

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

(WT/DS291/292/293)

Second Oral Statement of the
Argentine Republic
(Second Part)

Geneva, 21-22 February, 2005

III.- THE “DE FACTO” MORATORIUM MEASURE

III.1.- The measure addressed in these proceedings

Referring to the “de facto” moratorium, which is the lack of any approvals or rejections of any new agricultural biotech product since 1998, the EC has failed to approve a single application until 2004. Even at the moment of these approvals, the EC has recognized the existence of the “de facto” moratorium¹, which has taken place outside the timeframe of the terms of reference of this Panel.

Faced with this lack of approvals or rejections, the EC has limited itself to deny the existence of the “de facto” moratorium or, alternatively, to assert that if such a measure exists it would not be challengeable under WTO Agreements. Argentina has demonstrated throughout these proceedings that both assertions have no basis. The EC starts from the premise that the complainants have been “unable to identify an instrument or other text”² by which the “de facto” moratorium was established, and that the claims of the complainants “are all in reality complaints about delay.”³ This line of argument also gives rise to the EC’s attempt to divert the Panel’s attention toward what it calls issues “of procedure”, while avoiding the substantive issues: the “de facto” moratorium and the lack of scientific evidence supporting this measure.

The existence of the “de facto” moratorium has been recognized by high EC officials with jurisdiction over the matter addressed in this dispute in a number of opportunities, and this evidence was put before the Panel⁴. Hence, Argentina will not repeat references to this striking evidence.

As Argentina has already indicated, these acknowledgements of the “de facto” moratorium do not constitute “de facto” moratorium “per se” or the instrument establishing it, but rather are provided as facts demonstrating the existence of the measure⁵.

The characteristics of the measure “de facto” moratorium have also been explained before⁶ by indicating its features: it has been imposed “de facto”. It was not applied on the traditional modes in which WTO Members manifest their decisions (laws, decrees, regulations, etc).

¹ Written Rebuttal of the Republic of Argentina, dated 19 July 2004, paragraph 16.

² First Written Submission of the EC, paragraph 373.

³ First Written Submission of the EC, paragraph 373.

⁴ First Written Submission of the Argentine Republic, dated 21 April 2004, paragraphs 26, 42, 52, 120 (among others).

⁵ First oral presentation of Argentina, paragraph 18.

⁶ First Written Submission of the Argentine Republic, dated 21 April 2004, paragraph 34.

The “de facto” moratorium consists in a persistent conduct of the EC that reflects a practice. This pattern of conduct is a compound of acts and omissions that have as effect the stalling of all applications in the EC approval system. The “de facto” moratorium operates at the crucial stages of the procedures under EC regulations⁷.

As Argentina has indicated⁸, although some applications have moved within the approval procedures, this movement in no case has resulted in approval or rejection. This fact lies at the heart of the concept of the “de facto” moratorium, to pile in a “basket” all agricultural biotech products since 1998⁹. This is far from EC allegation that there is no moratorium because of this movement, and that the claim refers to “mere delays”.

The EC’s assertion about the impossibility of challenging the “de facto” moratorium under WTO Agreements was rebutted by Argentina in these proceedings. Argentina’s arguments are supported by GATT/WTO jurisprudence and they were explained in its First Written Submission¹⁰.

However, Argentina would like to stress that if we were to follow a narrow definition of “measure”, it would result in allowing WTO Members to circumvent legal scrutiny of their measures simply by not putting them in a piece of legislation. Moreover, it would also devoid WTO law of its meaning.

The first of these consequences (circumvention of legal scrutiny) was already referred to in Argentina’s First Written Submission¹¹, and even pointed out by third parties in these proceedings¹².

However, Argentina would like to refer to the second of these consequences (to devoid WTO law of its meaning).

⁷ First oral presentation of Argentina, paragraph 25.

⁸ First oral presentation of Argentina, paragraph 26.

⁹ First Written Submission of the Argentine Republic, dated 21 April 2004. See also the Written Rebuttal of the Republic of Argentina, dated 19 July 2004, title II.A.4 “The EC implements and maintains a «de facto» moratorium.”. See also the Supplementary Rebuttal of the Republic of Argentina, dated 15 November 2004, title II.A “The «de facto» moratorium.”

