

***European Communities – Measures Affecting the Approval and  
Marketing of Biotech Products***

***(DS291, DS292, DS293)***

**Oral Statement by the European Communities  
at the First Meeting of the Panel with the Parties**

**Geneva  
2 June 2004**



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Mr Chairman, Members of the Panel

**I. INTRODUCTION**

1. The European Communities would like to express its thanks to all three panellists for having accepted to serve on this Panel and to assist in the resolution of this difficult dispute. The complex and controversial issues before you are not only about science and societal values – they also raise some very difficult issues of legal interpretation.
2. By contrast, we have heard today statements which seek to present the issues in an excessively simple manner.
3. The European Communities hopes that its first written submission has contributed to clarifying the factual and legal issues at stake and we look forward to discussing them further with you today and tomorrow in order to clarify them even more. We are available to assist the Panel in all ways that may be helpful.
4. Now is not the time for a detailed refutation of all of the Complainants arguments – that must come later – but rather for a discussion of the essential issues. For that reason we shall try to be brief and leave as much time as possible for your questions. For the same reason we shall avoid repeating the arguments we made in our first written submission but instead seek to provide some additional thoughts and to emphasise some points on which we think the discussion should focus.
5. As you have just heard, the United States, Canada and Argentina allege that the European Communities has violated WTO law in the manner in which it has applied its regulation on GMOs. We disagree.
6. Despite the Complainants’ occasional attempts to suggest the contrary, this case is not about protectionism, nor is it about discrimination. This is, in the view of the European Communities, a case about regulators’ choices of the appropriate level

of protection of public health and the environment in the face of scientific complexity and uncertainty and in respect of which there is great public interest. It is a case essentially about time. The time allowed to a prudent government to set up and apply a process for effective risk assessment of products which are novel for its territory and ecosystems, and that have the potential of causing irreversible harm to public health and the environment.

7. In these matters there cannot be a “one size fits all” kind of solution and the Panel should resist the temptation to use simplistic approaches, as suggested by the Complainants. The European Communities is neither anti-GMO nor pro-GMO. It recognises both the potential benefits and the potential risks. That is why it has set up detailed approval systems for GMOs and GM products and has approved many of them. For the EC, each GMO and GM product must be examined on its individual merits and only approved once all the potential risks have been thoroughly assessed.
8. I will now leave the floor to my colleagues, Ms Fries, who will deal with some of the background factual and scientific issues, which the Complainants chose to ignore completely this morning , and to Mrs. Righini who will address a few of the legal issues.

## **II. GMOs ARE STILL IN THEIR INFANCY**

9. At a conference held in Brussels last year, on the options offered by life sciences and modern biotechnologies for sustainable agriculture for developing countries, Madame Louise Fresco, assistant director general of the FAO, likened the present state of the debate on GMOs to the situation of Alice, lost in the Wonderland, in Lewis Carroll’s famous book, when finding herself before a crossroads. I quote Madame Fresco’s speech:

Once upon a time, lost at a crossroads, a little girl met a cat. The cat told her: “If you do not know where you want to go, then it does not matter which road you take”. [ ] The Cheshire cat’s words have some relevance for our subject today. Like Alice, through the looking glass of fast-paced scientific progress, we are catching a glimpse of an exciting world. Like Alice, we are at a crossroads with many paths open in front of us, as new opportunities are created by tremendous technological advances. But we must carefully choose our destination, and the roads we can take to get there.

10. Over the last decade or so, the international Community has been busy considering what may be the appropriate roads to take, and has agreed that special rules are needed to address GMOs. That conclusion first emerged on 22 May 1992<sup>1</sup>, and was again restated decisively on 29 of January 2000<sup>2</sup>, when the international Community agreed that it was necessary to :

Establish and maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from [modern] biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking into account the risks to human health<sup>3</sup>.

The international Community has, thus, recognised that GMOs are inherently of a character which requires particular scrutiny and that, in the face of scientific uncertainty states’ actions should be based on precaution<sup>4</sup>.

