



## ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT

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

<b>Notifier:</b>	Pioneer Hi-Bred International Inc. and Mycogen Seeds
<b>Notification reference:</b>	NL/00/10
<b>Product:</b>	Maize genetically modified for insect resistance and herbicide tolerance, transformation event 1507.
<b>Scope:</b>	For the import and use of grain varieties derived from maize transformation event 1507, and conventional hybrids, as for any other maize excluding cultivation.
<b>Date:</b>	4 <sup>th</sup> February 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).**

**Advice:** ACRE has considered this notification for the import and use of insect resistant and herbicide tolerant maize based on transformation event 1507. The Committee considers that sufficient information has been provided by the notifier to demonstrate that import and use of 1507 maize does not pose a greater risk to human health and the environment than non-GM maize. In coming to this conclusion ACRE have taken into account the advice of the Advisory Committee on Animal Feedingstuffs (ACAF).

Whilst ACRE does not consider that case-specific monitoring is required, it advises that consent for release should be conditional on the notifier providing a more detailed general surveillance plan for monitoring the safety of 1507 maize as animal feed before it is imported into the EU. The Committee also recommends that monitoring reports should be provided by the applicant on an annual basis.

#### **Comment**

ACRE considered this notification in September 2003 and its primary advice was that sufficient information had been provided by the notifier to demonstrate that import and use of 1507 maize does not pose risks to human health and the environment (primary advice attached as Annex A).

However, ACRE did request clarification from the notifier about the DNA sequence to be targeted in event specific detection of this GMO. ACRE is content with the

notifier's response, 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.

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 amended post market monitoring plan which now includes general surveillance for unanticipated adverse effects associated with the use of 1507 maize as animal feed. Whilst ACRE agrees with the surveillance plan in principle, it considers the detail and timeframes suggested by the applicant to be inadequate. ACRE advises 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. As the aim of the case-specific part of the post market monitoring plan is to investigate risks identified in the environmental risk assessment (ERA) and also to test any assumptions included in the ERA, the Committee does not consider that case-specific monitoring is relevant to this release.

## Annex A: Primary Advice



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<b>Notification reference:</b>	NL/00/10
<b>Product:</b>	Maize genetically modified for insect resistance and herbicide tolerance, transformation event 1507.
<b>Scope:</b>	For the import and use of grain varieties derived from maize transformation event 1507, and conventional hybrids, as for any other maize excluding cultivation.
<b>Date:</b>	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 and use of insect resistant and herbicide tolerant maize based on transformation event 1507. The Committee considers that sufficient information has been provided by the notifier to demonstrate that import and use of 1507 maize does not pose risks to human health and the environment. In coming to this conclusion ACRE have taken account of the advice of the Advisory Committee on Animal Feedingstuffs (ACAF). However, ACRE considers that the following additional information is required by the regulatory authorities.

1. Further details concerning the PCR-based event-specific detection protocol.

#### **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. There is a discrepancy between this notification and information provided in notification C/ES/01/01. On page 63 of notification C/ES/01/01 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 4C of this notification it 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 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**

As maize does not grow or survive outside cultivated fields, ACRE agrees with the conclusions of the environmental risk assessment.

### **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 Committee does not consider that any case-specific monitoring is required in this case.