¹⁰ First Written Submission of the Argentine Republic, dated 21 April 2004, title II.A (among others).

¹¹ First Written Submission of the Argentine Republic, dated 21 April 2004, title II.A.1 and II.A.2 (among others)

¹² First Written Submission of New Zealand, paragraphs 2.06-2.08.

According to Argentina's point of view, from the GATT/WTO jurisprudence arises quite clearly that one central feature of WTO system is to ensure that Panels and the Appellate Body are able of scrutinizing all measures regardless the way by which WTO Members may have put them in place.

For example, if the meaning of "measure" was to be considered in a restrictive way by Panels and the Appellate Body, it would not have been possible for the Panel to analyze incentives for the private sector (based on governmental action) under GATT law, in "*Japan-Trade in Semiconductors*"¹³.

Also, if a restrictive way of interpreting "measure" under GATT/WTO law had been followed in the case "*Japan-Measures concerning films and photographic paper for consumer use*", the Panel would not had been able to deal with governmental measures that are not of a binding nature.

The same would be true, for the Appellate Body in "*Japan-Agricultural products*" because the Appellate Body would also be prevented of interpreting the term "measure" in Footnote 5 of SPS Agreement in a broad sense.

For example in "*United States-Sunset review Japan*" the Appellate Body would have faced similar situations in the sense that any act or omission attributable to a WTO Member can be a measure of that Member for purposes of dispute settlement proceedings. In other words, this confirms the possibility of performing the scrutiny of any measure inconsistent with WTO law, regardless the characteristics of the measure or the way in which it is imposed.

Summing up, from Argentina's point of view, such logic would lead not only to foster the lack of transparency by the WTO Members but also to deprive panels and the Appellate Body from analyzing any measure which infringes the covered Agreements.

This reasoning, from Argentina's point of view is not consistent with the way that panels and the Appellate Body have treated the issue. In the cases referred to by Argentina, jurisprudence was clear in interpreting GATT/WTO law in a broad sense, in order to assure that compliance with WTO law would not be circumvented simply because of the form in which a measure is imposed. Argentina deems that in the present dispute the EC should not use its own lack of transparency to avoid legal scrutiny of the "de facto" moratorium.

Therefore, Argentina requests that the Panel consider the existence of the "de facto" moratorium in this dispute.

III.2.- Inconsistency of the "de facto" moratorium with Article 5.1 SPS Agreement

¹³ First Written Submission of the Argentine Republic, dated 21 April 2004, paragraph 54.

The EC's legislation establishes that the assessment of biotech products must be on a "case-by-case" basis. However, the EC has imposed, without any scientific evidence, an across the board measure to all biotech products in the EC's approval system.

Since this measure lacks of any basis on scientific evidence, it infringes basic obligations contained in the SPS Agreement. Besides, this "de facto" moratorium undermines the EC's assertion that it has been assessing the risks on a "case-by-case" basis.

In fact, the EC has failed to put any risk assessment that justifies the "de facto" moratorium. Moreover, the only evidence that exists is the positive scientific opinions from the EC's Scientific Committees.

This evidence has not been contradicted by the experts during the meetings held in February 17th and 18th as Argentina has indicated in II.

From all this, it can be concluded that the "de facto" moratorium imposed to agricultural biotech products as a class, is scientifically unjustified and arbitrary.

III.3.- The EC cannot justify the "de facto" moratorium under Article 5.7 of SPS Agreement

Regarding this WTO case, Argentina considers that the EC has had sufficient relevant scientific information at hand, namely the positive opinions issued by its Scientific Committees which favored approval of the agricultural biotech products. These positive opinions constitute sufficient scientific evidence in terms of Articles 2.2 and 5.1 and have not been refuted either by the EC or by the experts appointed to assist the Panel.

As has been demonstrated during these proceedings, the positive scientific opinions of the EC's Scientific Committees remain valid (see II).

If the arguments of the EC were to be true, it would have been forced to recall from the market every biotech product approved before October 1998.

