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Report Highlights:

From January 1, 2021, the UK has been responsible for authorizing products of genetic engineering (GE) using retained EU law. Nine GE crops are currently out for public consultation as part of the new UK approval process, with a similar number still pending. As well as a recent announcement that will reduce administrative burden on plant field trials, there is political will to explore a more proportionate approach to regulation of plants and animals derived from simple genome editing as well as other plant and animal products that could have been achieved by traditional breeding methods. The UK government has a timeframe in mind of one to two years for the first phase of regulatory reform and a goal of five to seven years for a wider overhaul of biotechnology regulation.

## Executive Summary

One of the first actions taken by the UK government, as it began its first full year outside the European Union (EU), was to launch a public comment period starting a review of genetic technologies regulation on January 7, 2021 (note: for England only). Prime Minister Boris Johnson has a clear aspiration for the UK to become a ‘science superpower’ by 2030, and departure from the EU is seen as an opportunity to adopt a more scientific and proportionate approach to the regulation of organisms produced by genetic technologies such as genome editing. Approval for cultivation and livestock production is a devolved matter, meaning Scotland and Wales can decide what is produced in each country. However, the Internal Market Bill 2020 is likely to require that any products that are legally produced and sold in one country of the UK can be marketed and sold in all four countries. In terms of trade, the UK has yet to unilaterally approve any dossiers for food and feed imports into Great Britain (GB), and the Northern Ireland Protocol agreed between the UK and EU means that Northern Ireland will remain under the EU regulatory regime for food and feed imports.

The UK government [response](#) to the public comment period was published on September 30, 2021. It indicates that the first phase of a new regulatory approach will cover genome editing and genetic technologies in plants and animals 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. Before the end of 2021/early 2022, the UK government intends to use existing powers under the Environmental Protection Act 1990 to bring forward a Statutory Instrument that will make research and development easier for plants that have been produced by genetic technologies where the resulting genetic changes could have been developed using traditional breeding methods. The next step will be to review the regulatory definitions of a “Genetically Modified Organism (GMO)” to exclude certain organisms (both plants and animals) produced by gene editing and other genetic technologies if they could have been developed by traditional breeding. At the same time, the UK government will also consider what measures are needed to enable gene edited products to be brought to the market safely and transparently, considering consumer choice and traceability. According to the consultation [documents](#) of January 7, the timeline for these considerations and new regulations to pass is one to two years. In the government response, it infers that labeling policy may take longer to finalize, since it is not expected that gene edited products will appear on grocery shelves in the UK for some years.

As regards the import of GE food and feed, Great Britain currently lags the EU in approving around 18 new or renewal applications that have already been approved by the EU. The UK government is still building its capacity to assess applications and manage the approval of regulated products such as those falling under GE regulation.

The UK government has indicated a timeline of five to seven years for a review of the “Genetic Modification” (GM) legislation inherited from the EU. Despite being a relatively minor destination for U.S. products of genetic engineering, the UK embarking on a regulatory review of GE for agriculture and food applications could have much wider global influence.

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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. However, UK and EU laws may diverge in the future. To compare UK and EU laws this report should be read in conjunction with our EU Agricultural Biotechnology Annual report available here: [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: 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 legislation and UK 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.

# CHAPTER 1: PLANT BIOTECHNOLOGY

## PART A: PRODUCTION AND TRADE

### a) PRODUCT DEVELOPMENT

The UK crop science community undertakes limited product development of genetically engineered plants. However, crop trials have increased in recent years:

<b>Crop</b>	<b>Research Facility</b>
<a href="#">Wheat (multi-trait)</a>	Rothamsted Research [2017 and 2018]
<a href="#">Camelina (multi-trait)</a>	Rothamsted Research [2014-2023]
<a href="#">Camelina (Omega-3)</a>	Rothamsted Research [2014-2020]
<a href="#">Wheat (iron uptake)</a>	The John Innes Centre [2019-2021]
<a href="#">Broccoli (sulfur flavor)</a>	The John Innes Centre [2019-2021]
<a href="#">Potatoes (multi-trait)</a>	The Sainsbury Laboratory and partners [2017-2021]
<a href="#">Wheat (gene edited)</a>	Rothamsted Research [2021-2026]

