

Advisory Committee on Releases to the Environment

Advice on applications to import and process genetically modified (GM) crops that are unable to grow and flower outside of agricultural conditions 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 environmental monitoring (PMEM) components of the applications listed below.

Environmental risk assessment

The applications listed below 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 below 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, the approach is to assume that HGT of transgenes may occur and to consider the consequences.

Post-market environmental monitoring plans

Applications to market GMOs with an ability to germinate must include a 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 below.
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 below, 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.

Applications

Reference	Food type	Event	Applicant	Advice and date
RP608	Cotton	GHB614 Herbicide tolerant	BASF	No safety concerns identified 25/04/2023
RP1232	Cotton	GHB811 Herbicide tolerant	BASF Agricultural Solutions	No safety concerns identified 25/07/2023

Reference	Food type	Event	Applicant	Advice and date
RP1569	Cotton	281-24-236 x 3006-210-23 Insect resistant	Corteva Agriscience LLC	No safety concerns identified 07/06/2024
RP2148	Cotton	COT102 Insect resistant	Syngenta	No safety concerns identified 11/02/2025