

*European Communities – Measures Affecting the Approval and
Marketing of Biotech Products
(DS/291, DS292, DS293)*

**Supplementary Rebuttal Submission
by the European Communities**

**Geneva
15 November 2004**

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I. INTRODUCTION

1. The European Communities welcomes the course that the Panel has followed in this dispute after the Second Written Submissions. Rightly, the proceedings have come to focus on certain delays that are alleged to have occurred in individual product applications; and on the question whether such delays were justified.
2. At the same time, it has become clearer what the dispute is not about: The dispute is not about a general moratorium, but about individual delays. Furthermore, neither the Panel nor the experts consulted in this dispute are required to decide whether genetically modified organisms (GMOs) *per se* present a risk or not. Nor are they required to decide whether specific GMOs should or should not be authorised in the European Communities: those decisions will in any event have to be made by the authorities of the European Communities on the basis of the relevant legislation, whatever the outcome of this dispute may be. Rather, the experts have the important, but more limited, task to assist the Panel in understanding the scientific background of a number of requests for additional information or objections that have caused delays in the processing of individual product applications.
3. The Complainants have come to realize that they can only prove their case if they demonstrate instances of ‘undue delay’ for each individual product application. In their Second Written Submissions they had still relied almost exclusively on the existence of an ominous ‘general moratorium’. Manifestly, the assertion of such a moratorium (whatever the exact definition of such a non-measure may be) was to serve one main purpose, namely to relieve the Complainants of their burden of proof with respect to specific problems that the Complainants allege to have occurred during various product applications. To the extent they have at all addressed individual product applications their allegations are sketchy or manifestly unfounded. Supposedly it is with this Supplementary Rebuttal Submission that the Complainants now intend to finally address the issue of delay in a proper way.
4. The European Communities put all relevant facts ‘on the table’ in its First Written Submission. Since the Complainants have not so far come back to the facts and the legal arguments presented by the European Communities, there is little that the European Communities can add to its previous Submissions at this stage. In light

of the course the proceedings have taken, however, the European Communities would like to take the opportunity to address a few key issues it considers pertinent at this stage of the proceedings.

5. First, it would like to point out that the Complainants have not met the onus of proving their case. The European Communities then wishes to draw the Panel's attention to the role of panels and expert advice under the DSU with a view to assisting the Panel in making its factual findings. Finally, the European Communities will sketch certain implications that the principle of procedural fairness has on the Panel's selection of potential questions to experts in the Complainants' supplementary submissions.

II. THE BURDEN OF PROOF

6. As the European Communities explained in detail in its Second Written Submission,¹ it is for the Complainants to establish a *prima facie* case. The failure of the Complainants to address each and every delay in its Second Written Submission is particularly regrettable in view of the fact that the European Communities presented detailed chronologies and additional documentation since the very beginning of this procedure. Documents subsequently made available by the European Communities merely serve to support the facts known to the Panel, without adding any substantive new facts. On the basis of this information, the European Communities has entirely refuted the Complainants' original contention that the procedures have been "stalled". It has demonstrated that all notifications have been continuously processed and that, to the extent that delays have occurred, these delays occurred for legitimate reasons.
7. Since the European Communities has, thus, refuted the contention that procedures have been "stalled", it is for the Complainants to present a *prima facie* case of undue delay with respect to each individual product application. The Complainants have not taken this opportunity in their Second Written Submissions.
8. Instead of presenting detailed facts and arguments which would warrant the conclusion that 'undue delays' occurred, the Complainants' discussion of individual product applications is mostly reduced to a particular *legal* argument, which runs like a red thread through their Submissions: that the European Communities is under a WTO obligation to authorise a product application, once an advisory

¹ Paras 10 et seq.; paras. 248 et seq.

scientific committee has issued a 'favourable' scientific opinion. The European Communities has demonstrated that this legal argument is simplistic and erroneous as a matter of law.² In any event, a legal argument – persuasive or not – is never a substitute for a rigorous presentation of the facts that are necessary for the Panel to reach its conclusions.

