



ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT

Advice on a notification for marketing of insect resistant and herbicide tolerant GM maize

Notifier:	Pioneer Hi-Bred International Inc. and Mycogen Seeds
Notification reference:	ES/01/01
Product:	Maize genetically modified for insect resistance and herbicide tolerance, transformation event 1507.
Scope:	For the cultivation, import and use of grain varieties derived from maize transformation event 1507, and conventional hybrids, as for any other maize.
Date:	29 April 2004.

Advice of the Advisory Committee on Releases to the Environment (ACRE) under S.124 of the Environmental Protection Act 1990 (Part VI) to the Secretary of State for Environment, Food and Rural Affairs, Scottish Ministers, Ministers of the Welsh Assembly Government and the Department of Environment (Northern Ireland).

Secondary advice: ACRE has considered this notification for the import, use and cultivation of insect resistant and herbicide tolerant maize based on transformation event 1507. ACRE has assessed the notifier's responses to the further information the Committee requested (Appendix 1) and also the information provided in response to comments from other Member States. ACRE considers that the notifier has not adequately addressed the possible impact of the insect resistance trait on potential target insects in the environmental risk assessment or in its case-specific post-market monitoring plan. Consequently ACRE advises that consent for the cultivation of 1507 maize is not issued at this stage.

Comment:

ACRE first considered this notification in September 2003 and advised that further information was required for it to be able to assess whether the cultivation, import and use of 1507 maize poses a risk to human health and the environment (primary advice attached as Appendix 1): The notifier's response has been assessed by the Committee:

Event-specific detection

ACRE is content with the notifier's response to the request for clarification on the event-specific detection protocol for 1507 maize, but notes that whilst the DNA

sequence targeted for detection is event-specific (because it includes a rearranged fragment of insert DNA) it does not include any flanking host DNA.

Impact of altered weed management

In the further information provided, the notifier states that the scope of notification C/ES/01/01 is limited to the cultivation of 1507 maize without the application of glufosinate ammonium until the herbicide is licensed for this use. ACRE accepts this position but advises that if consent for cultivation of 1507 maize is issued, this should anticipate the licensing of glufosinate ammonium herbicides for use with GM maize and restrict the herbicide regime to that used in the Farm-scale Evaluation (FSE). This is line with ACRE advice on the FSE results, which concludes that cultivation of GM herbicide tolerant maize will not adversely affect the environment if cultivation is managed as in the FSE¹. If alternative herbicide regimes are proposed the Committee would expect to see evidence to demonstrate that these would not adversely affect the environment as compared to conventional management regimes with non-GM maize crops.

Impact of the insect resistance trait on target insects

ACRE advises that the environmental risk assessment (ERA) for 1507 maize does not adequately consider the potential impact of the insect resistance trait on non-target Lepidoptera that are present in the UK. Whilst the notifier has provided strong supporting evidence that there is a high degree of specificity in the biological activity of CRY1F protein against target Lepidopteran pests, it has not considered what Lepidoptera are associated with maize fields in the UK (including hedgerows) or provided experimental data that supports the prediction that these insects would not be adversely affected by the cultivation of 1507 maize. The Committee is aware that numerous studies have been conducted into the potential impact of the insect resistant trait on a diversity of non-target organisms besides the Monarch butterfly, however this information has not been included in the notification.

Post- market monitoring plan

Case specific

As the aim of the case-specific part of the post-market monitoring plan is to investigate risks identified in the ERA and also to test any assumptions included in the ERA, the Committee considers that case-specific monitoring for assumptions about the impact of the insect resistance trait on non-target Lepidoptera in the UK is relevant to this release. The plan should identify the insect species to be monitored and a description of the experimental design, which should include details of the experiment's duration, the selection of study sites including comparators and a consideration of its statistical power.

ACRE has taken into account the further information requested from the notifier by other member states. In particular, the Committee discussed the potential adverse effects on non-target organisms caused by tritrophic effects. Whilst the known target organisms of the CRY1F protein are not present in the UK (i.e. *Ostrinia nubilalis* and *Sesamia nonagrioides*), ACRE notes that the case-specific monitoring plan does not address assumptions about the potential indirect effects that the cultivation of 1507 maize might have on predators and parasitoids associated with these target organisms in European countries where they are found. An important consideration

¹ Link to ACRE advice on Farm-scale Evaluation results:
http://www.defra.gov.uk/environment/acre/advice/pdf/acre_advice44.pdf

in designing such monitoring experiments is the baseline against which levels of non-target organisms in 1507 maize fields should be compared. In areas of Europe where the target pest occurs, the conventional alternative to cultivating insect-resistant maize is to treat non-resistant varieties with chemical sprays.

General Surveillance

In its considerations, ACRE has taken into account the further information requested from the notifier by other member states. In particular, the Committee discussed the general surveillance plan for unanticipated adverse effects on non-target organisms. Whilst ACRE agrees with the principles of the surveillance plan outlined by the notifier, it considers the detail and timeframes suggested to be inadequate. Before this maize is cultivated in the EU the notifier should provide a more detailed general surveillance plan for monitoring unanticipated affects, which should include (1) the strategy for identifying which organisms will be monitored for in different member states (2) the strategy for identifying resources that will be used to provide information, including (where appropriate), which national surveillance programmes will be used (3) the monitoring frequency and the type of information that will be collated and (4) how the company will ensure participation to ensure a robust assessment. The Committee also recommends that monitoring reports be provided by the applicant on an annual basis.

