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GE Plants and Animals Report

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Report Highlights:
The United Kingdom's anticipated exit from the European Union (Brexit) will not change policy or trade in genetically engineered plants or animals in the short to medium term. The UK represents 14 percent of EU imports of soy, corn-related and other animal feed products likely to be derived from genetic engineering. UK imports of GE animal feed are declining gradually, but livestock industries remain protein-deficient and timely European Union approvals of new GE crops remains key. Relevant for both GE plant and animal research, the UK will continue its curiosity-driven science base, and is aiming to have public-private partnerships fund more applied science over time.

SECTION I: EXECUTIVE SUMMARY

The United Kingdom's (UK) exit from the European Union (Brexit) has the potential to change many policy areas, including agricultural biotechnology. However, in the short to medium term, the current landscape for cultivation and import of genetically engineered (GE) products is not expected to alter. As the countries of the European Union are the UK's largest trading partners, the UK will always be mindful of European Union import requirements and approvals when setting their own.

Scotland, Wales and Northern Ireland have "opted-out" of cultivating GE crops under EU legislation and these stances will not change post-Brexit. It is very unlikely that any of the large multi-national seed technology companies would invest in near-market research and commercialization of a crop that could only be marketed in England. Even if an application for commercial GE cultivation was to be brought forward in England, it is hard to gauge whether farmers would ultimately get the chance to plant GE crops. Non-governmental organizations (NGOs) would galvanize resources to oppose the plan, and successful farmer and food supply chain uptake would depend on the unique product attributes and balance of media exposure. Products derived from innovative biotechnologies may also be subject to NGO campaigning, trial by media and rejection by consumers.

At the upscale end of British shopping, the increasingly discerning customer is demonstrating that they will pay for the provenance of their food. This doesn't mean a national bias towards buying British - that comes secondary to the story that underpins the product and quality/sustainability of the ingredients. Of course, price remains paramount to the mainstream consumer, but they expect the retailer or foodservice chain to have high standards in their sourcing policies. Some ingredients or products may be sought more cheaply as UK food industries look for other supply options (as the devaluation of the local currency continues to bite). However, genetically modified or "GM" is something that the British public feels is an issue that has gone away, or at least has been managed out of the food supply. Since GE material is not found in food products, and products from animals that are fed GE feed is not labeled, there is much less sensitivity about GE animal feed. That said, there is a trend (borne out in the charts in the Imports section of this report) that the UK is sourcing less soy and corn products for their animal feed sector.

When comparing UK imports of soy, corn-related, and other animal feed products likely to be derived from genetic engineering against EU- 28 imports for marketing year 2014/15, the UK represents 14 percent of the existing EU import market (this assumes that all products are of non-EU origin). The UK particularly derives most of its Distillers' Dried Grains (DDGs) from the United States. In 2014/15, UK imports amounted to 220,000 metric tons of this product (including 70,000 trans-shipped from Ireland). This represents 44 percent of the EU total imports from the United States. These figures have been derived using UK and EU import data.

SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

The private sector's interest in developing varieties of GE plants suitable for UK and wider EU cultivation has waned. Almost all of the 60 or so GE crop trials conducted in the UK since 2000 have been subject to vandalism, and this, together with the uncertainty and delays characteristic of the EU approval process, amounts to an unattractive investment. While UK and EU publicly- funded laboratory and fieldwork into plant biotechnology continues, it is unlikely that any of the current or recent research, including those below will be brought forward for commercialization in the UK within the next five years.

Crop	**Research Facility**
Omega-3 oil camelina	Rothamsted Research [2014-2017]
Multi-enhanced potatoes	The Sainsbury Laboratory and partners [2016-2019]

(Late blight resistance, nematode resistance, reduced bruising, reduced acrylamide on cooking)

Innovative biotechnologies, such as CRISPR-Cas9, are being used in UK research projects. One example of a technology that is being shared locally, free of charge to the research community is targeted gene knock-outs in barley and *Brassica oleracea* using RNA-guided Cas9.

The UK's strength lies in curiosity-driven or basic research. However, there are signs that applied research may receive government funding over the long term, on a public-private partnership basis.

The Agri-Tech Strategy is an example of a funding stream that aims to improve the translation of research into practice: "*This strategy is about better integrating the UK's progressive food and farming businesses, and world class science base, with the government's support for trade, investment and international development.*" In addition, the UK's exit from the EU single market may necessitate a more economy-led science strategy.

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.

