WORLD TRADE ORGANIZATION

WT/DS291/R/Add.1
WT/DS292/R/Add.1
WT/DS293/R/Add.1
29 September 2006
(06-4232)

Original: English

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

Reports of the Panel

Addendum

This addendum contains Annex C to the Reports of the Panel to be found in document WT/DS291/R, WT/DS292/R, WT/DS293/R. The other annexes can be found in the following addenda:

- Annex D: Add.2
- Annex E: Add.3
- Annex F: Add.4
- Annex G: Add.5
- Annex H: Add.6
- Annex I: Add.7
- Annex J: Add.8
- Annex K: Add.9

ANNEX C

REPLIES BY THE PARTIES TO QUESTIONS POSED BY THE PANEL ON 3 JUNE 2004

ANNEX C-1

REPLY BY THE UNITED STATES TO THE QUESTION POSED BY THE PANEL ON 3 JUNE 2004

For all complaining parties:

4. Is there any scientific disagreement on the part of the co-complainants with the scientific arguments and facts submitted by the EC (including the member States)?

108. The United States will answer the panel's question in two ways – first, quite literally, and then in a more focused manner, based on the intent of the question.

109. First, on whether the United States has any scientific disagreements with the EC, there may well be some. The United States is in the process of preparing its rebuttal submission, and had planned in that time frame to decide whether to take issue with some of the scientific statements of the EC. Given the length of the EC submission, the United States cannot compress that time frame and give a definitive answer at this time. However, as the Panel will note, in the US oral statements and interventions to date, the United States has not taken issue with any scientific statements of the EC. This is because, to the knowledge of the United States, no dispositive issue in this dispute turns on a scientific issue.

110. Second, the United States would like to answer the Panel's question based on what we understand to be the intent of the question. Namely, are there dispositive scientific issues with respect to which the advice of scientific experts would be of assistance to the panel? As of this time, the United States has not been able to identify any such issues. As the United States has explained, in our view, the central issue in this dispute is that the EC announced and applied an across-the-board moratorium on biotech approvals. The adoption of this nontransparent measure results in "undue delay" under Annex C; is inconsistent with its obligations to publish measures promptly and to keep applicants informed of the progress of applications; is not based on a risk assessment as required under Article 5.1; and results in arbitrary or unjustifiable distinctions in the EC's chosen levels of protection.

- With regard to the general moratorium and product-specific moratoria, the EC's only defense is that the moratoria in fact never existed and that with respect to individual applications, the lengthy delays are not "unjustified." But, whether the EC's moratorium is a "measure" and thus subject to the disciplines of the SPS agreement is a legal, not a scientific question.

- Similarly, the question of whether delays are "unjustified" under the SPS Agreement also is a legal, not scientific question. The EC seems to be arguing that scientific concerns justified certain delays. But whether or not this is true for particular applications is not dispositive, because under the EC moratorium no products were allowed to reach final decision, regardless of the underlying science. This is clearly shown by, among other things, the fact that product applications were stalled for over two years by nothing more than "interservice consultations."

- Even aside from this fundamental problem with the EC argument, the United States has not identified any scientific issues that would be pertinent to the question of undue delay. In particular, science may identify and analyze risks. Indeed, the EC

completed risk assessments on many of the pending applications. But once the risks have been identified, it is up to the decisionmaker, not the scientist, to decide when to take a decision on the application.

– As the Panel is aware, in past disputes involving the SPS Agreement experts have been consulted to advise on issues related to the scientific basis for a Member's identification of risks and how this has been reflected in the Member's risk assessments. But in this dispute, the EC has put forward no risk assessment in an attempt to justify its moratorium.

– With respect to the member State measures, again the United States does not see any question that would call for scientific advice. The EC has claimed that risk assessments may support the member State measures, but it has not yet identified those assessments.

