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Report Highlights:

The first half of 2025 saw the United Kingdom (UK) progressed on two main items related to biotechnology, it (1) adopted secondary legislation needed to implement the Precision Breeding Act, (2) streamlined the market authorization process for Genetically Engineered (GE) regulated products. On the other hand, the UK made no new GE authorizations since the 2024 Biotech Annual report. Consequently, Great Britain (GB) has fallen further behind the European Union (EU) in its GE authorizations, with the backlog now standing at 28 GE events, despite the removal of the requirement for ten-yearly renewals in GB in March 2025. Additionally, the prospect of the UK entering a new Sanitary & Phytosanitary (SPS) deal with the EU appears to have placed any other changes by the UK in biotechnology on hold.

Executive Summary

Since the publication of the 2024 Agricultural Biotechnology Annual report ("2024 Biotech Report"), the United Kingdom (UK) has made some limited progress with regards to newly approved genetically engineered (GE) products, (1) by concluding a public consultation on three new authorizations for food and feed uses but approval for these authorizations remains outstanding, (2) adopting secondary legislation to implement the Precision Breeding Act and (3) bringing forward proposals to streamline and modernize the market authorization process.

Major updates since the last report include:

- **Proposed UK-EU Sanitary & Phytosanitary agreement**: The prospect of the UK entering a new Sanitary & Phytosanitary (SPS) deal with the European Union (EU), as part of a broader reset of UK-EU relations, looms large over any changes that have occurred in the UK since the 2024 Biotech Report. The UK government has stated its intention of seeking an exception for the Precision Breding Act from the default of aligning with EU food safety rules. It is unclear whether any carve out (if successfully negotiated) will be permanent or just a stop-gap measure until the EU implements its own New Genomic Techniques regulation.

- **The Genetic Technology (Precision Breeding) Regulations 2025**: In May 2025, over two years after the Precision Breeding primary legislation became law, the statutory instrument setting out the detailed regulations to implement it was adopted. An inbuilt six-month delay meant these regulations entered into force on November 13, 2025, and only then could the first applications for authorizations for Precision Bred Organisms (PBOs) be accepted.

- **GE food and feed**: Great Britain (GB) currently lags behind the EU in approving 28 new applications that have already been approved by the EU, as of the time of writing. Three new authorizations for GE organisms for food and feed uses that were subjected to public consultation starting in December 2024, but are still pending a final decision. GB has automatically renewed five GE events as part of streamlining changes, while the EU has authorized ten more events since our 2024 Biotech Report (including one renewal), further expanding the backlog since last year.

- **Streamlining of authorization process**: In an effort to reduce this backlog in GE approvals, legislation was made in March 2025 to enact two proposals from the Food Standards Agency (FSA) to streamline the market authorization process. This change removes the 10-year renewal requirement and also removes the need for an additional step of secondary legislation after a ministerial decision has been made to authorize the product. While these proposals had been subject to public consultation when writing the 2024 Biotech Report, the change was only enacted when the March 2025 regulations were made.

- **Further market authorization modernization proposals**: At its board meeting in June 2025, the FSA put forward five additional proposals to reduce the administrative burdens within the current GE authorization process. These included the possibility of using other country regulators' risk assessments, as well as using European Union Reference Laboratory (EURL) reports to fast-track the final stages of authorization.

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Reporting Notes:

1. The United Kingdom (UK) departed the European Union (EU) on January 31, 2020. While the UK retained most EU laws in the area of genetic engineering applications for food and agriculture, one significant divergence occurred in March 2023 when the Genetic Technology (Precision Breeding) Act became law. On May 19, 2025, the UK agreed to a Common Understanding with the EU committing the parties to negotiate a comprehensive new SPS agreement. Under these circumstances, further divergence between UK and EU laws may be limited. To compare UK and EU laws, this report should be read in conjunction with our EU Agricultural Biotechnology Annual report available on the Foreign Agricultural Service Global Agricultural Information Network: FAS/USDA GAIN Report Database

2. The term "agricultural biotechnology" refers to an evolving continuum of technologies. It is a broadly applied term that may or may not refer to crops developed through recombinant DNA technologies. Commonly used terms include: plant (or animal) biotechnology, transgenic, biotech, bioengineered, and genetically engineered (GE).

3. The U.S. government uses the term genetically engineered (GE) in addressing this topic. However, the EU legislation and the United Kingdom implementing regulations use Genetically Modified (GM) food and feed and Genetically Modified Organisms (GMO). These terms are used in quotes in this report when discussing EU and UK legislation and its implementation.

4. "Innovative biotechnologies" is an emerging term for breeding techniques that, by most common definitions, are not transgenic. Examples include New Genomic Techniques (NGT), New Plant Breeding Techniques (NPBT), Precision Breeding (PB), Plant Breeding Innovation (PBI) targeted mutagenesis, and genome editing. In the UK, the term Gene Edited is used in place of "innovative biotechnologies"; this term is used in quotes in this report when discussing new UK legislation and regulations on this subject.

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

The UK crop science community undertakes limited product development of GE plants. While crop trials have increased in recent years, the Wheat (delayed leaf senescence) at the University of Oxford is the only addition since the 2024 Biotech Report:

Crop	**Research Facility**
Wheat (delayed leaf senescence)	University of Oxford [2025]
Camelina (multi-trait)	Rothamsted Research [2024-2027]
Wheat (photosynthetic efficiency)	Wild Bioscience [2023-2027]
Wheat (gene edited)	Rothamsted Research [2021-2026]
Barley (multi-trait)	Cambridge University Crop Science Centre [2022-2026]

Since the previous 2024 Biotech Report, the UK has now adopted the implementing legislation needed to give effect to the Precision Breeding Act, which provides flexibility for plants produced using genetic technologies (e.g., "qualifying higher plants" (QHPs)) that could have otherwise been produced by traditional breeding techniques or could have arisen through natural processes in England, only. Under the Genetic Technology (Precision Breeding) Regulations 2025, made on May 13, 2025, which cover both release and marketing, corresponding "QHPs" are now defined as "Precision Bred Organisms (PBOs)" in England.

In the remainder of the United Kingdom (Northern Ireland, Scotland and Wales) which has not adopted/implemented the Precision Breeding Act, "QHPs" released for purposes other than research and development (for example, marketing and commercialization) are still regulated under the country-specific versions of the Deliberate Release Regulations (2019) (see below). "Genetically modified" (GM) plants that are not defined as "QHPs"/"PBOs" are regulated under the 2019 legislation.

The corresponding legislation and guidance include:

- The Genetic Technology (Precision Breeding) Regulations 2025 (PBOs released or marketed in England)
    - The UK government's Advisory Committee on Releases to the Environment (ACRE) has issued guidance for those developing Precision Bred plants.
    - The FSA has issued draft technical guidance for obtaining a market authorization.
- Genetic Technology (Precision Breeding) Act (2023) (marketing of QHP products)
- Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022 (administrative changes allowing for the use of QHPs)
    - Guidance available to help researchers decide if their plant is a QHP.

- Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (regulating GM plants)

For any new plant variety to be marketed in the UK, the grower must apply to add the new variety to the 'national lists', maintained by the Animal and Plant Health Agency (APHA). The UK government consulted on a proposed Precision Bred Plant Variety List for England in February 2025, with the consultation closing in April 2025. On October 9, 2025, Defra has now published a summary of the consultation responses as it applies to England. However, it is not yet accompanied by any definitive indication of the UK government's decision on how to implement the plant variety list.

b) COMMERCIAL PRODUCTION

Despite being a supporter of science, the UK has never planted a commercial GE crop and has no commercial GE crops under development. The limited portfolios of GE plant products that are approved for cultivation in the EU are not well-suited to UK growing conditions. Under previous EU membership, Scotland, Wales and Northern Ireland all formally opted out of GE cultivation. When the previous Conservative administration initiated its plans on Gene Editing (i.e. precision breeding), its January 2021 consultation document included a second section seeking views on the wider framework governing GE. Since July 2024, the Labour administration has still not provided a framework forward for GE.

c) EXPORTS

The UK does not produce or export GE crops or products to the United States or any other country.

d) IMPORTS

The UK is a protein-deficient market that needs to import grain and oilseed derivatives for livestock feed. Imports of animal feed products are influenced by animal stocking levels and domestic production of grains and oilseeds. **GRAPH 1** (below) shows UK imports of animal feed commodities that are predominantly derived from GE crops, and those that the United States may export to the UK when market conditions are favorable. The United States is the leading supplier of corn-derived Distillers Dried Grains with Solubles (DDGS) to the UK. The UK has a significant demand for animal feed, making it a major market for this byproduct of ethanol production, which can be used as a valuable protein source in livestock diets. Since the United States produces a large volume of DDGS due to its robust ethanol industry, this has traditionally made it a reliable supplier of DDGS to the UK market.