### **III. GMOs ARE CHARACTERISED BY SCIENTIFIC COMPLEXITY**

11. But why is there a need, identified as early as the end of the 1970s and systematically reiterated since, to address the potential risks of genetically modified organisms for human health and the environment differently compared to non-GM organisms ?

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<sup>1</sup> Date of adoption of the Convention of Biological Diversity.

<sup>2</sup> Date of adoption of the Cartagena Protocol on Biosafety.

<sup>3</sup> Article 8g of the Convention of Biological Diversity.

12. Due to the universality of the genetic code, which is the basis of any organism's heredity across all kingdoms of life and all species, genetic engineering, the technology producing genetically modified organisms, enables us for the first time to cross any species barrier, including across genus, or kingdoms, and this is something you cannot achieve through conventional breeding. You could not achieve, for instance, the introduction and expression of a bacterial gene – the insecticidal toxin Bt into a plant – maize – if it were not for the use of genetic engineering.
13. Consequently, genetic engineering has brought to us the ability to theoretically introduce within any living organism, as quickly as it takes to go from one generation to the next, any trait from any other organism, and more importantly, totally new properties to that organism, as yet inexistent in nature.
14. The science necessary to assess the risks of these new combinations, and in particular any long term, indirect, or delayed effects, has had and is having a hard time to catch up with the rapid development of new GM products. The science traditionally used in risk assessment is deterministic (some say reductionist) by nature, and that means that it has a difficult time to apprehend all the properties of highly complex individual organisms, the interaction between organisms, and the full picture of the ecosystems or the agroecosystems that might be affected.
15. In particular, the consequences of the introduction of GMOs into the open environment, intentionally or unintentionally, can – so says the science – be highly variable between different ecosystems – and thus between, or even within, countries – as regards their potential impacts on the environment at large (including the agricultural environment). As the brief by the “amicus coalition” points out, these risks are GMO- and site specific.
16. Furthermore, GMOs are living organisms, and they are able to reproduce autonomously. Any measure bringing a GMO into the environment has therefore a character of irreversibility, as the GMO will then be potentially able to reproduce autonomously and spread into that environment. This is not like putting a new car

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<sup>4</sup> Articles 10(6) and 11(8) of the Biosafety Protocol.

or a new pharmaceutical product on the market. If those create a problem, it is easy to take them out of the market - but with products that are to be released into the environment and/or are to be ingested by animals or human, withdrawing them is infinitely more complex, if not impossible. This aptly demonstrated by the experience in the United States concerning the product “Starlink.”

17. Another element to be considered is that the experience we have today of GMOs is still very limited both in time and in quality. The acquisition of this technology has happened at a pace which is unprecedented in the history of agriculture and which still grows at a rate of more than 10 % per year. This said, we are still talking about an extremely limited number of genes, that can be counted on your fingertips. Last year, herbicide tolerance accounted for 73 % of GMO cultivated areas, for two single sets of genes only, and insect resistance, through the use of two, in fact mainly one, bacterial BT gene, accounted for 18 %, - together accounting for more than 90 % of GM cultivated areas. Four species only, soybean (61 %), maize (23 %), cotton (11 %) and oilseed rape (5 %), accounted together for more than 99 % of GM cultivated areas, and among these, only two dominant unique combinations (a single soybean with one herbicide resistance trait, and maize with one particular insect resistance trait) accounted for three quarters of that cultivated area.
18. The existing experience is also not sufficiently evaluated. Very few systematic studies, in fact, exist or have been planned on this limited set of GMOs, so that at least the feedback from this experience of large scale cultivation could be used to better assess the indirect, delayed, long term impacts of these individual GMOs. As a consequence, many questions have remained as yet unanswered.
19. In other words, GMOs are still in their early days and scientists have just begun to understand how immense the challenges that protecting health, the global environment in general and biodiversity in particular really are. The debate on the uses of modern biotechnology and its potential impact on public health, sustainability and biodiversity should be seen against this growing awareness of the fragility of human conditions and natural systems.
20. On all of this, the Complainants are silent.

