MINISTRY OF NATURAL RESOURCES
AND ENVIRONMENTAL SUSTAINABILITY

BIOSYM
BIOSAFETY SYMPOSIUM 2025
21 AUGUST 2025

JABATAN BIOKESELAMATAN

BIOSAFETY SYMPOSIUM

STRENGTHENING BIOSAFETY FOR FUTURE SUSTAINABILITY

21 August 2025 | Thursday

DoubleTree by Hilton, Shah Alam

gef | UN environment programme | ASEAN MALAYSIA 2025 | MALAYSIA MADANI kemampanan | Visit Malaysia 2026 Truly Asia

Insights on Biosafety Regulatory Approach, Local Innovations and Public Engagement Initiatives

Jim M. Dunwell
Emeritus Professor of Plant Biotechnology, University of Reading, UK
j.m.dunwell@reading.ac.uk

1. Biosafety Regulatory Approach

Regulation Involves Two UK Government Departments/Agencies

Cultivation: Department for Environment, Food & Rural Affairs
https://www.gov.uk/defra

Food: Food Standards Agency
https://www.food.gov.uk/

Regulation

- Experimental field trials
- Commercial field trials
- Import regulation
- Labelling

Important Role of Advisory Committees:

For Releases to the Environment (ACRE) (Defra)
For Novel Foods and Process (ACNFP) (FSA)

GM: EU Definitions

"genetically modified organism (GMO)" means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination;

Techniques of genetic modification are *inter alia*:

(1) recombinant nucleic acid techniques
(2) direct introduction into an organism,
(3) cell fusion (including protoplast fusion)

Techniques not considered to result in genetic modification

(1) in vitro fertilisation,
(2) natural processes, e.g: conjugation, transduction, transformation,
(3) polyploidy induction.

GM: Exclusions

Annex IB:

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive

i) mutagenesis,
ii) cell fusion of plant cells of organisms which can exchange genetic material through traditional breeding methods.

GM Crops

Genetically modified organisms: applications, decisions and notifications

Information about releases of genetically modified organisms (GMOs) for research purposes, including lists of applications, consents and notifications.

Most recent Crop Application: GM wheat, University of Oxford, Consent given January 2025.

https://www.gov.uk/government/collections/genetically-modified-organisms-applications-and-consents

GM Food

https://www.food.gov.uk/business-guidance/genetically-modified-organisms-authorisation-guidance

Genetically modified organisms authorisation guidance GMO food and feed authorisations

Before a GMO food or feed product can be placed on the market in Great Britain (GB) it must be authorised under the assimilated Regulation (EC) 1829/2003 on Genetically Modified Food and Feed, (Opens in a new window) as amended .

The requirement for authorisation applies to products made from, containing or derived from GMOs that are ‘not live’ (e.g. soybean oil, maize starch) to be marketed for consumption by humans and animals.

https://data.food.gov.uk/regulated-products/gmo_authorisations

Food Standards Agency (FSA)

GMO authorisations

Last updated: 01 April 2025

Search | See Filters

Download as: CSV | MS Excel

Showing **1-10** of **280 results**

Sort by **Event**

1 2 ... Next» Last»

Select to collapse view

Rows per page **10**

1507 — Maize

Authorised use:
1. Foods and food ingredients
2. Feed
3. Other products for the same uses as maize with exception of cultivation

Last updated:
01 April 2025

Event:	Unique ID:	Status:	Applies in:
1507	DAS-Ø15Ø7-1	Authorised	England, Scotland, Wales

https://data.food.gov.uk/regulated-products/gmo_authorisations

1507

Download as: CSV MS Excel

Product details

← Back to previous

GM event	1507
Unique identifier code	DAS-Ø15Ø7-1
Authorisation holder	Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana, 46268-1054, United States of America Represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, England, CB21 5XE
Characteristics	The genetically modified maize 1507, as described in the application, expresses the Cry1F protein which confers resistance to the European corn borer (Ostrinia nubilalis) and certain other lepidopteran pests and the PAT protein which confers tolerance to glufosinate-ammonium based herbicides.
Detection method	Event specific real-time quantitative PCR based method for genetically modified maize DAS-Ø15Ø7-1. Validated by the Community reference laboratory established under Assimilated Regulation (EC) No 1829/2003, published at https://gmo-crl.jrc.ec.europa.eu/method-validations
Commodity	Maize
Authorised use	(1) Foods and food ingredients containing, consisting of, or produced from maize 1507; (2) Feed containing, consisting of, or produced from maize 1507; (3) Maize 1507 in products containing it or consisting of it for any other use than those provided for in points (1) and (2), with the exception of cultivation.

