



## ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT

### *Advice on notifications for import and processing of GM crops that are unable to grow under UK conditions*

- Product:** Genetically modified crops that cannot grow and flower under UK conditions.
- Scope:** For the import and processing of seed /grain derived from these crops. Scope excludes cultivation in the EU and use as food or feed.
- Date:** 16 March 2007

**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).**

#### **General advice on the import and processing of GM crops that cannot grow under UK conditions:**

This advice applies to the notifications listed in Annex 1. These notifications are for the import and processing of seed/ grain derived from GM crops that will not grow and flower in the UK if their seed/grain is spilled during transportation and processing. ACRE is satisfied that the import and processing of these GMOs in the UK does not pose a greater risk to the environment or human health than their non-GM counterparts. The use of these GMOs as food and feed is not within our remit and as such, this is not considered in this advice.

#### **Comment:**

##### Environmental risk assessment

This advice concerns notifications submitted under Regulation (EC) 1829/2003 (the GM Food and Feed regulation) to import and process seed/grain derived from GM crops that will not grow and flower in the UK if spillage of seed/grain occurs during transportation and processing. This advice applies to crops such as cotton and rice that have been genetically modified with traits that do not increase the crop's ability to establish and persist under UK conditions. Annex 1 to this advice, lists the notifications (and the GMOs that they concern) submitted under Regulation (EC) 1829/2003 to which this advice applies.

We have considered each of the notifications listed in Annex 1 on a case by case basis before deciding on whether this advice reflects the conclusions of our specific risk assessment.

The ability of seed, grain or tubers to develop into mature plants that produce flowers if spilled during transportation and processing is crucial in terms of the environmental consequences of importing GMOs. This is because the environmental risk posed by the GMO is a function of any hazards it presents to the environment and the exposure of the environment to these hazards. The notifications listed in Annex 1 are for crops that do not grow and flower under UK conditions. Since their genetic modifications do not increase the ability of these crops to survive and persist, their environmental exposure is negligible (i.e. restricted to decomposing seed/grain that may be spilled during transportation and processing).

Theoretically, it is possible that environmental exposure to GM proteins expressed by these GMOs, could increase if the transgenes encoding these proteins transferred to, and were expressed in soil bacteria. ACRE's view is that horizontal gene transfer (HGT) between plants and soil bacteria (under field conditions) is a very rare phenomenon, if it happens at all. However, our approach is to assume that HGT of transgenes may occur and to consider the consequences. ACRE is content that the GMOs listed in Annex 1 do not pose a greater risk to the environment than their non-GM counterparts.

This general advice is relevant to the UK only and ACRE recognises that the situation may be different in other EU countries.

#### Post-market monitoring plans

Notifiers submitting notifications for the import and /or cultivation of live GMOs into the EU under Directive 2001/18/EC and Regulation (EU) 1829/2003 must include an environmental post-market monitoring (PMM) plan. There are two components to PMM that the notifier must address. The first is case-specific monitoring. The aim of case-specific monitoring is to confirm that any assumption in the environmental risk assessment regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment is correct. ACRE considers that for notifications covered by this generic advice (please refer to Annex 1) there is no requirement for case-specific monitoring in the UK. This is because of the lack of any significant environmental exposure.

The second component of a PMM plan is general surveillance. The objective of general surveillance is to identify the occurrence of adverse effects of the GMO or its use on human health and the environment which were not anticipated in the environmental risk assessment. ACRE recommends that PMM plans 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 applicant will ensure participation to ensure a robust assessment.

## **Interaction of the Deliberate Release Directive with the GM Food and Feed Regulation**

The EU regulation (EC/1829/2003) governing the authorisation of GM Food and Feed came into force in April 2004. The European Food Safety Authority (EFSA) is the lead centralised body with responsibility for assessing GMFF applications made under EC/1829/2003 on behalf of Member States (MS). The lead Competent Authority (CA) in the UK for regulation 1829/2003 is the Food Standards Agency (FSA).

The environmental safety requirements as laid down in Directive 2001/18/EC apply to the evaluation of GM Food and Feed notifications to ensure that all appropriate measures are taken to prevent adverse effects on human health and the environment. Under these regulations, EFSA must consult the CA's for Directive 2001/18/EC regarding the environmental requirements. In the UK it is Defra, advised by ACRE, that is the lead CA for 2001/18/EC.

## Annex 1

<b>Notification reference</b>	<b>Crop type</b>	<b>GM Event</b>	<b>Notifier</b>	<b>Advice agreed by ACRE</b>
EFSA/GMO/NL/2005/13	Cotton	LLCotton25 (tolerant to glufosinate herbicides)	Bayer CropScience	16 <sup>th</sup> May 2007