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Advisory Committee on Releases to the Environment

General advice on applications for import and processing of GM crops that have a limited potential to grow and flower outside of agricultural conditions in the UK

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 have a limited potential to grow and flower outside of agricultural conditions in the UK
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 have a limited potential to grow and flower outside of agricultural conditions in the UK if their seed/ grain is spilled during transportation and processing.

ACRE is satisfied that in the UK, the import and processing of the GMOs listed below does not pose a greater risk to the environment or human health than their non-GM counterparts.

All of these applications include food and/or feed use within their scope. As such, they will not be authorised unless the notifier has demonstrated that the GMOs in question are as safe as their non-GM equivalents in terms of food/feed safety. However, it is not within ACRE's remit to consider food/ feed safety, it is ACRE's responsibility to assess the potential environmental impacts. Consequently, this advice concerns the environmental risk assessment and post-market environmental monitoring (PMEM) components of the applications listed below.

Comment

Environmental risk assessment

This 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 have a limited potential to grow and flower in the UK if spillage of seed/grain occurs during transportation and processing. This advice applies to crops that have been genetically modified with traits that do not increase the crop's ability to establish and persist under UK conditions. Listed below are the applications (and the GMOs that they concern) submitted under Regulation (EC) 1829/2003 to which this advice applies.

We have considered each of the applications listed below on a case-by-case basis before deciding on whether this 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.

In the case of the GMOs listed below, a very small proportion of seeds/grain spilt during transport and processing is likely to germinate and produce plants. In turn, these plants are very unlikely to flower. Plants that do not flower cannot pollinate other plants or set seed themselves. This restricts environmental exposure. The crops listed below do not have sexually compatible wild relatives in the UK.

Because of the low potential for plants to grow as a result of spillage in the UK, exposure of soil organisms to the GMOs listed below will be minimal. Indirect exposure of organisms to transgene-encoded proteins that might remain in manure and faeces from animals fed these GMOs will also be extremely low and of no ecological relevance. 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 monitoring plans

Applications for the import and /or cultivation of live GMOs must include a PMEM plan. There are two components to PMEM that the applicant must address. The first is case-specific monitoring. ACRE considers that for applications covered by this 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.

This advice applies to GMOs that do not show altered characteristics that could indicate a greater potential to persist or to invade new habitats; as such, plants that germinate from grain spilled during the importation of the GM soybean and maize events listed below are unlikely to survive for more than one generation in the receiving environments of the UK. ACRE advises that it is not necessary to control plants containing the GM events listed below unless monitoring indicates that they pose a greater risk to the environment than their non-GM counterparts.

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 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 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.

Table: Applications

Reference	Crop type	Event	Applicant	Advice agreed by ACRE
EFSA/GMO/NL/2005/12	Maize	59122 insect resistance and herbicide tolerance	Pioneer Hi-Bred International and Mycogen Seeds, c/o Dow Agrosciences	16 May 2007
EFSA/GMO/NL/2005/18	Soybean	A2704-12 herbicide tolerance	Bayer CropScience	27 Sept 2007
EFSA/GMO/UK/2004/01	Maize	NK603 x MON 810 herbicide tolerance	Monsanto	24 Oct 2017
EFSA/GMO/UK/2005/19	Maize	GA21 herbicide tolerance	Syngenta	6 Dec 2007
EFSA/GMO/NL/2006/36	Soybean	MON89788 herbicide tolerance	Monsanto	15 Aug 2008
EFSA/GMO/UK/2005/20	Maize	59122 x NK603 insect resistance and herbicide tolerance	Pioneer Hi-Bred International	10 Dec 2008
EFSA/GMO/NL/2007/37	Maize	MON89034 insect resistance	Monsanto	15 Jan 2009

Reference	Crop type	Event	Applicant	Advice agreed by ACRE
EFSA/GMO/UK/2005/21	Maize	59122 x NK603 x 1507 insect resistance and herbicide tolerance	Pioneer Hi-Bred International	28 April 2009
EFSA-GMO-RX-Bt11 (renewal)	Maize	Bt11 insect resistance and herbicide tolerance	Syngenta	28 April 2009
EFSA/GMO/NL/2005/15	Maize	59122 x 1507 insect resistance and herbicide tolerance	Pioneer Hi-Bred International & Dow AgroSciences	20 May 2009
EFSA/GMO/UK/2005/11	Maize	MIR604 insect resistance	Syngenta	2 July 2009
EFSA/GMO/CZ/2006/33	Maize	MON88017 x MON810 insect resistance and herbicide tolerance	Monsanto	2 July 2009
EFSA/GMO/UK/2007/49	Maize	Bt11 x GA21 insect resistance and herbicide tolerance	Syngenta	19 Oct 2009
EFSA/GMO/NL/2007/38	Maize	MON89034 x NK603 insect resistance	Monsanto	1 Nov 2009