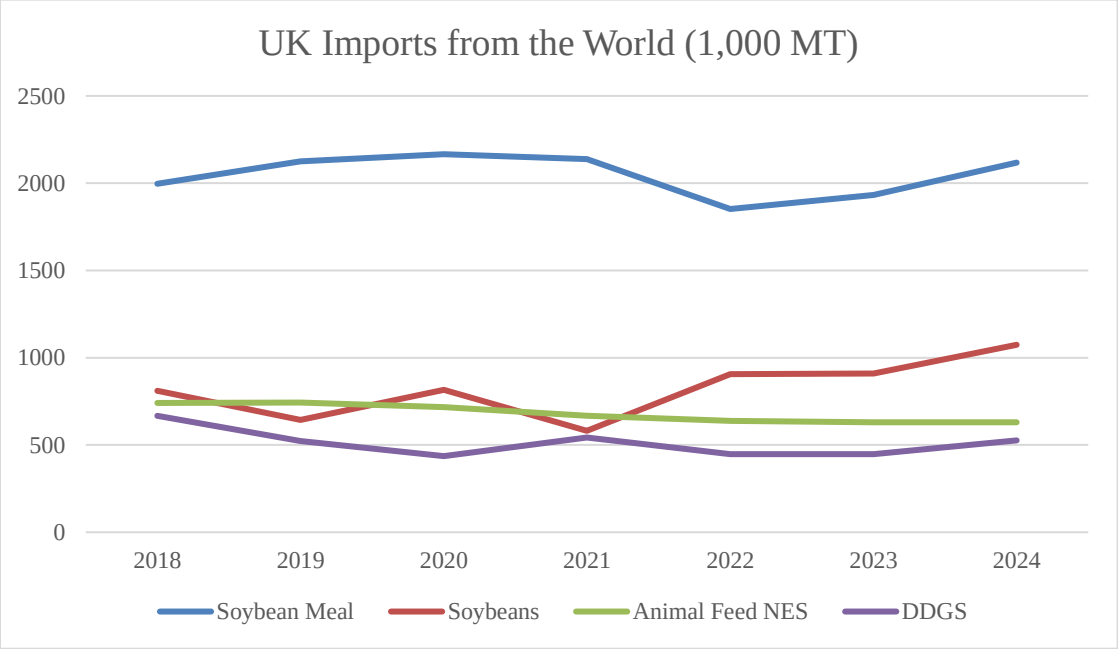
The ability for the UK to purchase from a particular country is dependent on whether there is the appropriate approvals, either historic (prior to 2021) EU approval for food and feed for GE crops cultivated by the exporting nation, or through a corresponding approval post Brexit. The UK's Food Standards Agency (FSA) has been slow to approve new GE crop applications for entry to Great Britain (GB). This delay has caused an asynchronous approval situation between the EU and GB markets for certain soy and corn traits that were approved by the EU since 2021. It is understood that much of the delay, particularly after the completion of the risk assessment phase, has been attributed to the time taken for the necessary assessments to be completed by the UK's National Reference Laboratory.

The main supplier countries for GE food and feed crops include Argentina, Brazil, and the United States. Low Level Presence (LLP) of unapproved GE events in bulk shipments remains a concern that dominates trade decisions. In the UK, the threshold for unapproved events found in animal feed is very low at 0.1 percent (and only pertains to traits already in the EU approval pipeline). There continues to be zero tolerance for unapproved GE events found in food and seed. One exception to this was the extension of a previously granted tolerance up to the 0.1 percent threshold for three GE events that were formally withdrawn from the market (Ms1×Rf1, Ms1×Rf2 and Topas 19/2). This was to ensure their accidental presence would not hinder the future trading of oilseed rape commodities, with the tolerance period extended up to the end of 2025.

Trade is also dependent on many other things, such as long-term supply chain investments for soybeans and soybean meal, availability of supply, demand, exchange rates, etc. The share of key commodities imported that are GE is estimated to be around 90 percent.

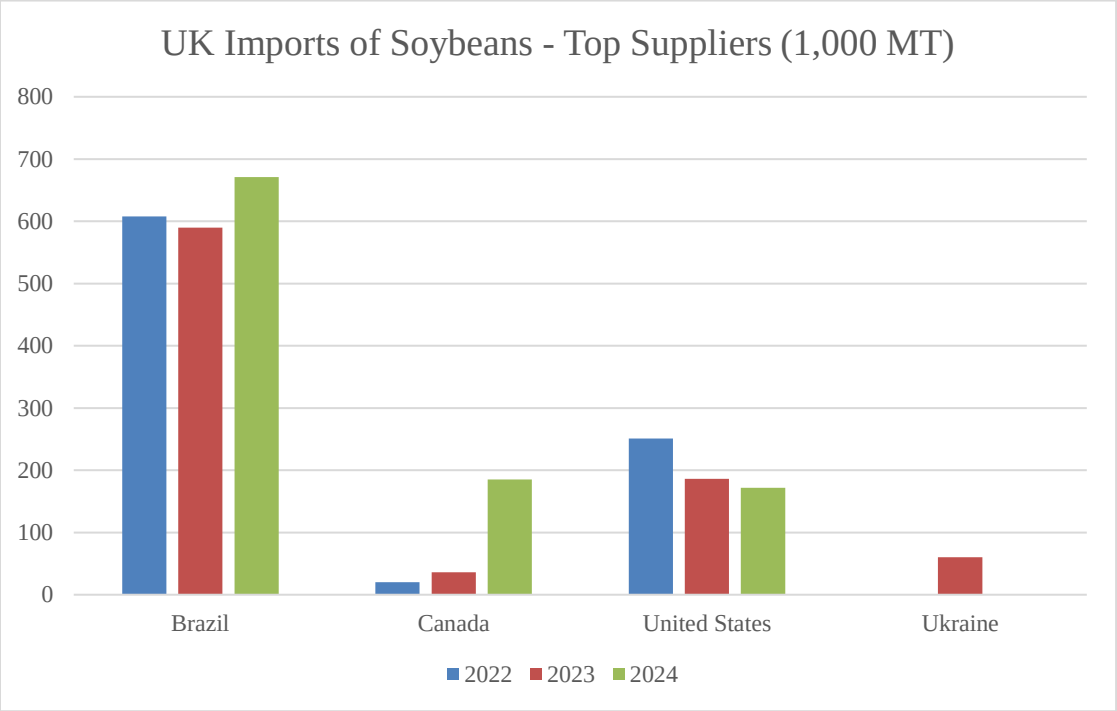
Please see graphs below for trade flows into the UK of the key GE commodities.

GRAPH 1. UK Imports from the World, 2018-2024: Soybean Meal, Soybeans, Distiller's Dried Grains with Solubles (DDGS), and Animal Feed (not elsewhere specified)



MT = metric tons; Calendar Year
Source: Trade Data Monitor/UK Data - His Majesty's Revenue and Customs (HMRC)

