Agriculture & Rural Development Committee ARD 18-01(p4)

Date:	Wednesday 5 December 2001
Time:	2.00pm to 5.15pm
Venue:	Committee Room, National Assembly Building

Responses to first consultation on the implementation of Directive 2001/18 on the deliberate release of GMOs into the environment.

Purpose

1. To inform the Committee of the main findings of the initial consultation on the implementation of Directive 2001/18 on the deliberate release of genetically modified organisms (GMOs) into the environment.

2. The Committee is asked to note the summary of responses at this stage and it will be consulted directly on the substance of the draft regulations themselves when they go out for consultation early next year.

Summary

3. The paper summarises the main findings for the consultation and groups them according to the specific questions respondents were asked to address. It also mentions any other significant themes that emerged.

Timing

4. The issue is being presented at this meeting because it is the earliest opportunity to bring the results to the attention of the Committee. It also provides another opportunity for Members to feed in their views before the draft regulations are drawn up. (Detailed consideration will take place early next year).

Background

5. At present controls on deliberate releases of GMOs into the environment are implemented through Directive 90/220/EEC. This has been replaced by Directive 2001/18/EC which strengthens the EU framework for controlling the deliberate release of GMOs into the environment.

6. The National Assembly for Wales, and the other UK administrations jointly, are responsible for implementation, and as the first part of that process the National Assembly for Wales issued a consultation on implementation which ran from 24 August to 16 November.

7. The National Assembly for Wales consultation reflected the Assembly view on genetically modified crops. It contained a clear statement of the Assembly's desire to operate the most restrictive policy on GM crops as is possible within EU legislation. The questions were focused on areas where there might be opportunities, either in the regulations or the guidance, to reflect Welsh concerns.

8. The consultation sought comments on the following specific issues:

- Scope of the risk assessment;
- How post-market monitoring should operate;
- Whether **all** antibiotic resistance markers should be phased out;
- How the traceability and labelling requirements should be implemented;
- How public consultation on releases should be carried out;
- How the information made available to the public could be improved;
- What could be done to improve the predictability and transparency of decisions within the Commission framework;
- Should the Assembly replace the existing simplified procedure with the differentiated procedure described in the Directive;
- How should ethical and socio-economic issues be taken into account;
- What are the priorities for guidance.

9. The following timetable for the subsequent process of implementing directive is proposed:

- Consultation on draft regulations with scrutiny in ARD running concurrently – Feb to April 02
- Lay before the Assembly – May/June 2002
- Regulations to be debated by the Assembly before the summer recess in 2002, so that if passed, they can come into force before the Commission deadline for implementation of 17th October 2002.

Consideration

10. The consultation was issued to over 165 individuals and organisations. Nine replies were received.

Scope of risk assessment

11. We asked:

What are your views on the scope and depth of the risk assessment set out in Annex II of the Directive?

Are there specific issues you think should be incorporated into the guidance?

12. Eight out of nine respondents commented on this issue. A number of the responses were very detailed and provided specific ideas about issues for inclusion.

13. The main themes in the responses were:

- The risk assessment proposals should be welcomed. (3 responses).
- Effective risk assessment is reliant on there being good information on existing biodiversity indicators and more research is required in this area. (3 responses).
- The risk assessment must look at the management practices associated with the release of a particular GMO, for example use of herbicides, and should include impact on the wider environment. (3 responses).
- The risk assessment should consider the cumulative impact of the release of more than one GMO. (3 responses).
- The risk assessment must examine the potential for indirect and/or long term impacts. (3 responses).
- Further research or guidance on the impact of GMOs is required to make risk assessment meaningful and cause and effect will be difficult to establish. (4 responses)
- The risk assessment should take into account factors like the potential impact on organic farmers. (3 responses)

14. Practical suggestions included limiting the number of GMO releases within a geographical area, limiting the total number of consents for plants that were particularly likely to cross-breed, early notification of plants being planned to ACRE and setting up a panel to review risk assessment evidence.

Post-market monitoring

15. We asked:

What are your views on the specific issues to be addressed in designing and carrying out a monitoring plan in line with the objectives and principles set out in Annex VII to the Directive?

16. Eight responses out of nine commented on this issue.

17. There were few strong themes running across the responses, but several people mentioned the importance of monitoring for indirect and long-term effects as well as more immediate or obvious impacts. One response cautioned that proving cause and effect would be difficult. Several responses also recommended that an independent body be set up to review or carry out post-market monitoring, rather than leaving it to the consent holder.

18. Ensuring that the monitoring plan was appropriate to the release was a theme in several responses, although there was a difference of opinion on what that meant. One response noted that the level of monitoring of environmental impacts could be lower where a plant could not cross-pollinate with other

plants in the wild. Other responses focused on additional things to monitor for when dealing with specific types of plant or modification.

19. There were a range of comments about how to use the information gained through monitoring. One response suggested that monitoring data should be shared between all Member States as a matter of course. A separate response commented that if evidence of a risk to human health or the environment emerged through monitoring the consent should be terminated immediately. Several responses mentioned the importance of comprehensive mapping or registers if plantings.

Antibiotic resistance markers

20. We asked:

Is there a scientific case to assess all antibiotic resistance markers as having an adverse effect on the environment or human health?

21. Six out of nine responses commented on this issue and their comments reflected a wide range of views.

22. Two responses pointed out that there were no proven risks from antibiotic resistance markers. One of these also noted that marker technology has progressed and that other methods are already replacing antibiotic resistance markers.

23. Several other responses welcomed the phasing out of antibiotic resistance markers, although one commented that they should be removed immediately rather than phased out.