Reference	Crop type	Event	Applicant	Advice agreed by ACRE
EFSA/GMO/NL/2007/39	Maize	MON89034 x MON88017 insect resistance	Monsanto	14 April 2010
EFSA/GMO/UK/2007/48	Maize	MIR604 x GA21 insect resistance and herbicide tolerance	Syngenta	27 May 2010
EFSA/GMO/UK/2007/50	Maize	Bt11 x MIR604 insect resistance	Syngenta	27 May 2010
EFSA/GMO/UK/2008/56	Maize	Bt11 x MIR604 x GA21 insect resistance and herbicide tolerance	Syngenta	27 May 2010
EFSA/GMO/CZ/2008/62	Maize	MON89034 x 1507 x MON88017 x 59122 insect resistance and herbicide tolerance	Dow AgroSciences and Monsanto	22 Oct 2010
EFSA/GMO/NL/2009/65	Maize	MON89034 x 1507 x NK603 insect resistance and herbicide tolerance	Dow AgroSciences and Monsanto	22 Oct 2010

Reference	Crop type	Event	Applicant	Advice agreed by ACRE
EFSA/GMO/UK/2007/43	Soybean	356043 herbicide tolerance	Pioneer	30 August 2011
EFSA/GMO/NL/2009/73	Soybean	MON87701 x MON89788 insect resistance and herbicide tolerance	Monsanto	27 April 2012
EFSA/GMO/NL/2010/78	Soybean	MON87705 herbicide tolerance and altered fatty acid profile	Monsanto	18 February 2013
EFSA/GMO/NE/2009/70	Maize	MON87460 drought resistance	Monsanto	18 February 2013
EFSA/GMO/NL/2010/93	Soybean	MON87708 herbicide tolerance	Monsanto	22 October 2013
EFSA/GMO/NL/2007/46	Maize	T25 herbicide tolerance	Bayer	28 October 2013
EFSA/GMO/NL/2009/64	Soybean	BPS-CV127-9 herbicide tolerance	BASF	17 February 2014
EFSA/GMO/NL/2007/45	Soybean	305423	Pioneer	16 May 2014

Reference	Crop type	Event	Applicant	Advice agreed by ACRE
		herbicide tolerance and high oleic acid		
EFSA/GMO/UK/2009/76	Soybean	MON87769 stearidonic acid content	Monsanto	9 June 2014
EFSA/GMO/NL/2005/22	Maize	NK603 herbicide tolerance	Monsanto	17 June 2014
EFSA/GMO/DE/2011/95	Maize	5307 insect resistance	Syngenta	18 May 2015
EFSA/GMO/NL/2012/108	Soybean	MON87708 X MON89788 herbicide tolerance	Monsanto	9 July 2015
EFSA/GMO/BE/2012/110	Maize	MON87427 herbicide tolerance	Monsanto	9 July 2015
EFSA/GMO/NL/20102/80	Maize	NK603 X T25 herbicide tolerance	Monsanto	11 August 2015

Reference	Crop type	Event	Applicant	Advice agreed by ACRE
EFSA/GMO/BE/2011/98	Soybean	FG72 herbicide tolerance	Bayer	11 August 2015
EFSA/GMO/NL/2011/100	Soybean	MON87705 X MON89788 herbicide tolerance, increased oleic acid content	Monsanto	11 August 2015
EFSA/GMO/NL/2010/85	Soybean	MON87769 X MON89788 herbicide tolerance, stearidonic acid content	Monsanto	16 November 2015
EFSA/GMO/DE/2009/66	Maize	Bt11 X MIR162 X MIR604 x GA21 insect resistance and herbicide tolerance	Syngenta	21 December 2015
EFSA/GMO/DE/2011/99* A minority view presented in the EFSA opinion was considered by ACRE. It is not considered pertinent to environmental risk assessment and is not, therefore, directly relevant to ACRE's remit.	Maize	Bt11 x 59122 x MIR604 x 1507 x GA21 insect resistance and herbicide tolerance	Syngenta	7 October 2016