Innovative biotechnologies, such as CRISPR-Cas9, are now commonly used in UK research projects conducted by the key plant science research institutes listed above. In addition, the James Hutton Institute has recently completed [work on barley](#) using CRISPR. As part of the UK government response to its consultation held in spring 2021, plans were announced in September 2021 to make it easier to conduct crop trials of products of simple 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. The proposed administrative changes will make it quicker, easier, and cheaper to apply for such a trial, but transfer to commercialization (if appropriate) will need a proportionate regulatory framework and additional support in the future.

### b) COMMERCIAL PRODUCTION

Despite being a supporter of the science, the UK has never planted a commercial GE crop and has no 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.

### c) EXPORTS

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

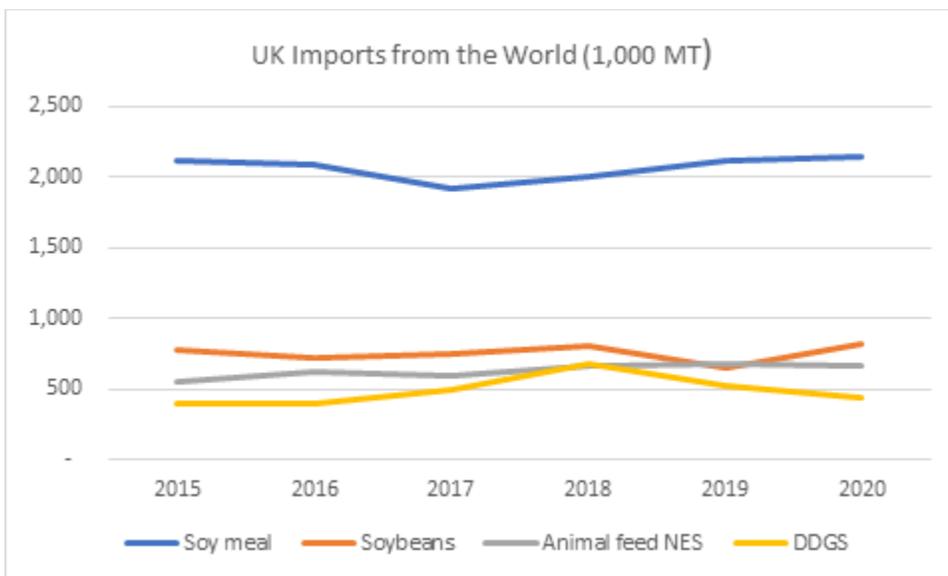
### d) IMPORTS

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. The charts below show 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 conditions are favorable. The United States is the leading supplier of corn-derived Distillers Dried Grains with Solubles (DDGS) to the UK.

Confidence 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 is yet to approve any [applications for entry to Great Britain](#) and there is an asynchronous approval situation between the EU and GB markets for certain soy and corn traits that were approved by the EU during 2021. The main supplier countries are located outside of the EU and 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. 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. Of course, trade is also dependent on many other things such as the fortunes of 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 genetically engineered is estimated to be 80 – 90 percent.

