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Report Highlights:

Following the departure of the United Kingdom (UK) from the European Union (EU) in 2021 there was optimism that the UK would adopt a more scientific and proportionate approach to the regulation of genetically engineered (GE) and genetic technology products. To date, the biotechnology approval process in the UK has lagged behind the EU. No new GE authorizations have been approved or consultations on new GE crops have been announced since the 2023 Biotech Annual report. Additionally, even though the Genetic Technology (Precision Breeding) Act received Royal Assent in March 2023, implementing legislation is still required for it to take effect.

Executive Summary

Since the publication of the 2023 Agricultural Biotechnology Annual report ("2023 Biotech Report"), the United Kingdom (UK) has made no updates with regards to newly approved genetically engineered (GE) products, consultations on GE crops or progress on genetic technology products, such as implementing legislation for the Precision Breeding Act.

Major updates since the last report include:

- **Genetic Technology (Precision Breeding) Act**: In April 2024, the UK circulated at the World Trade Organization (WTO) draft secondary legislation for plants under the Precision Breeding Act (G/TBT/N/GBR/83). However, with a change in administrations following the UK General Election in July 2024 to Labour, the UK government has made no further progress on passing this secondary legislation. Given the skepticism expressed during the passage of the bill by the Labour Party spokespeople, while in opposition, increased uncertainty now exists over the inclusion of animals in the precision breeding framework.

- **GE food and feed:** Great Britain (GB) currently lags behind the EU in approving around 23 new or renewal applications that have already been approved by the EU, as of the time of writing.

- **"Genetic Modification" (GM) legislation:** The previous UK government had indicated an aspiration to review all the "Genetic Modification" (GM) legislation inherited from the EU over a timespan of five to seven years. However, the newly elected Labour government does not appear to have this as a priority.

- **Proposed streamlining of authorization process:** In an effort to reduce the backlog in GE approvals, the Food Standards Agency (FSA) has consulted on two proposals to streamline the market authorization process. These would remove the 10-year renewal requirement and remove the need for an additional step of secondary legislation after a ministerial decision has been made to authorize the product. Legislation enacting these proposals is expected in early 2025.

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Reporting Notes:

1. The United Kingdom (UK) departed the European Union (EU) on January 31, 2020. To date, the UK has retained EU laws in the area of genetic engineering applications for food and agriculture. The newly elected Labour administration has stated a priority to engage with the EU on a sanitary and phytosanitary (SPS) and veterinary 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 Member State 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) PRODUCT DEVELOPMENT

The UK crop science community undertakes limited product development of GE plants. While crop trials have increased in recent years, the top entry of the following list is the only addition since the 2023 Biotech Report:

Crop	**Research Facility**
Camelina (multi-trait)	Rothamsted Research [2024-2027]
Wheat (photosynthetic efficiency)	Wild Bioscience [2023-2027]
Camelina (multi-trait)	Rothamsted Research [2014-2023]
Wheat (iron uptake)	The John Innes Centre [2022-2024]
Potatoes (multi-trait)	The Sainsbury Laboratory and partners [2022-2025]
Wheat (gene edited)	Rothamsted Research [2021-2026]
Barley (multi-trait)	Cambridge University Crop Science Centre [2022-2026]

Innovative biotechnologies, such as CRISPR-Cas9, are now commonly used in UK research projects conducted by the key plant science research institutes listed above. As referenced in the penultimate entry in the list above, Rothamsted Research has commenced work on wheat using CRISPR to reduce acrylamide formulation during cooking. Acrylamide has strong cancer-causing links. In August 2024, it was announced that, for the first time in the UK and Europe, that farmer-led trials of these experimental lines on conventional farms would aim to ramp up production levels to a commercial scale.

Since the previous 2023 Biotech Report, the UK has not managed to adopt 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. "QHPs" released for purposes other than research and development (for example, marketing and commercialization) are regulated under Deliberate Release Regulations (2019) (see below). "Genetically modified" (GM) plants that are not defined as "QHPs" are regulated under the same 2019 legislation.

The corresponding legislation and guidance include:

- 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)

b) COMMERCIAL PRODUCTION

Despite being a supporter of the 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. The UK government expects that once QHPs can be produced commercially then other GE plants could be accepted by UK consumers, and their commercialization legislated for. The timeline for such change is expected to be close to ten years.

c) EXPORTS

The UK does not 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. **TABLE 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.