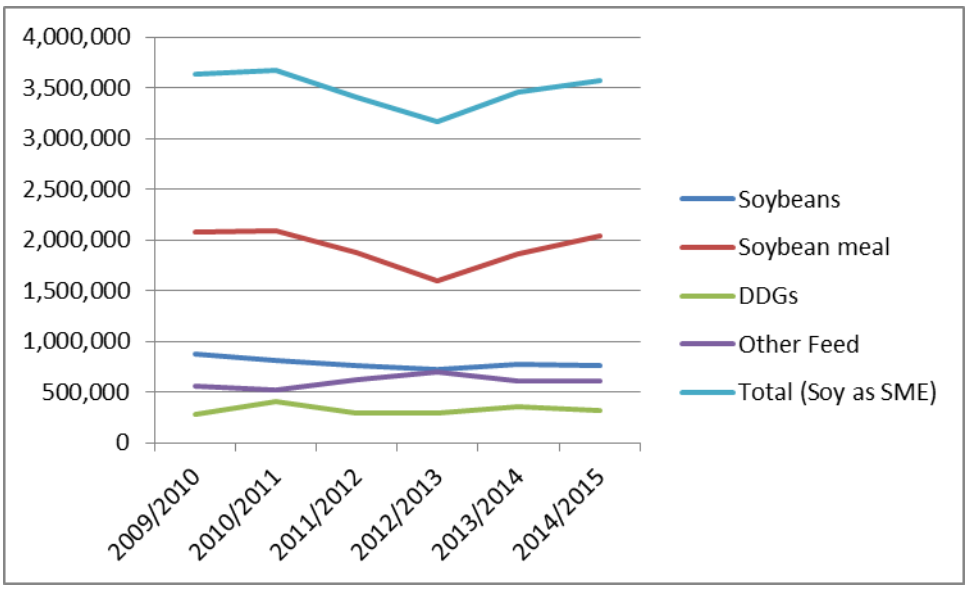
c) EXPORTS

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

d) IMPORTS

Like EU counterparts, UK livestock industries are protein-deficient. Total imports of animal feed products are influenced by animal stocking levels and relative success of the local feed grain harvest. The charts below show UK imports of animal feed commodities that are predominantly from GE crops, and those that the United States may export to the UK when conditions are favorable.

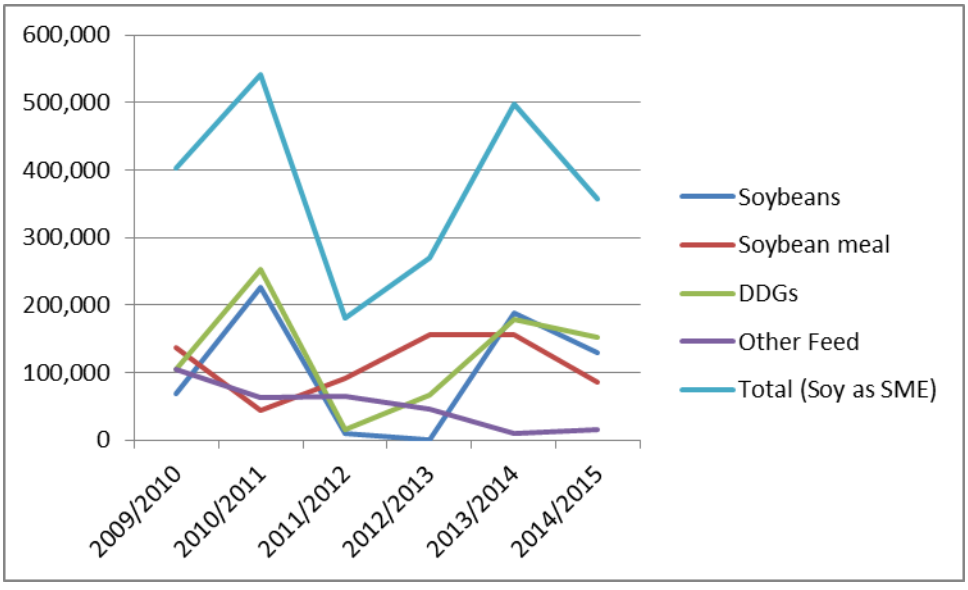
UK Imports from the World: Soybeans, Soybean Meal, Distillers' Dried Grains, and Other Animal Feed (metric tons)



SME = Soybean Meal Equivalent

Source: Global Trade Atlas/UK Her Majesty's Revenue and Customs (HMRC)

UK Imports from the United States: Soybeans, Soybean Meal, Distillers' Dried Grains, and Other Animal Feed (metric tons)



SME = Soybean Meal Equivalent

Source: Global Trade Atlas/UK HMRC

Total imports of these animal feed commodities rebounded after a dip was experienced in 2012/2013 when shipments to the EU were affected by low level presence detections of unauthorized GE events. Given the downward trend visible on the World Imports Chart, it is clear that the UK is steadily becoming more efficient at deriving its protein requirements from domestic sources, such as rapeseed meal, DDGs, and legumes.