https://www.efsa.europa.eu/en
European Food Safety Authority

https://www.efsa.europa.eu/en/events/webinar-adopted-scientific-opinion-protein-safety-assessment-genetically-modified-plants

Webinar on adopted scientific opinion on protein safety assessment in genetically modified plants

6 September 2025, 14.00 - 15.00 (CEST)

Current practice, challenges and future opportunities in the safety assessment of newly expressed proteins in genetically modified plants. EFSA Journal. 2025;23:e9568. 30th June 2025. https://doi.org/10.2903/j.efsa.2025.9568

An improved strategy for protein safety assessment could include:

(1) considering history of safe use (HoSU), read-across and phylogeny defining the type of data required and remove the need for specific in vitro or in vivo studies

(2) applying advanced in silico tools, including predictive computational models and improved phylogenetic analysis to enable more accurate comparisons with known allergens, toxins or ‘safe’ proteins

(3) using standardised in vitro gastrointestinal models that replicate physiological conditions

(4) developing targeted in vivo studies

(5) evaluating the role of exposure in the safety assessment; and, where necessary, (6) considering post-market monitoring for risk characterisation.

GM Inspection and Enforcement

Part of the Animal and Plant Health Agency (APHA)

The GM Inspectorate Key Responsibilities:

- **Inspection of GMO Deliberate Release Sites:**

The GM Inspectorate regularly inspects sites where GMOs are being intentionally released for research or other purposes, ensuring they adhere to the conditions of their consent.

- **Enforcement of GM Legislation:**

They are responsible for enforcing regulations related to the deliberate release and marketing of GMOs.

- **Investigating Breaches:**

The Inspectorate investigates potential unauthorized releases or other violations of GM legislation.

- **Advice to Policy Makers:**

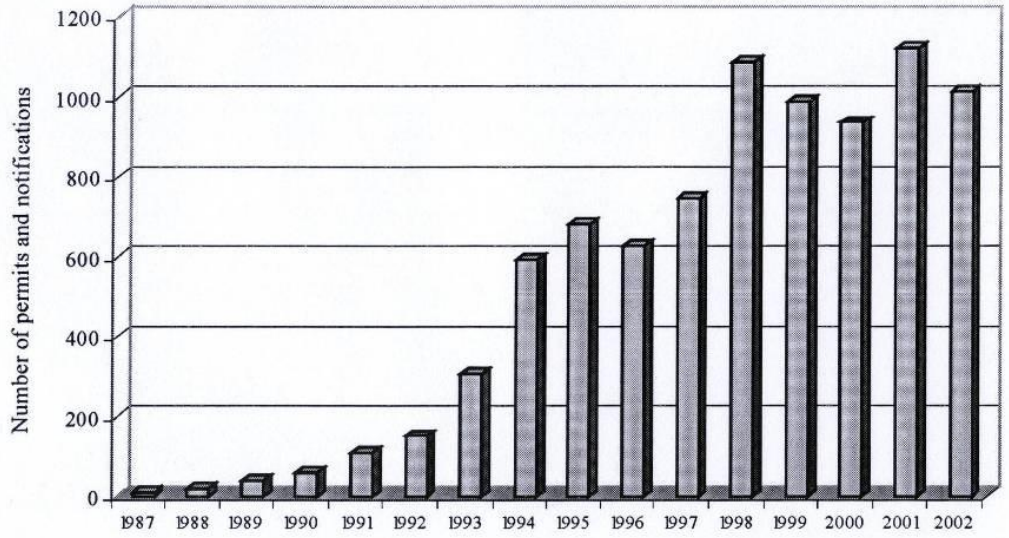
They provide expert, evidence-based advice to Defra and other stakeholders on GMO-related issues.

https://www.gov.uk/guidance/gm-inspectorate-deliberate-release-inspection-programme

