Advisory Committee on Releases to the Environment

Advice on applications to import and process genetically modified (GM) crops that have a limited potential to grow 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)

This advice applies to the applications listed below.

These applications are for the import of GMOs and their processing and consumption as food or feed. The advice is specific to GMOs (usually grain) derived from crops that have a limited potential to grow (i.e., establish a viable growing population) outside of agricultural (managed) conditions in the UK, e.g., if spilled during transportation or processing.

ACE 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 do their non-GM counterparts.

Authorisation will only be granted if the applicant has demonstrated that the GMOs in question are as safe as their non-GM equivalents. The Food Standards Agency (FSA) is responsible for food and feed safety. It is ACRE's responsibility to assess the potential environmental impacts. This advice concerns the environmental risk assessment (ERA) and post-market environmental monitoring (PMEM) components of the applications listed below.

Comment

Environmental risk assessment (ERA)

This advice applies to crops that have been genetically modified with traits that do not increase the crop's ability to establish and persist, unmanaged, under UK conditions.

We have considered the ERA, and the PMEP plan and reports for each application on a case-by-case basis before deciding whether this advice reflects the conclusions of the specific risk assessment.

We have considered the following potential pathways to environmental exposure.

The ability of reproductive material, e.g., grain, 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, grain spilt during transport and processing, and left unattended, are unlikely to establish a viable growing population. This restricts environmental exposure. The crops listed below do not have sexually compatible wild relatives in the UK.

Exposure of soil organisms to the GMOs listed below will be minimal due to a combination of the low risk of spillage and the limited potential for these plants to establish a viable growing population in the UK's climate.

Regarding indirect exposure of organisms to transgene-encoded proteins that might remain in decomposing food, feed or reproductive material and/or in manure or faeces from animals fed these GMOs, our assessment is that such exposure would 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. Our view is that horizontal gene transfer (HGT) between plants and soil bacteria under field conditions can occur but is a very rare phenomenon. ACRE is content that if the transgenes encoding these proteins did transfer from plants to soil bacteria, fungi or other plants, they would not pose a greater risk to the environment than their non-GM counterparts.

GM crops that have been processed into food or feed products do not pose an environmental risk as they cannot germinate.

This advice is relevant to the UK only and we recognise that the situation regarding germination and survival of spilled seed or grain may be different in other countries.

Post-market environmental monitoring plans (PMEMs)

All applications to market GMOs must include a PMEM plan. This plan should incorporate general surveillance for unanticipated adverse effects and, if necessary, case specific monitoring focusing on specific adverse effects identified in the ERA.

The ERAs relating to applications covered by this advice do not identify any requirement for case-specific monitoring in the UK

Consequently, general surveillance PMEMs are appropriate for applications covered by this advice.

We recommend that PMEM plans should include details of who will be responsible for providing any required information; what type of information is to be provided, and the frequency; and how the applicant will ensure participation to allow a robust assessment to be performed.

Summary conclusion

The plants listed below have a limited potential to establish a viable growing population in UK conditions. 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, any GM plants carrying the transgenic events listed below that may germinate from grain spilled during importation or transport will not persist or survive in the receiving environments of the UK. They do not pose a greater risk to the environment than their non-GM counterparts. We advise that it is not necessary to control plants containing the GM events listed below. Due to the lack of significant environmental exposure, we consider that general surveillance is appropriate.

Applications

References	Crop type	Event(s)	Applicant	Advice agreed by ACRE
EFSA/GMO/NL/2005/12	Maize	59122 Insect resistant. Herbicide tolerant	Pioneer Hi-Bred International and Mycogen Seeds, c/o Dow Agrosciences	16 May 2007
EFSA/GMO/NL/2005/18	Soybean	A2704-12 Herbicide tolerant	Bayer CropScience	27 Sept 2007
EFSA/GMO/UK/2004/01	Maize	NK603 x MON 810 Herbicide tolerant	Monsanto	24 Oct 2017
EFSA/GMO/UK/2005/19	Maize	GA21 Herbicide tolerant	Syngenta	06 Dec 2007
EFSA/GMO/NL/2006/36	Soybean	MON89788 Herbicide tolerant	Monsanto	15 Aug 2008