#### **IV. GMOs RAISE THE NEED FOR TARGETED REGULATORY APPROACHES**

21. In the face of the fast evolution of science, the European Communities, as well as many other governments, have chosen to act prudently, setting up effective processes for risk assessment to be performed before any of these new products is accepted for production, importation or commercialisation.
22. History demonstrates that health and environmental issues were not a dominant public concern at the beginning of the 20<sup>th</sup> century. It was only as the century progressed that these issues came to the forefront of public attention and thus became an issue for government intervention. Concerns over GMOs and GM products have contributed to raising awareness over possible effects of agriculture on health and the environment, and have thus been submitted to progressively higher standards of assessment. Countries that had developed early-on a regulatory framework had to revise it in recent years and to adapt it to take account of new scientific and economic issues. Both Canada and the United States are examples of countries which are in the process of developing more stringent regulatory frameworks.<sup>5</sup> That has not been contested by either of them today.
23. The same process of a growing awareness over time has been true for many other products brought about by new technologies. It was the case, for instance, of DDT, praised as a useful tool for agriculture, then withdrawn from the markets for its health consequences, and today, fifty years on, still to be found in human beings and animals - and DDT is just a chemical, not a living organism potentially capable of autonomous reproduction.
24. The likely consequence of this growing awareness is that the higher standards of health and environmental assessment developed for GMOs will be applied, in some fashion, to other agricultural technologies and practices.

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<sup>5</sup> First written submission of the European Communities, para 87 and Fn. 58.

25. Scientific evolution is not, however, the only factor to take into account. As the joint EU/US Biotechnology Consultative Forum concluded in December 2000:

Biotechnology, like many other technologies, offers both positive, intended, benefits and potential negative and often unforeseen consequences. Because these consequences may have both social and technical contexts, judgements about risk cannot be reduced to scientific assessment alone. There are legitimate concerns for which science, at least natural science, cannot provide answers. Such concerns may cover issues of distribution of power and influence, risks of concentration of knowledge and expertise to a few very large corporations, relations between different social groups and classes, between ethics and social values, between large corporations and small companies, between small-scale subsistence farmers and family farmers and the agroindustrial complex, between developed and developing countries. As is true of all technologies with the potential for far-reaching benefits, the societal consequences are far reaching as well.<sup>6</sup>

26. In order to master these technological developments and not to underestimate potential longer-term irreversible risks and dangers, the best course is to set up processes and mechanisms for strong, effective and forward-looking regulation in advance.
27. This move towards a strong regulatory process has not been limited to the national dimension. Genetic modification is a new technology of universal application, which deploys its effects across borders. GMOs are produced to be traded internationally and to become part of the environment of other countries. Thus, they require at the same time a country driven, tailor-made regulatory approach that takes account of the specific health and environmental characteristics of each country; and they also require global frameworks to deal with the concerns linked to their international movements. Along these lines, the international Community has been working through the last two decades in order to develop a proper framework to address the specificities of GMOs. In 2000 a specific international treaty was adopted to address this issue, and it has now entered into force.
28. By now, international consensus exists on a number of issues related to GMOs, such as:

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<sup>6</sup> Final Report of the Biotechnology Consultative Forum, released at the EU/US Washington Summit of 18 December 2000, available at [http://europa.eu.int/comm/external\\_relations/us/biotech/report.pdf](http://europa.eu.int/comm/external_relations/us/biotech/report.pdf) (last visited on 1 June 2004) (Exhibit EC-115).

- that GMOs require a regulatory regime that is tailored to the specific conditions of a country, or part thereof, with regard to issues such as health, environment, agricultural practices, etc. Every state is therefore entitled to take its own decisions on each and every GMO, on the basis of its specific environmental circumstances as well as other legitimate policy goals;
- that GMOs should be treated differently from conventional products<sup>7</sup>;
- that, in order to properly assess health and environmental effects, GMOs should be assessed each on its own merits, before obtaining access to the market, and on a case-by-case basis<sup>8</sup>;
- that the risk assessments they undergo should be based on scientific knowledge<sup>9</sup> (without prejudice to other factors informing regulatory decisions);
- that states have the right to adopt a precautionary approach when dealing with GMOs<sup>10</sup>;
- that GM products should be labelled<sup>11</sup>;
- that there is the need for post-marketing surveillance<sup>12</sup>.