In accordance with its advice on the FSE results², ACRE advises that as atrazine (the principal management practice for conventional maize) is to be phased out in April 2005, monitoring of the indirect effects associated with the management of 1507 maize in the UK should include a comparison of the impacts of new conventional management regimes with those of glufosinate ammonium herbicides used in association with 1507 maize. The FSE results show that weed seed biomass is a key indicator in such monitoring.

ACRE has previously issued advice on the import and use of 1507 maize, excluding its cultivation³ (notification C/NL/00/10), where it advised that consent for release be conditional on the applicant providing a more detailed plan for monitoring animal feed safety before this maize is imported into the EU. Further details should include: (1) precisely who will be requested to provide information; (2) what type of information will be requested and the frequency of requests and (3) how the company will ensure participation to ensure a robust assessment. The Committee also recommends that monitoring reports should be provided by the applicant on an annual basis.

² Link to ACRE advice on Farm-scale Evaluation results:
http://www.defra.gov.uk/environment/acre/advice/pdf/acre_advice44.pdf

³ Link to ACRE advice on C/NL/00/10:
http://www.defra.gov.uk/environment/acre/advice/pdf/acre_advice45.pdf

Annex 1: Primary Advice

Primary advice: ACRE has considered this notification for the import, cultivation and use of insect resistant and herbicide tolerant maize based on transformation event 1507. The Committee does not consider that sufficient information has been provided by the notifier to allow a full assessment of potential risks to human health and the environment of the cultivation of maize 1507. In coming to this conclusion ACRE have taken account of the advice of the Advisory Committee on Animal Feedstuffs (ACAF) Before ACRE can complete its assessment the following information is required.

1. Further details concerning the PCR-based event-specific detection protocol.
2. An environmental risk assessment of the impacts of altered management practices associated with the cultivation of 1507 maize, including consideration of the impact of the insect resistance trait, altered herbicide regime and any potential cumulative effects of the two traits and associated changes in management.
3. An improved post-market monitoring plan that takes into account any risks identified in the environmental risk assessment, and tests any assumptions made in the environmental risk assessment.

Comment

Molecular characterisation

ACRE considered carefully the thorough molecular characterisation of transformation event 1507 provided. The Committee is content that the data provided support the conclusions, and that the event (including rearrangements) has been thoroughly characterised and potential risks evaluated appropriately.

The Committee requests clarification concerning the PCR-based event-specific detection protocol. On page 63 of the notification it is stated that the amplified fragment is between the 3' end of the insert and adjacent sequence showing homology to the ORF25PolyA terminator whereas in Annex 15 states that the primers span the 3' end of the insert and an inverted repeated version of the *Cry1F* gene.

Animal feed safety

On the basis of the evidence supplied by the notifier (including information provided as part of notification NL/00/10) ACRE and ACAF are satisfied that maize line 1507 is as safe as any other commercial maize line when used as feed for animals and that its use poses no risks for consumers of animal products. The Committees are also satisfied that the Cry1F protein does not pose a risk for animals consuming maize line 1507 or for consumers of products derived from animals fed this line.

Environmental risk assessment

ACRE considered carefully the environmental risk assessment (ERA) for 1507 maize provided by the notifier. The Committee did not consider that this assessment had been carried out in full, especially as 1507 maize is both herbicide tolerant and insect resistant. In particular, the ERA does not consider the possible indirect effects due to

changes in management associated with the use of 1507 maize. There are a number of areas that need to be addressed before the ERA is complete:

- Impact of altered weed management. The notifier states that the glufosinate tolerance trait would allow alternative weed management strategies based on the use of this broad spectrum herbicide to be used. This may have an impact on the biodiversity of organisms dependent on weeds for food, which, in turn, may impact on higher trophic levels. The results of the Farm Scale Evaluations of herbicide tolerant crops in the UK, which will be published shortly, will inform this part of the risk assessment.
- Impact of insect resistance trait on target insects. While the notification considers the impact of the insect resistance trait on insects not targeted by the Bt toxin, the ERA does not consider fully the potential wider biodiversity impact of the insect resistance trait resulting from the effect on Lepidoptera. This consideration should not only include consideration of the primary targets *Ostrinia nubilalis* and *Sesamia nonagrioides* but also other potential maize or grass feeding Lepidoptera.
- Cumulative effect of changing management practices. As well as the assessment of the wider biodiversity impacts of the individual traits in 1507 maize, and their associated management practices, the ERA should also consider the potential cumulative impact of the traits. For example, is the impact of the insect resistance trait on non-target Lepidoptera likely to exacerbated by altered floristic balance within fields caused by changes in herbicide use?

Post market monitoring

The aim of the case-specific part of the post market monitoring plan is to investigate risks identified in the ERA, and also to test any assumptions included in the ERA. The current plan for case-specific monitoring is focussed on monitoring to test the effectiveness of the Insect Resistance Management (IRM) strategy. While the Committee consider the IRM and monitoring of resistance to be adequate, the notifier will need to modify considerably the case-specific monitoring plan to take into account the additional requirements for the ERA outlined above. For example, depending on the outcome of the revised ERA, it may be appropriate to monitor changes in populations of target and non-target insects. In drawing up a revised case-specific monitoring plan the notifier should also consider the appropriate timeframe for reporting the outcome of monitoring to the regulatory authorities – this should be as frequent as is compatible with the type of monitoring study being carried out.