GRAPH 2. UK Imports of Soybeans, 2022-2024

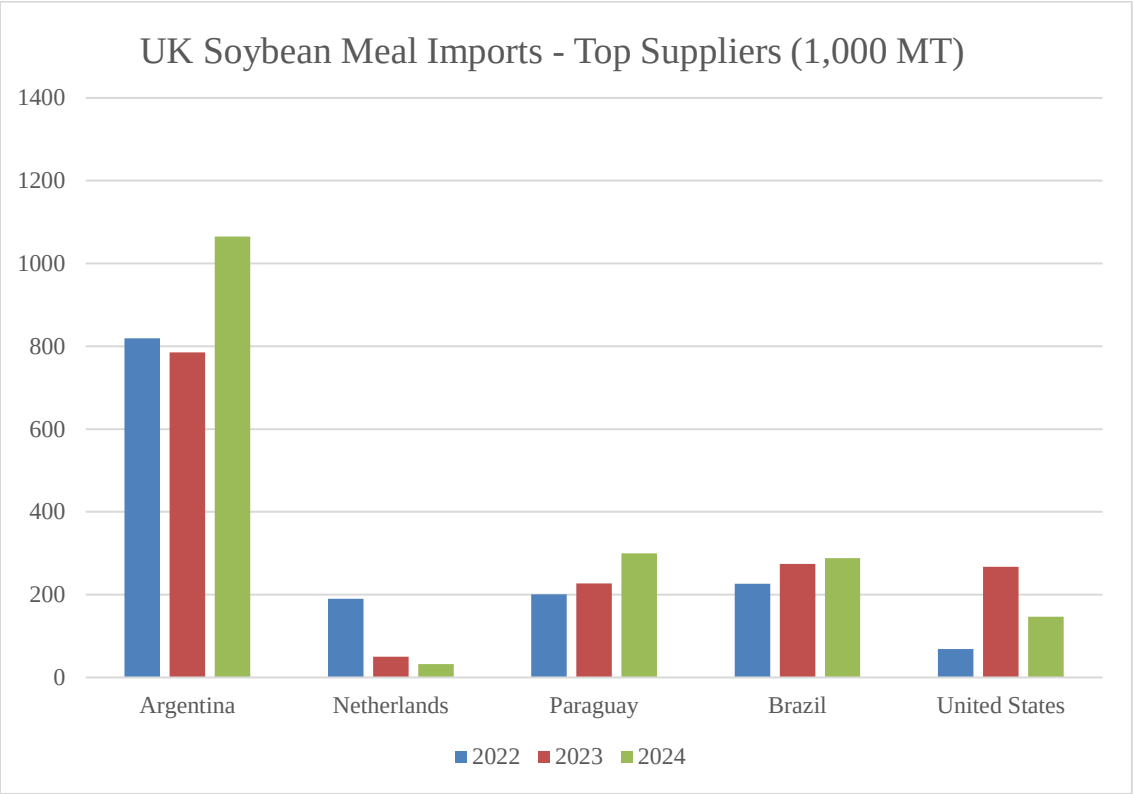


MT = metric tons
Source: Trade Data Monitor/UK Data - His Majesty's Revenue and Customs (HMRC)

Soybean imports (**GRAPH 1** and **GRAPH 2**) into the UK rose again in 2024, surpassing the previous record for the last 15 years set in 2023, with trade volumes holding steady in the latest January to September 2025 statistics. These large import volumes have been due to increased capacity of the single UK crush facility in the North-West of England.

Imports of soybean meal (**GRAPH 1** and **GRAPH 3**) have also increased in recent years to keep pace with demand, with the first nine months of 2025 showing a 28 percent increase compared to the same period the previous year. Over the same period, there has been a 35 percent increase in miscellaneous animal feed, with this indicative of the current strong demand for animal feed in the UK, particularly for the poultry but also the dairy sector whose access to forage has been constrained by the dry summer.

GRAPH 3. UK Imports of Soybean Meal, 2022-2024

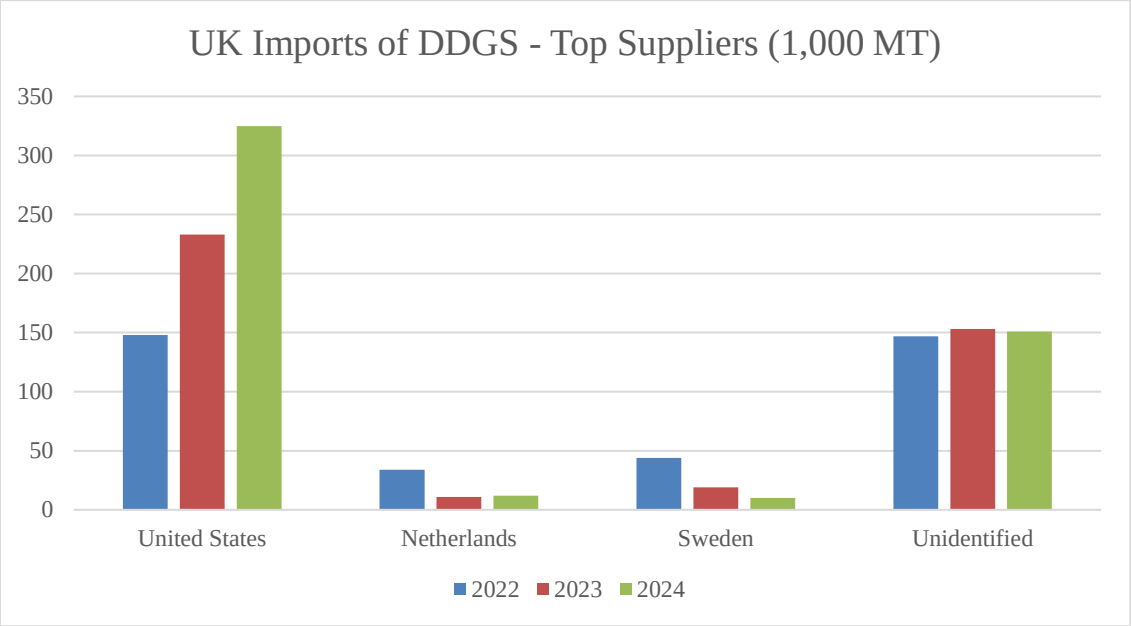


MT = metric tons
Source: Trade Data Monitor/UK Data - His Majesty's Revenue and Customs (HMRC)
Note: Supplies from Netherlands are trans-shipments from other sources

Between 2022-2024, DDGS imports into the UK were broadly stable. However, from January to September 2025, UK imports show a 16 percent increase year on year likely largely price driven compared to alternative sources of animal feed. In 2024, imports to the UK of DDGS from the United States, specifically, reached record high levels for the last 15 years (see **GRAPH 4**). With UK imports of U.S. DDGS volumes up 9 percent for the first nine months of 2025 compared to the same period in the previous year, it suggests trade may continue on an upward trajectory, with this linked to the abundant supply of DDGS as a byproduct of the expanding U.S. bioethanol industry.

With regards to EU exports of GE commodities to the UK, a significant volume of the key GE commodities is recorded as being imported from the Netherlands port of Rotterdam and from Ireland, two major trans-shipment ports for animal feed materials destined for the UK. This routing through other EU Member States makes it difficult to say definitively what proportion of UK imports can be attributed to the originating producer country, such as the United States, Brazil, Argentina, among others. However, most of these commodities are from outside of the EU as neither the Netherlands nor Ireland grows soy or corn in commercial quantities. This trans-shipment issue accounts for the discontinuity in imports from the Netherlands for soybean meal (**GRAPH 3)** and DDGS (**GRAPH 4** below), along with the significant volumes classified as 'Unidentified'.

GRAPH 4. UK Imports of Distiller's Dried Grains with Solubles (DDGS), 2022-2024



MT = metric tons
Source: Trade Data Monitor/UK Data - His Majesty's Revenue and Customs (HMRC)
Note: Supplies from Netherlands are trans-shipments from other sources, which partly accounts for the discontinuity in the data

e) FOOD AID

The UK's Foreign, Commonwealth & Development Office (FCDO) sends food packages, which do not include GE products, along with medical supplies to countries in need. The UK is not a recipient of food aid.

f) TRADE BARRIERS

Historically, U.S. exports of processed foods and beverages have been constrained by UK market conditions and local legislation pertaining to GE food products. Following the UK's departure from the EU, the UK incorporated without alteration EU regulations under "retained EU law" into domestic law, latterly known as assimilated law. Due to a long-standing negative image of agricultural biotechnology, UK supermarkets and food manufacturers formulate their grocery products to exclude GE ingredients. Usually, the GE element of processed foods is a small component of the overall product, for example, soy lecithin (used as an emulsifier). This means that the additional cost of sourcing non-GE ingredients adds only a small contribution to the finished price of the goods. However, for many U.S. companies, the additional burden to source non-GE ingredients to supply the EU and UK markets is often too large a hurdle to overcome. This is also increasingly the case for other countries wishing to supply the EU and UK. As around 30 countries now produce GE crops, it is becoming difficult to source non-GE ingredients. Private standards do still restrict the use of GE feed in animal feed rations. However, of the

major UK supermarkets, only the Waitrose retail supermarket commits to ensuring non-GM feed is used in its own-brand products, including eggs, chicken and turkey.

PART B: POLICY

a) REGULATORY FRAMEWORK

The UK left the EU on January 31, 2020, and adopted all relevant EU Directives and Regulations including those on "Genetically Modified Organisms" into a body of "retained EU law" that is now domestic law and as of January 1, 2024, is known as "assimilated law".