**V. THE REGULATORY CHOICES OF THE EUROPEAN COMMUNITIES ARE THOSE OF A PRUDENT, RESPONSIBLE GOVERNMENT**

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<sup>7</sup> This is the very purpose of the Biosafety Protocol, the scope of which is limited to the “transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health”.

<sup>8</sup> See Codex Alimentarius, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, doc. CAC/GL 44-2003, available at [ftp://ftp.fao.org/es/esn/food/princ\\_gmfoods\\_en.pdf](ftp://ftp.fao.org/es/esn/food/princ_gmfoods_en.pdf) (last visited on 1 June 2004) (Exhibit EC-116), point 12; Annex III, point 6, of the Biosafety Protocol.

<sup>9</sup> Codex Alimentarius, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, doc. CAC/GL 44-2003 (Exhibit EC-116), points 13 and 14.

<sup>10</sup> See Articles 10(6) and 11(8) of the Biosafety Protocol.

<sup>11</sup> Codex Alimentarius, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, doc. CAC/GL 44-2003 (Exhibit EC-116), point 19.

<sup>12</sup> Codex Alimentarius, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, doc. CAC/GL 44-2003 (Exhibit EC-116), point 19.

29. Against this background, the European Communities believes that its actions have been and are those of a prudent government. Over the years, far from having “stalled the process”, as is being alleged, the European Communities has worked diligently to design and put in place a regulatory environment for GMOs which takes into account health and environmental concerns while allowing their production, importation and marketing.
30. Unlike the type of regulations (at the federal level at least) which are applied by the United States, Canada and Argentina, which seek to use the available GM techniques with the objective of maximising return on investment, the European Communities has sought and still seeks to anticipate and manage the potential positive and negative impact of GMOs in the long term and in the interest of all its people. For these reasons, it has developed and revised a regulatory framework that allows the commercialisation of GMOs under specific conditions.
31. In parallel, and as demonstrated by the forty-nine detailed chronologies we have submitted in our first written submission it has continued the assessment of each individual application on a case-by-case basis, anticipating, to the extent possible, the application of the standards of review of the upcoming legislation to pending applications. This has always been done in a constant and continued dialogue between the various levels of the European Communities administration and the applicants.

## **VI. THE CASE OF BT 11 MAIZE**

32. Bt 11 Maize - the product that was granted a market authorisation two weeks ago - is a perfect illustration of the fact that the approval process, far from being stalled, has been steadily proceeding over the past years. It is representative of most of the applications currently pending and more approvals are in the pipeline.

33. The history of this application has been described in detail in the first written submission.<sup>13</sup> To briefly recall: Bt11 maize was notified in 2000 and moved up to the Community level quite quickly. The European Commission asked its scientific committee for advice on this dossier in December 2002. It took the Committee more than two years to issue its opinion. Why? Because it had requested further data from the applicant, which the applicant (who in the meantime changed from Novartis to Syngenta)<sup>14</sup> only provided more than two years later. By then, new legislation, requiring detection and validation methods was about to be adopted and the applicant, on a voluntary basis, agreed to provide the necessary materials to develop such methods. In spite of the readiness of the EC institutions to undertake (and co-finance) the work, it took more than a year to work out the circumstances of the submission of the necessary material and to actually then obtain it from the applicant. The detection and validation method was then rapidly finalised and the decision-making process launched immediately. The proposal for the decision has made its way through the decision-making procedures exactly as provided for in the legislation and, thus, the decision was adopted by the Commission two weeks ago. Let me just clarify, since this has been raised by the United States today, that it has already entered into force upon notification to the applicant Syngenta.
34. As it is clear from this brief excursus, the marketing authorisation of Bt11 has not happened overnight because of a sudden change in the European Communities' policy on GMOs or, as many have alleged, because of the present case. It is simply the result of a normal process of assessment, which has known no suspension and that has been conducted taking into account the reactions of the applicants, the constant evolution of the scientific and regulatory debate concerning GMOs and the entry into force of new legislation resulting from this debate.
35. Where is there a moratorium in all of this? Can you continue your approval process, authorize products and, at the same time maintain a moratorium? Let me

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<sup>13</sup> Paras 305 et seq.