Confidence to purchase from a particular country is dependent on whether there is EU approval (for food and feed) for new GE crops cultivated there. 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, since the threshold for feed is very low at 0.1 percent (and only for traits already in the EU approval pipeline) and continues to be zero tolerance for the food supply chain.

There is a marked difference between the stability of trade shown in the world imports chart above and the chart showing UK trade with the United States in animal feed commodities. It demonstrates that trade is affected by asynchronous approval timelines when a GE trait is commercially grown in the United States ahead of EU approval. Of course, trade is also dependent on many other things such as availability of supply, demand, exchange rates, etc. However, it is clear that short-term change in sourcing patterns by UK importers is largely linked to the issues of plant genetic engineering.

As can be seen in the chart below, many UK imports arrive via 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, it is clear that the vast majority of these commodities are from outside the EU as neither the Netherlands nor Ireland grows soy or corn in commercial quantities.

Comparing UK imports of soy, corn-related and other animal feed products likely to be derived from genetic engineering against EU- 28 imports for marketing year 2014/15, the UK represents 14 percent of the existing EU import market (this assumes that all products are of non-EU origin). In the same year, direct shipments to the UK accounted for 28 percent of miscellaneous other animal feed, 11 percent of soybean meal imports and (as the UK has only one crushing facility) five percent of EU imports of soybeans. The UK particularly looks to the U.S. for DDGs. In 2014/15, UK imports amounted to 220,000 metric tons (including 70,000 trans-shipped from Ireland), this represents 44 percent of the EU total imports from the U.S.

Imports of Selected Animal Feed Tariff Lines during MY 2014-2015, in metric tons

	Total EU Imports from All Origins	UK Imports from All Origins	UK Intra-EU Imports	UK Imports from Third Countries	Top Source Countries for UK Imports (as indicated by trade data only)
Soybeans (1201)	13,916,934	763,780	81,626	682,154	Brazil, United States, Argentina
Soybean meal (2304)	12,587,268	2,035,333	684,796	1,350,537	Argentina, Netherlands, Brazil, Paraguay
DDGs (230330)	610,391	323867	172,020	151,847	United States, Ireland, Sweden, Germany
Other Feed (2308)	1,899,720	604825	64,821	540,004	Argentina, Ireland, Russia

Source: Global Trade Atlas/UK HMRC

e) FOOD AID RECIPIENT COUNTRIES

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 nearly two decades, U.S. exports of processed foods and beverages have been constrained by market conditions and EU legislation pertaining to GE food products. As a result of an historically negative image of agricultural biotechnology, UK supermarkets and food manufacturers formulate their regular 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 approximately 30 countries now produce GE crops it is becoming ever-harder to source non-GE ingredients.

PART B: POLICY

a) REGULATORY FRAMEWORK

While still a Member State, the UK must implement all EU Directives and Regulations since novel foods and processes is an aspect of food law that is harmonized throughout the EU.

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, EU 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 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. EU Directive 2001/18/EC

Defra provides the secretariat for the Advisory Committee on Releases to the Environment (ACRE). ACRE is the independent body which 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."

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 Northern Ireland, Scotland and Wales have jurisdiction over agriculture, fisheries, and food policy in their regions. These countries have a higher proportion of "Less Favored Areas" for agriculture under EU Common Agricultural Policy definitions than England, and they trade heavily on their 'pristine and natural environment' image.

In 2015, Wales, Scotland and Northern Ireland notified the European Commission that they wished to "opt-out" of cultivation of GE crops. These more rural communities generally believe that growing GE crops may damage the reputation of their produce, and that outweighs any benefits that agricultural biotechnology might bring.