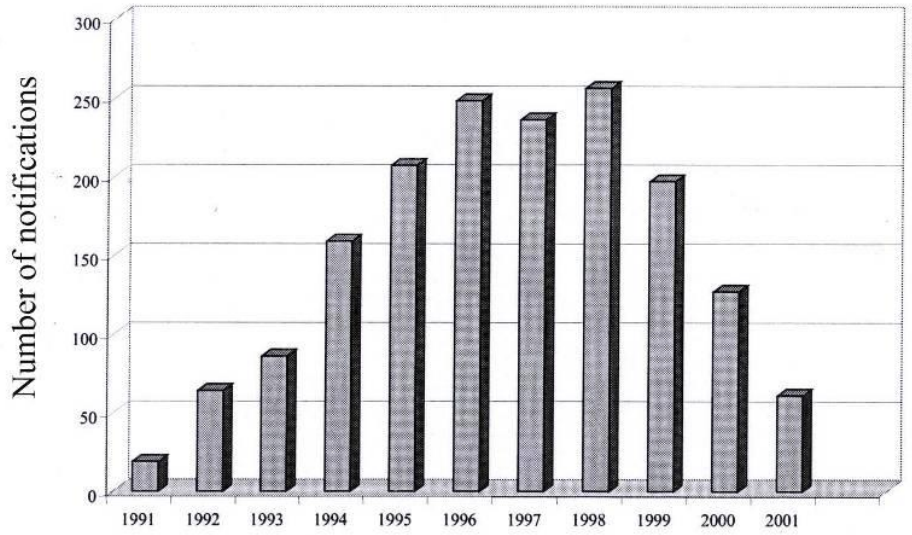
2. Local GMO related innovation

GM Field Trials

USA

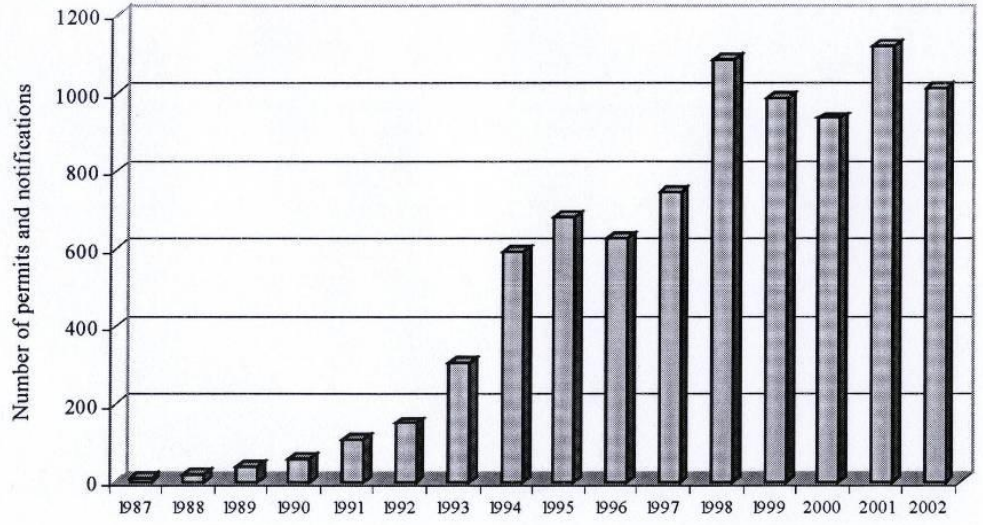


Europe

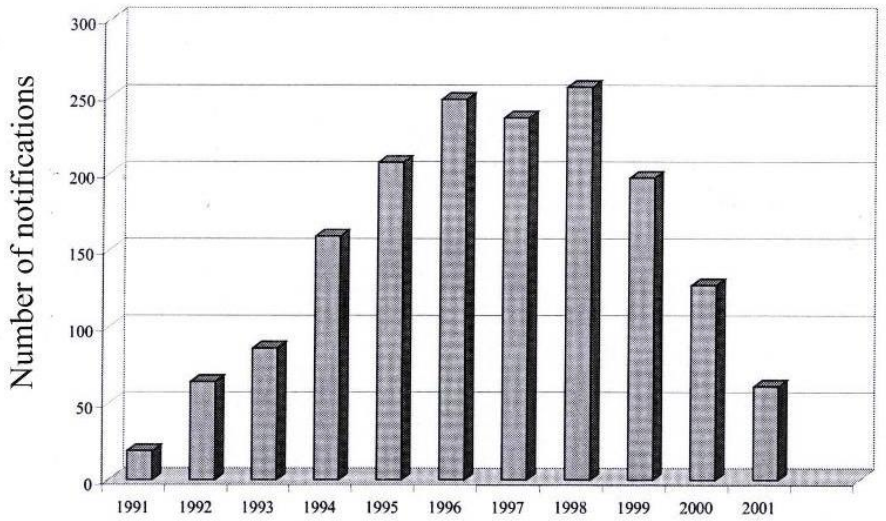


GM Field Trials: Transatlantic divide

USA



Europe



1995: USA 684, UK 37 (EU 213)
2013: USA 590, UK 1 (~EU 25)

First GM Product in UK 1996

Reduced level of polygalacturonase (PG) enzyme: 1.6 m cans sold 1996-99

No GM Crops are Cultivated Commercially in the UK, but there some GM Food Ingredients in Products imported from USA

Ingredients

Milk Chocolate Flavoured Coating (65%) [Sugar*; Cocoa Butter; Cocoa Mass; Skimmed **Milk** Powder; **Milk** Fat; Lactose (**Milk**); Emulsifiers, **Soya** Lecithin* (E322), Polyglycerol Polyricinoleate (E476)], Peanut Butter Crème Center (35%) [**Peanuts**; Sugar*; Dextrose*; Cocoa Butter; Partially Hydrogenated Vegetable Oil (Palm Kernel and Palm Oil); Salt; Emulsifier, Polyglycerol Polyricinoleate (E467); Antioxidant, TBHQ (E319)],

*Produced from Genetically Modified Sugar Beet, Corn and Soya Beans

Increased Anthocyanins in GM Purple Tomatoes: use of *Antirrhinum* Transcription Factor.

