



ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT

Advice on the EFSA draft guidance document for the risk assessment of genetically modified plants and derived food and feed

Date: 29 April 2004

A. Introduction

1. The European Food Safety Authority (EFSA) was requested by the Commission to provide detailed guidance to assist applicants in the preparation and presentation of applications for authorisation of GM food and/or feed under Regulation 1829/2003 which came into force on 18 April 2004. EFSA published draft guidance on 7 April for the risk assessment of genetically modified plants and derived food and feed. Comments on the draft guidance document to EFSA have been requested by 9 May.
2. ACRE has concentrated its comments to elements of the document relating to environmental issues. The Committee notes that the guidance document is also being considered by the Advisory Committee on Animal Feedstuffs (ACAF) and Advisory Committee on Novel Foods and Processes (ACNFP) who will focus on animal feed and human food issues.

B. Advice

3. ACRE considered that in general the guidance document was comprehensive and appropriate. The Committee has focussed its specific comments on the following three areas.

Molecular Characterisation

4. The Committee agreed that the sections on molecular characterisation of the GM plant were very good and noted that much of the guidance is in agreement with ACRE's own guidance documents on best practice in GM crop design¹ and molecular data requirements². ACRE did not have any specific comments or suggested amendments to the sections on molecular characterisation.

Environmental risk assessment

5. As with molecular characterisation ACRE was of the view that the sections on environmental risk assessment were complete and cohesive but had the following specific comments.

¹ <http://www.defra.gov.uk/environment/acre/bestprac/index.htm>

² <http://www.defra.gov.uk/environment/acre/molecdata/index.htm>

6. In section 7.1, comparative assessment, the first paragraph on choice of comparator is unclear and requires a more precise explanation as to how a comparator is selected. Examples may be useful here.
7. In section 9.8, effects on biogeochemical processes, the Committee considers that it would be extremely difficult for any applicant to comment fully on the effect of GM plants on biogeochemical processes. In relation to this section a definition of soil fertility is required.
8. ACRE welcomed the reference to a tested, appropriate and cost effective approach to risk assessment as exemplified by the pragmatic interpretation of the results of the UK Farm Scale Evaluations. In risk assessment this type of analogy should be sought wherever possible.

Post-Market Monitoring

9. ACRE agreed that the section on post-market monitoring was generally very good and would be helpful to applicants. However, Members had concerns that in some places, the guidance did not go far enough in terms of practical advice to applicants. For example, there could be more reference to approved sources of methodologies. The Committee would like to draw EFSA's attention to ACRE's own recently published guidance on best practice in the design of post-market monitoring plans³ which the GMO panel may find informative.
10. The Committee noted that section 11.2 of the guidance suggests that case-specific monitoring is only required to determine the significance of any adverse effects identified in the risk assessment and hence is not obligatory. ACRE feels that, as in section 11.1, the role of case-specific monitoring is to "verify the risk assessment" which includes both adverse effects and any assumptions made about the lack of such effects. Hence the Committee feels it would be better practice if applicants who are proposing to have no case-specific monitoring were encouraged to provide strong arguments in support of this position. These arguments should relate to the assumptions they have made in the e.r.a., as well as to the lack of any identified adverse effects. Where case-specific monitoring is proposed, it should use a defined experimental approach to test a specific hypothesis derived from the e.r.a.
11. In general the Committee felt that there were examples of monitoring which EFSA labelled as general surveillance which ACRE would classify as case-specific. For example, the "more focussed in-depth studies" described in section 11.3 would normally be categorised as case-specific monitoring. Also, section 11.4b covers parameters which seem to be beyond the scope of general surveillance and only possible to address through case-specific monitoring, if it is feasible to address them at all (see below).
12. The Committee's main concern on the post-market monitoring guidance is in relation to section 11.4b. This paragraph was considered unhelpful to applicants. It is all encompassing and impractical, with a lack of detail as to how these goals could be achieved. For example, is it really feasible to ask applicants to observe "ecosystem biodiversity"?

³ <http://www.defra.gov.uk/environment/acre/postmarket/index.htm>

13. ACRE supports section 11.5 on implementing general surveillance and thought that the section on existing infrastructures in particular was excellent. However, the Committee felt that the provisions under local surveillance would be an excessive requirement for applicants. In addition, it is unclear as to how local surveillance relates to general surveillance and case-specific monitoring. The Committee is of the view that monitoring actions would routinely fall into either general surveillance or case-specific monitoring.
14. ACRE agrees with the provisions and timings laid out for reporting the results of post-market monitoring, section 11.6.
15. Finally ACRE noted with interest and welcomes a reference to consideration of the potential advantages of the introduction of a GM plant into the environment, final paragraph of section 11.1.