In formulating overall UK agricultural biotechnology policy, central government (based in London) solicits views from a wide range of stakeholders, including the devolved Parliaments.

b) APPROVALS

The EU approval process distinguishes between the regulatory treatment of the approval for food, feed, processing, and environmental release. For information on EU policy, approval process and pending approvals, please see EU-28 Agricultural Biotechnology Annual report coordinated by FAS/USDA Paris at: FAS/USDA GAIN Report Database

c) STACKED or PYRAMIDED EVENT APPROVALS

In the EU the approval process for stacked events is similar to that for single events. For import or cultivation in the UK, these types of GE events must also apply through the EU legislation and approvals system for stacked or pyramided events. Further information on the EU approval process can be found here: European Food Safety Authority and Page 8 of: EFSA Guidance for Risk Assessment

Also, for more information, please see EU-28 Agricultural Biotechnology Annual report coordinated by FAS/USDA Paris at: FAS/USDA GAIN Report Database

d) FIELD TESTING

The Department of the Environment, Food and Rural Affairs (Defra) are the lead agency. However, the devolved administrations of Scotland, Wales and Northern Ireland have powers over cultivation on their territory.

While the UK is still an EU Member State, an application for a field trial is made to Defra under Part B of the EU's Deliberate Release Directive (2001/18/EEC) which covers release for research and development.

Around 60 GE crop trials have been conducted in the UK since 2000, mainly on corn, sugar beet, oilseed rape, wheat and potatoes.

The Sainsbury Laboratory has a current field trial with a potato that has multiple beneficial traits (late blight resistance, nematode resistance, reduced bruising, reduced acrylamide on cooking). More information: The Sainsbury Laboratory

e) INNOVATIVE BIOTECHNOLOGIES

The EU has not yet provided clear guidance on which, if any, innovative biotechnologies fall under their existing legislation – EU Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms

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.

These technologies are evolving rapidly, and are an example of where legislation has not kept up with development. The EU Commission or other EU institution, such as the European Court of Justice may provide an interpretation of where these technologies may fit into existing law. See: EU Commission website

In October 2014, the UK's biotechnology research funder, Biotechnology and Biological Sciences

Research Council (BBSRC), published a position statement on new crop breeding techniques. It highlights uncertainties with the EU regulatory process for these technologies, but explains the potential benefits of funding this stream of science. See: BBSRC Press Release on New Crop Breeding Techniques

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

For consumer-ready grocery products, labeling is triggered by the 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: EU Commission Traceability and Labeling

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

Also, see the EU-28 Agricultural Biotechnology Annual report for further details on labeling requirements: FAS/USDA GAIN Report Database

Seed Labeling Legislation

In the absence of any EU seed labeling regulation for the adventitious presence of GE seed, the European Commission has advised that 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 EU. 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 unless the EU Rapid Alert System has flagged a particular product and origin for

additional measures. The food supply chain conducts its own testing to satisfy import specifications, labelling obligations, and customer assurance.

i) LOW LEVEL PRESENCE (LLP) POLICY

The EU has a zero tolerance policy for low-level presence of GE products in food and feed. As the EU's authorization procedures for new agricultural biotechnology varieties tend to be slower than those of other countries, a time-lag known as 'asynchronous authorization' occurs. To deal with the possible presence of unauthorized varieties in imports of commodity crops, the EU has adopted a measure, Regulation 619/2011, which defines "zero" with a "technical solution" level 0.1 percent for varieties that have a valid application for an EU authorization has been made and which fulfill the requirements set out in Article 2 of the Regulation. There is no set technical solution for food. The EU's Joint Research Centre has published guidance on the application of Regulation (EU) No 619/2011.

Above this threshold, the product is not allowed on the EU market. Operators must demonstrate that the presence of "GM" material was adventitious or technically unavoidable. The UK must adhere to the EU's technical solution for unapproved GE traits found in shipments. For more information, please see EU-28 Agricultural Biotechnology Annual report coordinated by FAS/USDA Paris at: FAS/USDA GAIN Report Database

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 or through the European Patent Office.

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) CARTEGENA PROTOCOL RATIFICATION

The UK has ratified the Cartagena Protocol on Biosafety. Defra is the contact point.

The enforcement of this regulation has been implemented in England by way of the Genetically Modified Organisms (Trans-boundary Movements) (England) Regulations 2004. Similar regulations have been implemented in Scotland, Northern Ireland and Wales).

