

## Advice on applications to market genetically modified (GM) food or feed in England

This advice applies to the applications listed below. The applications are for the consumption, importation, and / or processing of food and/ or feed consisting of, made from, or containing a GM organisms where the crop from which the food or feed is derived does not have the ability to grow in climatic conditions in England.

As the applications are for GMOs to be used as food and, or, feed products, they will not be authorised unless the applicant has demonstrated that the GMOs in question are as safe as their non-GM equivalents in terms of food and feed safety. However, it is not within ACRE's remit to consider food or feed safety; this is the responsibility of the Food Standards Agency. It is ACRE's responsibility to assess the potential environmental impacts of the GMOs rather than food or feed processed from them. Consequently, this advice concerns the environmental risk assessment and post-market monitoring components of the applications listed in Table 1.

### **Environmental risk assessment**

The applications listed in Table 1 are for GM food and/ or feed products where the originating crop species does not grow under climatic conditions in England. GM crops that have been processed into food or feed products do not pose an environmental risk as they cannot germinate.

ACRE has assessed each of the applications listed in Table 1 on a case by case basis, including consideration of the following:

- the ability of reproductive material such as seeds, tubers or grains to germinate and establish if spilled during transportation and processing (this is a crucial aspect in terms of environmental protection because the potential 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);
- whether the genetic modification alters the ability of the crop to survive and persist.
- potential pathways to environmental exposure, for example decomposing food, feed or reproductive material that may be spilled during transportation or processing or transgene-encoded proteins that might remain in manure and faeces from animals fed these GMOs.
- the theoretical possibility that environmental exposure to GM proteins could increase if the transgenes encoding the proteins transferred to, and were expressed

by, soil bacteria. [ACRE’s view is that such horizontal gene transfer (HGT) between plants and soil bacteria under field conditions is a very rare phenomenon.]

However, our approach is to assume that HGT of transgenes may occur and to consider the consequences).

## Post-market monitoring plans

Applications to market GMOs with an ability to germinate must include a post-market environmental monitoring (PMEM) plan, of which there are two components:

1. case-specific monitoring - the aim of this 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 is correct. Due to the lack of any significant environmental exposure, ACRE considers that for applications covered by this advice, there is no requirement for case-specific monitoring in England, unless specifically stated in Table 1.
2. general surveillance – the objective is to ascertain the occurrence of any adverse effects of the GMO or its use on human health and the environment that were not anticipated in the environmental risk assessment. Unless otherwise stated in Table 1, 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.

**Table 1**

<b>Application reference</b>	<b>Food type</b>	<b>Event</b>	<b>Applicant</b>	<b>Advice and date:</b>
RP608	Cotton	GHB614 Herbicide tolerant	BASF	No safety concerns identified 25/04/2023
RP 1232	Cotton	GHB811 Herbicide tolerant		No safety concerns identified 25/07/2023