Traceability and labelling

24. We asked:

How can the traceability and labelling requirements outlined in Article 26 and the relevant sections of Annex IV best be implemented?

25. Seven out of nine responses commented on this issue. The comments were wide-ranging and focused on a number of different aspects of the traceability and labelling requirements.

26. One response noted that a key benefit of traceability and labelling would be that they helped to promote consumer choice; another response focused on its importance for seeds purity.

27. There were several comments on the scope of traceability and labelling. One response indicated that labelling should be as comprehensive as possible, including for example, labelling the manure of

animals fed on GM feed. Another response suggested that GM products should be marked with a warning stating that there is a risk with purchasing them.

28. One response suggested that the labelling and traceability regime should be overarching across GM, non-GM and organic crops using the same concepts of identity preservation.

29. There were two comments on thresholds. One noted that the technology is in place to deliver the requirements of the Directive and the other commented that the proposed 1% threshold was too high.

Public consultation

30. We asked:

How should the public be consulted on proposals for GMO release and how should their views be taken into account?

31. Five out of nine responses discussed this issue. These generally focused on ensuring that the public is given adequate notice so that they participate effectively.

32. There were a number of practical suggestions about how public consultation could be improved. Three responses recommended that local authorities, including community councils, and farming interests should be specifically consulted. One response developed this idea further suggesting that applicants should be obliged to appear at a local meeting and that a local referendum should decide if the Part B consent should be granted. Two responses suggested that an independent or public body should be set up to feed into decision-making.

33. Several responses stated that consultation period needed to be longer, with two suggesting that the planning application process was a good model.

34. There was some disagreement on the value of the internet as a tool. Two responses felt that it would be a good medium for getting applicants to engage with local concerns; whereas another response felt that a limited number of people access government sites and that they do not represent a good sample of the public. There was general agreement that newspapers and other local information sources are a good place to canvas opinion.

35. Some of the comments on the level of information provided to the public, given in the section below, are also relevant to this subject.

Information to the public

36. We asked:

What should be done to improve the information made available to the public on the deliberate release and marketing of GMOs?

37. Six out of nine responses commented on this issue and there was some disagreement about the level of information necessary.

38. Most of the responses commented that any information provided should be jargon-free and accessible. Several suggested that summaries should accompany some of the more detailed documents such as the risk assessment.

39. Three responses expressed concern that too much information or too much technical detail could be confusing. Two of these responses also noted that there might be limits on the information that could be made available because excessive requirements might represent a barrier to trade.

40. Other comments included ensuring that details of the location of all Part B and C releases are available and using the information requirements of the planning system as a model.

Decision-making

41. We asked:

What should be done to improve the predictability of transparency of decision-making within the deadlines set by the Directive?

42. Four out of nine responses commented on this issue. One response felt that the existing system is already transparent, but that attempting to consider socio-economic issues, which are not strictly based on evidence, would be more difficult.

43. Two responses were in favour of maximum consent lengths and another response felt that improved information to the public and better public consultation would do much to enhance transparency.

Differentiated procedures

44. We asked:

Should the Assembly make a proposal under the new Directive's provisions on differentiated procedures to replace the existing simplified procedure for Part B applications in Wales?

45. Six out of nine responses addressed this issue and a range of views were expressed.

46. Two responses were supportive of a move away from simplified procedures towards differentiated

procedures, although one added the caveat that this was subject to their not being a reduction in public consultation. Another response felt that 15 days were far too short a notification period and a two others commented that the simplified procedures are fine as they are.

47. A fifth response commented that simplified procedures should not be used if they entail a reduction in the full application of a full risk assessment or consultation with the public.

Ethical and socio-economic issues

48. We asked:

How can the Assembly best address the general ethical and socio-economic issues raised in the Directive?

49. Five out of nine responses commented on this and highlighted a number of issues.

50. One response suggested that socio-economic issues would come within the remit of a public consultative forum, which would feed back views to the National Assembly for Wales.

51. Two responses expressed reservations about working these issues into the formal risk assessment process, with one suggesting that further research on how socio-economic issues could be incorporated into decision making was necessary. This echoed the comments in two other responses: both of which were in favour of taking account of socio-economic issues, but felt that further guidance should be sought either from Europe or national advisory bodies such as Agriculture and Environment Biotechnology Commission (AEBC).

Guidance

52. We asked:

Do you have views on the priorities for guidance on issues that would help understanding and effective implementation of the Directive?

53. Two responses commented specifically in response to this question; although many of the points raised under other questions are also relevant.

54. One response stated that the emphasis should be on risk assessment, monitoring principles and labelling.

55. The other response felt that risks from transgene stacking was a priority area for guidance. It also focused on guidance on methods for assessing the magnitude of indirect risks to the environment, and

defining what constitutes harm, as important.

Other comments about the Directive on the National Assembly for Wales policy on GMOs

56. There were a number of other general comments. Several responses made reference to issues around agricultural co-existence such as the need for separation distances and a liability regime to protect organic and conventional farmers.

57. Four of the responses overtly stated support for the National Assembly for Wales policy on GMOs.

Compliance

58. The main powers that will enable the National Assembly to implement the Directive are contained at Part VI of the Environmental Protection Act 1990 and have been transferred to the Assembly by Transfer of Functions Order made under section 22 of the Government of Wales Act 1998. The Privy Council made a designation order at their meeting on 31 October to transfer of the remaining powers, under Section 2(2) of the European Communities Act 1972.

59. The financial implications of implementing the Directive will be assessed as part of a regulatory appraisal, which along with the draft regulations, will be sent out for consultation early next year.

Action for ARD

60. To note the summary of responses and that the Committee will be asked to consider the draft regulations in detail next year.

Contact point
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