UK plant genetics: a regulatory environment to maximise advantage to the UK economy post Brexit

Briefing paper

Graham Brookes

PG Economics Ltd

Dorchester, UK
September 2018

Table of Contents

Executive summary

This paper examines the economic value of the UK plant genetics sector[1] and the most appropriate regulatory environment for maximising long-term benefits to the UK economy.

UK plant genetics sector baseline

Size of the sector

Currently, the UK plant genetics sector is small (eg, the private sector employs about ten full-time equivalents (FTEs), with an annual expenditure at about £1.25 million). To place this in context, this contrasts with the size of the sector 20 years ago when the private sector employed 480 FTEs and research and development expenditure was £45-£50 million.

Regulation

Currently, the EU regulatory framework for crop biotechnology applies to the UK, with all GM crop innovations requiring EU level authorisation. In addition, on the basis of the (July-2018) Court of Justice of the European Union (CJEU) decision, innovations using NBTs based on mutagenesis techniques developed since 2001 will be subject to the GMO regulatory framework.

The EU regulatory system for GMOs has consistently failed to operate in the manner originally intended. This is widely acknowledged (eg, in the EU Commission's review of the decision-making process for GMOs (document Com 2015, 176 final) and by the European Ombudsman ruling of mal-administration in January 2016[2]. The average time to complete authorisations is significantly longer than the time intended in the original legislation, scientific opinions from the body specifically established to provide advice to EU policy makers[3] are frequently ignored and some member state governments consistently vote against authorisation of GMOs on non-scientific grounds.

Importation, use and production of GM derived crops

No commercial GM crops are, or have been, planted in the UK. There is limited GM and NBT crop experimental research being undertaken, almost all in the public sector.

The UK is a substantial importer and user of GM soybeans and its derivatives (soymeal and oil), mostly for use as animal feed. Whilst a market for certified non-GM soybeans and derivatives exists, mostly in the food use sector, GM origin soybeans and derivatives probably account for about 90% of total UK usage (reflecting the dominance of this form of production in global supplies because of the cost saving and yield advantages this technology brings to farmers[4]). In relation to use of maize, rapeseed and their derivatives, almost all supplies are non-GM because these supplies mostly originate from domestic UK and EU production, where GM crop technology is not available (or in the case of maize, used on only 1% of the total crop).

---

[1] The plant genetics sector is defined as parts of the sector (private and public-sector research organisations) that focuses on plant genetics research and the development of traits using genetic modification (GM) and more recently developed breeding techniques (NBTs) that are provided to farmers via seed

[2] Case 1582/2014/php, ruling of 16 January 2016

[3] The European Food Safety Authority (EFSA)

[4] See for example Brookes G and Barfoot P (2018) Farm income and production impacts of using GM crop technology 1996-2018, GM Crops and Food, 2018. DOI: 10.1080/21645698.1464866

The relatively slow and mal-administered EU authorisation process for GMOs has, however, created business uncertainty, disrupting trade and use of commodities and contributed to driving away research and development investment from the sector. In relation to trade/use of commodities, it has mostly affected some animal feed ingredients, notably those derived from maize (eg, maize gluten feed). UK importation and use of these feed ingredients has fallen tenfold since the early/mid 2000s as traders moved away from sourcing GM-derived feed ingredients due to the risk associated with having import shipments rejected for presence of EU unapproved GMO traits. In terms of research/development investment this has substantially declined from levels 20 years ago.

Relevance of plant genetics sector to the UK economy

The plant genetics sector is important because it contributes to the creation of income and employment via research and development and provides UK agriculture with better seed that can contribute to improved competitiveness and better meeting consumer demands.