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

**UK Imports from the World: Soybean Meal, Soybeans, Distiller’s Dried Grains with Solubles (DDGS), and Animal Feed (not elsewhere specified)**

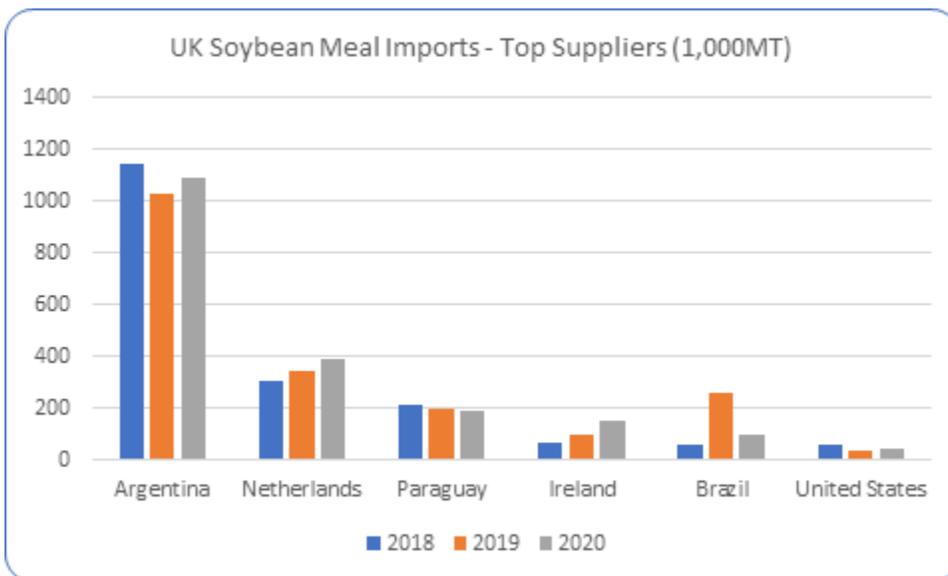


MT = metric tons; Calendar Year

Source: Trade Data Monitor/UK Data - Her Majesty’s Revenue and Customs (HMRC)

The latest figures to August 2021 show a 40 percent increase over January to August 2020 in DDGS imports into the UK. Soybean imports into the UK in 2020 reached a peak, and the latest January to August 2021 statistics show a correction to this with a decrease of 26 percent. The UK had a very short wheat crop in 2020 and these products have filled the gap. Over the same period, there has been a one percent decrease in soybean meal imports, and a four percent decline in miscellaneous animal feed. A significant volume of the key GE commodities is recorded as being imported from other EU destinations, particularly from the Netherlands port of Rotterdam. Ireland is also a key trans-shipment country for animal feed materials ultimately 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 original country, such as the United States, Brazil, Argentina, etc. However, most of these commodities are from outside the EU as neither the Netherlands nor Ireland grows soy or corn in commercial quantities.

**UK Imports of Soybean Meal, 2018-2020**

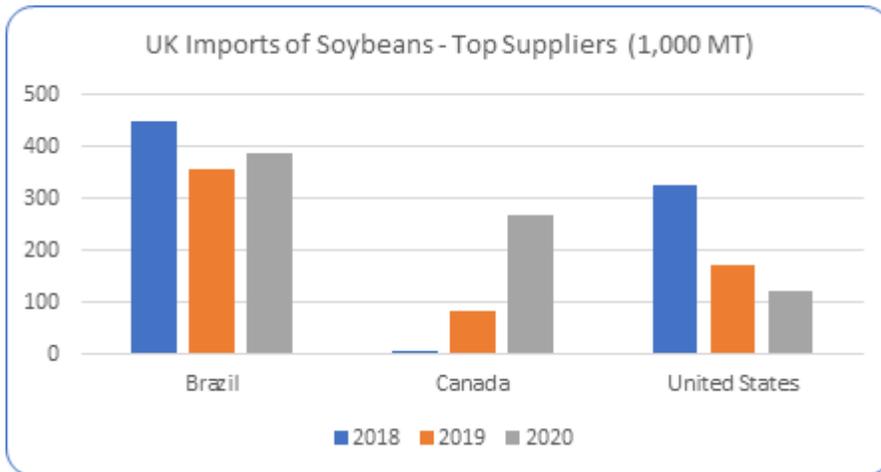


MT = metric tons

Source: Trade Data Monitor/UK Data - Her Majesty’s Revenue and Customs (HMRC)