Biological Diversity is an increasing area of work for the UK government, as agricultural innovation seeks to increase production while at the same time reducing environmental and biodiversity impacts. See more at: UK biodiversity indicators

Increasingly, countries with experience of growing GE crops will be asked how they measure the impact of monoculture/short rotation on wildlife, and for hard statistical results.

m) INTERNATIONAL TREATIES/FORA

The UK is an active participant in all major plant health and international regulatory fora including the International Plant Protection Convention (IPPC), European Plant Protection Organization (EPPO), Food and Agriculture Organization of the United Nations (FAO), World Trade Organisation (WTO), Codex Alimentarius, and the Organization for Economic Cooperation and Development (OECD). In all fora, 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: MARKETING

a) PUBLIC/PRIVATE OPINIONS

The UK has a number of academics that are vocal on both sides of the debate. Most are proponents of the technology and are invited to speak publicly through the Science Media Centre when they receive requests from journalists for specialist information and comment.

There are a number of organizations actively campaigning against the technologies, including but not limited to GeneWatch, Friends of the Earth, the Soil Association, and Royal Society for the Protection of Birds.

For the majority of the British public, genetic engineering in food is irrelevant. There are very few mainstream grocery products that contain GE as an outright ingredient and, with this invisibility, UK consumers consider the "GM problem" to have gone away.

For those that 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. An example that illustrated that these technologies may be more accepted if derived from publicly funded projects is that of the wheat field trial at Rothamsted Research. Scientists there appealed to the public not to vandalize their work and empathetically communicated the nature and purpose of the trial. The trial reached a successful conclusion, despite involving a food staple.

b) MARKET ACCEPTANCE/STUDIES

The food price spikes of 2008, and the ensuing debate and focus on how to deliver global food security,

while addressing climate change and feeding a burgeoning population, resulted in generally positive media coverage in the UK for agricultural biotechnology. This has never translated into a blanket acceptance for the presence of GE ingredients in the UK food supply.

Economic turmoil over Brexit may mean that there is a need for the UK government to support areas that could create economic growth and skilled labor. The food and drink industry is the UK's largest manufacturing sector. However, the majority of consumers look to grocery store chains to determine the quality to price ratio, and to rigorously check the safety and traceability of the food they purchase. In turn, retailers or foodservice companies exert pressure on the supply chain. Experience has shown that unless the sector is up against global shortages that lead to significant price rises, sourcing GE ingredients is a last resort.

As the number and adoption of GE products worldwide continues to increase exponentially, availability and the cost of sourcing and segregating GE products has become a real issue for the UK supply chain. No single retailer wants to be the first to undo its previous general stance on agricultural biotechnology on any product category. However, movement has been necessary on the animal feed side as the availability of non-GE has rapidly decreased and the cost increased. In 2010, Asda (Walmart) was the first to move to acceptance of GE feed for their private label meat and poultry products and Wm Morrisons Supermarkets followed. More recently (April 2013), Tesco, Cooperative Group, Marks & Spencer, and Sainsbury Supermarkets also communicated to their customers that the poultry and livestock supply chains could no longer source sufficient quantities of non-GE animal feed at a reasonable cost. Organic options are available for those who wish to avoid GE-fed livestock, and the up-scale Waitrose chain (capitalizing on the opportunity to differentiate from its competitors) now requires non-GE feed where possible for both its poultry and pig meat products.

There have been calls by lobby groups to label meat and poultry products from animals fed with GE feed (currently exempt from EU labeling law). Some commentators believe that voluntary labeling will help acceptance of GE feed and food, since the labeling will be become familiar. Others cite concerns that meat and poultry products from animals fed with GE feed will be seen as the option for the poorest in society, while the richest will have alternatives. However, it is more likely, if given the information and a choice, a large majority of UK consumers will vote with price uppermost in mind.

Imports of food products containing soy and corn-based products have been particularly negatively affected. In addition, products containing glucose or other sugar components of GE sugar beet or oilseed rape (Canola) must also label, and by doing so the GE presence is highlighted. Some supply chains may decide that they do not want GE ingredients/labeled products and the product may not be listed or carried in UK inventories as a result. 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, specialty candy bars and 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.