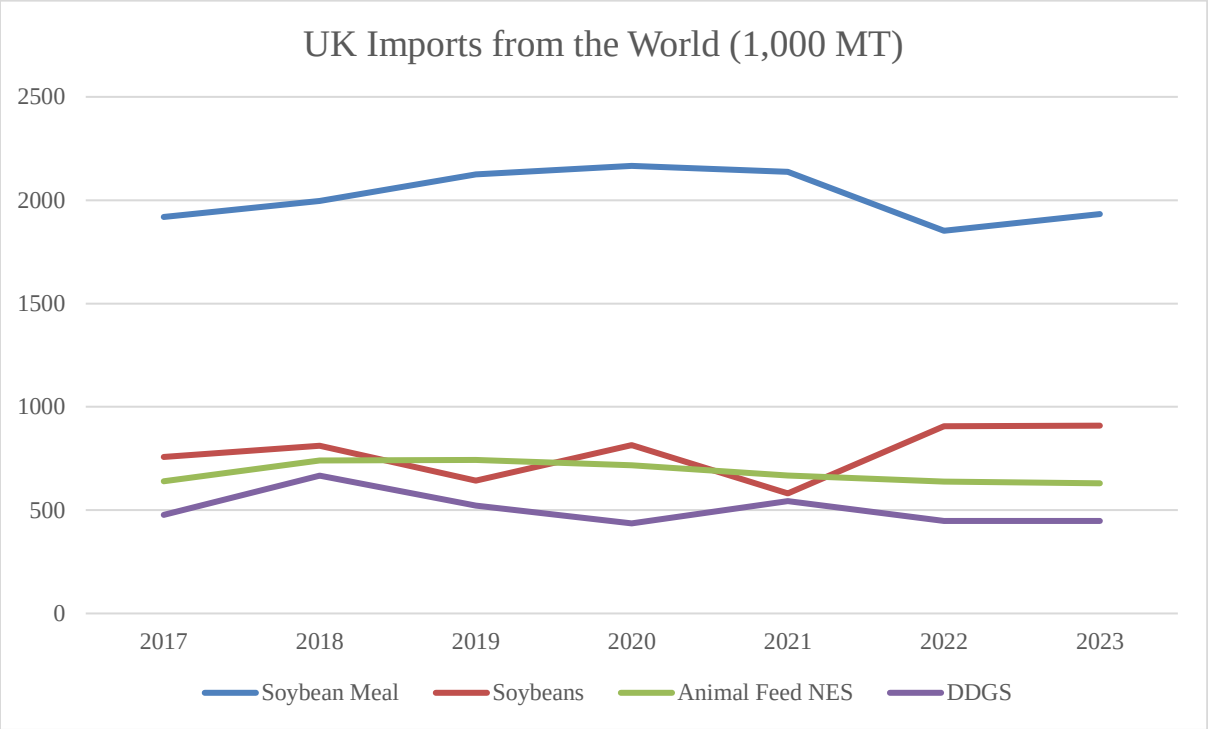
The ability for the UK to purchase from a particular country is dependent on whether there is historic (prior to 2021) EU approval for food and feed for GE crops cultivated by the exporting nation. The UK's Food Standards Agency (FSA) has been slow to approve new GE crop applications for entry to Great 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.

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.

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 80 to 90 percent.

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

TABLE 1. UK Imports from the World, 2017-2023: 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)