III.4.- The "de facto" moratorium infringes Article 5.5 of SPS Agreement

The written responses of the experts, which were confirmed during the meeting of February 17-18 (see II) have ratified that the treatment given by the EC to agricultural biotech products compared with "non-biotech" products (such as those obtained by mutagenesis, which have not faced any restriction to enter the EC), is inconsistent with Article 5.5. This is because it was demonstrated that agricultural biotech products entail similar risks than those arising from "non-biotech" products.

Argentina has asserted in these proceedings that the agricultural biotech products and the “non-biotech” products entail the same kind of risks. As the experts have confirmed, the method used in developing the product does not alter the nature of the potential risks¹⁴.

Despite the fact that there are no different risks in agricultural biotech products compared with “non biotech” products, the EC has not imposed any moratorium on the latter.

Considering the existence of comparable risks (first requirement), the different treatment given to agricultural biotech products compared to “non biotech” products resulting in different levels of protection (second requirement), and the existence of an evident disguised restriction to international trade (third requirement), Argentina considers that the EC has acted against Article 5.5.

III.5.- Conclusions with respect to the “de facto” moratorium

In short, Argentina has demonstrated the existence of the measure “de facto” moratorium as a measure (the EC itself has admitted the existence of the measure in dispute¹⁵) and its inconsistency with the SPS Agreement.

This measure was imposed even though the EC’s Scientific Committees have issued positive opinions on various agricultural biotech product applications¹⁶, and the experts confirmed the lack of scientific evidence to justify the “de facto” moratorium in their written responses and during the meeting held on February 17-18.

Argentina has also demonstrated the inconsistency of the “de facto” moratorium with the specific Articles of the SPS Agreement of its claims, without being confronted with any defense on the side of the EC, putting aside the Article 5.7 argument -that has been properly refuted by Argentina¹⁷-.

¹⁴ Dr. Squire and Dr. Andow did agree with the statement of Dr. Squire (“... *there is no reason to suppose that biotech crops confer different degrees of impurity compared with crops produced from, say, induced mutagenesis*”), and Dr. Squire and Dr. Andow did agree with the statement of Dr. Snow (“*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. (...)*”), as reminded above.

¹⁵ See Annexes ARG-7, ARG-8, ARG-9, ARG-10, ARG-11, ARG-12 and ARG-14.

¹⁶ See Annexes ARG-21, ARG-22, ARG-23, ARG-24, ARG-25, ARG-26, ARG-27, ARG-34, ARG-41, and ARG-42.

¹⁷ Written Reputtal of the Republic of Argentina, dated 19 July 2005, title D, applicable “mutatis mutandi” to the general approach and to all claims in this dispute.

For this reason, Argentina respectfully requests that the Panel first confirm the inconsistency of the “de facto” moratorium with the claims made under the SPS Agreement.

IV. THE “SUSPENSION AND FAILURE TO CONSIDER” IS NOT BASED ON SCIENTIFIC EVIDENCE, AND THEREFORE VIOLATES WTO OBLIGATIONS

Argentina refers to all arguments advanced mentioning the conclusions from the expert meeting, since they are also applicable here. However, Argentina wants to stress the relevant issues concerning the specific products of our particular interest.

➤ Bt-531 cotton

Regarding Bt 531 cotton, we believe that the ECs alleged scientific arguments remain refuted as they were since the Rebuttals, in which Argentina clearly established that Bt 531 cotton had obtained a positive scientific opinion within the EC since July 1998¹⁸, and that this evidence has not been contested by other relevant scientific evidence.

As regards the meetings from 17-18 February, the issue affecting Bt 531 cotton has been analyzed in a broader scope (this is, the use and effects of Bt in general), and from the responses from the experts the EC cannot invoke any valid or relevant scientific evidence which could refute the positive scientific evidence arising from the opinion of the EC Scientific Committee from July 1998.

➤ RRC-1445 cotton

Referring to RRC 1445 cotton, Argentina considers that the meetings from 17-18 February did clarify the questions, and confirmed our argument in the sense that there is no scientific evidence within the information submitted by the EC that could refute the positive opinion by the EC Scientific Committee dated July 1998¹⁹ which favored the approval of RRC 1445 cotton.

Furthermore, we particularly mention the clarification made by Dr. Squire referred to the alleged possibility of horizontal gene transfer, confirming Argentina’s point²⁰. Being so, we cannot accept the EC assertion²¹ as a valid scientific statement.