ANNEX C-2

REPLIES BY THE EUROPEAN COMMUNITIES TO QUESTIONS POSED BY THE PANEL ON 3 JUNE 2004

Question 1

1. Please document cases of conflicting scientific views, including at the member States level, with respect to at least one particular application.

2. Describe the chronology of what happened in this case(s).

1. The European Communities is going to reply to your question by reference to three distinct cases:

- sweet corn Bt11
- maize Bt176
- oilseed rape MS8/RF3

2. **I. Sweet corn Bt11, submitted under Regulation (EC) Nr. 258/97 (Exhibit EC-092)**

3. In this case, conflicting scientific views existed on:

- the methodology used for the safety assessment;
- toxicity;
- allergenicity; and
- molecular characterisation.

Conflicting technical views existed on the proposed detection method.

4. Chronology of the application:

5. After the Netherlands submitted their initial positive risk assessment report in May 2000, the Commission circulated it to the other Member States. Several of them objected to the Dutch risk assessment on the basis of their national scientific evaluations on the following grounds:

- compositional analysis;
- molecular characterisation;
- toxicity; and
- allergenic effects.

6. In December 2000, the Commission referred the matter to the Scientific Committee on Food (SCF). On 17 April 2002, the SCF delivered its opinion in which it concluded that the product was safe for human consumption.

7. In June 2002, the Commission agreed with the notifier that it needed to provide reference material and a detection method to be validated by the Community's reference laboratory, as requirements for an appropriate risk management of the product.

8. During the validation process, it became apparent that there were conflicting technical views between the Community's reference laboratory and the national reference laboratories, as well as with the notifier, on how to comply with the requirements for an appropriate detection method. The validation process was finally completed by the Community reference laboratory after over a year of work on 2 October 2003.

9. On 8 November 2003, the Commission submitted a draft proposal to the Regulatory Committee. On Member States' request, the Commission did not ask for its formal vote, given that several Member States considered that the scientific questions they had formulated earlier on the basis of their conflicting national scientific evaluations were still open, and others were still awaiting further scientific risk assessments of their national scientific committees.

10. Between October and early December 2003, three new risks assessment were issued by the Member States, all of which conflicted with the SCF opinion. In particular:

– the French one confirmed its earlier finding i.e. further studies were needed on toxicity;

– the Austrian scientific body issued a new risk assessment concluding that the risk of allergenicity and toxicity of Bt11 sweet maize has not been sufficiently addressed;

– a Belgian risk assessment was issued raising issues on the molecular characterisation of the product.

The Austrian study was also presented to EFSA[1] which disagreed with its conclusions.

11. The Commission maintained its decision to follow the scientific opinion of the SCF and submitted the draft measure again to the Regulatory Committee for an opinion on 8 December 2003. The Committee did not deliver an opinion. The Member States which abstained or voted against did so on the basis of their conflicting national scientific evaluations.

12. Against this background, the Commission finally adopted a decision for the placing on the market of this product on 19 May 2004.

13. **II. Maize Bt176, submitted under Directive (EEC) Nr 90/220**[2]

14. In this case, conflicting scientific views existed on:

– presence of a non-expressed antibiotic resistance gene (Ampicillin);

– possible effect of Bt toxin to non-target species and development resistance by target organisms;

[1] EFSA, the European Food Safety Authority, has been established by Regulation (EC) 178/2002, and is carrying over the advisory missions of the former scientific committees, such as the SCP.

[2] Chronology of the procedure outlined in Exhibit EC-139.

– presence of an herbicide resistant gene.

15. Chronology of the application:

16. The application for placing on the market of BT176 was submitted in 1994 to France and covered all uses of that BT maize.

17. In 1995, a scientific opinion was issued by the French relevant scientific committee, on the basis of which France issued a positive risk assessment report and forwarded the application to the Community level in 1995.

18. The Commission circulated the application and the risk assessment report to the competent authorities of the other Member States according to Directive 90/220/EEC.

