

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

EFSA GUIDANCE ON RISK ASSESSMENT OF GM PLANTS

Issue

The Committee is invited to comment on updated guidance that is being developed by the European Food Safety Authority (EFSA) for the risk assessment of GM plants and derived food and feed.

Background

1. The European Food Safety Authority is responsible for assessing application dossiers submitted under the European regulation on GM food and feed (EC regulation 1829/2003). EFSA GMO Panel adopted guidelines for the risk assessment of GM plants in 2004 and has continued to keep these guidelines under review in the light of experience and advances in science and technology. For example, in 2005 EFSA considered the assessment of plants that contain two or more "stacked" events and issued an additional guidance document in 2007 (see information paper ACNFP/84/11).
2. The GMO Panel has now drawn up an updated version of its GM plant guidance document (**Annex**) which incorporates the Panel's latest thinking. This document is to issued for public consultation from July to September 2008.
3. As before, the updated guidelines are consistent with internationally agreed Codex Alimentarius principles for the assessment of GM plants. The basic strategy is to compare the properties of the GM plants with existing (non-GM) comparators, and for the assessment to focus on the similarities and differences and their impact on human health, animal health and the environment. The assessment is therefore founded on the underlying assumption that traditionally bred crops have a history of safe use and familiarity for the consumer (or animal) and the environment.
4. In addition to updating its detailed approach to risk assessment the Panel has attempted to clarify the data requirements in the various chapters, and the toxicological section has been updated to make reference to relevant international (OECD) standards for the design of the relevant studies. The most significant changes are described below:

(please note that the pages on this version of the document are not numbered; references to the text can be by section number and/or line number)

Stacked events

5. In various places, the draft guidelines incorporate the Panel's existing guidance on the assessment of plants that contain two or more "stacked" events, which was issued separately in 2007 (see ACNFP/84/11).

Comparative analysis (Section 7.1)

6. The existing guidelines set out the general principles for the design of these studies but do not include specific requirements. The new document provides clarity by defining minimum requirements for the design of field trials, including the number of replications and the inclusion of commercial varieties at each site.
7. The GMO Panel has proposed that the compositional data be analysed in two ways, to test the hypotheses that: (a) that the new GM line is different to a non-GM comparator (as a present) and (b) that the GM line is strictly equivalent to existing commercial varieties.
8. The use of this mixed model will maximise the use of the data generated by the recommended study design and is intended to provide a better appreciation of the relationship between the GM event and existing crop varieties, grown under the same conditions.

Animal studies (Section 7.2.5)

9. The document incorporates the conclusions reached by an EFSA Working Group on Animal Trials, whose report was published in March 2008¹. The GMO Panel recognises the difficulties associated with the design of meaningful feeding studies with whole foods and also is mindful of the desirability of avoiding unnecessary animal testing. The Panel recommends that feeding trials should not be conducted routinely but on a hypothesis-driven basis in cases where the composition of the plant has been substantively altered, or where there are indications of unintended effects from the molecular, compositional or agronomic data. The Panel considers that 3 month feeding studies in rodents are sufficiently sensitive and predictive for long-term effects.

Risk characterisation (Chapter IV)

10. The document includes an updated chapter explaining how the results from the different parts of the risk assessment are to be interpreted and considered in characterising the overall risk from the GM plants.

¹ Food and Chemical Toxicology volume 46, supplement 1, pages S1-S70 (2008)

Committee Action Required

11. The Committee is asked to consider EFSA's draft updated guidance and to provide any comments, for inclusion in the Agency's formal response to the public consultation.

**Secretariat
July 2008**

Annexes attached:

Annex – Draft updated EFSA guidance document for the risk assessment of GM plants and derived food and feed (Restricted)
this is an advance copy of the consultation document that will be issued by EFSA for public comment via its website efsa.europa.eu