Cathie Martin, John Innes Centre
ACS Food Sci. Technol. 2025, 5, 1, 19–28
https://doi.org/10.1021/acsfoodscitech.4c00692
Published November 5, 2024

https://www.youtube.com/watch?v=ifDr6ueBUPA#t=17

UK GM field trials: Rothamsted Research

Rothamsted Research agrees Global Commercial License with Yield 10 Bioscience to produce Omega-3 Products in Camelina. Jun 2024.
https://www.rothamsted.ac.uk/news/rothamsted-research-agrees-global-commercial-license-yield-10-bioscience-produce-omega-3

Camelina Breakthrough Could Transform Natural Astaxanthin Production. June 2025.
https://www.rothamsted.ac.uk/news/camelina-breakthrough-could-transform-natural-astaxanthin-production

Gene Editing

Is it GM or a form of Mutagenesis?

Legal limbo

- Status of gene editing, GM or a form of mutagenesis?

- Case referred by France to the European Court of Justice in October 2016

- Preliminary report issued 18th Jan 2018

(https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-01/cp180004en.pdf)

Nature, 23rd Feb 2017

ECJ Verdict, 25th July 2018

With regard to the question whether the GMO Directive may also be applicable to organisms obtained by mutagenesis techniques that have emerged since its adoption, the Court considers that the risks linked to the use of these **new mutagenesis techniques** might prove to be similar to those that result from the production and release of a GMO through transgenesis, since the direct modification of the genetic material of an organism through mutagenesis makes it possible to obtain the same effects as the introduction of a foreign gene into the organism (transgenesis) and those new techniques make it possible to produce genetically modified varieties at a rate out of all proportion to those resulting from the application of conventional methods of mutagenesis.

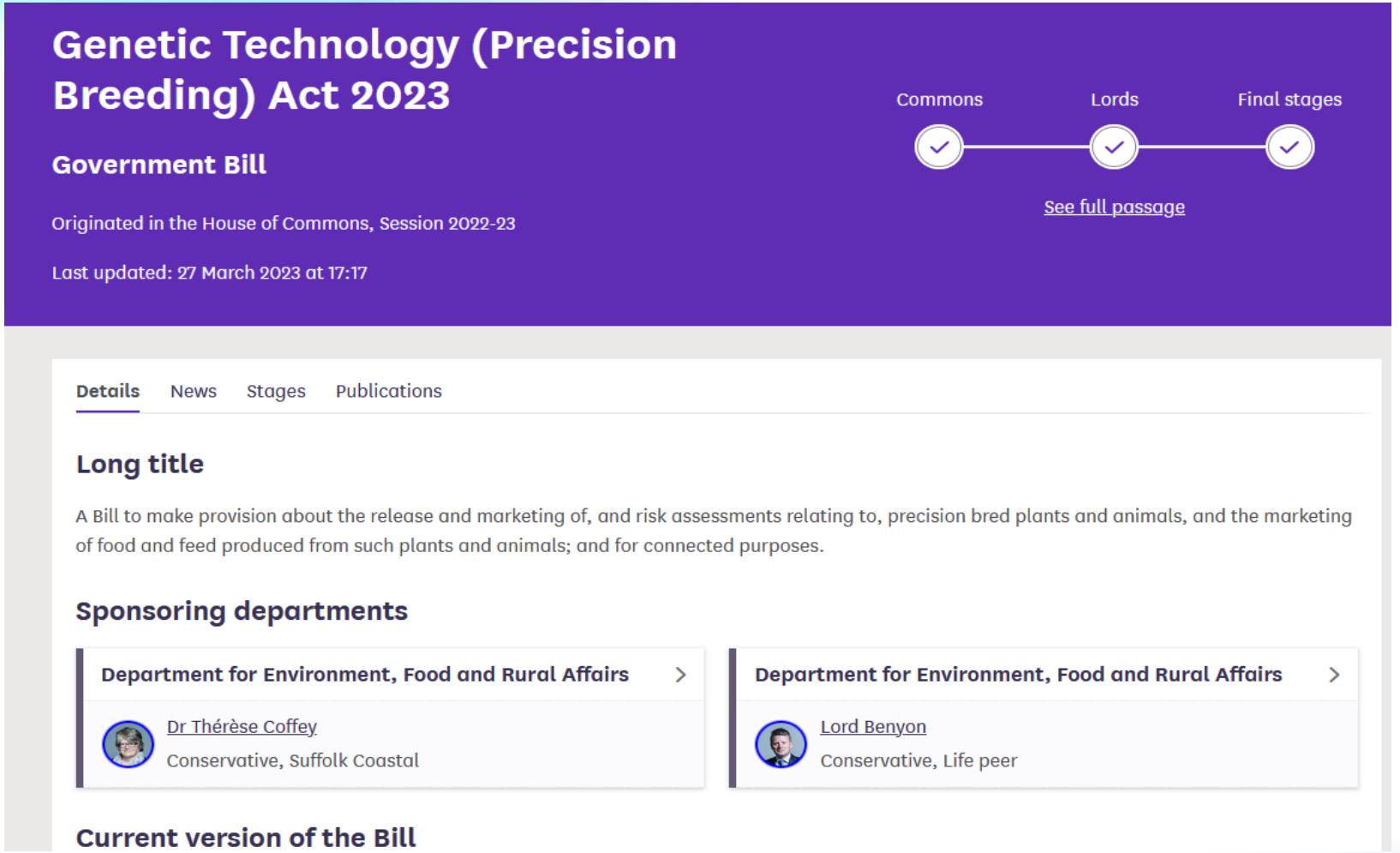
ECJ Verdict, 25th July 2018, cont.