<sup>14</sup> See first written submission of the European Communities, footnotes 156 and 159.

re-phrase: How else can you prove the absence of a moratorium if not through demonstrating that the approval process moves on and results in decisions?

## **VII. LEGAL ISSUES**

### *A. Preliminary legal remarks*

36. Before coming to the legal issues in this case, the European Communities will make two introductory comments about the way in which this case is being conducted by the Complainants.
37. First, we are struck by the fact that all the Complainants, who have the burden of proof, are requesting the Panel NOT to have recourse to scientific and technical advice. The European Communities finds this difficult to understand and cannot believe that the Panel would rule on this case without taking such advice once the issues in dispute are clarified. It is interesting to note that it is only the defendant who is open to a clarification of the facts in this case on the basis of expert advice.
38. Since the Complainants have not abandoned their claims on receipt of the European Communities' first written submission, it is definitely not the case that there are no scientific facts in dispute. In order to dispel the misunderstanding that seems to subsist on the part of Canada (as demonstrated by its letter on the need for scientific and technical advice), let me state that we definitely do contest that the risks involved in GMOs are no different from those presented by conventional products. Quoting statements of persons and bodies in the EC will not contradict the fact that the EC legislature has established a specific regulatory approval system for GMOs different from and stricter than anything applicable to conventional products.
39. Let me also correct Argentina's and Canada's and the US' assertions repeated even here today in front of you that the opinions of the European Communities' scientific committees are sufficient scientific evidence for disposing of this case

and that the scientific advice of these committees should be regarded as the only evaluations the EC can rely on for the products at issue. These assertions call for a number of clarifications: First of all, there are several committees involved in GMO risk assessment under the European Communities' procedures. Some of these are at national, Member States' level, others are at Community level. Second, these committees only reply to specific questions put to them and thus their opinions are not exhaustive, they do not necessarily cover all issues at stake. Also, the committees only provide advisory opinions and their views do not necessarily have to be homogenous. In particular, and contrary to what was alleged today by Argentina and Canada, the views of the European Communities' scientific committees, now regrouped under the European Food Safety Authority, have no formal overriding effect on the opinions of the corresponding national committees. Indeed, in several instances, at the national level subsequent studies have been carried out which have demonstrated conclusively that concerns expressed by the Member States were justified. Thus, the resolution of any scientific differences in the assessment of GMOs and GM products has ultimately to be sought by the political instances in the risk management phase taking into account all relevant scientific information, including studies, reports and opinions from outside the EC. This is perfectly in line with the WTO case law and in particular with the Appellate Body's ruling in *EC Hormones*.

40. Second, it is also remarkable that the Complainants (and in particular the US) would have the Panel apply only the *SPS Agreement* - and thus actually impose fewer obligations on the European Communities. As we have explained in our first written submission, this approach is too simplistic and simply not tenable. In any event, the European Communities is confident that its behaviour is compatible with all its WTO obligations.
41. In fact, both these features of the way in which the Complainants are conducting their case are illustrative of one fact. That the Complainants want to avoid that the Panel enters into any detailed factual or legal analysis of the European Communities' actions, which they intentionally misrepresent. They want this Panel to rule on certain issues of general concern for all WTO Members, but in a biased way and in the light of only limited information. Again, it is the defendant,

the European Communities, that is prepared to confront these complexities fairly and squarely and seek to resolve them.

42. The European Communities can agree with the Complainants on one thing : this case is a simple one - because there is no moratorium and no suspension to rule on. There is only a series of prudent actions in response to concerns shared by responsible governments around the world.