Note: Supplies from Netherlands and Ireland are trans-shipments from other sources

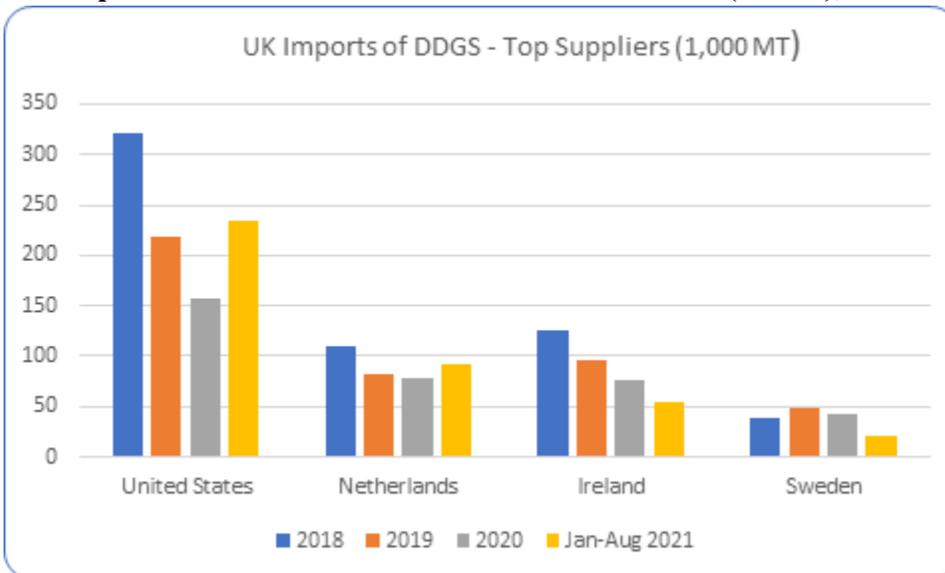
## UK Imports of Soybeans, 2018-2020



MT = metric tons

Source: Trade Data Monitor/UK Data - Her Majesty's Revenue and Customs (HMRC)

## UK Imports of Distiller's Dried Grains with Solubles (DDGS), 2018-August 2021



MT = metric tons

Source: Trade Data Monitor/UK Data - Her Majesty's Revenue and Customs (HMRC)

### 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 market conditions and local legislation pertaining to GE food products. 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 is often too large a hurdle to overcome. This is also increasingly the case for other countries wishing to supply the EU. As more than 30 countries now produce GE crops it is becoming difficult to source non-GE ingredients. Private standards are increasingly affecting the incorporation of GE feed into animal feed rations. Depending on the product line, high end grocery chains 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 departed 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. 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](#)

In addition:

[The Genetically Modified Food and Feed \(Amendment etc.\) \(EU Exit\) Regulations 2019](#)

Amend: [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 of the above legal texts have been made for Scotland, Wales, and Northern Ireland.

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.

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.

In formulating overall UK agricultural biotechnology policy, the central government (based in London) solicits views from a wide range of stakeholders, including the devolved Parliaments. As outlined in the Executive Summary, there is a move by UK central government to extend powers under existing legislation to facilitate plant genome editing research and to amend legislation to aid cultivation of genome edited plants in England only. The UK government is considering changing the definition of “Genetically Modified Organisms” (as it is currently defined under the UK’s [Environmental Protection Act 1990](#)) to a definition that would exempt simple gene editing applications from the scope of “GM” regulation. The UK government has also stated an intent to review the entire framework of “GM” regulation over the next 5-7 years.

#### b) APPROVALS

From January 1, 2021, the UK has been managing its own approval system for GE products, continuing to distinguish between approval for food, feed, processing, or environmental release following the approach laid out in EU retained law [Directive 2001/18/EC, Regulation (EC) 1829/2003 and Regulation (EC) 1830/2003]. These 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 Food Standards Agency has said that in most cases, applications will take at least a year. With regard to approval for

cultivation in the UK, application must be made to the competent authority individually 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 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. Please see: [list of consents for field trials in England](#).