In view of these shared risks, excluding organisms obtained by new mutagenesis techniques from the scope of the GMO Directive would compromise the objective pursued by that directive, which is to avoid adverse effects on human health and the environment, and would fail to respect the precautionary principle which that directive seeks to implement. It follows that **the GMO Directive is also applicable to organisms obtained by mutagenesis techniques that have emerged since its adoption**.

Post Brexit: Which way for the UK?

Decision to introduce new legislation

Present position in the UK



Genetic Technology (Precision Breeding) Act 2023

Government Bill

Originated in the House of Commons, Session 2022-23

Last updated: 27 March 2023 at 17:17

Commons ✓ — Lords ✓ — Final stages ✓

See full passage

Details | News | Stages | Publications

Long title

A Bill to make provision about the release and marketing of, and risk assessments relating to, precision bred plants and animals, and the marketing of food and feed produced from such plants and animals; and for connected purposes.

Sponsoring departments

Department for Environment, Food and Rural Affairs >

Dr Thérèse Coffey
Conservative, Suffolk Coastal

Department for Environment, Food and Rural Affairs >

Lord Benyon
Conservative, Life peer

Current version of the Bill

https://www.legislation.gov.uk/ukpga/2023/6/contents/enacted

The Act

Removes precision bred plants and animals from regulatory requirements for GMOs

Introduces two notification systems (i) research and (ii) marketing purposes. Information will be published on a public register.

Provision of powers to establish a regulatory system for PB animals to safeguard animal welfare.

Provision of powers to establish a new science-based authorisation process for food and feed products derived from PBOs (FSA).

The Act will be brought into force by commencement regulations

Context and Guiding Principles

Product is more relevant than process

Genomes of single crops are very variable

What is a Precision Bred Organism?

Currently all organisms produced by Modern Biotechnology are classed as genetically modified organisms

A precision bred organism (PBO) is a plant or animal produced by Modern Biotechnology where the end product could have been developed using traditional breeding.

For example, gene edited plants in which the transgene has been bred-out or cisgenic plants.

Sainsbury Laboratory Norwich Blight Resistant Potatoes

Maris Piper tuber infected with the late blight pathogen

https://www.tsl.ac.uk/

Gene edited tomatoes

Biofortified tomatoes provide a new route to vitamin D sufficiency

After treatment with UVB light to turn the 7DHC into Vitamin D3, one tomato contained the equivalent levels of vitamin D as two medium sized eggs or 28g tuna – which are both recommended dietary sources of vitamin D.

John Innes, UK (23rd May 2022)

https://www.jic.ac.uk/research-impact/our-strategic-research-programmes/harnessing-biosynthesis-for-sustainable-food-and-health-hbio/impact/biofortified-tomatoes-to-combat-vitamin-d-deficiency/

https://www.nature.com/articles/s41477-022-01154-6

Tropic Biosciences(https://tropic.bio/)
Use of Gene Editing induced gene silencing (GEiGS® system)

Philippines Clears Gene-edited Bananas Developed to Reduce Food Waste
June 26, 2024
https://tropic.bio/tropics-non-browning-gene-edited-banana-cleared-for-production-in-the-philippines/

Precision engineering for PRRSV resistance in pigs

Costs the pig industry around $2.5 billion (£1.75bn) each year in lost revenue in the US and Europe alone.