9. The failure on the part of the Complainants to present a *prima facie* case with regard to each individual product application cannot be 'compensated' by reference to additional information that may be contained in expert opinions. The Panel must not make the case for the Complainants. In *Japan – Varietals*, the Appellate Body confirmed this fundamental rule of evidence valid also in WTO proceedings:

Article 13 of the DSU and Article 11.2 of the *SPS Agreement* suggest that panels have a significant investigative authority. However, this authority cannot be used by a panel to rule in favour of a complaining party which has not established a *prima facie* case of inconsistency based on specific legal claims asserted by it. A panel is entitled to seek information and advice from experts and from any other relevant source it chooses, pursuant to Article 13 of the DSU and, in an SPS case, Article 11.2 of the *SPS Agreement*, to help it to understand and evaluate the evidence submitted and the arguments made by the parties, but not to make the case for a complaining party.³

10. Hence, the Panel can only base its findings on expert advice *to the extent that Complainants have asserted all such facts necessary to substantiate their claims*. The Appellate Body in *Japan – Varietals* overruled the panel on the ground that it based itself on information not expressly asserted by the complaining party:

In the present case, the Panel was correct to seek information and advice from experts to help it to understand and evaluate the evidence submitted and the arguments made by the United States and Japan with regard to the alleged violation of Article 5.6. The Panel erred, however, when it used that expert information and advice as the basis for a finding of inconsistency with Article 5.6, since the United States did not establish a *prima facie* case of inconsistency with Article 5.6 based on claims relating to the "determination of sorption levels".⁴

11. The European Communities welcomes the fact that the Panel took the opportunity to seek extensive background information and technical advice from experts. At

² The procedure requires the *regulator* (other than the scientific body) to take account of various non-SPS concerns and the Community legislation which sets this procedure is not at issue in this case. See Second Submission of the European Communities, paras. 27 et seq.

³ Appellate Body Report, *Japan-Measures Affecting Agricultural Products*, WT/DS76/AB/R, para. 129.

⁴ Appellate Body Report, *Japan-Measures Affecting Agricultural Products*, WT/DS76/AB/R, para. 130.

the same time, it invites the Panel to be mindful of the fact that such expert advice does not alter the burden of proof. It is entirely on the Complainants to present a *prima facie* case of inconsistency with WTO law; and to refute any such evidence presented by the European Communities to the contrary.

III. THE ROLE OF THE PANEL

12. The present dispute has arrived at a very delicate junction. The Panel has used its right pursuant to Article 13 of the DSU and Article 11.2 of the *SPS Agreement* to consult several experts on certain aspects of GMOs. The Panel has sought expert advice both with a view to receiving general background information and to clarifying specific questions of science regarding individual product applications. As a result, the Panel will need to evaluate extensive scientific evidence to reach its finding. To assist the Panel in this task, the European Communities wishes to draw the Panel's attention to the particular role of panels and experts under the DSU.
13. The role of panels in WTO dispute settlement is set by Article 11 of the DSU. It provides that a panel must make an "objective assessment" of the facts. Consequently, the standard of review to be applied by panels is neither 'total deference' to a factual determination by a Member's authority nor a *de novo* review of such a determination, allowing the panel complete freedom to come to a different view than the competent authority.⁵ As the Appellate Body noted, a panel is not tasked to "substitute [its] own conclusions for those of the competent authorities."⁶
14. A distinguished, former chairman of the Appellate Body wrote on this issue: "the panel should accord a considerable degree of discretion to national authorities in the determination and assessment of facts." In particular, a panel cannot "displace the national authority" by rejecting findings made by such an authority on the grounds that it considers other findings more warranted. Finally, a panel is bound to "respect the parameters of the national authority's own investigation."⁷

⁵ Appellate Body Report, *EC-Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, para. 117.

