

Updated June 2024

Advisory Committee on Releases to the Environment

## General advice on applications 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 applications listed below. These applications 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 ACRE's remit and as such, this is not considered in this advice.

### **Comment:**

#### **Environmental risk assessment**

This general advice concerns applications 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. The applications (and the GMOs that they concern) submitted under Regulation (EC) 1829/2003 to which this general advice applies are below.

The applications listed below were assessed on a case by case basis before deciding on whether this general advice reflects the conclusions of the 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 applications listed below 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, the approach is to assume that HGT of transgenes may occur and to consider the consequences. ACRE is content that the GMOs listed below 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 environmental monitoring plans**

Applications for the import and /or cultivation of live GMOs must include a post-market environmental monitoring (PMEM) plan. There are two components to the PMEM that the applicant 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 applications covered by this generic advice 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 PMEM 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 PMEM 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 GM food/feed applications made under (EC)1829/2003 on behalf of Member States (MS). The lead Competent Authority (CA) in the UK for Regulation (EC) 1829/2003 is the Food Standards Agency.

The environmental safety requirements as laid down in Directive 2001/18/EC apply to the evaluation of GM food and feed applications 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, that is the lead CA for 2001/18/EC.

**Table: applications**

<b>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 herbicide tolerance	Bayer CropScience	23/03/2007
EFSA/GMO/UK/2004/04	Rice	LLRICE62 herbicide tolerance	Bayer CropScience	21/02/2008
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 <sup>1</sup>	Cotton	MON 88701 Herbicide tolerance	Monsanto	10/05/2017
EFSA-GMO-NL-2011-94	Cotton	GHB614 x LLCotton25 x MON15985 Insect resistance and herbicide tolerance	Bayer CropScience AG	18/05/2018

EFSA-GMO-NL-2014-122 <sup>2</sup>	Cotton	GHB614 x T304-40 x GHB119  Insect resistance and herbicide tolerance	Bayer CropScience N.V.	24/08/2018
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<sup>1</sup> EFSA concluded that there was insufficient evidence to conclude on food/ feed safety.

<sup>2</sup> EFSA updated its opinion in 2020 but did not alter its conclusion on the ERA