The current small size of the UK plant genetics sector and the lack of seed innovations derived from GM/NBTs has resulted in economic costs or foregone benefits to the UK economy over the last 20-25 years. More specifically:

- The low level of employment and significant loss of FTEs between 1996 and 2006 are primarily high value-added research scientist jobs;
- There has been a UK crop trait research and development 'gap' for some 20 years which may have constrained the potential commercial development of new (crop biotechnology) traits with specific applicability to UK arable crops. The blight resistant potato case study example in Appendix one is one such example that could be made available to UK potato farmers. This technology, if widely adopted, could lead to farm level economic benefits associated with higher yields and lower costs of production, supply chain and consumer benefits of better-quality potatoes, less wastage and reduced health risks (lower exposure to acrylamide in cooked potato products) and environmental gains from reduced fungicide application and carbon dioxide emission savings. Currently, this UK-developed innovation is being exploited commercially only for the benefit of US potato farmers and consumers;
- The regulation-related business uncertainty for traders and processors/users of imported agricultural commodities like maize and their derivatives may have contributed to the loss of income (salaries), value added and employment generated in the UK-based crop user/processing sectors, if they re-located or focused, more of their businesses in countries/regions where greater regulatory clarity and access to more flexible and competitive sources of raw materials are available;
- Whilst some economic gains are available from supplying the market that requires certified non-GM raw materials and ingredients, this market is relatively small. Therefore, these economic gains are limited relative to the significantly larger economic losses/loss of competitiveness associated with not using GM (and the newer breeding) technology in production sectors servicing markets that express no preference for non-GM status supplies.

Plant genetics sector development post Brexit

The future of the UK plant genetics sector was examined for a number of potential post-Brexit regulatory and trade arrangements (Table 1).

Table 1: Post Brexit regulatory and trade arrangement scenarios examined

Scenario 1: The status quo – continued alignment with the EU	**Scenario 2: improved implementation and some change; making the existing GMO system work 'as intended' and some NBTs not subject to GMO regulations**	**Scenario 3: UK sets its own path - divergence from EU regulations on both GMOs and NBTs**
UK regulation of crop biotechnology (importation and use and planting) and timing of approvals changes in line with EU regulatory developments	UK regulation of crop biotechnology based on EU regulation but operating as originally intended - UK approvals made as soon as EFSA scientific risk assessment opinions given rather than after EU comitology delays and flexibility provisions relating to scientific data requirements[5] applied	UK sets own science-based regulations and guidelines for GMOs approval for planting crops and the importation and use of crops/derivatives derived from/containing GMOs which are in line with international norms
UK regulation of new breeding techniques remains aligned with EU decisions – plant breeding innovations derived from NBTs subject to the GMO regulations	UK regulation of NBTs diverges from the EU: some innovations derived from NBTs are not fully subject to GMO regulations[6]	As scenario 2 – some plant breeding innovations derived from NBTs not fully subject to GMO regulations

Under regulatory scenario one:

a) Uncertainty relating to the timing of approvals will continue, causing trading difficulties and additional cost for the user sectors of imported commodities;
b) The current low level of GM crop-related research and development is unlikely to change, with only limited income opportunities arising from the existing licencing UK-developed research to businesses located outside the EU. There is also a low probability of any GM crop technology ultimately being commercialised in the UK;
c) With the regulatory position of many NBTs assumed to be the same as for GMOs, there is likely to be:

- A reduction in the current (relatively small) level of private and public sector commitment to/involvement in NBT crop-related research and development;
- The potential for significant (and new) trade disruption for the food, feed and livestock production sectors, especially if the main grain/oilseed crop producing countries (eg, US, Brazil, Argentina) and major importers (eg, China, Japan) decide these techniques do not merit GMO-style regulatory approval for cultivation, importation and use. This has the (increasing) potential to create short term raw material shortages, together with possible higher prices/costs of production to the agri-food/feed supply chains (and consumers),

[5] As laid down in Article 5 of Regulation 503/2013

[6] Broadly assumed to be those associated with altering the existing DNA of a plant, not where new DNA is inserted from other plants

and additional, longer term losses of competitiveness, jobs and value-added in the UK (and EU) agri-ingredient processing sectors;

- With reduced plant genetics sector presence in the EU and the focus of its NBT-related innovations likely to be on crop traits of benefit to farmers located outside the EU, additional competitiveness losses for UK and EU agriculture can be expected from not having access to both GMO and NBT-derived new/improved crop varieties.

