**ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT**

# Advice on notifications for import and processing of GM crops that have a limited potential to grow and flower outside of agricultural conditions in the UK.

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| **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 in the EU and use as food or feed. |
| **Date :** | 18th February 2013 |

**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, Welsh Ministers and the Department of Environment (Northern Ireland).**

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

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 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 in Annex 1 does not pose a greater risk to the environment or human health than their non-GM counterparts.

All of these notifications 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 our responsibility to assess the potential environmental impacts. Consequently, this

advice concerns the environmental risk assessment and post-market monitoring components of the notifications listed in Annex 1.

## Comment:

Environmental risk assessment

This 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 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. Annex 1 to this advice, lists the notifications (and the GMOs that they concern) submitted under Regulation (EC) 1829/2003 to which this advice applies.

We have considered each of the notifications listed in Annex 1 on a case by case basis before deciding on whether this 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.

In the case of the GMOs listed in Annex 1, 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 in Annex 1 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 in Annex 1 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, 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 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 notifications covered by this 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.

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 in Annex 1 are unlikely to survive for more than one generation in most EU receiving environments. However, it is possible that in some areas of Southern Europe plants from spilled grain (non-GM and GM) could establish, flower and set seed. ACRE considers it appropriate to monitor (in accordance with EFSA's opinions) at locations where the live GMO could be spilled (e.g. along roads linking ports with processing facilities) in regions where there is evidence that this spilled grain could germinate and produce plants that flower and produce seed. ACRE advises that it is not necessary to distinguish between GM and non-GM plants at these sites unless monitoring indicates unexpected changes (e.g. in the number of these plants). Similarly, it is not necessary to control plants containing the GM events listed in Annex 1 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 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 | Event | Applicant | Advice agreed by ACRE |
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| EFSA/GMO/NL/2005/12 | Maize | 59122<br><br>insect resistance and herbicide tolerance | Pioneer Hi-Bred International and Mycogen Seeds, c/o Dow Agrosciences | 16th May 2007 |
| EFSA/GMO/NL/2005/18 | Soybean | A2704-12<br><br>herbicide tolerance | Bayer CropScience | 27th Sept 2007 |
| EFSA/GMO/UK/2005/19 | Maize | GA21<br><br>herbicide tolerance | Syngenta | 6th Dec 2007 |
| EFSA/GMO/NL/2006/36 | Soybean | MON89788<br><br>herbicide tolerance | Monsanto | 15th Aug 2008 |
| EFSA/GMO/UK/2005/20 | Maize | 59122 x NK603<br><br>insect resistance and herbicide tolerance | Pioneer Hi-Bred International | 10th Dec 2008 |
| EFSA/GMO/NL/2007/37 | Maize | MON89034<br><br>insect resistance | Monsanto | 15th Jan 2009 |
| EFSA/GMO/UK/2005/21 | Maize | 59122 x NK603 x 1507<br><br>insect resistance and herbicide tolerance | Pioneer Hi-Bred International | 28th April 2009 |
| EFSA-GMO-RX-Bt11 (renewal) | Maize | Bt11<br><br>insect resistance and herbicide tolerance | Syngenta | 28th April 2009 |
| EFSA/GMO/NL/2005/15 | Maize | 59122 x 1507<br><br>insect resistance and herbicide tolerance | Pioneer Hi-Bred International & Dow AgroSciences | 20th May 2009 |

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| EFSA/GMO/CZ/2005/27 | Maize | MON88017<br><br>insect resistance and herbicide tolerance | Monsanto | 20th May 2009 |
| EFSA/GMO/UK/2005/11 | Maize | MIR604<br><br>insect resistance | Syngenta | 2nd July 2009 |
| EFSA/GMO/CZ/2006/33 | Maize | MON88017 x MON810<br><br>insect resistance and herbicide tolerance | Monsanto | 2nd July 2009 |
| EFSA/GMO/UK/2007/49 | Maize | Bt11 x GA21<br><br>insect resistance and herbicide tolerance | Syngenta | 19th Oct 2009 |
| EFSA/GMO/NL/2007/38 | Maize | MON89034 x NK603<br><br>insect resistance | Monsanto | 1st Nov 2009 |
| EFSA/GMO/NL/2007/39 | Maize | MON89034 x MON88017<br><br>insect resistance | Monsanto | 14th April<br><br>2010 |
| EFSA/GMO/UK/2007/48 | maize | MIR604 x GA21<br><br>insect resistance and herbicide tolerance | Syngenta | 27th May 2010 |
| EFSA/GMO/UK/2007/50 | Maize | Bt11 x MIR604<br><br>insect resistance | Syngenta | 27th May 2010 |
| EFSA/GMO/UK/2008/56 | Maize | Bt11 x MIR604 x GA21<br><br>insect resistance and herbicide tolerance | Syngenta | 27th May 2010 |

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| EFSA/GMO/CZ/2008/62 | Maize | MON89034 x 1507 x MON88017 x 59122<br><br>insect resistance and herbicide tolerance | Dow AgroSciences and Monsanto | 22nd Oct 2010 |
| EFSA/GMO/NL/2009/65 | Maize | MON89034 x 1507 x NK603<br><br>insect resistance and herbicide tolerance | Dow AgroSciences and Monsanto | 22nd Oct 2010 |
| EFSA/GMO/RX/40-3-2 (renewal) | Soybean | MON 40-3-2<br><br>herbicide tolerance | Monsanto | 26th Jan 2011 |
| EFSA/GMO/NL/2008/52 | Soybean | A5547-127<br><br>Herbicide tolerance | Bayer CropScience | 14th July 2011 |
| EFSA/GMO/BE/2010/79 | Soybean | MON87707<br><br>insect resistance | Monsanto | 30th August 2011 |
| EFSA/GMO/UK/2007/43 | Soybean | 356043<br><br>herbicide tolerance | Pioneer | 30th August 2011 |
| EFSA/GMO/NL/2009/73 | Soybean | MON87701 x MON89788<br><br>insect resistance and herbicide tolerance | Monsanto | 27th April 2012 |
| EFSA/GMO/DE/2010/82 | Maize | MIR162<br><br>insect resistance | Syngenta | 31st July 2012 |
| EFSA/GMO/NL/2010/78 | Soybean | MON87705<br><br>herbicide tolerance and altered fatty acid profile | Monsanto | 18th February 2013 |
| EFSA/GMO/NE/2009/70 | Maize | MON87460<br><br>drought resistance | Monsanto | 18th February 2013 |