*B. The correct approach to interpretation*

43. The European Communities exhorts the Panel to go beyond the loose, vague approach to the law proposed by the Complainants, and to ensure, on the contrary, a correct interpretation of the balance of rights and obligations contained in the WTO agreements. In particular, the Panel has to ensure:

- First, a close and careful reading of the text of the individual agreement in question: It is well-established that an international agreement has to be interpreted systematically through an analysis of its text, context and object and purpose<sup>15</sup>. In particular, the Appellate Body has specified that

A treaty interpreter must begin with, and focus upon, the text of a particular provision to be interpreted<sup>16</sup>.

And it has added that

one of the corollaries of the "general rule of interpretation" in the *Vienna Convention* is that interpretation must give meaning and effect to all the terms of a treaty. An interpreter is not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility<sup>17</sup>. (footnote omitted)

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<sup>15</sup> Article 31 of the Vienna Convention on the Law of the Treaties.

<sup>16</sup> Appellate Body Report, *US – Shrimps*, para. 114.

<sup>17</sup> Appellate Body Report, *US – Gasoline*, p. 21.

The Complainants have supported the correctness of this view in several other cases<sup>18</sup> and the Panel should now make sure that the various provisions invoked in this case are given full meaning and effect.

- Second, the Panel has to ensure a reading of the relevant WTO provisions in accordance with other international law instruments: International movements in GMOs have been considered to raise such specific issues to deserve a specialized international agreement, negotiated outside and subsequently to the WTO Agreement, as well as the development of a number of other international standards<sup>19</sup>. This fact cannot be ignored. Argentina, this morning invited you to override the Appellate Body’s finding on the need to take into account the “contemporary concerns of the community of nations about the protection and conservation of the environment<sup>20</sup>”. We note in passing that in contrast Canada and the US are not objecting to your having regard to relevant international instruments. In US Shrimps, the Appellate Body has also already expressed the view that the existence of consensual and multilateral standards addressing transboundary problems and of “concerted and co-operative efforts” to negotiate them is a clear sign of the maintenance of equilibrium between the substantive rights and obligations provided for in the WTO agreements<sup>21</sup>. Thus, the provisions at stake in this case will have to be interpreted not in clinical isolation from, but rather in the light of, the other existing instruments of international law referred to in the European Communities’ first written submission.

44. These observations are not merely theoretical. The implications of this method of interpretation, flowing from the Appellate Body’s decisions, as opposed to the method proposed by the Complainants, may be illustrated by an analysis of the following three points.

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<sup>18</sup> See, for instance, Appellant Submission of the United States in *US – Countervailing Duties on Certain Corrosion-Resistant Carbon Steel Flat Products from Germany*, para. 7.

<sup>19</sup> See, first written submission of the European Communities, section II.B.4.

<sup>20</sup> Appellate Body Report, *US – Shrimps*, para. 129.

<sup>21</sup> Appellate Body Report, *US – Shrimps*, para. 166-175.

*C. The SPS Agreement alone cannot dispose of all the issues linked to GMOs*

45. The Complainants have all alleged violations of the *SPS Agreement*. The Complainants have attempted half-hearted explanations of how and why this agreement can be considered to apply to the measures at issue, picking only those issues that best fit their case.
46. However, the scope of the *SPS Agreement* is precisely identified in the text of Annex A, point 1, as relating exclusively to measures to protect animal or plant life or health within the territory of the Member from precise risks such as “the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms”; “additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs”; or “diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests”.
47. The text of this provision is very clearly phrased and has to be strictly interpreted and applied. In particular, contrary to the Complainants’ approach, it cannot be read as applying to all products and all risks in all circumstances. Following such an approach amounts to reducing the whole of point 1 of Annex A to inutility.
48. As already explained at length in the European Communities’ first written submission, the measures under consideration in this case were adopted (or exist) for reasons that fall in part within the *SPS Agreement*, and in part outside it. The Panel will thus have to assess under the *SPS Agreement* only those measures adopted for reasons that fall within the scope of that Agreement, whilst the other measures will have to be considered under the other relevant provisions of the WTO agreements, such as the *TBT Agreement*, if it is relevant, or the GATT. Argentina appears to subscribe to this view, since it has notified at least two measures related to GMOs under the *TBT Agreement*<sup>22</sup>. And the United States and Canada have notified in the past measures considered as falling under both the *SPS* and the *TBT Agreements*.<sup>23</sup>

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<sup>22</sup> See documents G/TBT/N/ARG/127 of 20 August 2003 and G/TBT/N/ARG/134 of 29 August 2003.