Overall, under the 'status quo' regulatory scenario, additional negative economic consequences relative to the current position are to be expected.

Under regulatory scenario two:

- With greater clarity on the timing and granting of approvals for importation and use, uncertainty will be reduced for traders and users of imported commodities and their derivatives. The application of the flexibility provisions relating to the scientific data requirements (where relevant) provided for in Regulation 503/2013[7] will also provide for both cost and time savings to the GMO approval process. These changes will offer greater flexibility and a wider choice of feed ingredients and may result in lower cost of raw materials to the livestock production sector. In turn, this may improve the competitiveness of the UK livestock production sector;
- The unfavourable environment for conducting research/development and commercialisation of GM crop technology will, nevertheless continue, with no significant change to the level of income and employment generated by the 'GMO part of the plant genetics sector';
- For crop innovations using most NBTs there is likely to be a more positive environment for the research and development of crops derived from these technologies. Commitments to fund research and development of crops containing such innovations in crops suitable for growing in the UK are more likely from private sector plant genetics companies, together with increased interest in collaborative research and development with the UK public research community. New UK-based private sector investment in research expenditure and employment could be forthcoming, that may, in the longer-term lead to the commercial development of new crop traits for UK farmers and food processors. These may offer a range of benefits from improved agronomic performance, reduced cost of new seed and higher quality products such as altered grains and oilseeds (see appendix 1).

Overall, a commitment to make the existing implementing regulations applicable to importation and use of GMOs operate 'as intended' plus divergence from the CJEU decision relating to the regulation of some NBTs, (eg, site directed nucleases like CRISPR) has the potential to deliver economic gains from a combination of improvement in the competitiveness of the agricultural commodity user sectors and from new plant genetics sector investment in NBT research and development. It also avoids the likely negative economic consequences of scenario one.

[7] Not typically applied by EFSA in the current EU approval system

Under regulatory scenario three:

- As under scenario two, uncertainty will be reduced for traders and users of imported commodities providing greater flexibility, a wider choice of feed ingredients and may result in lower cost of raw materials to the livestock production sector. In turn, this may improve the competitiveness of the UK livestock production sector;
- A move to GMO regulation based on international norms, where approval for planting is based on scientific risk assessment only and no linkage to the EU approval process/decisions will represent a more favourable environment for the commercialisation of GM crop technology. Commitment to fund research and development of GM crops suitable for growing in the UK is more likely from private sector plant genetics companies, together with increased interest in collaborative research and development with the UK public research community. Initially, this is likely to focus on research but it is possible that this may lead to the commercial development of new crop traits for UK farmers in the longer term. An indication of potential benefits that may accrue from these developments are provided in the GM crop case study example (blight resistant potatoes) referred to above and detailed in Appendix 1;
- As under regulatory scenario two, with some plant breeding innovations derived from NBTs not being subject to GMO-style regulations, this is likely to create a positive environment for the development of crops derived from these technologies. Commitment to fund NBT-related research and development of crops suitable for growing in the UK may be put in place by private sector plant genetics companies, together with increased interest in collaborative research and development with the UK public research community. In the longer-term this may lead to the commercial development of new crop traits for UK farmers and food processors offering a range of benefits from improved agronomic performance, reduced cost of new seed and higher quality products such as altered grains and oilseeds (see appendix 1).

The potential long-term gains to the UK economy are likely to be highest under regulatory scenario three. With a regulatory environment favourable to both NBTs and GM techniques, this is likely to result in higher levels of UK-based plant genetics sector research expenditure and employment than under scenario two. It may also lead to the commercial development of more new crop traits based on NBTs or GMOs becoming available to UK farmers and food processors than under scenario two.

Conclusions
In terms of the overall potential impact of these three regulatory scenarios, Table 2 summarises the likely outcomes; scenario one has negative impacts, with scenarios two and three, providing for more plant genetics-friendly regulatory environments, offering the potential for economic gains. Scenario three is likely to offer the highest level of long-term economic and wider societal benefits to the UK economy.