19. Several Member States objected to the French risk assessment on the basis of their national scientific evaluations of BT176 on the following grounds:

– presence of a non-expressed antibiotic resistance gene (Ampicillin);

– possible effect of Bt toxin to non-target species and development resistance by target organisms;

– presence of an herbicide resistant gene.

Furthermore, they objected to the absence of appropriate labelling requirements.

20. The Member States maintained their opinions based on their conflicting national scientific evaluations and their other concern on labelling throughout the decision making process in the Regulatory Committee and in the Council. Therefore the Commission decided to seek the opinion of the three following scientific committees:

– scientific committee on pesticides on possible effect of Bt toxin to non-target species and development resistance by target organisms;

– scientific committee on food on presence of a non-expressed antibiotic resistance gene; and

– scientific committee on animal nutrition on the same issue.

21. The committees requested the applicant to provide additional information.

22. On the basis of the new information provided, that included a new molecular characterisation of the antibiotic marker gene, these three committees concluded that there were "no reasons to believe that the introduction of the genes concerned into the maize would have any adverse effect on human health and environment".

23. The Commission decided to follow the opinion of the scientific committees and on 23 January 1997 it adopted a decision for the placing on the market of this product.

24. Luxembourg and Austria invoked on 14 February 1997, measures based on Article 16 of Dir. 90/220 in order to prohibit the use and/or the sale of these products on their territory on the grounds of their conflicting risk assessments on possible effect of Bt toxin to non-target species, development resistance by target organisms, and presence of a non-expressed antibiotic resistance gene. Germany also adopted a similar measure on 4 April 2000 for the same reasons.

25. The Commission consulted its relevant scientific committees on the national measures and these committees confirmed their initial opinions.

26. On 2 April 2004, EFSA issued a new opinion dealing with the use antibiotic marker genes. There, it recommended, in line with the previous risk assessments of the Member States which maintained national measures, the phasing out of the use of Ampicillin resistant marker gene.

27. **III. Oilseed rape MS8/RF3, submitted under Directive (EEC) Nr. 90/220 and 2001/18 (Exhibit EC-063)**

28. Finally, the EC would like to come back to the case which it mentioned as an example yesterday because it illustrates another problem that this Panel has to take into consideration: how evolving scientific views have also affected the lapsing of time in the application processes.

29. As the chronology underneath will show, the issue at stake in this case does not relate so much to the existence of conflicting scientific views but rather to the evolution of scientific knowledge with regard to:

- molecular characterisation and detection method;
- monitoring plan and stewardship programme; and
- good agricultural practices.

30. Chronology of the application:

31. Belgium transmitted its initial positive risk assessment report to the Commission on 7 January 1997. The Commission transmitted it to other Member States.

32. Between March and April 1997, AU, DE, DK, ES, FI, FR, UK, IT , NL, SW raised several objections to the Belgian risk assessment on the basis of their national scientific evaluations on the following grounds:

- out-crossing, gene flow;
- molecular characterisation of the product;
- compositional analysis; as well as
- potential unintended and long term effects on the environment.

33. In the light of these objections, in January 1998 the Commission decided to consult the Scientific Committee on Plants (SCP). The SCP issued an opinion on 19 May 1998, where it concluded that there was no evidence to indicate that the marketing of the product was likely to cause adverse effects on human health and the environment. However, the SCP highlighted the existence of scientific uncertainty on potential long terms effects on the environment and thus recommended that the authorisation of the product be conditioned to the availability of a Code of Good Agricultural practices and a monitoring programme. In addition, the SCP requested to be kept informed of the results of the monitoring programme as well as research studies in Member States.

34. In January 1999, the applicant provided a stewardship plan for post-market guidance and monitoring, which was reviewed by the competent Belgium scientific committee, the Biosafety Council in March of the same year.

35. Following an "interim approach" to anticipate the new requirements of the forthcoming directive 2001/18, the Commission and the Member States in October 1999 agreed with the notifier that it needed to provide further information than that considered sufficient by the SCP and relating an updated environmental risk assessment, post market monitoring, agricultural guidelines and identification and detection method.