The following UK regulations and amendments to Genetically Modified Organisms (UK), Genetically Modified Food and Feed (UK), and Precision Breeding (for England only) are listed in chronological order.

Genetically Modified Organisms:

The UK regulation that removes references to EU institutions and provides UK sovereignty is:
The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019
This is an amendment to:
Genetically Modified Organisms (Deliberate Release) Regulations 2002, which supplements the primary legislation – the Environmental Protection Act 1990 – that provides the general powers and responsibilities to control the deliberate release of products of GE in England.

A further relevant Statutory Instrument that has not been amended is:
The Genetically Modified Organisms (Traceability and Labelling) (England) Regulations 2004 Similar regulations covering all the above legal texts have been made for Scotland, Wales, and Northern Ireland. They can be found by searching for "Genetically Modified Organisms" on the UK legislation website, linked to here.

The administrative changes, which entered into force in April 2022 to make field trials of "QHPs" easier, are contained in:

The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022.

Genetically Modified Food and Feed:

The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019
This is an amendment to: The Genetically Modified Food (England) Regulations 2004

A piece of secondary legislation, entering into force in April 2023, which authorizes the placing on the market of specified genetically modified food and feed products in England is:

The Genetically Modified Food and Feed (Authorisations and Modifications of Authorisations) (England) Regulations 2023.

After the FSA consulted on a first tranche of proposals aimed at streamlining the market authorization process for GE regulated products in April 2024, the associated secondary legislation came into force on a GB-wide basis on April 1, 2025, in the form of The Food and Feed (Regulated Products)(Amendment, Revocation, Consequential and Transitional Provision) Regulations 2025.

The two main changes the regulations contain:

- remove the renewal requirements for feed additives, food or feed containing, consisting of or produced from genetically modified organisms (GMOs) and smoke flavorings, and
- allow regulated product authorizations to come into effect on publication following a ministerial decision.

With renewals comprising about one in five of the total regulated product applications, the first of these changes is intended to relieve some of the resource pressures that are contributing to the backlog of GE authorizations. By removing the requirement to lay secondary legislation to authorize GE regulated products, FSA estimates it could accelerate the approval timeline by at least three months.

At its June 2025 Board meeting, FSA discussed a further suite of proposals aimed at modernizing its market authorization service for regulated food and feed products. Significant among the list of six ideas was the proposed ability of the FSA to directly use risk assessments from other countries regulators, without needing to repeat detailed aspects of the risk assessment. The assessments thought eligible would be from regulators from other countries where the scientific assessment meets the UK's standards and internationally recognized risk analysis principles.

In describing the potential delivery timeframe for these proposed changes, the FSA's June Board paper stressed the dependency with the UK Government's stated ambition to negotiate a Sanitary and Phytosanitary (SPS) agreement with the EU. Consequently, the FSA Board agreed to defer consulting on the proposed changes until at least the fall of 2025, in the hope that more clarity might be available then on the nature of the UK-EU SPS deal.

Precision Breeding (England only):
As noted above, confirmed as an act of Parliament is the:
Genetic Technology (Precision Breeding) Act 2023.
This Act contains provisions for regulating the placing on the market of food and feed produced from Precision Bred Organisms in England.

The secondary legislation setting out the detailed provisions for PBOs released or marketed in England was made on May 13, 2025, following debates in both Houses of Parliament: The Genetic Technology (Precision Breeding) Regulations 2025. An inbuilt six-month delay meant these regulations entered into

force on November 13, 2025, and only then could the first applications for authorizations for Precision Bred Organisms (PBOs) be accepted.

Responsible UK authorities

- The Health and Safety Executive (HSE) regulates "genetically modified organisms (GMOs)" in contained use (e.g., in a laboratory). Link to HSE

- The Department for Environment, Food & Rural Affairs (Defra) is responsible for the control of the deliberate release of GE agricultural products and for national and international policy on the environmental safety of such products. Link to Defra, see Appendix 7, the term used is "GM".

Defra is the competent authority that implements and enforces the content of the assimilated Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of GE agricultural products genetically modified organisms. Link to EU Directive 2001/18/EC

Defra provides the secretariat for the Advisory Committee on Releases to the Environment (ACRE). ACRE is an independent advisory body that reviews applications for field trials of GE agricultural products. Link to Defra/ACRE

- The Food Standards Agency (FSA) controls the assessment of GE food for human consumption (food and feed), and consumer labeling of GE foods. Link to FSA, term used is "GM".
- The FSA is advised on both GE and novel foods by an independent body of experts called the Advisory Committee on Novel Foods and Processes (ACNFP) and on GE animal feed by the Advisory Committee on Animal Feedingstuffs (ACAF). The ACNFP is responsible for assessing the safety of novel and GE food, and ACAF is responsible for assessing the safety of GE feed. The ACNFP's latest annual report published in June 2025 reports that 9 applications for new plant GE authorizations were reviewed by the committee between January 2024 and March 2025.

Devolved competences – The United Kingdom is comprised of England, Wales, Scotland, and Northern Ireland. The devolved governments of Wales, Scotland, and Northern Ireland have jurisdiction over agriculture, fisheries, and food policy in their regions. These countries have a higher proportion of 'Less Favored Areas' (difficult to farm landscapes) than England and traditionally have traded on their 'pristine and natural environment' image. Many of the farmers in these rural areas are receptive to new scientific techniques that could safeguard their future livelihoods and increase productivity, but their respective governments have avoided incorporating new agricultural biotechnology practices.

In formulating overall UK agricultural biotechnology policy, the central government in London solicits views from a wide range of stakeholders, including the devolved Parliaments. As noted in the 2024 Biotech Report, under the previous administration the UK extended powers under existing legislation to

facilitate plant genome-editing research and amended legislation to aid cultivation of genome-edited plants in England only. This has been controversial, and there is disagreement from the devolved government of Scotland on how this interacts with the UK Internal Market Act. Since last year's report, the Scottish agriculture industry has urged the Scottish government to align with England's precision breeding legislation to avoid competitive disadvantage.

b) APPROVALS/AUTHORIZATIONS

Since the 2024 Biotech Report, the UK has **not approved any new GE products**. This is despite launching a consultation on three new authorizations for GE organisms for food and feed uses (one cotton, one corn and one soybean event) in December 2024, as part of a broader list of proposed authorizations. The summary of responses to this consultation, anticipated to be released in May 2025, was only published on October 16, 2025.

For additional background and legislation on the UK approval process, please see below.

From January 1, 2021, the UK is responsible for the approval of GE products. The UK continues to follow the approach laid out in EU assimilated law [Directive 2001/18/EC, Regulation (EC) 1829/2003 and Regulation (EC) 1830/2003] and distinguishes between the approval for food, feed, processing, or environmental release. The following links provide information on how to apply to the UK for regulated food or feed approval under "GM" law: Regulated Product Authorisation Application, Regulated Product Application Guidance, and Genetically Modified Organisms Guidance. The FSA has said that in most cases, applications will take at least a year. However, no new applications have been approved by the UK since April 2023. Regarding approval for cultivation in the UK, applications must be made to the relevant competent authorities in England, Wales, Scotland, and Northern Ireland. More information on the approval system for environmental release can be found here: Defra GMO approval process.

As noted in 2024 Biotech Report, the FSA has removed the 10-yearly renewal requirement for certain previously approved regulated food and feed products, including GE products.

c) STACKED or PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS

The approval process for stacked events is the same as that laid out for single events above. The UK continues to base its approach to risk assessment and management of multiple traits within one product on EU legislation. See: European Food Safety Authority, and Page 8 of EFSA Guidance for Risk Assessment.

d) FIELD TESTING

Defra is the lead agency for authorizing and overseeing field testing. However, the devolved administrations of Scotland, Wales, and Northern Ireland have powers over cultivation on their territory.

An application for a GE field trial must be made to Defra under Part B of the EU assimilated law [Reference: Deliberate Release Directive (2001/18/EEC)], which covers release for research and

development. Notification must be given before a QHP field trial starts. Please see: list of consents for field trials in England, including QHP notifications.

Hundreds of GE crop farm-scale evaluation trials have been conducted in the UK since 2000, mainly on corn, sugar beet, oilseed rape, wheat, and potatoes. These trials include crops now covered by the QHP procedure. See Part A, section a) Product Development for further information on current field trials.

e) INNOVATIVE BIOTECHNOLOGIES

Innovative biotechnologies include CRISPR-Cas9, oligonucleotide-directed mutagenesis (ODM), zinc finger nuclease (ZFN), cisgenesis and intragenesis, grafting, agro-infiltration, RNA dependent DNA methylation, reverse breeding, and synthetic genomics.

