



ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT

Advice on a notification for import and processing of herbicide tolerant GM oilseed rape

- Reference:** EFSA-GMO-UK-2005-25
- Product:** Oilseed rape, line T45, genetically modified to introduce tolerance to glufosinate ammonium herbicides.
- Scope:** For the import and processing seed derived from T45 oilseed rape and use as food or feed. Scope excludes cultivation in the EU.
- Date:** 4 June 2008

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 on the import and processing of seeds derived from glufosinate tolerant T45 oilseed rape (OSR):

ACRE is satisfied that in the UK the import and processing of the T45 OSR does not pose a greater risk to the environment or human health than its non-GM counterparts.

This notification includes food/feed use within its scope. Thus no authorisation will be given unless the notifier has demonstrated that the GMO in question is as safe as its non-GM equivalent in terms of food/feed safety. However, it is not within ACRE's remit to consider food/ feed safety. ACRE's responsibility is to assess the potential environmental impacts. Consequently, this advice concerns the environmental risk assessment and post-market monitoring components for this notification.

Comment

Environmental risk assessment

This advice concerns a notification submitted under Regulation (EC) 1829/2003 (the GM Food and Feed regulation) to import and process seed derived from T45 GM oilseed rape (*Brassica napus*). T45 oilseed rape (OSR) has been genetically modified so that it

is tolerant to glufosinate ammonium herbicides. The plant expresses a phosphinothricin acetyl-transferase (PAT) enzyme that acetylates glufosinate thereby conferring tolerance to glufosinate-ammonium herbicides (such as Liberty® and Basta®). The *pat* gene encoding this enzyme was inserted into the OSR genome using an *Agrobacterium* vector. The transformation event T45 contains a synthetic version of the native *pat* gene which was originally isolated from a common non-pathogenic soil microbe *Streptomyces viridochromogenes*.

The level of exposure of the environment to the GMO is an important element of the risk assessment. OSR seed has the potential to germinate, grow, flower and establish in the UK if seed is accidentally spilled during transportation and processing. These seeds can also persist and remain viable in the soil for several years (Lutman 2005¹). Weedy oilseed rape populations occur in other crops and feral oilseed rape populations are found along transport routes in the UK and other parts of Europe, particularly where the ground has been disturbed (Crawley and Brown 1995²). Escaped seed of GM oilseed rape has similarly been found to form volunteer or feral populations in Canada and Japan (Hall 2000³; Aono *et al* 2006⁴; Yoshimura *et al* 2006⁵) and would be expected to do so under European conditions. Exposure may therefore occur through the escape of seeds, or through pollen flow.

As seed from T45 OSR varieties is no longer being sold or distributed, only small amounts of this GMO are likely to be present in imported material. Therefore, whilst it is possible that T45 OSR plants could grow from spilled seed, the incidence of feral plants is likely to be low.

OSR is predominantly self-pollinating, but it is also sexually compatible with a number of wild relatives in the UK, especially *Brassica rapa* (OECD 1997⁶; Chèvre *et al* 2000⁷, Chèvre *et al* 2003⁸, Ford *et al* 2006⁹, FitzJohn *et al* 2007¹⁰). Gene flow may therefore occur through cross-pollination of feral or volunteer populations of T45 oilseed rape with compatible wild relatives or with other oilseed rape crops.

ACRE has considered this aspect and advises that neither feral T45 OSR nor hybrids containing its transgenes would show enhanced fitness, persistence or invasiveness in the absence of glufosinate ammonium herbicides. This is because (i) seeds from GM

¹ Lutman *et al* 2005 Persistence of seeds from crops of conventional and herbicide tolerant oilseed rape (*Brassica napus*). *Proc Biol Sci*, 272, 1909-15.

² Crawley, M. J. and Brown, S. L. (1995). Seed limitation and the dynamics of feral oilseed rape on the M25 motorway. *Proc. Roy. Soc. Lond. B* **259**, 49-54.