<sup>23</sup> See the United States’ notification of the “Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002” as document G/SPS/N/USA/691 of 6 February 2003 and as document G/TBT/N/USA/32 of 13 February 2003; and the Canadian

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49. Nor can the application of these latter agreements be excluded for the mere fact that a single measure pursues also one or more SPS objectives. The same measure can pursue multiple objectives which fall within the scope of different WTO agreements. Thus, for instance, in the case of Bt, its direct impact on animal and plant health falls within the objectives of the *SPS Agreement* while its potential impact on soil micro-organisms or the wider ecosystem and biological diversity does not. As a consequence of these multiple objectives, a part of this measure will fall under the *SPS Agreement* and part under either the *TBT Agreement* or the GATT. This possibility is not only inherent in the text of the agreements<sup>24</sup> but it is also recognised, as noted above, by the current practice of other Members of the WTO. Thus, for instance, in its notifications of the Living Modified Organisms Regulations, Canada has considered the objective of protection of plant health as falling under the scope of the *SPS Agreement*, whilst those of protection of human health and the environment as falling under the scope of the *TBT Agreement*<sup>25</sup>.

*D. The issue of delay*

50. The Complainants are alleging that the approval processes have been stalled, are not moving forward, are being systematically delayed. The European Communities in its submission has fully demonstrated that this is not the case. Delays have occurred where additional information has been requested and the European Communities has shown its readiness to answer to the Panel for each and every instance of such alleged delays under the WTO Agreements.

51. Indeed, there can be no doubt and the European Communities does not contest that the WTO Agreements apply to delays, or more generally to omissions or failures to act. However, the issue is not, as Canada insisted even today, whether delays can be measures under the WTO Agreement. The issue is quite obviously that the

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notification of the “Living Modified Organisms Regulations” implementing the Biosafety Protocol as document G/SPS/N/CAN/144 of 4 October 2002 and as document G/TBT/N/CAN/46 of 14 October 2002.

<sup>24</sup> See, first written submission of the European Communities, point 438-441.

<sup>25</sup> See documents G/SPS/N/CAN/144 of 4 October 2002 and G/TBT/N/CAN/46 of 14 October 2002.

- WTO Agreements only apply where they contain obligations that address such omissions and failures to act.
52. The *SPS Agreement* contains such obligations. Members are answerable for “undue delays” and other failures in the application of approval procedures. Accordingly, the European Communities has replied to the alleged violation of Article 8 and Annex C of the *SPS Agreement* in its submission.
53. It has not replied, however, to the alleged violations of all other provisions listed by the Complainants, precisely because they do not contain obligations that address omissions and failures to act within a specific time frame in the context of a procedure for granting marketing approvals. These other provisions contain obligations that address the very opposite, namely actions or acts. They address the development and content of SPS measures, not their application. The Complainants have tried to construe the existence of such an SPS measure. A measure that would be something other than a delay, but that would also not be the European Communities’ approval system itself (since they are not challenging the latter). Their attempts to twist the facts in a effort to fit the arguments they wish to make must fail.
54. The European Communities has no intention of avoiding responsibility for its actions. However, it has a specific as well as a systemic interest in the correct qualification of the individual WTO obligations at stake.

*E. Article 5.7 SPS Agreement*

55. In its first written submission, the European Communities stated that to the extent that the national safeguard measures came under the *SPS Agreement* at all they were regulated by Article 5.7 of the *SPS Agreement* and not by the other provisions of the agreement invoked by the Complainants. We note that China, as a third party, has taken the position that the European Communities has the burden of proving that the conditions of Article 5.7 are met, presumably because it considers that it is an exception rather than an autonomous right.