⁶ Appellate Body Report, *United States – Safeguard Measures on Imports of Fresh, Chilled or Frozen Lamb Meat from New Zealand and Australia*, WT/DS177/AB/R, para. 106.

⁷ Cf. C.-D. Ehlermann, N. Lockhart, 'Standard of Review in WTO Law', 7 *JIEL* (2004) 491, at 502.

15. In *US-Cotton Yarn*, the Appellate Body had the occasion to further elaborate on and clarify the line that is to be drawn between permissible “objective assessment” and prohibited “*de novo* review”:

In our view, a *panel* reviewing the due diligence exercised by a Member [...] has to put itself in the place of that Member at the time it makes its determination. Consequently, a panel must not consider evidence which did not exist *at that point in time*. A Member cannot, of course, be faulted for not having taken into account what it could not have known when making its determination. If a panel were to examine such evidence, the panel would, in effect, be conducting a *de novo* review and it would be doing so without having had the benefit of the views of the interested parties. The panel would be assessing the due diligence of a Member in reaching its conclusions and making its projections with the benefit of hindsight and would, in effect, be reinvestigating the market situation and substituting its own judgement for that of the Member. In our view, this would be inconsistent with the standard of a panel’s review under Article 11 of the DSU.⁸

16. The Appellate Body’s ruling in *US-Cotton Yarn* is of perfect relevance for delimitating the panel’s standard of review in the present case. The obligation “to put itself in the place of that Member at the time it makes its determination” has several consequences for the present Panel. Thus, the Panel must look at the state of scientific information and data existing at the time of the measure in question (in this case, the alleged ‘delay’) rather than, from an *ex post* perspective, at the current state of scientific knowledge.⁹ On this basis, all answers by the experts to questions which relate to specific products as well as to those that aim at giving the Panel a scientific background to the dispute need to take into account this *décalage* in time between the current scientific knowledge and the scientific knowledge at the time of the alleged ‘delay’.

⁸ Appellate Body Report, *United States – Transitional Safeguard Measure on Combed Cotton Yarn from Pakistan*, WT/DS192/AB/R, para. 78 (emphasis in the original).

⁹ Cf. also C.-D. Ehlermann, N. Lockhart, cited above, at 502: “This constraint influences the temporal scope of the panel’s factual review. To remain in the ‘place’ of the national authority, the panel is not entitled to examine new facts that were not, or could not, have been included in the national authority’s investigation.”

17. Moreover, the requirement of an “objective assessment of the facts” largely depends on the concrete question at issue and the provisions of WTO law on which a claim is based. As the same distinguished commentator put it, “[c]ertainly, panels perform an ‘objective assessment’; but the scope and intensity of the panel’s assessment is not the same for every issue, in every dispute.”¹⁰ For the *SPS Agreement*, the Appellate Body stated in *EC – Hormones*:

The standard of review appropriately applicable in proceedings under the *SPS Agreement*, of course, must reflect the balance established in that Agreement between the jurisdictional competences conceded by the Members to the WTO and the jurisdictional competences retained by the Members for themselves. To adopt a standard of review not clearly rooted in the text of the *SPS Agreement* itself may well amount to changing that finely drawn balance; and neither a panel nor the Appellate Body is authorized to do that.¹¹

18. Hence, in the present case, the Panel must take account of the carefully struck balance between jurisdictional competence of the WTO and the sovereignty of its Members as reflected in the relevant covered agreement. This balance, in turn, is expressed differently in different provisions of the covered agreement. In the case of the *SPS Agreement*, an Article 5.2 claim may warrant a relatively strict review of the examination undertaken by a Member’s competent authority. By contrast, the more general wording of Article 1(a) of Annex C of the *SPS Agreement* (“without undue delay”) indicates a more deferential standard of review.
19. The latter provision is central to the present dispute. The ‘fine balance’ drawn by the *SPS Agreement* is reflected in the notion of “undue delay”. When considering the issue of “undue delay”, the Panel is not required (or permitted) to engage in a *de novo* review of individual product applications. Rather, the Panel merely needs to look at the applications to satisfy itself that such delays that may have occurred were based on a reasonable justification. In other words, the Panel is not asked to determine whether a prudent government, in the abstract, *should* have behaved or not in a certain manner thus causing delay. It merely needs to find whether, in the concrete case and in light of the factual information and the legal arguments before the relevant authorities, that behaviour which in the end caused a delay *could* justifiably have been adopted.