Prior to the election of the Labour Party in July 2024, UK Conservative government stated in documents alongside its public consultation on regulation of genetic technologies conducted in early 2021 that it disagrees with the European Court of Justice ruling in 2018 that organisms obtained by mutagenesis and through genome editing are "GMOs" and within the scope of the EU's Deliberate Release Directive 2001. The UK government intervened in the case to present a different view based on scientific evidence and to argue that the regulatory regime should be proportionate to risk. When opening the public consultation on regulation of genetic technologies, the UK government stated that where genetic alterations and combinations are of the type that are selected for in traditional breeding, the environmental release of these plants should not be regulated in the same way as the environmental release of "Genetically Modified Organisms (GMOs)".

England Only: In April 2022, the UK Conservative government altered the definition of a "GMO" so that plant products of genome editing and genetic technologies that do not result in the introduction of DNA from different species but produce targeted changes to existing DNA in an organism that could be made more slowly using traditional breeding methods, or occur naturally, no longer fall within "GM" regulations. This was introduced as a first step in regulatory reform in England, although the change was not replicated in Scotland, Wales, or Northern Ireland. These 2022 regulations – the Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations – have now been replaced by the requirements of The Genetic Technology (Precision Breeding) Regulations 2025. These have the same effect for research trials but go further to introduce the processes to allow a route to market outside the current "GMO" framework.

f) COEXISTENCE

As part of the Parliamentary scrutiny leading to the adoption of the Precision Breeding secondary legislation, Defra was pressed on stakeholder concerns regarding the risk precision bred material could enter organic supply chains, which is prohibited under UK organic legislation. On May 6, 2025, in response, Defra noted that its engagement with the industry had suggested that the first products that would come to market would not undergo significant further processing. Consequently, they could be kept separate from traditionally bred material, which would mean that the exposure of organic production to precision-bred material would be very limited in the short term.

As part of its evidence to the House of Lords Secondary Legislation Scrutiny Committee, published on March 25, 2025, Defra also noted that it was working closely with the organic sector to prepare for the medium-term and longer-term impacts by discussing non-legislative options for supply chain coexistence, including facilitating discussions to establish which measures currently used by industry could be used by farmers to enable coexistence between precision-bred and non-precision-bred crop production. This was, Defra suggested, in line with how things are approached internationally. As part of this process, the British Society of Plant Breeders, representing the plant breeding industry, has committed to maintaining a register of precision bred varieties to complement the statutory Defra and FSA registers.

g) LABELING AND TRACEABILITY
There have been no changes to the UK regulations since last year's report.

For consumer-ready grocery products, the UK continues to follow retained EU law where labeling is triggered by intentional inclusion in a product and if there is accidental presence of 0.9 percent or more approved "GM" ingredients as a percentage of the individual ingredient. The list of ingredients should contain a reference, for example: "contains soya oil from genetically modified soya". More at: GMO Traceability and Labelling (England) Regulations (similar regulations exist in all UK regions).

Guidance on labeling GE products, ingredients, or processing aids can be found here: Food Standards Agency "GM" Labelling

Animal feed materials and compound feeds that contain "GM" or "GM-derived" material must indicate this on the feed label. Labeling is not required for animal feed consignments containing unexpected or technically unavoidable traces of "GM" material that contain less that 0.9 percent of approved "GM" varieties. More information is available at: "GM" in animal feed

The Defra position on mandatory labelling of PBO food, when asked by Parliamentarians during the scrutiny of the secondary legislation, as noted in the March 20, 2025 report, was as follows:

> "Products of precision breeding will only contain genetic changes that could also occur through traditional breeding. The scientific advice is that these organisms pose no greater risk than traditionally bred counterparts. The Precision Breeding Act 2023 does not contain provisions for mandatory labelling of any precision bred organism, or derived food, feed, or plant reproductive material. This was debated and approved in Parliament. As such, there are no labelling requirements in the Genetic Technology (Precision Breeding) Regulations 2025."

The UK government's further assertion was that:

> "The registers published by Defra and FSA will contain information about precision bred organisms, including those approved for use in food and feed. The public registers will enable businesses to develop product lines to meet customers' market demand for food and feed made

without precision bred products. In addition, businesses will be able to voluntarily label that their products contain precision bred crops."

The FSA also emphasized that there was "no justification" for mandatory labelling on grounds of consumer safety, as there was no evidence that PBOs were intrinsically more hazardous than traditionally bred organisms. The Defra Minister in the House of Lords did note cryptically in a debate on May 6, 2025 that "there are discussions within Defra at the moment about how labelling for consumers could be improved", but provided no further details.

Seed Labeling Legislation

Any seed lot containing "GM" seed authorized for the cultivation has to be labeled as containing "GMOs." Seed lots containing GE seeds that are not authorized for cultivation cannot be marketed in the UK. In the UK, this is enforced by the "GM" Inspectorate of the Animal and Plant Health Agency (APHA GM Inspectorate). There have been no changes to these regulations since last year's report.

Between February and April 2025, Defra conducted a public consultation which, among other questions, explored the mandatory inclusion of precision bred status in labels for precision bred seed and other plant reproductive material. To implement such an obligation would necessitate legislative changes as this is not a current requirement within existing Precision Breeding legislation. A summary of the consultation responses was published on October 9, 2025, albeit without a definitive indication of the UK government's decision on the subject.

h) MONITORING AND TESTING

All UK imports continue to be subject to random or more frequent testing (depending on product) upon border entry. Since it is not a food safety concern, testing for GE material is normally randomized. Both feed and food supply chains conduct testing to satisfy import specifications, labeling obligations, and customer assurance. Field trials for non-QHP/PBO crops are subject to inspections by the GM Inspectorate.

i) LOW LEVEL PRESENCE (LLP) POLICY

To deal with the possible presence of unauthorized varieties in imports of feed commodities, the UK continues to follow the approach inherited from EU Regulation 619/2011. This defines "zero" with a "technical solution" level of 0.1 percent for GE varieties provided that a valid application for a UK authorization has been made and that requirements set out in Article 2 of the Regulation have been followed. There is no set technical solution for food or seed. Above this threshold, the product is not allowed on the UK market. Operators must demonstrate that the presence of "GM" material was adventitious or technically unavoidable.

j) ADDITIONAL REGULATORY REQUIREMENTS

The UK has no additional regulatory requirements.

k) INTELLECTUAL PROPERTY RIGHTS (IPR)

The UK has a comprehensive system to address Intellectual Property Rights, including an Intellectual Property Office (IPO) that covers plant breeders' rights. A patent can be granted at a national level through the IPO.

The Animal and Plant Health Agency (APHA) takes the lead on plant intellectual property and plant variety rights. See: Guidance on Plant Breeders' Rights

This Precision Breeding legislation does not make provision in relation to intellectual property rights in precision bred organisms or the technologies used to produce them, which will continue to be regulated under existing intellectual property law. UK patent law excludes plants and animals from patent protection if they were developed using essentially biological processes such as crossing and selection. However, there is no such exemption for plants and animals produced using technical processes, such as precision breeding. Therefore, patents may be granted to precision bred plants and animals which have arisen from patentable methods despite the end product having genetic changes which are similar to those that could arise naturally.

l) CARTAGENA PROTOCOL RATIFICATION

The UK is a signatory to the United Nations' Convention on Biological Diversity and has ratified the Cartagena Protocol on Biosafety. Defra is the contact point.

England implemented EU Council Regulation EC No. 1946/2003 by way of the *Genetically Modified Organisms (Trans-boundary Movements) (England) Regulations* 2004. Similar regulations have been implemented in Scotland, Northern Ireland, and Wales. These regulations establish a common system of notification and information for transboundary movements of GE organisms and ensures coherent implementation of the provisions of the Cartagena Protocol on Biosafety.

m) INTERNATIONAL TREATIES/FORUMS

The UK is an active participant in all major plant health and international regulatory forums including the International Plant Protection Convention (IPPC), European Plant Protection Organization (EPPO), Food and Agriculture Organization of the United Nations (FAO), World Trade Organization (WTO), Codex Alimentarius, and the Organization for Economic Cooperation and Development (OECD). The UK generally supports evidence and science-based risk assessments in these forums.

n) RELATED ISSUES

There are no related issues.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS

The UK has several academics that are vocal on both sides of the debate. Most are proponents of responsible use of biotechnology. The Science Media Centre plays a role in fielding relevant experts to speak publicly following requests from journalists for specialist information and comment. Science for Sustainable Agriculture is a relatively new industry policy group that is a vocal supporter of UK wide access to "innovative biotechnologies" and GE, although it accepts that GE is a bigger challenge for the sector to access. Its website features regular articles from researchers and politicians, providing a timely contribution to the public discourse.

