Advisory Committee on Releases to the Environment

Advice on notifications for import and processing of oilseed rape with tolerance to glufosinate ammonium and/or glyphosate herbicides

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

**General advice on the import and processing of genetically modified oilseed rape with tolerance to glufosinate ammonium and/or glyphosate herbicides**

**Product:** Genetically modified oilseed rape with tolerance to glufosinate ammonium and/or glyphosate herbicides

**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.

This advice applies to the notifications listed in Annex 1. These notifications are for the import and processing of seed/ grain derived from genetically modified oilseed rape with tolerance to glufosinate ammonium and/or glyphosate herbicides

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. Although 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 environmental monitoring components of the notifications listed in Annex 1.
Comment

Scope

This advice concerns notifications submitted under Regulation (EC) 1829/2003 (the GM Food and Feed regulation) to import and process seed/grain derived from genetically modified oilseed rape with tolerance to glufosinate ammonium and/or glyphosate herbicides. Oilseed rape which is modified for other traits will be considered separately.

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. This advice is relevant to the UK only and ACRE recognises that the situation regarding use of the herbicides in semi-natural environments and location of crushing and processing plants may be different in other EU countries.

Environmental risk assessment

The environmental risk posed by a GMO is a function of any hazards it presents to the environment and the exposure of the environment to these hazards. ACRE is satisfied that in the UK, the import and processing of oilseed rape, genetically modified for tolerance to glufosinate ammonium and/or glyphosate herbicides, would not pose a greater risk to the environment or human health than non-GM varieties of oilseed rape. This is based on the following:

- oilseed rape has the potential to grow and flower in the UK if spillage of seed/grain occurs during transportation and processing. However, feral oilseed rape populations in the UK are not self-perpetuating and therefore will decrease over time unless the grain is replenished through further spillage.

  herbicide tolerance provides a potential selective advantage only in the presence of the herbicide. In the UK, the use of glufosinate ammonium and glyphosate herbicides is not significant in semi-natural environments. In the absence of the herbicide, ACRE does not consider that herbicide tolerance in oilseed rape or compatible relatives would result in a selective advantage or an increase in persistence and invasiveness

- in the UK, crushing and processing plants are located at receiving ports. Only non-living material will be transported inland. As a result environmental exposure due to any spillage of oilseed rape grain during import and processing will be limited

Each of these factors act independently to safeguard the environment. Together they provide three layers of control. ACRE does not therefore consider that tolerance to glufosinate ammonium and glyphosate herbicides would increase the ability of oilseed

1 Devos et al 2011 Feral genetically modified herbicide tolerant oilseed rape from seed import spills: are concerns scientifically justified? Transgenic Res 10.1007/s11248-011-9515-9
rape to establish and persist under UK conditions as a result of import and processing of grain.

**Post-market environmental monitoring plans**

Applications for the import and/or cultivation of live GMOs into the EU under Directive 2001/18/EC and Regulation (EU) 1829/2003 must include a post-market environmental monitoring (PMEM) plan. There are two components to 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 notifications covered by this advice (please refer to Annex 1) there is no requirement for case-specific monitoring in the UK.

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 for import and processing, 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.

In addition, ACRE recommends that in all cases applicants provide clear guidance to operators to ensure that environmental exposure is further minimised. The guidance should specify that good port practice needs to be employed to minimise spillage of imported seed and clean up spillage should it occur. I should also provide information on how to identify and control of any volunteer plants occurring within port and processing areas. It should be specifically stated that control must not include the use of the herbicide to which imported oilseed rape is tolerant. This is in line with existing schemes, based on Hazard Analysis of Critical Control Point (HACCP) principles, which are currently implemented by operators.
### Annex 1

<table>
<thead>
<tr>
<th>Notification reference</th>
<th>Event</th>
<th>Applicant</th>
<th>Advice agreed by ACRE</th>
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<tbody>
<tr>
<td>EFSA/GMO/UK/2005/25</td>
<td>T45 Glufosinate ammonium tolerance</td>
<td>Bayer Bioscience</td>
<td>4&lt;sup&gt;th&lt;/sup&gt; June 2008 *</td>
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<tr>
<td>EFSA/GMO/BE/2010/81</td>
<td>MS8 x RF3 Glyphosate tolerance and hybrid control system</td>
<td>Bayer BioScience</td>
<td>30&lt;sup&gt;th&lt;/sup&gt; Jan 2012 *</td>
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<tr>
<td>EFSA/GMO/NL/2010/87</td>
<td>GT73 Glyphosate tolerance</td>
<td>Monsanto</td>
<td>28&lt;sup&gt;th&lt;/sup&gt; October 2013 **x</td>
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<td>EFSA/GMO/BE/2011/101</td>
<td>MON88302 Glyphosate tolerance</td>
<td>Monsanto</td>
<td>4&lt;sup&gt;th&lt;/sup&gt; August 2014</td>
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<td>EFSA/GMO/NL/2009/68</td>
<td>Ms8 x Rf3 x GT73 glufosinate-ammonium- and glyphosate-tolerant</td>
<td>Bayer CropScience and Monsanto</td>
<td>10&lt;sup&gt;th&lt;/sup&gt; June 2016</td>
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<tr>
<td>EFSA/GMO/NL/2013/119</td>
<td>MON 88302 x MS8 x RF3 glufosinate-ammonium- and glyphosate-tolerant</td>
<td>Monsanto Company and Bayer CropScience</td>
<td>22 May 2017</td>
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* ACRE has previously provided separate advice on these applications. The advice provided here also applies to these applications. In the case of applications which also contain the MS8 x RF3 hybrid control system, ACRE has considered the environmental risks of this trait separately.

**x The scope of this application covers placing on the market food or food ingredients produced from GT73 oilseed rape, including its pollen and the accidental presence of viable seeds.