¹⁰ Cf. C.-D. Ehlermann, N. Lockhart, cited above, at 496.

¹¹ Appellate Body Report, *EC-Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, para. 115.

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20. In this context, the European Communities notes that some questions to the experts¹² could be interpreted as coming close to a (prohibited) *de novo* review of product applications. For example, in the General Questions section, the Panel repeatedly asked whether “[o]n the basis of the information before the Panel, [there is] any scientific evidence to support the hypothesis that” certain risks may ensue from GMOs. The European Communities does not dispute the right of the Panel to request such *background* information that it considers useful for its understanding of the current scientific debate on GMOs. However, when making its findings, the Panel must be mindful of the proper standard of review. In line with the Appellate Body holding in *US-Cotton Yarn*, the relevant point in time is the time of the adoption of the measure alleged to be WTO inconsistent. For example, to decide whether a request for information was justified, it will be necessary to inquire in the state of scientific knowledge or uncertainty at the time the information was requested.¹³

IV. THE FUNCTION OF EXPERT ADVICE

21. The proceedings have moved to the stage of expert consultation. In deciding to consult experts pursuant to Article 13 of the DSU and Article 11.2 of the *SPS Agreement*, the Panel has acknowledged the importance of certain scientific questions for resolving the present dispute.
22. The European Communities notes that many of the questions invite the experts to respond “on the basis of the information before the Panel” or “given the information before the Panel”.¹⁴ As the European Communities has previously noted, the experts should also be requested to provide the Panel with other information of which they may be aware even if it is not “before the Panel”. The European Communities, therefore, welcomes the fact that the Panel has invited the experts to do this in its letters to the experts.
23. As the European Communities has previously argued,¹⁵ it is not open to the Panel to ignore the various scientific positions (in addition to the views expressed by the EC’s own scientific Committees) that have evolved on risk assessment and risk

¹² Questions to Experts of 12 October 2004.

¹³ The European Communities previously expressed this concern in its comments of 24 September 2004 on the draft questions to experts, cf. Explanation Nr. 2 regarding draft Question 1.

¹⁴ See for example point 7 of Annex D to the letter of 23 September.

¹⁵ Final Position of the European Communities on the Need to Seek Scientific or Technical Expert Advice, 21 July 2004; Letter of 27 July 2004 to the Chairman of the Panel.