³ Hall *et al* 2000. Pollen flow between herbicide-resistant *Brassica napus* is the cause of multiple-resistant *B. napus* volunteers. *Weed Science*, 48, 688-694.

⁴ Aono *et al* 2006). Detection of feral transgenic oilseed rape with multiple-herbicide resistance in Japan. *Environ Biosafety Res*, 5 77-87.

⁵ Yoshimura *et al* 2006. Transgenic oilseed rape along transportation routes and port of Vancouver in western Canada. *Environ Biosafety Res*, 5, 67-75.

⁶ OECD 1997. Consensus document on the biology of *Brassica Napus* L. (oilseed rape). Series on harmonization of Regulatory Oversight in Biotechnology No 7 OECD/GD (97)63. Organisation for Economic Co-operation and Development.

⁷ Chèvre *et al* 2000. Assessment of interspecific hybridization between transgenic oilseed rape and wild radish under normal agronomic conditions. *Theoretical and Applied Genetics*, 100, 1233-1239.

⁸ Chèvre *et al* (2003). Gene flow from oilseed rape to weedy species. *Acta Agriculturae Scandinavica section B – soil and plant science* **53**, 22-25.

⁹ Ford *et al* 2006. Spontaneous gene flow from rapeseed (*Brassica napus*) to wild *Brassica oleracea*. *Proc Biol Sci*, 273, 3111-5.

¹⁰ FitzJohn R.G. *et al*. Hybridisation within *Brassica* and allied genera: evaluation of potential for transgene escape. *Euphytica*, **158**, 209-230.

OSR that are tolerant to glufosinate-ammonium herbicides do not exhibit enhanced dormancy (Hails *et al* 1997¹¹, Lutman *et al* 2005¹), and (ii) glufosinate-tolerant OSR has not been found to be any different in survival or invasiveness in semi-natural habitats in the UK over a 10 year period (Crawley *et al* 1993¹², 2001¹³). Glufosinate ammonium herbicides are not widely used in arable farming systems in the EU and there is no evidence that glufosinate-tolerance enhances invasiveness or persistence of feral populations except in the presence of the herbicide.

Because of the potential for plants to grow as a result of accidental spillage in the UK, exposure of soil flora and fauna to T45 OSR although minimal, still requires consideration. Theoretically, it is possible that environmental exposure to GM proteins could increase if the transgenes encoding these proteins transferred to, and were expressed by 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. Genes encoding PAT are known to be common in soil microbial populations. In the unlikely event of HGT occurring following accidental release and establishment of T45 oilseed rape in the environment, it is very unlikely that new traits will be introduced into microbial communities or confer selective advantage or increased fitness. ACRE is therefore content that T45 OSR does not pose a greater risk to the environment than its non-GM counterparts.

This 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 the T45 OSR notification covered by this advice there is no requirement for case-specific monitoring in the UK as no potential risks have been identified from the environmental risk assessment.

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 considers that for the T45 OSR notification covered by this advice there is a satisfactory general surveillance plan since the scope of the ERA of the application does not cover cultivation and did not identify any adverse environmental effects.

ACRE advises that appropriate management systems should be in place to minimise accidental spillage of GM OSR seed during transportation.

¹¹ Hails *et al* 1997. Burial and seed survival in *Brassica napus* subsp. *oleifera* and *Sinapis arvensis* including a comparison of transgenic and non-transgenic lines of the crop. *Proc Biol Sci*, 264, 1-7.

¹² Crawley *et al* 1993. Ecology of transgenic oilseed rape in natural habitats. *Nature*, 363, 620 – 623.

¹³ Crawley *et al* 2001. Transgenic crops in natural habitats. *Nature*, 409, 682-3.

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 CAs for Directive 2001/18/EC regarding the environmental requirements. In the UK it is Defra, advised by ACRE, which is the lead CA for 2001/18/EC.