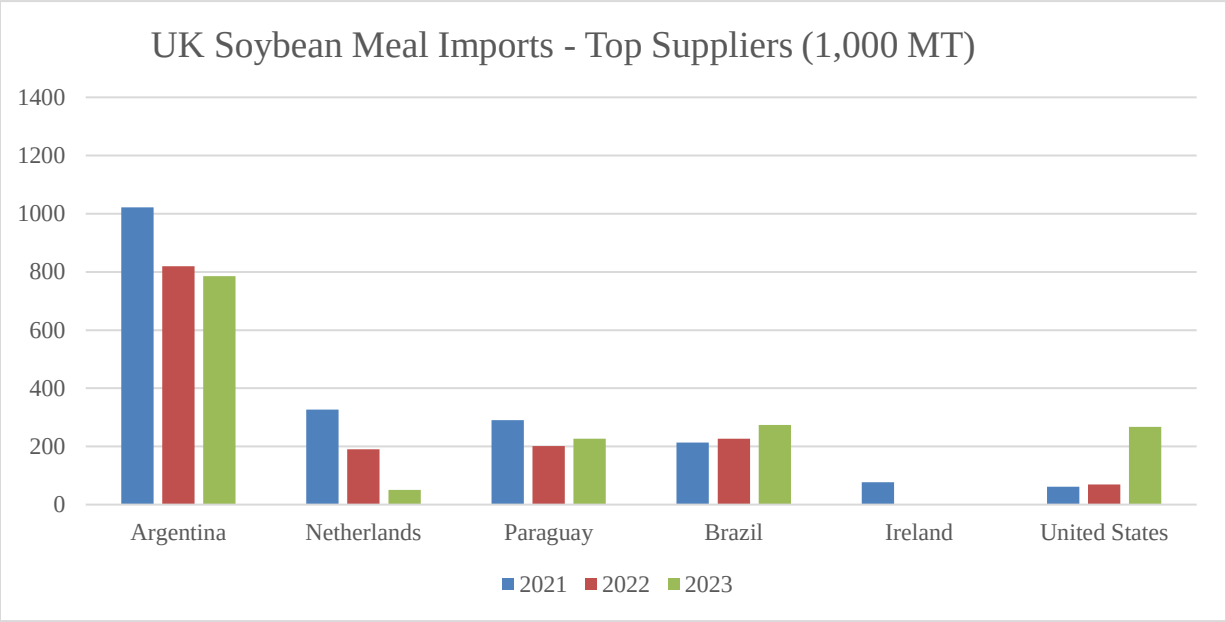
Following an approximate 17 percent decrease between 2021 and 2022 in DDGS imports into the UK, inward trade plateaued in 2023. The latest figures for January to July 2024 show a 12 percent increase compared to the same period the previous year, which is suspected to be largely price driven.

Soybean imports (**TABLE 1** and **TABLE 3**) into the UK rose to record levels in 2023 for the last 15 years, only falling back slightly according to the latest January to July 2024 statistics. Over the same period, there has been a one percent decrease in soybean meal imports and a 17 percent decline in miscellaneous animal feed, with the later probably compensated for by the rise in DDGS.

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

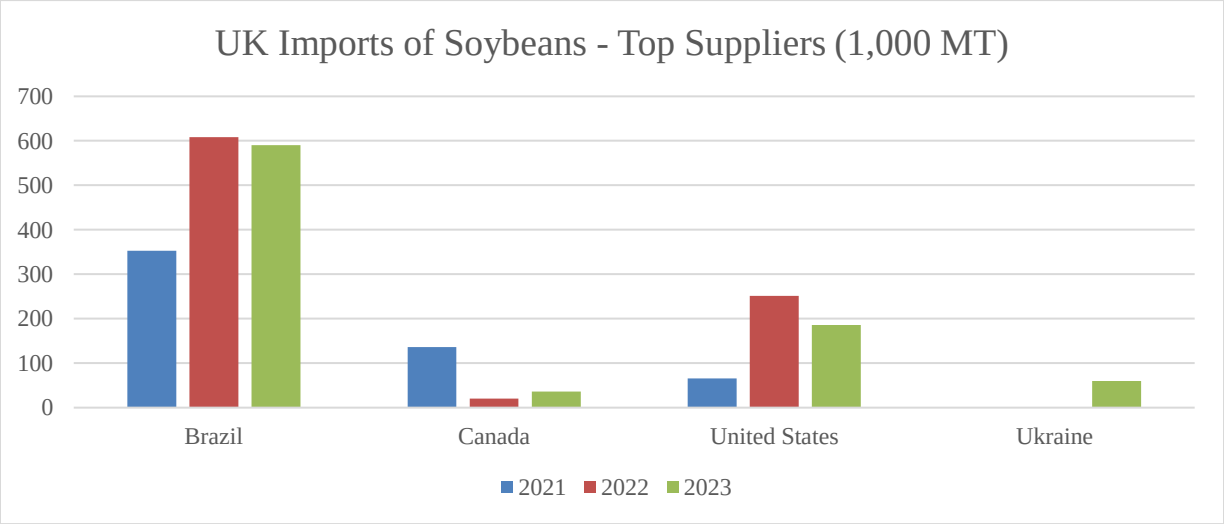
discontinuity in imports from the Netherlands and Ireland for soybean meal and DDGS in **TABLE 2** and **TABLE 4** below, along with the significant volumes classified as 'Unidentified'.