Over 75 GE crop trials have been conducted in the UK since 2000, mainly on corn, sugar beet, oilseed rape, wheat, and potatoes. See 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 UK government has 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. As mentioned earlier in this report, the UK government is intending to amend the definition of a “GMO” so that 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.

#### f) COEXISTENCE

The UK currently does not have a policy. The basis for any UK coexistence policy is likely to be the extensive work carried out and published by the Supply Chain Initiative on Modified Agricultural Crops (SCIMAC) in 2006. Information on their proposals for coexistence and liability can be found here: [SCIMAC](#)

The UK government's policy on coexistence of GE crops with conventional or organic crops states: "If and when genetically modified crops are grown in England commercially, we will implement pragmatic and proportionate measures to segregate these from conventional and organic crops, so that choice can be exercised, and economic interests appropriately protected."

#### g) LABELING AND TRACEABILITY

For consumer-ready grocery products, the UK is following 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 contains less than 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](#)).

#### h) MONITORING AND TESTING

All UK imports are subject to random or more frequent testing (depending on product) upon border entry. Since it is not a food safety concern, testing for genetically enhanced material is normally randomized testing. Both feed and food supply chains conduct testing to satisfy import specifications, labeling obligations, and customer assurance. Field trials 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 follows 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.

There are many organizations actively campaigning against the technologies, including but not limited to GeneWatch, GM Freeze, Friends of the Earth, the Soil Association, 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, 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

Over 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 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 low-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 genetically engineered. 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 chain (capitalizing on the opportunity to differentiate from its competitors) now states that “No Waitrose food is genetically modified”. See more here: [Waitrose policy statement](#) Waitrose has five percent of the grocery retail market, and organic sales are approximately 1.5 percent of the overall food and drink market.

### Marketing Studies

The most recent study (2021) of UK consumer opinion was commissioned by the Food Standards Agency and looked at [consumer perceptions of genome edited food](#). The study was both qualitative (online workshops with 80 participants from England, Wales, and Northern Ireland), and quantitative (comprising an online survey of 2,066 consumers from those nations). It was found that British consumers have a low awareness and little knowledge of genome edited food. Most had not heard of genome edited food or confused it with “GM” food. However, the more informed consumers were, or became, the more accepting they were of genome edited food, despite some still having concerns. The surveyed consumers reportedly perceived genome edited food as safer and more natural (although others still felt genome editing was unnatural and more closely aligned with “GM” than conventional breeding). A quantitative survey result that bodes well for the future includes a figure of 50 percent positive unprompted responses from consumers aged 16-24 years old who were more likely to say that genome edited foods should be available for sale in the UK.

The most recent survey of British farmers was a Twitter poll by industry magazine Farmers’ Guardian ([subscription required](#)) in 2019, where more than three quarters of farmers said they would adopt GE crops if regulations changed.

There have been many consumer attitude studies conducted over the last three decades. The identity of the entities that paid for the research tends to influence the acceptance of the data. In general, it is possible to say that over time there has been movement towards greater understanding of the benefits that genetic engineering can bring. If the roll-out of innovative technology adoption goes smoothly, it may pave the way for greater investment in GE applications for the UK market.

## CHAPTER 2: ANIMAL BIOTECHNOLOGY

### PART D: PRODUCTION AND TRADE

#### a) PRODUCT DEVELOPMENT

In July 2021, Genus (an animal genetic improvement company) and the Roslin Institute (affiliated to the University of Edinburgh) signed an agreement to work together towards commercial production of gene-edited pigs that are resistant to Porcine Reproductive and Respiratory Syndrome (PRRS). Multiple generations of pigs will be studied to compile data for an application to the U.S. Food and Drug Administration in the first instance.