Marketing Studies

A YouGov survey of the British public conducted in February 2014 showed that 46 percent of those polled hold negative views on "GM" foods. Thirty-one percent don't know (whether their views of "GM" foods have become more positive or negative in the preceding 12 months), and only 23 percent hold positive a view. YouGov Poll Results

According to consumer research conducted by the Institute of Grocery Distribution, growing public understanding has had little impact on opinion which has remained broadly consistent for more than a decade (to 2014). In 2014, their survey showed that 38 percent of consumers oppose GE technology, 44 percent are neutral, and 20 percent are supportive. Institute of Grocery Distribution Factsheet

The Food Standards Agency commissioned research into public attitudes to "GM" food in 2009 and held a public consultation on potential EU harmonization of "GM-free" labeling in 2013. See: Food Standards Agency Consumer Research on GM and Novel Foods

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

Research is the main focus for animal biotechnology in the UK. 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	Oxitec
GE olive fly	Oxitec
GE pest insects	Pirbright Institute
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 (mice) and fish are produced in the UK for research purposes. According to statistics from the UK government's Home Office, procedures on GE animals were higher than the number on non-GE animals in 2013. With regards to products from animal biotechnologies, embryo progeny of clones or embryos of clone progeny have been 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 has exported GE mosquito eggs for development and subsequent release in Brazil and the Cayman Islands. Apart from these, the UK does not export GE animals, livestock clones, or products from these animals. Given the aforementioned reference to the beef and dairy sector, 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 GE animals or livestock clones.

e) TRADE BARRIERS

No known trade barriers exist 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. The UK does not have any country specific legislation or registration requirements on animal biotechnology; it must implement and follow all EU legislation in this area.

With regards to EU legislation, the EU Novel Foods Regulation from 1997 is currently the only EU legislation covering animal cloning. Under the Novel Foods Regulation, food "produced from nontraditional breeding techniques" (implicitly including cloning) – but not from their offspring – requires a pre-market authorization in order to be imported or sold in the EU. The European Commission has presented two new proposals - one on the cloning of animals and one on food from

cloned animals. More information is available here.

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. FAnGR

b) INNOVATIVE BIOTECHNOLOGIES

As featured in the Product Development section above, UK researchers are using innovative biotechnologies in the laboratory.

The EU has not yet provided clear guidance on which, if any, innovative biotechnologies fall under their existing legislation – EU Directive 2001/18/EC

c) LABELING AND TRACEABILITY

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

Also, see the EU-28 Agricultural Biotechnology Annual report for further details on labeling requirements: FAS/USDA GAIN Report Database

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

e) INTERNATIONAL TREATIES AND FOR A

The UK liaison point for Codex Alimentarius is Defra: codex@defra.gsi.gov.uk
While still a member of the EU, the UK only speaks or votes on issues in areas of exclusive or mixed UK/EU competence.

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 a number of organizations, such as the Roslin Institute and the BBSRC, active in public, positive engagement on animal biotechnologies. There are also a number of organizations actively campaigning against the technologies, including but not limited to GeneWatch, Friends of the Earth, the Soil Association, and Compassion in World Farming (CIWF).

The UK population has a generally low understanding of the science behind the technologies. Many object to 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, accepting a product that has animal benefits will always remain secondary to a product that the consumer needs or wants because of inherent benefits to them.

Publicly funded research is more trusted than that undertaken by the private sector, there being an inherent bias towards the acceptance of technology provided free to all as a public good over that perceived to be created for financial reward by private companies. In fact, UK-based breeding companies have distanced themselves from the technologies, preferring to maintain the trust of the public in their other research.

b) MARKET ACCEPTANCE/STUDIES

No independent market research has been undertaken that provides statistics on the potential acceptance of marketing animal biotechnologies in the UK.

Every couple of years a survey is conducted by Ipsos MORI, on behalf of the UK government, that takes a snapshot of current public opinion on the use of animals in medical research. The 2014 survey shows that there continues to be an overall majority support for the use of animals in medical research, although the level of support dropped by two percent since the 2012 survey.

The Farm Animal Welfare Committee (FAWC) is an expert committee of Defra. It provides advice to Defra on the welfare of farmed animals, including farmed animals on agricultural land, at market, in transit and at the place of killing. In November 2012, the Committee published its "Opinion on the welfare implications of breeding and breeding techniques in commercial livestock agriculture." The detailed report is available here. Among its many conclusions, it is notable that it encourages publicly funded animal biotechnology researchers to "engage closely with the livestock breeding industries to target the research effort better towards traits that are likely to have the greatest impact on animal welfare."

Reporting Notes:

1. The United Kingdom (UK) is a member of the European Union (EU) and this report should be read in conjunction with the EU-28 Agricultural Biotechnology Annual report, coordinated by the Foreign Agricultural Service in Paris, France. The EU Report, is 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 are: plant 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 parentheses in this report when discussing EU legislation and UK implementation.