



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 import and use of grain varieties derived from maize transformation event 1507, and conventional hybrids, as for any other maize including cultivation.
Date:	25 September 2003

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).

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.