¹⁸ Annex ARG-21.

¹⁹ Annex ARG-23.

²⁰ 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.”*

➤ **NK-603 maize**

Argentina is pleased that NK 603 maize has been properly addressed by the experts, both in their written responses and during the meetings held on 17-18 February.

As regards the former, we agree with Dr. Andow, when he correctly asserted that there were no reasons to dismiss the positive opinion from the EC Scientific Committees in the way the EC tried to do in these proceedings²².

Referring to the meetings from 17-18 February, we are also pleased that the original extent and value of the positive opinions by the EC Scientific Committees²³, favoring the approval of NK 603 maize, have been clearly established, especially when Dr. Nutti specifically addressed an issue contained in the positive assessment²⁴ and which the EC tried to turn into an hypothetical question. Additionally, we also appreciate that the experts did recognize that monitoring is not needed when the product is intended to be only for import and not for cultivation²⁵.

➤ **GA-21 maize**

The application for GA 21 maize was withdrawn in September 2003, and Argentina states that this withdrawal precisely demonstrates the effect of the “de facto” moratorium and the “suspension or failure to consider”.

GA 21 maize did receive a positive scientific assessment both under Directive 90/220/EEC - September 2000-²⁶ and under Regulation (EC) 258/97 -February 2002-²⁷. The EC did ignore for years this scientific evidence favoring approval, until the applications were withdrawn.

²¹ 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.*”

²² Responses to Questions, submitted by David A. Andow, answers to questions 37 and 38 of the Panel.

²³ Annexes ARG-25 and ARG-27.

²⁴ Annex ARG-25, page 2, paragraph 4. The same applies to Annex ARG-27, page 2, paragraph 4.

²⁵ The positive opinions by the Scientific Committees were clear on this point. See Annexes ARG-25 and ARG-27.

²⁶ Annex ARG-41.

²⁷ Annex ARG-42.

Considering the meeting with the experts, Argentina mentions the response by Dr. Nutti, when asked (by both the EC²⁸ and the Panel) about the weight of a positive food safety assessment, when considering a feed safety assessment.

Conclusions with respect to the “suspension and failure to consider”

Summing up, Argentina respectfully requests the Panel to find that the “suspension and failure to consider on applications of products of particular interest of Argentina” are inconsistent with the EC’s WTO obligations.

In that sense, Argentina would like to recall that all the evidence submitted in the present case demonstrated the inconsistency. Moreover, from the written responses by the experts, and from the meetings from 17-18 February, the Argentinean arguments related to the specific products of our interest have been confirmed, in the sense that these products have been stalled with no scientific evidence to justify these stallings.

All these facts and proof did enforce our claims made throughout these proceedings, on the infringement by the EC of substantive obligations of the SPS Agreement.

V.- THE “UNDUE DELAY”

Regarding the “undue delay” in the approval of products of particular interest of Argentina, we remind our argument in the sense that Article 8 of SPS Agreement establishes two different obligations: the first one refers to the commitment to comply with the disposition of Annex C, and the second one establishes the obligation to ensure that “their procedures are not inconsistent with the provisions of this Agreement”.

Given the fact that Argentina has demonstrated that Article 5.1 has been infringed, the delay in the approval of agricultural biotech products of interest to Argentina is not justified, as it is not based on scientific evidence. Moreover, favorable risk assessments do exist and, as Argentina has already demonstrated from the experts’ written responses and during the meeting held on 17-18 February (see II and III), there is no evidence that contradicts them. Therefore, there is no reason that justifies the delay.

This is without prejudice of the particular infringement to paragraph a), b), c) and e) of Annex C.1 of SPS Agreement, as has been developed in Argentina’s submissions.

²⁸ Questions to Experts by the European Communities, 18 February 2005, “E. Monsanto Roundup Ready corn (GA 21), C/ES/01 EC 78, C/GB/97/M3/2, EC 85”, paragraph 14 “Question to Dr. Nutti (Question 40)”

VI.- THE MEMBER STATE BANS ARE NOT BASED ON SCIENTIFIC EVIDENCE, AND THEREFORE VIOLATE THE SPS AGREEMENT

Argentina wishes to note that the specific products affected by the measures applied by Germany, Austria, Italy and Luxembourg had prior approval by the EC²⁹, based on scientific opinions issued by the EC's own Scientific Committees³⁰.