Removal of receptor binding site for Porcine Reproductive and Respiratory Syndrome (PRRS) virus.

Genus PIC. PLoS Pathog 13(2): e1006206.

The US Food and Drug Administration has approved the use of a gene-editing technology that makes pigs resistant to PRRS for the US food supply chain. (May 2025)

Application for a food and feed marketing authorisation

There are two routes to authorisation for PBOs used in food and feed, set out Regulation 20 and Regulation 22 of the Genetic Technology (Precision Breeding) Regulations 2025:

1.Regulation 20: PBOs that are very similar to traditionally bred varieties, which consumers are familiar with and for which potential safety risks are understood. Applicant-led Tier 1 safety assessments are required but there is no requirement for a Tier 2 FSA safety assessment and there would be a simpler route to market.

2.Regulation 22: PBOs with traits where the risks are not fully understood. Specifically, this would include novelty or PBOs that have compositional changes which could affect nutritional quality, toxicity or allergenicity, or other safety concerns where potential food and feed safety risks need further consideration. There would be a bespoke Tier 2 safety assessment process, including a more detailed examination of the characteristics of the PBO.

https://www.food.gov.uk/business-guidance/regulated-products/pbo-application-guidance/legislative-requirements

UK Latest: 2nd November 2024

Scientists dismayed as UK ministers clear way for gene editing of crops - but not animals

https://www.theguardian.com/science/2024/nov/02/scientists-dismayed-as-uk-ministers-clear-way-for-gene-editing-of-crops-but-not-animals

Qualifying Higher Plants (QHP)
https://www.legislation.gov.uk/uksi/2022/347/regulation/2/made
“qualifying higher plant” means a higher plant which is a genetically modified organism but which has not been genetically modified other than to make modifications—
(a) that could have occurred naturally, or
(b) that could have been made using one or more of the techniques set out in regulation 5(2);”.

22 applications to date for non-commercial field trials.

Most recent:-
https://www.gov.uk/government/publications/qualifying-higher-plant-notification-reference-25q07/qualifying-higher-plant-notification-reference-25q07
11th April 2025.

Title of Project: Short vegetative phase (SVP) cis-regulation in bread wheat

We hypothesise that discrete sequences within the promoter of SVP-A1 in wheat are required to correctly regulate its expression pattern. We further hypothesise that loss of promoter sequence leads to an increase in gene expression, a broadening of the genes' expression domains, and subsequently cause an increase in glume, grain size and specific weight.

To test this hypothesis, we used the CRISPR/Cas9 system to delete these putative cis-regulatory sequences in the promoter of SVP-A1. We have obtained stable gene-edited lines with a 478-bp deletion in the promoter of SVP-A1 and with absence of foreign DNA (confirmed by whole genome sequencing).

A Platform to Rate Organisms Bred for Improved Trait & Yield – PROBITY

Led by the British On-Farm Innovation Network (BOFIN), PROBITY is a three-year £2.2m multi-partner project, funded by Defra's Farming Innovation Programme, which is delivered by Innovate UK.

A project bringing trials of precision-bred cereal crops onto commercial farms for the first time in Europe is now underway.

The three cereal varieties in the project are:

- A wheat with superior baking, toasting and processing properties
- A barley making high lipid, high energy forage aimed at lowering livestock methane emissions
- A wheat with a bigger bolder grain size promising a step change in productivity