36. In February 2000, the company informed the Commission of its intension to modify the scope of the application and to proceed with gradual commercialisation in order to collect data to finalise the agricultural guidelines as well as the post-market monitoring.

37. In March 2000, in a meeting of the Regulatory Committee, additional questions were raised by Member States on the updated environmental risk assessment with regard in particular to:

– potential effect of the protein expressed from the transgene on physiological processes of the GMO;

– potential effect of the same protein on soil biological and chemical processes;

– gene transfer and effects on other plants.

38. In the period leading up to September 2001, the company supplied further information, as well as reference material and a detection method. This data was assessed by the Belgium scientific committee and concluded that molecular characterisation needed to be further elaborated. In Nov 2001, the company informed Belgium that additional work was still needed to answer the pending questions on characterisation of flanking regions. The Company provided the information in December 2001.

39. In March 2002, the Belgium scientific committee assessed the new information and requested additional clarification on the molecular data. In May 2002, the company replied to the request for clarifications and in January 2003 submitted an updated dossier in accordance with the new Directive 2001/18.

40. During 2003, a further series of exchanges of correspondence took place between Belgium and the applicant to clarify further issues such as molecular characterisation (i.e. bioinformatics analysis of so called Open Reading Frames), detection method, conditions of the marketing, etc.

41. In October 2003, the results of a 3 years farm scale evaluation research carried out in the UK were published. The product MS8 x Rf3 oilseed rape was part of the trial. The FSE showed that the large scale cultivation of the product in accordance with its intended use (i.e. in combination with the herbicide) would affect on-farm biodiversity to a greater extend than conventional oilseed rape cultivation, a risk that had been raised by some Member States' risk assessment but that had not been addressed by the SCP's opinion.

42. The Belgian scientific body took account of the new scientific data to complete its assessment report which was transmitted to the Commission in February 2004. The dossier is currently being reviewed by the other MS scientific bodies.

2. Is the EC requesting a meeting with scientific experts? If so, what would be the appropriate time for such a meeting?

43. The European Communities requested the Panel to seek appropriate scientific and technical advice in their submission of 27 May but considered that the issues in dispute were not yet sufficiently defined for this to be done at that stage. On the basis of the hearings over the past two days, where the complainants admitted to be in agreement only with the favourable, positive scientific opinions of the scientific committees at community level, the Communities is confirmed in its view of the need for such advice, and repeat its request for a meeting with scientific and technical experts.

44. The Communities consider that, in line with its first submission on this issue and some comments from the complainants, that it might be counterproductive to draft questions too early, and to request such advice before scientific and technical issues in dispute have been well identified. The Communities is therefore of the view that it is necessary to do so after the reception of the written rebuttal submissions of the Parties, where such issues in dispute will be identified.

45. The Communities can therefore accept that such a meeting with scientific and technical experts be held back to back, before the second substantive meeting of the parties, provided (i) that sufficient preparatory work on the identification of the experts and of the questions could have been set aside, and (ii) that it would leave the possibility open for the Panel to seek further scientific and technical advice, in particular on the basis of the outcome of the second substantive meeting of the parties, and its follow up.

3. Please prepare for consideration by the Panel suggested terms of reference for expert consultation.

I. INTRODUCTION

46. The Communities are at the disposal of the Panel to be consulted in identifying the appropriate areas of scientific and technical expertise on which input will be needed and on the identification of appropriate persons and/or institutions whose advice or input may be sought once the scientific and technical issue in dispute would be identified.

47. The Panel now asks the EC to propose draft terms of reference for this scientific and technical advice.

II. TERMS OF REFERENCE

48. In previous cases, panels have always referred technical and scientific questions to a series of individual experts rather that to an expert review group or international organisations. The terms of reference have been very cursory. The EC is not suggesting that the panel should follow these precedents but if they did, each expert could be requested, for example:

- To advise the panel, in the areas of his relevant expertise, on the questions submitted to him.
- To act in his individual capacities and maintain independence and impartiality
- To submit an opinion in written form within the time specified by the panel
- To consider the written comments of the other experts and the parties on his own opinion and revise his opinion as appropriate
- To discuss the opinion with the other experts, the panel and the parties at a meeting.