TABLE 2. UK Imports of Soybean Meal, 2021-2023



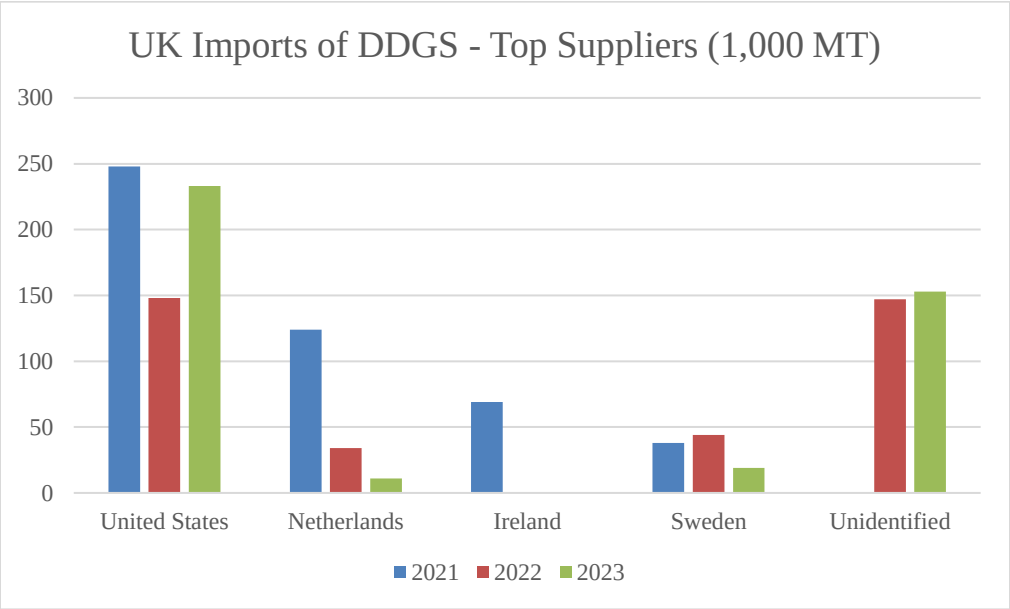
MT = metric tons
Source: Trade Data Monitor/UK Data - His Majesty's Revenue and Customs (HMRC)
Note: Supplies from Netherlands and Ireland are trans-shipments from other sources

TABLE 3. UK Imports of Soybeans, 2021-2023



MT = metric tons
Source: Trade Data Monitor/UK Data - His Majesty's Revenue and Customs (HMRC)
Note: Imports from the United States January-July 2024 have increased by 63 percent compared to the same period in 2023

TABLE 4. UK Imports of Distiller's Dried Grains with Solubles (DDGS), 2021-2023



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

e) FOOD AID

The UK's Department for International Development (DFID) 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

For three decades, 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 more than 30 countries now produce GE crops, it is becoming difficult to source non-GE ingredients. Private standards are increasingly restricting the use of GE feed into animal feed rations. For example, depending on the product line, high-end grocery chains in the UK may make it a condition of supply that the animals have been fed a non-GE diet.

PART B: PLANT BIOTECHNOLOGY 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 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.

In addition:
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 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.

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.

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.

As noted above, now 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.

Since the last report, draft secondary legislation for plants was circulated to the WTO in April 2024 (G/TBT/N/GBR/83). On September 30, 2024 the new Labour administration reaffirmed the intention of

passing domestic secondary legislation to implement the Precision Breeding Act, but without a definitive date for this legislations' adoption.

There were 11 pieces of legislation with "genetic modification" in the title listed in the revocation schedule which, as of the end of 2023, have now been 'sunsetted' as part of the Retained EU Law (Revocation and Reform) Act 2023. This exercise was regarded as tidying up obsolete regulations, so none of these removals are significant.

Responsible UK authorities

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

2. 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 retained 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

3. 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".
4. 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.

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 they trade heavily on their 'pristine and natural environment' image. Traditionally, these more rural communities generally believe that growing GE crops may damage the reputation of their produce, and that this outweighs any benefits that agricultural biotechnology might bring. Many of the farmers in these rural areas are, however, receptive to new science that could safeguard their future livelihoods and increase productivity. The principal concern though is negative market response to new methods of production.

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 2023 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.