https://bofin.org.uk/probity/

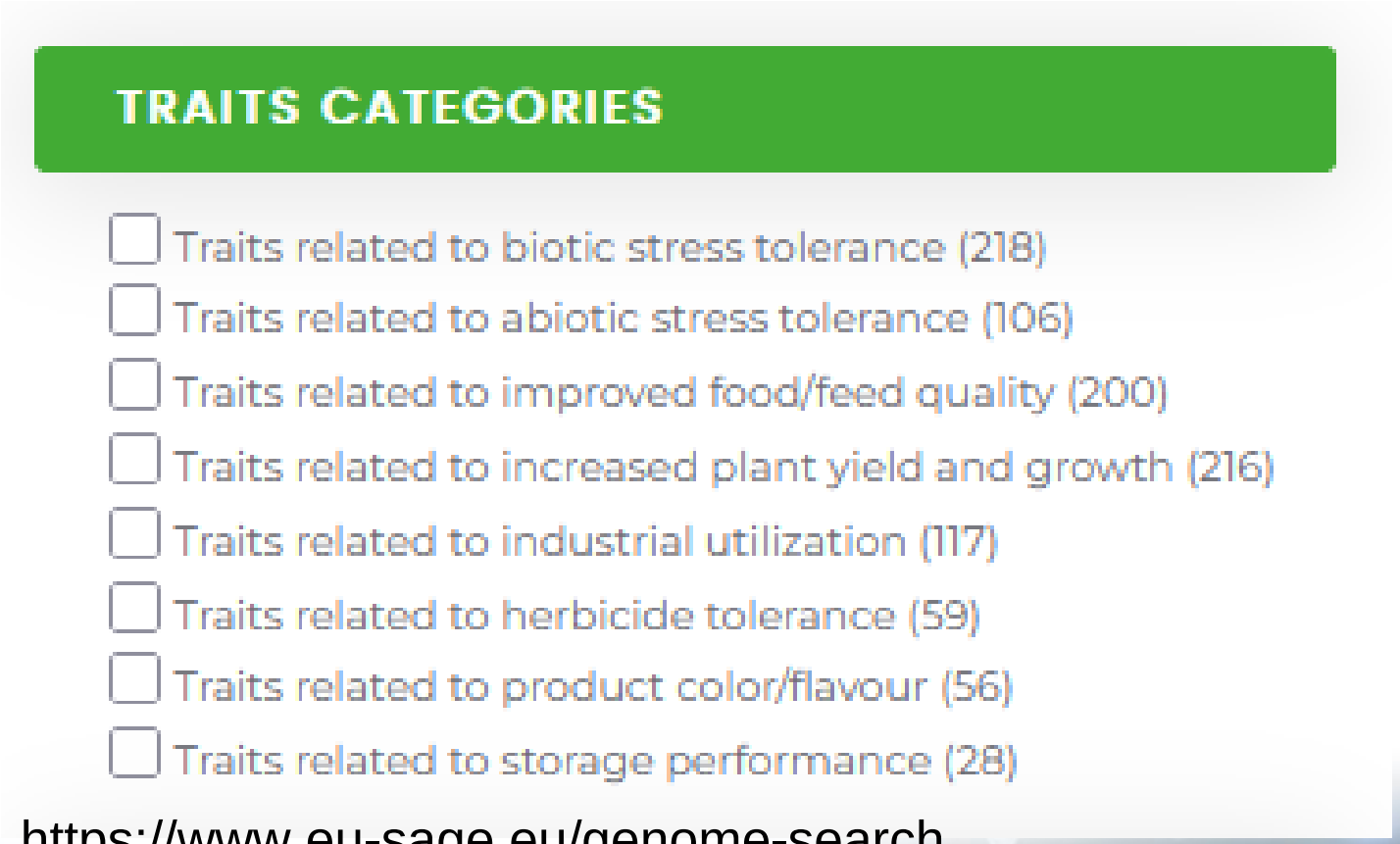
Commercial applications for marketing.

UK regulations for crops will come into force in November 2025.

This requires confirmation from ACRE of PBO status.

European Sustainable Agriculture Through Genome Editing

Database



https://www.eu-sage.eu/genome-search

GLOBAL GENE EDITING Regulation Tracker

Crops / Food | **Animal**

Regulations of gene editing and new breeding techniques (NBTs) worldwide are quickly evolving. Click on a country or region for more information on its regulatory status, what crops are approved or in development, and reactions from regional NGOs. The Gene Editing Index ratings represent their current status and will be updated as new regulations are approved.

Updated May 2024

* Approved crops

^ Field trials

https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/

3. Public engagement/ public awareness

GM Plants: First Test of Public Opinion in UK

Final report : UK National Consensus Conference on Plant Biotechnology : London, 2-4 November 1994. John Durant. Science Museum, 1994.

Dale, P.J. UK Consensus Conference on Plant Biotechnology. *Plant Mol Biol Rep* **13**, 290–292 (1995). https://doi.org/10.1007/BF02670907

Joss, S., & Durant, J. (1995). The UK National Consensus Conference on Plant Biotechnology. *Public Understanding of Science*, *4*(2), 195-204. https://doi.org/10.1088/0963-6625/4/2/006

