the context of this question, I agree. In Europe, maybe the presence is not wanted, although there is no effect.”*

²⁴ Dr. Andow responded: *“I agree.”*

²⁵ Dr. Allison Snow “Responses to Scientific Questions from the Panel”, “Comparable novel non-biotech products (such as plant products produced by selective breeding, cross-breeding and induced mutagenesis), answer 103, second paragraph; 5 January 2005.

²⁶ Follow-up Question 6 from the Panel to Experts, dated 17 February 2005, referring to “General questions”, “Safeguard measures” and “Comparison of biotech products to other type of products”. Dr. Andow answered: *“I would agree.”*

²⁷ Follow-up Question 7 from the Panel to Experts, dated 17 February 2005, referring to “General questions”, “Safeguard measures” and “Comparison of biotech products to other type of products”. Dr. Andow answered: *“I would agree. There is no sense in «biotech vs. non-biotech».”*

This said, we consider that it has been confirmed by the experts that agricultural biotech products with a positive scientific opinion by the EC Scientific Committees do not require a different treatment from the “non-biotech” products, as regards the food and feed safety issue and from the environmental point of view.

III.- CONCLUSION

Mr. Chairman, in concluding this section we would like to sum up the main conclusions advanced by the Argentina in the Introduction, that we believe have been fully confirmed by the Experts’ Meeting.

First, the fact that-as we advance during this proceedings- the amount of documents submitted by the EC were just information which is far away from being considered as scientific evidence allowing the EC to impose and maintain the “de facto” moratorium.

Second, and related with the defence alleged by the EC, the relevance of scientific uncertainty should be discarded after the Experts’ Meetings.

Finally, in the light of the Panel request contained in letter dated 7 February 2005, Argentina believes that there is no more evidence needed to be submitted in these proceeding, particularly after the outcome of the expert meeting. Putting it in a different way, the scientific evidence submitted by Argentina -the EC Scientific Committees positive opinions- was no matched by the mere information presented by the EC. This is without prejudice of the date of 25 February to respond to the comments of the EC of 31 January.

We hope all these elements would be taken into account by the panel in their assessment of the factual elements of the case.