56. The European Communities disagrees and notes that on this point it shares the position of the United States. At the meeting of the DSB held on 10 December 2003 when the panel report in the case DS245 *Japan – Fireblight* was adopted, one of the points of disagreement expressed by the US delegate related to that panel's approach to the burden of proof under Article 5.7. According to the report, from which I quote:

The second point the United States wished to note was the Panel's conclusion that the Member maintaining the measure had the burden of establishing that it met the requirements of Article 5.7. Neither Japan nor the United States had supported this conclusion, taking the position that here, as with other claims, the complaining party had to bear the burden of proving that the measure did not meet the obligations set forth in a WTO provision.<sup>26</sup>

57. Thus, the European Communities, and the United States, as it also appears from its statement today, see the relationship between Article 5.7 and the rest of the agreement in the same way as the Appellate Body saw the relationship between Articles 3.3 and 3.1 of the *SPS Agreement* – as an autonomous right.<sup>27</sup>

*F. The precautionary principle is a general principle of international law*

58. Article 5.7 of the *SPS Agreement* is of course one expression of the precautionary principle – Article 3.3 is another.<sup>28</sup> This is another reason why Article 5.7 is an autonomous right, an autonomous right that is also recognised in the Biosafety Protocol.<sup>29</sup>

59. The European Communities would like to make some additional comments on the precautionary principle which it maintains has by now become a fully-fledged and general principle of international law.

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<sup>26</sup> WT/DSB/M/160 of 27 January 2004 at para 9.

<sup>27</sup> Appellate Body Report, *EC – Hormones*, para.169 to 172.

<sup>28</sup> Appellate Body Report, *EC – Hormones*, para.124.

<sup>29</sup> See Article 10(6) and Article 11(8).

60. The precautionary principle was first recognised in the World Charter for Nature, adopted by the UN General Assembly in 1982 and was subsequently incorporated into various international conventions on the protection of the environment. At the beginning of nineties, the Rio Declaration that concluded the 1992 Rio Conference on the Environment and Development, codified an application of this principle in its Principle 15, which states that:

in order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

61. Since then, the United Nations Framework Convention on Climate Change and the Convention of Biological Diversity both refer to the precautionary principle. More recently, and in the specific field of GMOs, the Biosafety Protocol has confirmed the key function of the precautionary principle in the decision to restrict or prohibit imports of GMOs in the face of scientific uncertainty.

62. On the basis of Article 5.7 of the *SPS Agreement*, measures adopted in application of the precautionary principle,<sup>30</sup> that is, when the evidence is inadequate, are provisional and imply that efforts be undertaken to try to obtain the necessary scientific data. In this regard it should be noted that the right to the maintenance of "provisional" measures adopted on the basis of Article 5.7 is not to be assessed with regard to a time limit but to the development of scientific knowledge.<sup>31</sup>

## **VIII. CONCLUSION**

63. In conclusion, the Panel has been called upon to decide what the reasonable attitude of a prudent government should be faced with scientific complexity and uncertainty of a kind and on a scale unique and unprecedented in the history of trade in agricultural products. It is an important and delicate task and it will have

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<sup>30</sup> Appellate Body Report, *EC – Hormones*, para.124.

<sup>31</sup> See *Communication of the European Commission on the Precautionary Principle*, WT/CTE/W/147, G/TBT/W/137, of 27 June 2000.

consequences far beyond this case. GMOs are not an issue which is confined to the WTO and the close attention of states, other international organisations, civil society, industry and others, rests on the work of this Panel.

64. The European Communities is confident that, apart from the absence of any moratorium, the Panel will also find that in applying a regulatory process for effective and forward-looking governance, based on a precautionary approach, the European Communities has acted in accordance with its obligations under the WTO agreements.

**LIST OF EXHIBITS**

- EC-115      Final Report of the Biotechnology Consultative Forum, released at the EU/US Washington Summit of 18 December 2000
- EC-116      Codex Alimentarius, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, doc. CAC/GL 44-2003