The All-Party Parliamentary Group on Science and Technology in Agriculture has provided a similar forum for discussion, with its members directing letters to Ministers to encourage faster progress in implementing precision breeding legislation.

There are many organizations actively campaigning against the use of genetic technologies, including but not limited to GeneWatch, GM Freeze, Beyond GM, Friends of the Earth, the Soil Association, Slow Food in the UK and the Royal Society for the Protection of Birds.

For most of the British public, GE in food is not a consideration as there are very few mainstream grocery products that clearly contain GE ingredients. For this reason, most UK consumers consider the "GM problem" to be disconnected from everyday grocery purchases.

For those who distrust the technology or have limited knowledge and hold only "a sense" or "a feeling" on the subject. In questionnaires/surveys, UK respondents often cite the concentration of power over staple food crops by big business as their main concern with regards to biotechnology.

b) MARKET ACCEPTANCE/STUDIES

In recent years, there has been positive media coverage that sets agricultural biotechnology in the context of its potential to support global food security, while addressing climate change, and feeding a burgeoning global population. However, this has not translated into general acceptance for the presence of GE ingredients in the UK food supply.

"Choice editing" by retailers or foodservice companies determines what is sourced by the supply chain. Due to the zero-tolerance for un-approved GE material in food, the food manufacturing sector actively avoids and substitutes GE ingredients.

The existence of GE crops in the global marketplace has negatively affected imports of food products containing GE soy and corn-based products. In addition, products containing glucose or other sugar components of GE sugar beet, sugar cane, or oilseed rape (Canola) must be labeled, and by doing so the GE presence is highlighted. Some supply chains may decide that they do not want GE ingredients/labeled products, as this may cause the product to no longer be listed or carried in UK

retailers. There are a few examples of products overcoming the hurdles, labeling appropriately, and achieving sales success. These products are usually those where consumers have a desire for the product or there is a price incentive that counters the presence of GE ingredients, for example, “cult” confectionery, candy bars, or lower-cost cooking oils.

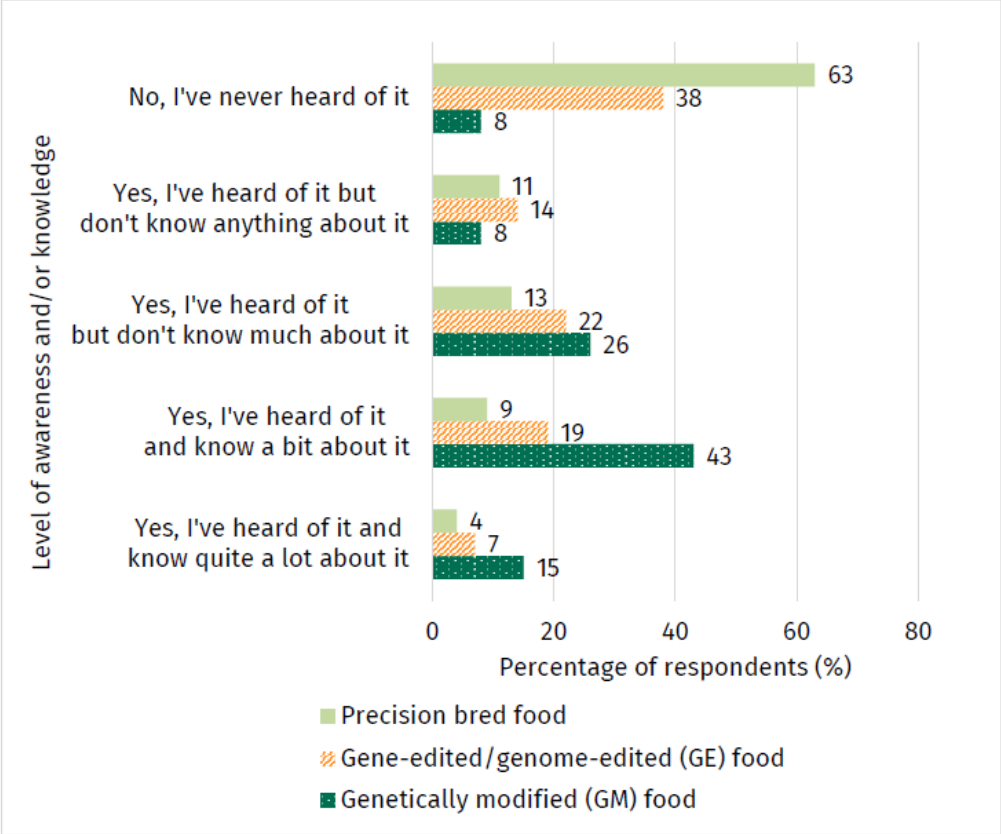
Innovative biotechnologies (e.g., precision bred products) may have a smoother path to consumer acceptance. This will depend on the nature and purpose of the change that is created, and how any consumer benefits are communicated.

In the animal feed sector, the majority of soybean and corn-derived feeds are GE. There is much less sensitivity about feeding GE feed to animals, as finished meat, dairy, and poultry products do not need to be labeled, and there is no GE material in the final product. Organic options are available in the market for those who wish to avoid GE-fed livestock products, and the UK supermarket retailer Waitrose (capitalizing on the opportunity to differentiate from its competitors) states that “No Waitrose food is genetically modified”, meaning that no food or drink sold under its own brand is GE or contains GE ingredients or additives.

Marketing Studies

The UK Food and You survey offers the most recent (March 2025) consumer opinions on a wide variety of topics, including GE and “innovative biotechnologies”. The survey is primarily carried out online using a methodology known as ‘push-to-web’. This is a quantitative data collection method in which participants are contacted using an offline means of approach and asked to complete an online survey. Fieldwork for the Wave 9 report was conducted between April 2024, and July 2024. A total of 5,526 adults from 3,908 households across England, Wales, and Northern Ireland completed the survey. A consistent finding across the ‘Food and You 2’ survey (see Wave 2, 3, 4, 5, 6, 7, 8, 9) is that, although 58-64 percent of participants state that they are concerned about “genetic modification” in food when prompted, “GM” is never listed as a top-ten concern when participants are asked an unprompted question about food concerns.

In terms of appreciation of particular terms, the Wave 9 report showed that respondents reported greater awareness and knowledge of “Genetically Modified” food compared to other descriptors, with just eight percent stating they had never heard of it. Gene-edited food is not so well-known with 38 percent of respondents saying they had not heard of it, while 63 percent were not aware of precision bred food. These figures show a steady but significant increase in awareness compared to the previous report.



Source: Food and You 2: Wave 9

The publication of the Precision Breeding secondary legislation in March 2025 and the accompanying Impact Assessment and Parliamentary scrutiny, brought into the public spotlight findings of surveys FSA and Defra had commissioned in 2022 to inform their internal analysis. Some noteworthy findings from the Ipsos survey for the FSA on consumer attitudes to precision bred food products included:

- Half of survey respondents (50 percent) said that precision bred food products should be available for sale in the UK in the future, compared to fewer than three in ten (29 percent) who said they should not be.
- 50 percent of respondents thought that precision bred foods are safe to eat while 22 percent thought they are unsafe and 28 percent did not know.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

During the last year, the animal biotechnology developments most widely publicized have focused on advancing veterinary vaccines, including August 2025 report on plans to establish a new veterinary vaccine hub. There have been few additional production developments since the 2024 Biotech Report to report on. For historical reference please refer to the prior report.

No UK cloning research is currently taking place that will result in live farm animals, although pet cloning services have expanded, albeit through the use of international partners for the actual cloning. GE animals, such as those below, are under development but none are expected to be on the market in the UK imminently.