As repeatedly indicated by Argentina, the Member State bans have ignored this scientific evidence and maintain restrictions on the entry of these products into their territories.

Furthermore, some of these countries have attempted to seek protection under safeguard procedures to try to justify their measures, which has resulted in new scientific opinions issued by EC Scientific Committees. These new opinions by the Scientific Committees not only reaffirmed the support of the original scientific opinion favoring the approval of the agricultural biotech products in question, but also specifically refuted the grounds for the state measures³¹. Consequently, these State measures became also unlawful within the EC's regulatory system.

In other words, the same biotech product that has a positive opinion from the respective Scientific Committee at the community level, may then be banned at the state level, and in fact, the ban by some EC Member States has been verified and found to be groundless. Consequently, Argentina requests that, independently from the findings on the "de facto" moratorium, on the suspension and on the "undue delay", the Member States bans also be found WTO inconsistent. Otherwise, any prior approval within the EC would become meaningless if the EC Members States were allowed to impose bans of their own.

The foregoing, as well as the experts' written responses, and the ones submitted during the meeting held on 17-18 February, demonstrate the lack of scientific evidence supporting the measures currently maintained by Germany, Austria, Italy and Luxembourg, and confirm the arbitrary and unjustified distinction made with respect to the affected products. For this reason, as in the foregoing sections, we request that the Panel confirms the inconsistency with the SPS Agreement.

With respect to the EC's argument on Article 5.7 of the SPS Agreement, Argentina has already refuted it, demonstrating the inconsistency of the EC assertion³².

²⁹ See Annexes ARG-6, ARG-35, ARG-36, ARG-37 and ARG-38.

³⁰ See Annexes ARG-30, ARG-31, ARG-32 and ARG-33.

³¹ See Annexes ARG-43, ARG-44, ARG-45, ARG-46 and ARG-47.

³² Written Rebuttal of Argentina, paragraphs 214 and following.

VII.- CONCLUSION

In relation with the “de facto” moratorium, Argentina points out that the EC has simply denied its existence, and has not advanced any argument in this respect. It just tried to argue that the “de facto” moratorium (to which the EC refers to as mere delays) is permitted by Article 5.7 of the SPS Agreement.

Additionally, the arguments about the inconsistency of EC allegations was explained in detailed by Argentina. In that sense, it is worth to note that the EC has opposed no defense on the specific claims of Argentina referring to Articles 2.2, 5.1, 2.3, 5.5, 5.6, 7, 8 and 10.1 of SPS Agreement. Consequently, Argentina respectfully asks the Panel to find the “de facto” moratorium to be inconsistent with the above mentioned provisions.

Furthermore, related to the specific products of interest of Argentina, the information submitted by the EC does not amount to scientific evidence capable of overriding the positive opinions by the EC Scientific Committees that favored the approvals of these products. Consequently, Argentina respectfully requests the Panel find that this infringes relevant provisions of the SPS Agreement related to these specific products. The fact that there was an approval of one product (NK 603 maize) should not impair the Panel’s ability to find the inconsistency within the terms of reference set forth in this WTO case.

Argentina also requests the Panel to find the infringement of Article 8 and Annex C:1, paragraphs a), b), c) and e) of the SPS Agreement, because of the “undue delay” that arose in the approval proceedings due to the “de facto” moratorium.

Argentina respectfully asks the Panel to find the inconsistency of the EC Member States measures (from Germany, Austria, Italy and Luxembourg) applied to products of particular interest of Argentina with the relevant provisions of the SPS Agreement, rejecting the application of the Article 5.7 argument raised by the EC.

Finally, Argentina wants to reaffirm its allegations and claims, as has been stated and proved in its First Written Submission, in its First Oral Statement, in its answers to the questions of the Panel, in its Written Rebuttal, in its Supplementary Rebuttal, in its Comments to the Responses by the Experts to Panel’s Questions, and in its comments during the meetings with the experts.