49. The European Communities believes it is too early to address precisely and definitively all of the questions which might be put to the experts. It gave a number of reasons for this in its submission of 27 May but will now elaborate.

50. It is evident that there are different approaches to the legal and factual issues in this case. The European Communities follows a very different approach to that of the Complainants. Even the Complainants do not agree on the analysis of the issues between themselves.

51. However, different approaches will require different kinds of scientific and technical advice for the Panel to be able to decide properly this case. For example the issues that may justify delay differ from those that might justify an outright suspension of procedures. Also, if the Panel agrees that the national safeguard measures are provisional measures under Article 5.7, it would not need to ask questions on these measures since the Complainants have not raised this in their panel requests. Even if this issue were within the jurisdiction of the Panel, the relevant questions would depend on who has the burden of proof. If the Complainants have the burden of proof but have not made a prima facie case, there is no need to pursue the claims. But if it were on the EC, the situation may be different.

III. PROVISIONAL QUESTIONS

52. In order to assist the Panel in its reflections, the European Communities is however prepared to advance, by way of example, some technical and scientific questions that could potentially be put to experts (on the basis of the issues that presently appear to divide the parties).

53. One series of questions might be designed to assist the Panel to come to a view on the length of time that might be needed for, *inter alia*:

- The validation of an appropriate detection method for a specific GMO;
- The development of an appropriate plan for monitoring the development of resistance to the Bt toxin in target insects; or
- The measurement of appropriate baselines before the implementation of monitoring plans.

54. Another series of questions might be designed to assist the Panel to come to a view on whether there was material scientific uncertainty on certain issues such that it could justify seeking further scientific and technical evidence on specific GMO products for the purposes of considering their authorisation:

- What is the state of scientific understanding and how has it evolved on the risk of horizontal transfer of antibiotic resistance genes from GMO food or feed into bacteria?
- What is the state of scientific understanding and how has it evolved on the risk of out crossing of herbicide resistance genes from GMO plants into the same or other plants species, and in particular into wild relatives?
- What is the state of scientific understanding and how has it evolved on adverse effects of the consequences of the expression of Bt toxins from GMO plants on target and non-target organisms?
- What is the state of scientific understanding, and how has it evolved, on the extent of the information necessary for a proper molecular characterisation of a GMO and the issues

that may arise from any changes in the data to be provided by an applicant on the molecular characterisation of a specific product?

55. Another possible series of questions that the Panel could ask would focus on the specific GM applications and aim to identify whether the potential risks that may be in dispute in the 23 outstanding product applications for approval may be of relevance for the conduct of the approval procedures by the EC.

56. Yet another possible series of questions that the Panel could ask would focus on the possible scientific and technical unique properties of GMOs, that would justify addressing them differently from their traditional counterpart.

57. The EC offers these examples in order to assist the discussion. It does not suggest that all of these are, or relate to, all of the scientific and technical issues in dispute, or that answering all these questions are relevant to the resolution of the legal issues. The hearings have indicated that the parties are also divided on important definitional issues (e.g. toxins, allergens, etc). In the view of the Communities the resolution of these differences would be assisted by independent scientific advice.

IV. CONCLUSION

58. The EC hopes that the above comments are of assistance. It would recall that it has discussed a series of other issues, including the form in which advice could be sought and the potential sources of expertise in its submission of 27 May. Rather than repeat these issues now, the EC would respectfully refer the Panel to that submission.

59. The European Communities remains at the disposal of the Panel to be consulted for any further help that the Panel may deem appropriate in identifying the appropriate expertise and the issues requiring such advice.