

Advisory Committee on Releases to the Environment

General advice on notifications for import and processing of GM crops that are unable to grow under UK conditions

Advice of the Advisory Committee on Releases to the Environment (ACRE) under S.124 of the Environmental Protection Act 1990 (Part VI) to UK ministers and ministers in the Devolved Administrations

Product: Genetically modified crops that cannot grow under UK conditions.

Scope: For the import and processing of seed /grain derived from these crops. Scope excludes cultivation and use as food or feed.

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 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 general 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 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 general advice applies.

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

The ability of reproductive material such as seed, grain, tubers etc. to germinate and establish if spilled during transportation and processing is a crucial aspect 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 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/ processing and to transgene-encoded proteins that might remain in manure and faeces from animals fed these GMOs). 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. 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 advice is relevant to the UK only and ACRE recognises that the situation regarding germination and survival of spilled seed may be different in other countries.

Post-market monitoring plans

Notifiers submitting notifications for the import and /or cultivation of live GMOs 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

Notification reference	Crop type	GM Event	Notifier	Advice agreed by ACRE
EFSA/GMO/NL/2005/13	Cotton	LLCotton25	Bayer CropScience	23/03/2007
EFSA/GMO/UK/2004/04	Rice	herbicide tolerance LLRICE62	Bayer CropScience	21/02/2008
EFSA/GMO/NL/2005/16	Cotton	281-24-236x3006-210-23 insect resistance	Dow AgroScience	14/07/2010
EFSA/GMO/NL/2011/97	Cotton	T304-40 insect resistance and herbicide tolerance	Bayer CropScience	16/7/2013
EFSA/GMO/NL/2010/77	Cotton	GHB614xLLCotton25 herbicide tolerance	Bayer CropScience	2/6/2014
EFSA/UK/2008/57 & EFSA/GMO/RX/MON15985	Cotton	MON15985 insect resistance	Monsanto	9/9/2014
EFSA/GMO/UK/2007/41	Cotton	MON88913 herbicide tolerance	Monsanto	21/10/14
EFSA/GMO/NL/2009/68	Cotton	281-24-236x3006-210-23x MON88913 insect resistance and herbicide tolerance	Dow Agro Sciences and Mycogen	29/04/16
EFSA/GMO/NL/20011/96	Cotton	GHB119 Insect resistance and herbicide tolerance	Bayer CropScience AG	14/12/16
EFSA/GMO/NL/2013/114 ¹	Cotton	MON 88701 Herbicide tolerance	Monsanto	10/05/2017
EFSA-GMO-NL-2011-94	Cotton	GHB614 x LLCotton25 x	Bayer CropScience AG	18/05/2018

		MON15985 Insect resistance and herbicide tolerance		
EFSA-GMO-NL-2014-122 ²	Cotton	GHB614 x T304-40 x GHB119	Bayer CropScience N.V. Insect resistance and herbicide tolerance	24/08/2018

¹EFSA concluded that there was insufficient evidence to conclude on food/ feed safety.

² EFSA updated its opinion in 2020 but did not alter its conclusion on the ERA