In 2020, Genus and Tropic Biosciences (a UK-based agricultural biotechnology company) announced a collaboration to explore the application of Tropic's Gene Editing induced Gene Silencing (GEiGS) technology in porcine and bovine genetics.

Also in 2020, Tropic Biosciences provided a license for GEiGS to be used by eggXYt to develop avian flu resistance in poultry.

No UK cloning research is currently taking place that will result in live farm animals. Genetically Engineered 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	<a href="#">Oxitec/Intrexon</a>
GE olive fly, medfly, bollworm	<a href="#">Oxitec/Intrexon</a>
GE pest insects	<a href="#">Pirbright Institute</a>
GE insects	<a href="#">Beta Bugs</a>
Suppression of avian influenza transmission in GE chickens	<a href="#">Roslin Institute</a>
Gene-edited (ZFNs and TALENS) Pig 26 (for biomedical research)	<a href="#">Roslin Institute</a>

## b) COMMERCIAL PRODUCTION

Genetically Engineered 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 fish genetic engineering 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 pro-science 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. 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 applies to animal applications (see Executive Summary).

The Department for Environment, Food, and Rural Affairs (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) INNOVATIVE BIOTECHNOLOGIES

As covered in the PART A 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.

#### c) 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](#)

#### d) 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](#)

#### e) 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](mailto: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.

## 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, 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

In September 2021, the Nuffield Council for Bioethics (NCB - an independent body that examines and reports on ethical issues in biology and medicine) published a [report](#) from a public dialogue on genome editing in farmed animals. The public dialogue involved a group of 42 participants from across the UK and three online workshops with input from a panel of experts over the course of June and July 2021. Among the findings was a range of concerns of the impact of genome editing on humans and animals, on farming systems, and on nature/the natural order. Animal welfare, sustainability, and the quality of meat were considered as important factors for the future of farming and seen as potential application areas for genome editing. However, the argument that gene editing can be viewed as an extension of traditional breeding was not considered as an ethical basis for its use. Participants expressed concerns over commercial drivers of genome editing in farmed animals, as well as the ability of governance and regulatory systems to control the technology in a way that meets public aspirations for the UK's future food system. Despite the limited participant base for this study, it is a useful summary of the key elements of future debate in this area. The public dialogue has provided feedback into an inquiry by NCB launched in 2019 but delayed due to coronavirus. A final [report](#) from NCB's inquiry on gene editing and farmed animals was published on December 1, 2021, and can be expected to feed into future UK government stakeholder consultations.

In a 2021 opinion study commissioned by the Food Standards Agency looking at [consumer perceptions of genome edited food](#), the British consumers surveyed found the application of transgenic “GM” technology in plants more acceptable than genome edited animals. Many consumers draw the line at “playing with nature” when it comes to animals, although traits that improved welfare were positively considered overall.

## 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)	<a href="#">Tate &amp; Lyle</a>	Corn•Starch•Fructose•Allulose using biotech microbe derived enzyme
Nootkatone (Flavor and Scent of Grapefruit)	<a href="#">Oxford Biotrans</a>	Oranges•Valencene•Nootkatone using P450 biotech derived enzyme
Animal-free milk proteins	<a href="#">Better Dairy</a>	Synthetic biology and yeast fermentation to produce dairy products without cows
Algae for protein needs	<a href="#">Algenuity</a>	<a href="#">Unilever</a> and Algenuity partner to develop microalgae for plant-based foods
Omega-3 rich micro-algae	<a href="#">MiAlgae</a>	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. For example: [RebelBio](#) and [Startupbootcamp Food Tech](#). 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, flavour, 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

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/129.pdf.](https://www.hse.gov.uk/pubns/priced/129.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.

#### c) LABELING AND TRACEABILITY

The UK adopted all pertinent EU law in this subject into its own regulations. See Chapter 1, Part B, Section 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 adopted 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, 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