Event	**Organization**
GE mosquitoes to control dengue fever, malaria	Oxitec/Intrexon
GE olive fly, medfly, bollworm	Oxitec/Intrexon
GE pest insects	Pirbright Institute
GE insects	Beta Bugs
Suppression of avian influenza transmission in GE chickens	Roslin Institute
Gene-edited (ZFNs and TALENS) Pig 26 (for biomedical research)	Roslin Institute

In the context about the debate on progress with domestic legislation, attention has been given to the considerable potential gene editing has to accelerate the delivery of health and welfare, environmental and productivity benefits in farmed animals by, for example, developing genetic resistance to diseases such as porcine reproductive and respiratory syndrome (PRRS) in pigs, avian influenza in poultry and bovine viral diarrhea (BVD) in cattle.

The potential to tangibly realize these benefits was exemplified in April 2025 when British genetics firm Genus plc received approval from the U.S. Food & Drug Administration for its gene edited PRRS resistant pig, which was co-developed with UK researchers at the Roslin Institute. Institutes like Roslin at the University of Edinburgh, Pirbright, and the University of Nottingham are internationally renowned for their work on animal biotechnology.

b) COMMERCIAL PRODUCTION

GE animals (particularly mice, some rats) and fish are produced in the UK for research purposes. Mice and rats are used in the safety testing of some chemicals and medicines, while GE fish is mainly for breeding purposes.

In addition, GE invertebrates such as fruit flies and nematode worms are widely used by UK researchers. With regards to products from animal biotechnologies, embryo progeny of clones or embryos of clone progeny are imported for use in the dairy sector. Bovine semen is also imported, including from U.S. Holstein herds, so it is possible that this has been sourced from clones or their progeny.

c) EXPORTS

The UK exports GE mosquito eggs for development and subsequent release in countries where Oxitec has received approval for its GE insects e.g. Brazil and the Cayman Islands. Apart from these, the UK does not export GE animals, livestock clones, or products from these animals. It is possible that the UK exports products produced from, and genetics from, the progeny or subsequent generations of clones.

d) IMPORTS

As mentioned above, the UK has imported embryo progeny of clones or embryos of clone progeny as well as bovine semen which may have come from clones or their progeny. No import data is available as these products are not differentiated from other embryos or semen. The UK has not imported live GE animals or livestock clones, although commercial house pet cloning is beginning to take off.

e) TRADE BARRIERS

Ethical and welfare concerns exist, but there are no known physical trade barriers in the UK. Given some developments in this area involve insects, it is noteworthy that there has been growing UK media attention devoted to the welfare of farmed insects and the appropriate methods of dispatch.

PART E: POLICY

a) REGULATORY FRAMEWORK

As with plant biotechnologies, the UK government takes a generally science-based approach to animal biotechnologies. At present, the UK does not have any country specific legislation or registration requirements on animal biotechnology. It is currently following the EU legislation that it has inherited in this area – it is the same as covered under the plant section above, excluding the relaxing of field trial regulations.

Before the July 2024 election of the Labour Administration, the intent of the UK Conservative government to amend legislation to facilitate the removal of products of genome editing from the scope of "GM" regulations also applied to animal applications, with this manifest in the debate over the Genetic Technology (Precision Breeding) Act. As previously noted, Labour has not provided guidance on their position with regards to "GM", including animal biotechnology.

Genetic Technology (Precision Breeding) Act 2023 gives powers for a regulatory system for precision bred animals to be established. To date no regulatory framework has been proposed to allow for precision bred animals. The inclusion of animals within the scope of the legislation was questioned by

some stakeholders on health and welfare grounds and opposition parties tabled amendments seeking to restrict the application of precision breeding of animals.

In seeking to reassure Parliamentarians during the passage of the legislation, the government noted that, under the Act, animals may only ever be used in science where there are no alternatives, where the number of animals used is the minimum needed to achieve the scientific benefit, and where the potential harm to animals is limited to that needed to achieve that benefit. It was further highlighted that three licenses are required under this legislation: a personal license for each person carrying out the procedures on animals; a project license for the program of work; and an establishment license for the place in which the work is carried out.

While the secondary legislation implementing the Precision Breeding Act provisions for plants was made in May 2025, the similar statutory instrument required for animal applications has not yet been finalized. The process was deferred for additional welfare assessments. On March 31, 2025, the Defra minister responding to the debate in the House of Commons, Emma Hardy, summarized the government's position on animals as follows: "While we are continuing the research that supports policy development of the animal welfare declaration, no decision has yet been taken on introducing legislation to implement the 2023 Act in relation to precision-bred animals". On May 6, 2025, the responsible minister in the House of Lords, Baroness Hayman of Ullock, noted that Defra was currently continuing research, but while this was ongoing, "we will not be bringing forward any legislation on animals".

Defra plays an overarching role in the implementation of animal biotechnology regulation in the UK. The Health and Safety Executive helps to control the contained use of genetically engineered organisms in the UK to ensure no products or animals are released or exposed to humans without safety inspections and approvals. Further information on Defra's role in the regulation of GE animals and/or livestock clones, is available here.

The Farm Animal Genetic Resources Committee (FAnGR) gives advice to the UK government on issues to do with farm animal genetics. See: FAnGR

b) APPROVALS/AUTHORIZATIONS

Aside from the Soy Leghemoglobin application referred to in Chapter 3, Part H, sub-paragraph b) below, all the information collated by UK authorities on "Genetically modified organisms (GMOs) as food and feed" relates to authorizations/applications for plant biotech-derived food ingredients.

c) INNOVATIVE BIOTECHNOLOGIES

As noted in the Product Development section above (Chapter 2, Part D, sub-paragraph a), UK researchers are using innovative biotechnologies in research applications and there is potential for commercialization of UK research in North America, such as the PRRS resistant pigs.

d) LABELING AND TRACEABILITY
Guidance on labeling GE products, ingredients, or processing aids derived from GE animals or clones can be found here: Food Standards Agency "GM" Labelling

e) ADDITIONAL REGULATORY REQUIREMENTS
There are no known additional biotechnology-related regulatory requirements that negatively impact U.S. exports of animal biotech-derived food ingredients.

f) INTELLECTUAL PROPERTY RIGHTS (IPR)
The UK has a comprehensive system to address Intellectual Property Rights, including an Intellectual Property Office (IPO) that covers animal breeders' rights. A patent can be granted at a national level through the IPO or through the European Patent Office. See: Guidelines for Patent Applications relating to Biotechnological Inventions

g) INTERNATIONAL TREATIES AND FORUMS
The UK is a very active participant in international forums and can generally be relied upon to be a pragmatic and proportionate regulator. The UK is a member of Codex Alimentarius and the direct liaison point is Defra: codex@defra.gsi.gov.uk

As regards the World Organization for Animal Health (OIE), Defra is the liaison point for Great Britain (England, Scotland, Wales) and the Department of Agriculture, Environment and Rural Affairs (DAERA) represents Northern Ireland in that forum.

h) RELATED ISSUES
None

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS
The UK has several organizations, such as the Biotechnology and Biological Science Research Council (BBSRC), the British Society of Animal Science, and the Roslin Institute, active in public, positive engagement on animal biotechnologies. The industry policy group, Science for Sustainable Agriculture, has published a number of articles urging the UK government to make progress with precision breeding in farmed animals (here and here, for example). Providing the counterpoint, there are many organizations actively campaigning against the technologies, including but not limited to GM Freeze, Beyond GM, GeneWatch, Friends of the Earth, the Soil Association, the Royal Society for the Prevention of Cruelty to Animals, and Compassion in World Farming (CIWF).

The UK population has a generally low level of understanding of the science behind these technologies. Many object to cloning and GE animals on ethical grounds, and there are sensitivities relating to perceived animal welfare issues associated with the technologies. Opinions vary with the intended use, with medical applications (improved medicines) being the most accepted. If consumers' level of

awareness regarding the positive animal welfare traits were higher (such as the example of breeding cattle without horns so that they do not have to be de-horned) then it could be expected that this would increase the acceptance of the technologies. However, some animal rights supporters oppose any intervention, even new welfare-friendly practices, as animals have no say.

The Animal Welfare Committee (AWC) is an expert committee of Defra (previously Farm Animal Welfare Committee – FAWC). It provides advice to Defra on the welfare of animals, including farmed animals on agricultural land, at market, in transit and at the place of killing. Historic FAWC reports and advice provided to the UK government can be found here: FAWC publications

b) MARKET ACCEPTANCE/STUDIES

In the survey FSA commissioned from Ipsos in 2022, just 35 percent said precision breeding of animals was acceptable. The YouGov poll Defra commissioned that same year similarly found consumer acceptance of precision breeding in animals was lower than in plants. When asked about the use of gene edited animals for food production, the proportion finding it acceptable (very/slightly) was 32 percent compared to unacceptable (very/slightly) at 52 percent, with 'Don't know' at 16 percent. This level of acceptability rose to 39 percent faced with the proposition of modifying farm animals by removing allergens from milk and eggs. When the proposition changed to making farm animals more resistant to disease, net acceptability rose still further to 56 percent, compared to 31 percent net unacceptable.