The UK government has made minor changes to the definition of "Genetically Modified Organisms" (as it is currently defined under the UK's Environmental Protection Act 1990) to exempt simple gene-editing applications in plants from the scope of "GM" regulation. The previous UK government had indicated an aspiration to review the entire framework of "GM" regulation over the next five-seven years. Since the 2023 Biotech Report, following the change of administration, the focus is more on publishing implementing legislation for precision breeding in plants. Plans for a wider review of GM assimilated regulations may well be shelved in the immediate term.

In April 2024, the FSA consulted on a first tranche of proposals aimed at streamlining the market authorization process for GE regulated products. The two proposals were to:

- remove 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, likely to an official register, following a ministerial decision.

With renewals comprising about one in five of the total regulated product applications, the first of these proposals would be 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 estimated it could accelerate the approval timeline by at least three months. According to FSA Board papers from September 2024, new UK Government ministers have confirmed they are content to proceed with FSA's two initial market authorization reform proposals and, subject to decisions on legislative timetabling, FSA hopes to introduce legislation for these proposals in early 2025.

b) APPROVALS

Since the 2023 Biotech Report, the UK has not approved any new GE products or published consultations on new GE crops. 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.

c) STACKED or PYRAMIDED EVENT APPROVALS

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 retained 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.

More than 75 GE crop 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.

The previous UK 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)”.

In April 2022, the UK 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. In England, these plant products are now classified as "QHPs" and trials must be notified to the Defra Secretary of State before being planted. This change was not replicated in Scotland, Wales, or Northern Ireland.

f) COEXISTENCE

The newly elected Labour government is under discussions with stakeholders to determine their policy on coexistence of GE crops with conventional or organic crops.

g) LABELING AND TRACEABILITY

With the change in administrations, the Labour Defra Minister of State Daniel Zeichner has not confirmed whether the UK will move forward with the prior administration's position on labeling of products produced through "QHPs". Under the prior administration, FSA intended to provide an enhanced register that will go further than the basic information required by industry and enforcement officers and will include information requested by consumers such as the purpose of the edit and any relevant safety assessment.

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. There have been no changes to the regulations since last year's report. 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 contains less that 0.9 percent of approved "GM" varieties. More information is available at: "GM" in animal feed

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.

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 genetically engineered material is normally randomized testing. Both feed and food supply chains conduct testing to satisfy import specifications, labeling obligations, and customer assurance. Field trials for non-QHP 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

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). In all

forums, the UK consistently takes a pragmatic position based on evidence and science-based risk assessment.

n) RELATED ISSUES
There are no related issues.

PART C: PLANT BIOTECHNOLOGY 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 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.

In October 2023, the Royal Society – the oldest scientific academy in continuous existence – published a briefing paper entitled 'Enabling genetic technologies for food security'. This paper highlights the opportunities of genetic technologies for the UK, given the country's academic plant science and commercial plant breeding expertise. Additionally, the study recommends learning from the regulatory experience of other countries and is critical of the UK's approach to GE and beneficial GE traits.

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, genetic engineering in food is irrelevant. There are very few mainstream grocery products that clearly contain GE ingredients. With this invisibility, most UK consumers consider the "GM problem" to have gone away.

For those who distrust the technology or have limited knowledge and hold only "a sense" or "a feeling" on the subject, many cite the concentration of power over staple food crops by big business as their main concern.

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 never 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 the product may not be listed or carried in UK inventories. However, 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.

