



ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT

General advice on notifications for import and marketing of GM maize grain

- Product:** Maize grain genetically modified for herbicide tolerance and / or insect resistance.
- Scope:** For the import and processing of grain derived from GM maize only. Scope excludes cultivation and use as food or feed.
- Date:** 17 May 2006

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 import and marketing of GM maize grain:

ACRE is satisfied at this stage on the basis of the evidence previously provided in several herbicide tolerant and / or and insect resistant GM maize import notifications that the risk to human health and the environment arising from marketing such products for importation and processing will be no different from that of conventionally bred maize imported for processing.

The assessment of environmental risks associated with cultivation or use as food or feed of herbicide tolerant and / or and insect resistant GM maize is not addressed in this advice.

Comment

The general advice given here only addresses general environmental safety issues relating to the import and processing of live GMOs (i.e., grain) of maize (*Zea mays* sp.). This advice does not relate to a specific GM maize product, it has developed from previous advice given by ACRE on a number of maize import notifications made under 2001/18/EC¹. This advice does not relate to cultivation or food and feed safety of GMOs.

¹ Maize import notifications assessed under 2001/18/EC by ACRE are for events Bt11, 1507, NK603, MON810, MON863, and hybrids NK603 X MON810 and MON863 X MON810. Specific advice issued by ACRE on these GMOs can be found at: <http://www.defra.gov.uk/environment/acre/pubs.htm#advice>

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

The EU regulations (EC/1829/2003) governing the authorisation of GM food and feed (GMFF) came into force in April 2004². 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 GMFF 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 regarding the environmental requirements. In the UK it is Defra, advised by ACRE, that is the lead CA for 2001/18/EC.

Due to the experience gathered by the Committee through its consideration of Directive 2001/18 dossiers, ACRE has issued this advice on its general requirements for ensuring environmental safety during the import and transport of GM maize grain for processing. This advice will be applied to specific cases on the understanding that Defra will seek further advice from ACRE if necessary, for example for a GM trait not previously assessed by ACRE. For GMFF applications involving cultivation, the Committee will continue to make independent and case-by-case evaluations of environmental risk assessments.

Assessment of environmental risks

ACRE has previously assessed the potential risks arising from importation and commercial use of GM maize grain. In arriving at its advice the Committee has considered such notifications against the requirements of the legislation as it relates to the UK and in particular:

- Capacity to survive, establish and disseminate
- Potential for gene transfer
- Genetic and phenotypic stability
- Expressed products from the inserted sequences
- Potential adverse effects for humans and animals: toxic and allergenic effects
- Interactions with other organisms
- Potential effects on biogeochemical processes.

In respect of each of these assessment criteria ACRE has developed the following comments over a number of assessments:

- **Capacity to survive, establish and disseminate**

Since maize does not establish properly outside the agricultural environment and is chilling-sensitive, the impact of escape of grain during storage or transport on gene transfer into other maize crops or weeds is considered to be extremely low. Members consider that because of the low germination rate and subsequent low viability of any germinated maize volunteer plants there are no anticipated environmental risk

² EC/1829/2003

http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf

problems. No differences in dissemination capacity or increased potential for gene transfer have been observed in pollen, seed and vegetative material from GM maize compared with non-GM maize.

- **Potential gene dissemination by pollen or seed**

Due to the low germination rate and subsequent low viability of any germinated maize plants there are no anticipated environmental risk problems.

- **Potential for gene transfer**

The potential for transfer of genetic material from GM maize is no different to that for conventional maize varieties. Gene flow will only occur into other cultivated maize plants, and the likelihood of gene transfer is low due to a combination of biological barriers. Additionally, this advice only relates to import and processing of maize grain, where the incidence of fertile male or female flowers will be extremely low.

The Committee is of the view that the presence of specific antibiotic resistance marker genes in particular genetic contexts should be considered on a case-by-case basis and has previously advised that antibiotic resistance marker genes should be avoided in the design of future GM crops³. ACRE recognises that antibiotic resistance marker genes raise concerns because of the impact that they may have on antibiotic resistance in bacterial populations. On the specific issue of the presence of the *npII* marker gene in MON863 maize (conferring resistance to the antibiotics neomycin and kanamycin) the Committee has previously advised that it does not constitute a risk to human health or the environment

- **Genetic and phenotypic stability**

In general, the environmental risk assessments for imports of GM maize grain have not identified any potential differences between conventionally bred maize and non-transgenic maize varieties for phenotypic characteristics, with the exception of the new characteristics introduced by the genetic modification, such as tolerance to glyphosate (e.g. NK603), tolerance to glufosinate ammonium (e.g. Bt 11; 1507) and insect resistance conferred by a Cry toxin gene (e.g. Cry 1Ab in MON810 and Bt11; Cry3Bb1 in MON863; Cry1F in 1507).

- **Genetic stability of hybrid GMOs**

In general, ACRE considers that confirmation of the safety profile of the two parent lines is sufficient to support a positive assessment of a GM hybrid that has been produced by conventional breeding. In cases of hybrid GM maize assessed to date ACRE has been satisfied with the evidence presented by notifiers for the genetic stability of the inserts and the negligible likelihood and potential consequences of recombination between the inserted genetic sequences during the production of hybrid GM maize. However, the Committee is also of the view that GM hybrids should be considered on a case-by-case basis, particularly if one or more of the parental GM lines have not been previously assessed by ACRE.

- **Potential effects on biogeochemical processes**

Potential effects on biogeochemical processes, or impacts resulting from changes in management methods, arising from cultivation of the herbicide tolerant maize do not apply directly to notifications in which the GM maize is not for cultivation. The likelihood of any potential effects being manifest on biogeochemical processes arising from unintentional introduction of the GM maize into the environment is considered to be extremely low.

³ <http://www.defra.gov.uk/environment/acre/bestprac/guidance/index.htm>

Post-market monitoring

The aim of the case-specific part of the post-market monitoring plan (PMMP) is to investigate any risks identified in the environmental risk assessment, and to test any assumptions made in the risk assessment. In general, ACRE has agreed that on the basis of previous risk assessments for import of GM maize made under 2001/18/EC, there has been no requirement for case-specific monitoring to date. However, the committee recommends that provision of the detailed arrangements for general surveillance PMMPs should be made a condition of any consent. Details in the PMMP 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.