EFSA/GMO/UK/2005/20	Maize	Maize 59122 x NK603 Insect resistant Herbicide tolerant	Pioneer Hi-Bred International	10 Dec 2008
EFSA/GMO/UK/2005/21	Maize	59122 x NK603 x 1507 Insect resistant Herbicide tolerant	Pioneer Hi-Bred International	28 April 2009
EFSA/GMO/NL/2005/15	Maize	59122 x 1507 Insect resistant Herbicide tolerant	Pioneer Hi-Bred International	20 May 2009
EFSA/GMO/NL/2007/39	Maize	MON89034 x MON88017 Insect resistant	Monsanto	14 April 2010
EFSA/GMO/UK/2007/48	Maize	MIR604 x GA21 Insect resistant Herbicide tolerant	Syngenta	27 May 2010
EFSA/GMO/UK/2007/50	Maize	Bt11 x MIR604 Insect resistant	Syngenta	27 May 2010
EFSA/GMO/UK/2008/56	Maize	Bt11 x MIR604 x GA21 Insect resistant Herbicide tolerant	Syngenta	27 May 2010

EFSA/GMO/NL/2010/78	Soybean	MON87705 Insect resistant Herbicide tolerant	Monsanto	18 February 2013
EFSA/GMO/NE/2009/70	Maize	MON87460 Drought resistant	Monsanto	18 February 2013
EFSA/GMO/NL/2010/93	Soybean	MON87708 Herbicide tolerant	Monsanto	22 October 2013
EFSA/GMO/NL/2007/46	Maize	T25 Herbicide tolerant	Bayer	28 October 2013
EFSA/GMO/NL/2007/45	Soybean	305423 Herbicide tolerant High oleic acid	Pioneer	16 May 2014
EFSA/GMO/UK/2009/76	Soybean	MON87769 Stearidonic acid content	Monsanto	09 June 2014
EFSA/GMO/NL/2005/22	Maize	NK603 Herbicide tolerant	Monsanto	17 June 2014

EFSA/GMO/DE/2011/95	Maize	5307 Insect resistant	Syngenta	18 May 2015
EFSA/GMO/NL/2012/108	Soybean	MON87708 X MON89788 Herbicide tolerant	Monsanto	09 July 2015
EFSA/GMO/BE/2012/110	Maize	MON87427 Herbicide tolerant	Monsanto	09 July 2015
EFSA/GMO/NL/20102/80	Maize	NK603 X T25 Herbicide tolerant	Monsanto	11 August 2015
EFSA/GMO/BE/2011/98	Soybean	FG72 Herbicide tolerant	Bayer	11 August 2015
EFSA/GMO/NL/2011/100	Soybean	MON87705 X MON89788 Herbicide tolerant High oleic acid	Monsanto	11 August 2015

EFSA/GMO/DE/2009/66	Maize	Bt11 X MIR162 X MIR604 x GA21 Insect resistant Herbicide tolerant	Syngenta	21 December 2015
EFSA/GMO/DE/2011/99*	Maize	Bt11 x 59122 x MIR604 x 1507 x GA21 Insect resistant Herbicide tolerant	Syngenta	7 October 2016
EFSA/GMO/NL/2010/89	Maize	DAS-40278-9 Herbicide tolerant	Dow AgroSciences	13 January 2017
EFSA/GMO/NL/2011/91	Soybean	DAS-68416-4 Herbicide tolerant	Dow AgroSciences	24 April 2017
EFSA/GMO/NL/2013/120	Soybean	FG72 x A5547-127 Herbicide tolerant	Bayer CropScience	05 May 2017
EFSA/GMO/NL/2012/106	Soybean	DAS-44406-6 Herbicide tolerant	Dow AgroSciences	08 June 2017
EFSA/GMO/NL/2007/47	Soybean	305423 x 40-3-2 Herbicide tolerant	Pioneer	08 September 2017