Market acceptance studies in the area of genome editing and farmed animals have also been conducted by Nuffield Council on Bioethics (NCB) in 2021 and 2022 along with a public dialogues – by the Parliamentary Office of Science and Technology in January 2022 – and an opinion study by FSA on consumer perceptions in 2021. For further details on these studies, please refer to the 2023 Biotech Report.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION

The UK produces food ingredients derived from microbial biotechnology. The domestic food industry receives much of its biotech microbes from China, as well as from multi-national companies based in the United States, Denmark, Germany, and the Netherlands.

Examples of UK products manufactured using enzymes or other processing aids from biotech microbes include:

Product	Company	Process
Allulose (Sugar Substitute)	Tate & Lyle	Corn‣Starch‣Fructose‣Allulose using biotech microbe derived enzyme
Nootkatone (Flavor and Scent of Grapefruit)	Oxford Biotrans [now defunct]	Oranges‣Valencene‣Nootkatone using P450 biotech derived enzyme
Animal-free milk proteins	Better Dairy	Synthetic biology and yeast fermentation to produce dairy products without cows
Algae for protein needs	Algenuity	Unilever and Algenuity partner to develop microalgae for plant-based foods
Omega-3 rich micro-algae	MiAlgae	Food and drink industry by-products are processed to replace marine ingredients in fish feed

The UK has a number of venture capital firms tailored to support food application biotechnology. The U.S. has by far the most venture capitalists in this space, but China and the UK are also active in this arena.

An example of a British company that produces specialist microbes using genetic engineering is: Biocatalysts - developing and manufacturing specialty enzymes in small to large scale quantities for a variety of industries, such as food, flavor, fragrance, life science, pharma and fine chemicals. Biocatalysts offer a rapid, low-cost specialty enzyme service from discovery phase through to global shipment of regulatory compliant enzymes.

b) EXPORTS

There are no official statistics or estimates on exports of microbial biotechnology products. However, trade is likely to be substantial as the UK exports alcoholic beverages, dairy products and processed products that may contain microbial biotech-derived food ingredients.

c) IMPORTS
There are no official statistics or estimates on imports of microbial biotechnology products. However, given the significant size of the UK's food manufacturing sector, imports are likely to be considerable. Enzymes, flavorings, colors, etc, and the related final food ingredients, which derive from microbial biotech, are imported by the UK and are used throughout every food manufacturing sector – for example, alcoholic beverages, dairy products, bakery products and other processed products. The UK also routinely imports finished alcoholic beverages, dairy products, and processed products which may contain microbial biotech-derived food ingredients.

d) TRADE BARRIERS
Besides trade barriers described in the GE plants chapter of this report, there are no known additional biotechnology-related trade barriers that negatively affect U.S. exports of microbial biotech-derived food ingredients or processed food products containing microbial biotech-derived food ingredients.

PART H: POLICY

a) REGULATORY FRAMEWORK
In the Genetic Technology (Precision Breeding) Act (2023), there is no mention of microbial foods. Some in the academic community regard this as a lost opportunity as genetic engineering of microorganisms is a more rapid process than in plants or animals, research cycles are shorter, and microbes can create products faster.

There have been no changes to the regulatory framework for microbial products since the 2024 Biotech Report. The primary UK government department responsible for microbial biotechnology is the Health and Safety Executive (HSE). However, Defra may also have oversight if deliberate release to the environment is involved.

The Scientific Advisory Committee on Genetic Modification (Contained Use) (SACGM(CU)) is a non-statutory scientific advisory committee established in 2004. SACGM(CU) provides scientific advice to the competent authorities on the contained use of 'GMOs', particularly in respect of hazard identification and risk assessment.

The regulation of microbial biotechnology is governed by:
the Genetically Modified Organisms (Contained Use) Regulations 2014

These regulations transpose and implement assimilated European Council Directive 2009/41/EC on the contained use of genetically modified microorganisms.
Guidance on the contained use regulations is available here:
https://www.hse.gov.uk/pubns/priced/l29.pdf

The regulation listed above sets out the duties of the person responsible to ensure that contained use involving "genetically modified microbes (GMMs)" is assessed before any work starts and that any relevant risks are identified, and controls assigned. These include risks (whether immediate or delayed) to the health of humans and the environment, arising from the contained use of "GMMs." Following the risk assessment process (laid out in the regulations), a notification of contained use must be sent together with operator address details to the HSE. The responsible person must also have in place containment and control measures, and emergency plans.

There are no known pending UK regulatory developments that have the potential to affect U.S. exports.

b) APPROVALS/AUTHORIZATIONS

The FSA includes novel microbial foods in the broad category of "novel foods", a largely unspecified label applied to any food not commonly used for human consumption in the UK or EU prior to 1997. The UK does not collate information on biotech microbes and/or derived food ingredients approved or registered for use, import, and export. Similarly, there is no public information available on techniques used to alter microbes. This is commercially held and sensitive information.

The HSE maintains a public register of notifications indicating contained use of "GMOs" here: https://www.hse.gov.uk/biosafety/assets/docs/publicregister.pdf However, this public register is mostly biomedical research and probably less than one percent food and agriculture-related activity.

In March 2021, the U.S. company, Impossible Foods, submitted an application dossier for the authorization of Soy Leghemoglobin produced from genetically modified *pichia pastoris* for use in food in the UK. Leghemoglobin is a protein found in plants that carries heme, an iron-containing molecule that makes some meat taste so 'meaty'. The heme in the Impossible burger is made using a yeast genetically engineered with the gene for soy leghemoglobin.

As of November 2024, Impossible Foods' applications in the EU received a positive European Food Safety Authority (EFSA) assessment of the safety of heme as an ingredient produced from a genetically modified source, following its positive opinion on heme as a food additive issued earlier in 2024. This EFSA decision moves the application process towards a vote in Committee by EU Member States – and to scrutiny by the European Parliament in case of the food additive application – the final stage of EU approval.

On the other hand, GB has reviewed this ingredient under (1) the Joint Expert Group on Additives, Enzymes and other Regulated Products (AEJEG) in April and June 2025 and (2) the Advisory Committee on Novel Food & Processes Subcommittee on products of genetic technologies destined for food and feed purposes (ACNFP–PGT) in each of its quarterly meetings in 2025, but there are still a number of additional steps required which are expected to significantly delay the approval process. As discussed above (Part B, section a), the FSA has halted relevant reform proposals due to anticipated changes arising from the UK-EU SPS agreement negotiations, a development that is likely to present a significant roadblock for regulated product applications.

c) LABELING AND TRACEABILITY
The UK has assimilated all pertinent EU law in this subject into its own regulations. See Chapter 1, Part B, sub-paragraph g. There are no known plans to revisit this element in the near future.

Products that are not legally defined as ingredients according to Article 6.4 of Directive 2000/13/EC, such as processing aids (like food enzymes produced from GE microorganisms) are exempt from labeling obligations.

d) MONITORING AND TESTING
Since January 31, 2020, the UK has assimilated all pertinent EU law in this subject into its own regulations. See Chapter 1, Part B, Section h. There are no known plans to revisit this element in the near future.

The UK enforces mandatory monitoring plans for environmental effects and for use as food or feed. However, biotech microbes fall outside of monitoring and testing requirements since they are usually filtered out before final product is achieved.

e) ADDITIONAL REGULATORY REQUIREMENTS
There are no known additional biotechnology-related regulatory requirements that negatively impact U.S. exports of microbial biotech-derived food ingredients.

f) INTELLECTUAL PROPERTY RIGHTS (IPR)
Microbial biotechnology is covered under the same rights and laws as GE plants and animals. Please see Chapter 1, Part B, Section k.

g) RELATED ISSUES
None

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS
Microbial biotechnology has never been high on the political agenda in the UK, and there is currently no high-profile lobbying for or against its use in food. In general, the public is not aware that microbial biotechnology is an essential part of today's food production. There is also very limited media coverage of the issue.

b) MARKET ACCEPTANCE/STUDIES
There is little to no awareness of microbial biotechnology in food production by the British public.

Attachments:

No Attachments