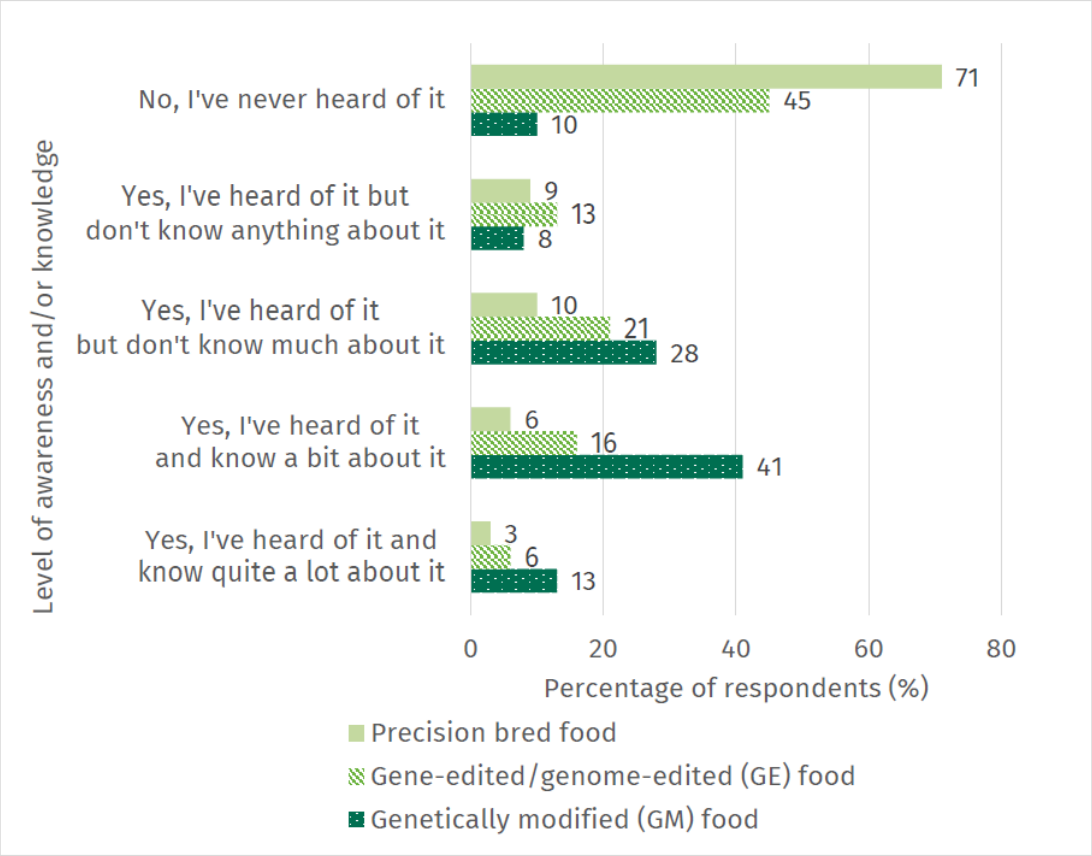
Innovative biotechnologies may have a smoother path to consumer acceptance. This will depend on the nature and purpose of the change that is created, and how any consumer benefits are communicated.

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 upscale Waitrose grocery chain (capitalizing on the opportunity to differentiate from its competitors) now states that "No Waitrose food is genetically modified".

Marketing Studies

The UK Food and You survey offers the most recent (September 2024) 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 contact and asked to complete an online survey. Fieldwork for the Wave 8 report was conducted between October 2023, and January 2024. A total of 5,808 adults from 4,006 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) 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 8 report showed that respondents reported greater awareness and knowledge of "Genetically Modified" food compared to other descriptors, with just ten percent stating they had never heard of it. Gene-edited food is not so well-known with 45 percent of respondents saying they had not heard of it, while 71 percent were not aware of precision bred food.



Source: Food and You 2: Wave 8

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

There have been no additional production developments since the 2023 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. GE animals, such as those below, are under development but none are expected to be on the market in the UK within the next five years.

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

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.

e) TRADE BARRIERS
Ethical and welfare concerns exist, but there are no known physical trade barriers in the UK.

PART E: POLICY

a) REGULATORY FRAMEWORK
As with plant biotechnologies, the UK government takes a science-based and generally positive, pragmatic, and progressive 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 General Election, the intent of the UK 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. However, as noted in the Executive Summary above, there is more uncertainty about the new administration's plans in this area.

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
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 covered in the Chapter 1, Part A, sub-paragraph a) - Product Development section above, UK researchers are using innovative biotechnologies in research applications and there is potential for commercialization of UK research in North America.

Genetic Technology (Precision Breeding) Act 2023 gives powers for a regulatory system for precision bred animals to be established. 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. The finalized provisions of the Act mean that changes to regulations for animals will not be introduced until the regulatory system is in place. The legislation also establishes a new science-based authorization process for food and feed products developed using "precision bred organisms" (PBO).

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) and the Roslin Institute, active in public, positive engagement on animal biotechnologies. There are also 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.

Publicly funded research is more trusted than that undertaken by the private sector. There is a positive bias towards technology provided for free as a public good compared to that perceived to be created for financial reward by private companies.

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

Market acceptance studies in the area of genome editing and farmed animals have 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
There have been no changes to the regulatory framework for microbial products, with this being part of the wider package planned to be addressed at a later stage. 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 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

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/gmo/notifications/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.

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 post-EU departure.

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 post-EU departure.

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: MICROBIAL BIOTECHNOLOGY 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