

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

REPORT ON THE LONG TERM EFFECTS OF GENETICALLY MODIFIED CROPS

Issue

Members are invited to consider a report prepared for the European Commission by a consortium of German organisations on the long term effects of genetically modified (GM) crops and to provide advice on what conclusions may be drawn from this work.

Background

1. The report entitled: “Long-term effects of genetically modified (GM) crops on health and the environment (including biodiversity): prioritisation of potential risks and delimitation of uncertainties”, was prepared for the Commission by a consortium of three partners: the German Federal Office of Consumer Protection and Food Safety, BLaU-Umweltstudien and Genius GmbH. The acronym for this project is BEETLE (Biological and Ecological Evaluation, Towards Long-term Effects).
2. The study was undertaken to examine the question of potential long-term (10-20 years) effects on health and the environment (including biodiversity) of genetically modified plants that are marketed in the EU. The report (attached at **Appendix 1**) focused on the four GM crops most relevant to the EU, i.e. insect resistant maize (specifically Bt maize), herbicide tolerant oilseed rape and sugar beet, and starch-modified potato.
3. The contractors used outputs from literature reviews, online surveys and a workshop to rank the likelihood of adverse long-term effects from crop-trait combinations. The analysis focusses on the likelihood of adverse effects, identifies uncertainties and makes suggestions for ways of minimising these uncertainties (such as modelling and improvements in monitoring methodology), and for other specific actions that could increase knowledge (e.g. research areas). The report does not consider the possible magnitude of the risks due to lack of quantitative information (because of the nature of long-term effects), nor measures to mitigate them.

Objectives of the study

4. The key objectives of the study were:

- To collect and collate information on established or potential long term effects of GM crops on health, biodiversity and the environment
- To prioritise the potential risks of the main crop-trait combinations of relevance to the EU
- To identify the areas of the greatest scientific uncertainty and their origin
- To identify indicators for measuring the development of long term impacts on the environment over time

Study design

5. This paper considers only those parts of the report that relate to long term effects on human and animal health (Chapter 6 of the report and Annex 5) and the molecular characterisation and stability of the GM inserts (Chapter 4 of the report); the sections of the report that relate to long term effects on the environment are not considered here. It should be noted that the main focus of the project was on the potential long term environmental effects rather than health effects. The 'step by step' approach used was as follows:
 1. A literature review of over 81 peer reviewed papers, reports and internet resources, by 'experts' in the field (Annex 4)
 2. Compilation of biological processes that may lead to long term effects
 3. An online survey questionnaire to assess the probability of the occurrence of processes that may lead to long term effects and the associated uncertainties (likelihood of occurrence), with contributions from invited health experts (Annex 5)
 4. Prioritisation of biological processes, crop trait combinations and categories that may lead to long term health effects
 5. Final prioritisation of long term risks (biological processes leading to potential adverse effects and their estimated probability of occurrence)
6. Steps 2, 4 and 5 involved consultation of a peer review Committee of international experts who gave their views on the completeness of the list of risks, finalised the rankings and identified areas of uncertainty.

7. A "CREA space" workshop to discuss ways of minimising uncertainty in relation to risk also formed part of the overall study, but this workshop involved environmental experts only and did not consider health.

Literature review

8. For human health, the review concentrated on various aspects of the risk assessment of GM crops, namely: nutritional assessment, toxicology and allergenicity.
9. For animal health, the review considered published experimental studies on the effects of GM crops on animal health, including a focus on nutritional assessment, toxicology, the fate of transgenic DNA and the fate of novel proteins.

Online health survey

10. Based on the literature review, questions for an online health survey were prepared. The categories of questions were based on; nutritional value, toxicity, horizontal gene transfer and allergenicity, as well as how the risk assessment process might be improved. Fifty-two of 185 invited health experts responded to the questionnaire.
11. The authors state that in the main the results of the literature survey were confirmed by the health survey and additional information was generated for the prioritisation process and the identification of areas of uncertainty.

Molecular characterisation and stability of the transforming DNA

12. Chapter 4 of the main report covers the molecular characterisation and stability of the inserted transgene and discusses the data available in the scientific literature, mainly in relation to the stability of the transgene. The report concluded that, while it was clear that rearrangements of the transgenic DNA occurred at the time of insertion into the plant genome, there was no convincing evidence of subsequent instability of the GM insert. Therefore GM DNA instability was not considered to be a health issue.

Ways forward

13. The CREA space workshop identified three main tools that could be utilised to decrease uncertainty and close knowledge gaps concerning potential long term effects of GM crops: research studies, modelling and monitoring. While the workshop discussed only environmental long term effects, these tools could be considered to be equally applicable to potential long term effects on health.

Conclusions of the report

14. The report concludes that no adverse long term effects of GM crops on human or animal health have yet been established.
15. However, the report notes that GM crops are becoming more complex, with greater numbers of stacked events (multiple GM traits in the same variety) and increasing potential for interactions and subsequent exposure to allergens.
16. Consequently, the authors recommend that further improvement of the risk assessment process for (human and animal) health, accompanied by surveillance/monitoring (e.g. for allergenicity) is the way to identify any potential long term effects.
17. The report also recommends that, if health related differences are to be detected between food (or feed) derived from a GM crop and its most closely related non-GM comparator, more conventional crop varieties should be used in feeding trials in order to cover the natural biological range of the parameters covered.
18. In relation to toxicological assessment, a range of comparators will help to assess whether any statistical differences between the GM plant and its non-GM comparator are biologically relevant.

Committee action sought

19. The Committee is asked to consider the report and to provide advice on what conclusions may be drawn from this work.
20. In particular members are asked to consider the use of survey-based approaches as a tool for identifying the range of opinion (divergent and convergent) among the scientific community.

**Secretariat
June 2009**

Appendices attached:

Appendix 1: The main body of the BEETLE report, with Annexes 4 and 5