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- management issues in the international scientific community. To understand the background of this dispute, the Panel must be aware of the various risks that were debated in the scientific world during the relevant period of time. The ‘General Questions’ to the experts demonstrate that the Panel shares this view.
24. Moreover, scientific expertise is essential to assist the Panel in determining whether certain delays that may have occurred were ‘undue’. In this context, the Panel may need to decide whether, for example, the time needed to develop a monitoring plan was excessive, whether certain concerns by the Belgian Biosafety Council were legitimate and reasonable in light of a field study, or whether at the time of a delay, there was a degree of scientific uncertainty about a particular issue. The Panel has understood this second function of expert advice by asking several detailed questions regarding individual product applications.
25. By contrast, neither the Panel nor the experts consulted in this dispute are called upon to decide whether GMOs *per se* present a risk or not. Expert advice under the DSU and the *SPS Agreement* does not have the purpose of resolving scientific controversies. Rather, expert advice is provided for assisting the Panel in its limited task of making findings in the dispute between the parties.
26. It is implicit in the function of expert advice to ‘assist’ the Panel that the power to make legal findings, as such, remains a prerogative of the Panel. Pursuant to Article 13.2 of the DSU, expert opinions serve to clarify “a factual issue concerning a scientific or other technical matter”. Experts enable panels to fully understand any scientific and technical facts of a case. By contrast, expert opinions do not relieve the Panel of its duty to make an independent *legal* assessment of those facts.
27. A final point on the role of expertise in the present dispute seems pertinent to the European Communities. Expert advice on GMOs is limited to clarifying certain questions relating to scientific risks (i.e. risk assessment in the narrow sense).¹⁶ By contrast, expert advice cannot offer the Panel much indication as to whether certain conduct was reasonably justified from a risk management or risk communication perspective. Just as scientific opinions do not conclude the risk assessment process,¹⁷ scientific expert advice in WTO proceedings does not conclude the Panel’s assessment whether certain measures could reasonably and justifiably be undertaken. Instead, the Panel will need to reconstruct a process of complex

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Cf. Second Submission by the European Communities, paras. 21 et seq.

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Second Submission by the European Communities, para. 31.

interaction with multiple actors – risk assessment bodies, risk managers or regulators – to evaluate the WTO consistency of the European Communities’ actions. Expert advice can only assist the Panel in fulfilling part of this task. The ultimate, overall assessment remains the prerogative and the duty of the Panel.

V. PROCEDURAL FAIRNESS AND THE ADMISSION OF ADDITIONAL QUESTIONS

28. The principle of procedural fairness requires that each party be able to comment on factual assertions and legal arguments put forward by the opposing party. As the flip side of the same coin, the principle of procedural fairness equally requires that each party present factual evidence as early as possible. This side of the principle is reflected in Appendix 3 to the DSU, which requires a party to present the facts of the case in its first written submission. Each party can, thus, legitimately expect the opposing party to prepare its submissions in accordance with the principles of sound administration of justice.
29. The European Communities notes that the Panel, in its timetable circulated on 28 October 2004, afforded the parties an opportunity to suggest additional questions for the experts at this already exceptional third round of submissions. The Complainants had extensive opportunity to comment and to suggest questions during the consultation on the draft questions in September. Indeed, the Complainants, at the time, insisted on obtaining more time in order to review allegedly new information submitted by the European Communities.
30. To the extent that the Complainants, for reasons of strategy or negligence, failed to previously comment on the European Communities’ Submissions and to propose the relevant questions, the European Communities respectfully requests that the Panel refrain from considering such questions now.¹⁸
31. Such a selective approach would be in line with the Panel’s previous practice in this dispute. The Panel has been very selective, even restrictive, in choosing from the parties’ proposals such questions that would be addressed to the experts, rejecting a number of questions proposed by the European Communities. In exercising its discretion with regard to the selection of questions, the Panel has the opportunity to take into consideration the fundamental principles of procedural fairness outlined above.

¹⁸ It may not be entirely coincidental that the Complainants asked for a Supplementary Submission on 10 August, i.e. right after the Panel’s decision to consult experts.

32. The European Communities reserves its right to suggest additional questions concerning any *new* facts and arguments presented in the Complainants' Supplementary Rebuttal Submissions. For the rest, the European Communities considers it a question of procedural fairness not to re-address, in the disguise of questions to experts, any 'old' issues that have already been on the table since its First Submission.
33. The principle of procedural fairness raises another issue in this context. According to the timetable, the European Communities will be provided the opportunity to comment on any questions suggested by the Complainants on 17 November. The European Communities notes that it will have merely four working days to comment on a potentially, large number of scientific questions. In view of the extensive time available to the Complainants to prepare such questions, the European Communities doubts whether four days will offer sufficient time to study the questions in the appropriate detail and to provide well-founded comments. The European Communities, thus, respectfully invites the Panel to reconsider its timetable in this respect.