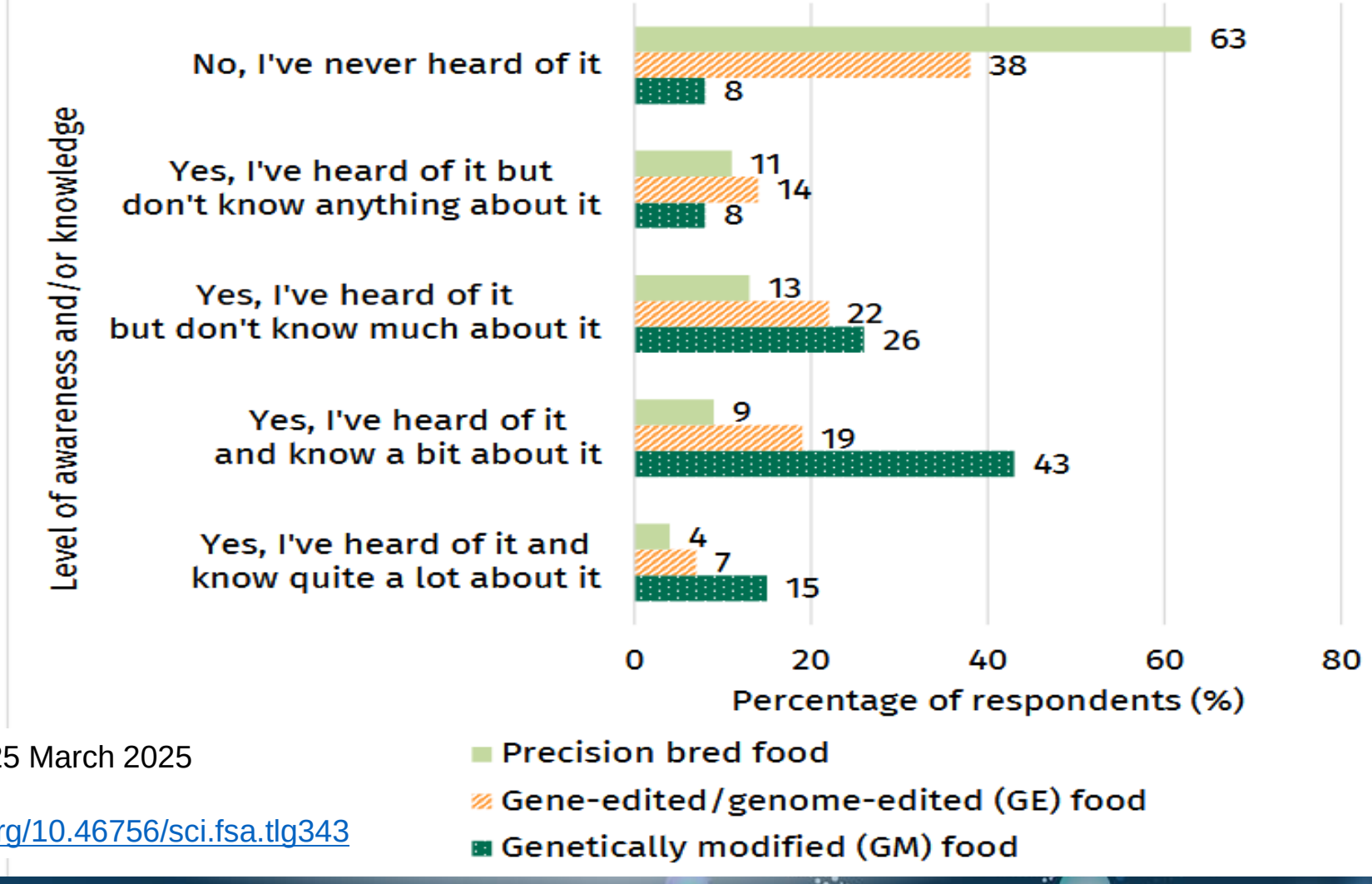
There have been a very large number of academic and other surveys over the last 30 years.

FSA Consultation on applications for nine genetically modified organisms for food and feed uses: summary of stakeholder responses. launched on 30 November 2021 and closed on 25 January 2022.

https://www.food.gov.uk/print/pdf/node/8496

FSA: Food and You 2 is a biannual ‘official statistic’ survey

Awareness and knowledge of genetically modified (GM), gene-edited/genome-edited (GE) and precision bred food.



Date published: 25 March 2025

DOI: https://doi.org/10.46756/sci.fsa.tlg343

Public Opinion Survey

https://yougov.co.uk/topics/politics/explore/issue/Genetically_modified_food

Conclusions

Although some GM products (eg Camelina) are still being developed in the UK, the emphasis in both crops and animals is now on gene editing.

All changes in UK legislation are subject to prior consultation, and all applications/permissions are available online.

THANK YOU

Useful Web Sites

https://www.foodevolutionmovie.com/
http://www.senseaboutscience.org/data/files/resources/9/MSofGM2011.pdf
http://royalsociety.org/policy/publications/2009/reaping-benefits/
https://royalsociety.org/topics-policy/projects/gm-plants/
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/292174/cst-14-634a-gm-science-update.pdf
Talking about GM: Approaches to Public and Stakeholder Engagement.
https://sciencewise.org.uk/wp-content/uploads/2018/12/Talking-about-GM-published.pdf
https://royalsociety.org/news/2023/10/gm-crops/