Reference	Crop type	Event	Applicant	Advice agreed by ACRE
EFSA/GMO/NL/2010/89	Maize	DAS-40278-9 herbicide tolerance	Dow AgroSciences	13 January 2017
EFSA/GMO/NL/2013/116	Soybean	DAS-81419-2 herbicide tolerance	Dow AgroSciences	27 January 2017
EFSA/GMO/NL/2011/91	Soybean	DAS-68416-4 herbicide tolerance	Dow AgroSciences	24 April 2017
EFSA/GMO/NL/2013/120	Soybean	FG72 x A5547-127 herbicide tolerance	Bayer CropScience	5 May 2017
EFSA/GMO/NL/2012/106	Soybean	DAS-44406-6 herbicide tolerance	Dow Agrosciences	8 June 2017
EFSA/GMO/BE/2013/117	Maize	MON 87427 x MON 89034 x NK603 herbicide tolerance	Monsanto	1 Sept. 2017
EFSA/GMO/NL/2007/47	Soybean	305423 x 40-3-2 herbicide tolerance	Pioneer	8 Sept. 2017
EFSA-GMO-BE-2013-118	Maize	MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 insect resistance and herbicide tolerance	Monsanto	8 Sept 2017

Reference	Crop type	Event	Applicant	Advice agreed by ACRE
EFSA-GMO-NL-2011-92	Maize	1507 x 59122 x MON 810 x NK603 insect resistance and herbicide tolerance	Pioneer	22 December 2017
EFSA-GMO-RX-006	Sugar beet	H7 – 1 herbicide tolerance	KWS SAAT SE and Monsanto Company	10 January 2018
EFSA-GMO-BE-2015-125	Maize	MON87403	Monsanto Europe	2 May 2018
EFSA-GMO-NL-2014-123	Maize	4114 insect resistance and herbicide tolerance	Pioneer Overseas Corporation	15 June 2018
EFSA-GMO-NL-2015-124	Maize	MON87411 insect resistance and herbicide tolerance	Monsanto	6 August 2018
EFSA-GMO-DE-2010-86	Maize	Bt11 x MIR162 x 1507 x GA21 insect resistance and herbicide tolerance	Syngenta	07 August 2018
EFSA-GMO-NL-2014-121	Soybean	MON87751 Insect resistance	Monsanto	28 August 2018
EFSA-GMO-DE-2016-133	Maize	MZHG0JG Herbicide tolerance	Syngenta	17 December 2018

Reference	Crop type	Event	Applicant	Advice agreed by ACRE
EFSA-GMO-NL-2013-112	Maize	MON 89034 x 1507 x NK603 x DAS 40278-9 Insect resistance and herbicide tolerance	Dow AgroSciences	13 February 2019
EFSA-GMO-NL-2013-113	Maize	MON 89034 x 1507 x MON 88017 x 59122 x DAS-40278-9 Insect resistance and herbicide tolerance	Dow AgroSciences	14 February 2019
EFSA-GMO-DE-2011-103	Maize	Bt11 x MIR162 x MIR604 x 1507 5307 x GA21 Insect resistance and herbicide tolerance	Syngenta	08 May 2019
EFSA-GMO-NL-2016-135	Soybean	MON 87708 × MON 89788 × A5547-127 Herbicide tolerance	Monsanto	30 July 2019
EFSA-GMO-NL-2016-131	Maize	MON 87427 X MON89034 X MIR162 X NK603 Herbicide tolerant, insect resistant.	Monsanto	15 August 2019
EFSA-GMO-NL-2016-134	Maize	MON84727 x MON87460 x MON89034 x MIR162 x NK603	Monsanto	06 September 2019

Reference	Crop type	Event	Applicant	Advice agreed by ACRE
		Herbicide tolerant, drought tolerant, insect resistant.		
EFSA-GMO-NL-2017-144	Maize	MON84727 x MON89034 x MIR162 x MON87411 Herbicide tolerance and insect resistant	Monsanto	29 November 2019
EFSA-GMO-DE-2012-111	Soybean	SYHT0H2 Herbicide tolerance	Syngenta	23 February 2020
EFSA-GMO-NL-2015-126	Soybean	MON87705 x MON87708 x MON89788 Herbicide tolerance	Monsanto	17 June 2020
EFSA-GMO-DE-2017-142	Maize	MZIR098 Herbicide tolerance and insect resistant	Syngenta Crop Protection	21 July 2020
EFSA-GMO-NL-2016-132	Soybean	DAS–81419–2 x DAS–44406–6 Herbicide tolerance and insect resistant	Dow AgroSciences LLC	15 December 2020