EFSA-GMO-BE-2013-118	Maize	MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 Insect resistant Herbicide tolerant	Monsanto	08 September 2017
EFSA-GMO-NL-2011-92	Maize	1507 x 59122 x MON 810 x NK603 Insect resistant Herbicide tolerant	Pioneer	22 December 2017
EFSA-GMO-RX-006	Sugar beet	H7-1 Herbicide tolerant	KWS SAAT SE and Monsanto Company	10 January 2018
EFSA-GMO-BE-2015-125	Maize	MON87403 High ear biomass	Monsanto Europe	02 May 2018
EFSA-GMO-NL-2014-123	Maize	4114 Insect resistant Herbicide tolerant	Pioneer Overseas Corporation	15 June 2018
EFSA-GMO-DE-2010-86	Maize	Bt11 x MIR162 x 1507 x GA21 Insect resistant Herbicide tolerant	Syngenta	07 August 2018

EFSA-GMO-NL-2014-121	Soybean	MON87751 Insect resistant	Monsanto	28 August 2018
EFSA-GMO-DE-2016-133	Maize	MZHG0JG Herbicide tolerant	Syngenta	17 December 2018
EFSA-GMO-NL-2013-112	Maize	MON 89034 x 1507 x NK603 x DAS 40278-9	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 resistant Herbicide tolerant	Dow AgroSciences	14 February 2019
EFSA-GMO-DE-2011-103	Maize	Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 Insect resistant Herbicide tolerant	Syngenta	08 May 2019
EFSA-GMO-DE-2012-111	Soybean	SYHT0H2 Herbicide tolerant	Syngenta	23 February 2020

EFSA-GMO-NL-2015-126	Soybean	MON87705 x MON87708 x MON89788 Herbicide tolerant	Monsanto	17 June 2020
EFSA-GMO-DE-2017-142	Maize	MZIR098 Insect resistant Herbicide tolerant	Syngenta	21 July 2020
EFSA-GMO-NL-2016-132	Soybean	DAS–81419–2 x DAS–44406–6 Insect resistant Herbicide tolerant	Dow AgroSciences LLC	15 December 2020
RP188	Soybean	A5547-127 Herbicide tolerant	BASF	25/04/2023
RP212	Soybean	MON 40-3-2 Herbicide tolerant	Bayer	25/04/2023
RP652	Maize	MIR162 Insect resistant	Syngenta	25/04/2023

RP1506	Maize	DP4114 x MON810 x MIR604 x NK603 Insect resistant Herbicide tolerant	Pioneer Overseas Corportation	25/07/2023
RP1123	Soybean	GMB151 Insect resistant Herbicide tolerant	BASF Agricultural Solutions Seed US LLC	07/11/2023
RP1274	Maize	3272 Thermostable alpha amylase	Syngenta Crop Protection	07/11/2023
RP1791	Maize	NK603 x T25 x DAS-40278-9 Herbicide tolerant	Pioneer Overseas Corporation	07/11/2023
RP1868	Maize	MON95379 Insect resistant	Bayer Agriculture BV	07/11/2023
RP1962	Maize	MON87429 Herbicide tolerant	Bayer Agriculture BV	07/11/2023
RP1565	Soybean	MON 87701 Insect resistant	Bayer CropScience LP	07/06/2024

RP1566	Soybean	MON 87701 x MON 89788 Insect resistant Herbicide tolerant	Bayer CropScience LP	07/06/2024
RP2023	Maize	GA21 x T25 Herbicide tolerant	Syngenta Crop Protection	14/11/2024
RP2044	Maize	Bt11xMIR162xMIR604 xMON89034x5307xG A21 Insect resistant Herbicide tolerant	Syngenta Crop Protection	10/02/2025
RP2149	Soybean	MON 87705 x MON 87708 x MON 89788 Herbicide tolerant	Monsanto Company	12/02/2025
RP2152	Maize	MON89034 x 1507 x MIR162 x NK603 x DAS-40278-9 Insect resistant Herbicide tolerant	Dow AgroSciences	13/02/2025
RP2242	Maize	D-915635 Insect resistant	Pioneer Hi-Bred International Inc.	27/06/2025

* 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.