Table 2: Summary of potential economic (and wider) benefits of the different post Brexit regulatory scenarios

	Scenario 1: The status quo – continued alignment with the EU	**Scenario 2: improved implementation and some change; making**	**Scenario 3: UK sets its own path -divergence from EU regulations on**

		the existing GMO system work 'as intended' and some NBTs not subject to GMO regulations	both GMOs and NBTs
Importation and use of commodities/derivatives that may contain GMOs	Ongoing uncertainty and disruption to import supplies of food and feed ingredients, higher cost of raw materials and loss of competitiveness	Reduced uncertainty = greater flexibility in use of raw materials leading to lower costs of feed and a more competitive livestock product production sector	Reduced uncertainty = greater flexibility in use of raw materials leading to lower costs of feed and a more competitive livestock product production sector
Plant genetics sector research and development (annual) expenditure	Reduced	Potential for increase relating to some plant breeding innovations derived from NBTs	Potential for increase relating to both GMOs and NBTs – to a level higher than under scenario 2
Plant genetics sector employment	Reduced	Potential for increase relating to NBTs	Potential for increase relating to both GMOs and NBTs – to a level higher than under scenario 2
Longer term economic benefits from GMO/NBT innovations	Probably negative	Reasonable prospect of new crop innovations from NBTs being available to UK farmers in longer term: higher yielding crops, lower costs of production, more efficient seed production sector, better quality raw materials for food and industrial processing sectors	Reasonable prospect of new crop innovations from GMOs and NBTs being available to UK farmers in longer term: higher yielding crops, lower costs of production, more efficient seed production sector, better quality raw materials for food and industrial processing sectors
Wider UK societal benefits	Probably negative	Some possible long-term benefits: depends on traits - potential for environmental improvements (reduced pesticide application) and improved products/health benefits (eg, high oleic oils)	Some possible long-term benefits - depends on traits - potential for environmental improvements (eg, reduction in fungicide application with GM blight resistant potatoes and improved products/health benefits (eg, better quality potatoes, low acrylamide potatoes)

Note: if under scenario one, the EU resolved to exempt some NBTs from having to comply with its GMO regulations (via amendment to the GMO Directive 2001/2001/18/EC), the negative economic impacts would likely not occur and the net economic effect would be one of little change from the current position

1 Introduction

As the UK moves to leave the European Union, the regulatory environment for technology used in the agricultural sector may change. Against this background, this paper examines the economic value of the UK plant genetics sector and the most appropriate regulatory environment for maximising long-term economic benefits to the UK economy.

The paper is structured as follows:

- Firstly, it examines the past and current baseline of the plant genetics sector;
- It then examines the likely economic impacts associated with the development of the sector under three different post-Brexit regulatory environments;
- And finally, explores the most appropriate regulatory environment for maximising long-term economic benefits to the UK economy.

The plant genetics sector is classified as businesses and public-sector research organisations that undertake plant genetics research and the development of traits (in seed for farm use) using crop biotechnology and more recently developed breeding techniques (NBTs). Within this:

- Plant breeding innovations/NBTs, including technologies such as; genome editing and clustered regularly interspaced short palindromic repeats (CRISPR). Other techniques include; cisgenesis and intragenes, zinc finger nucleases (ZFN) and transcription activator-like effector nucleases (TALENS);

- Crop biotechnology based on plant breeding innovations derived from altering/adding genetic material to plants. These include agronomic traits such as insect/pest resistance, environmental resilience, virus resistance, herbicide tolerance or quality traits such as higher oil content or increased overall yields.

2. UK plant genetics sector baseline

2.1 Introduction

The development and exploitation of plant genetics in seeds is important because it contributes to the creation of income and employment in the economy via research and development conducted in the UK. The 'outputs' of this sector, in terms of the commercial development of new and improved seed varieties also provide UK agriculture with better tools of production (eg, higher yielding seed, improved quality traits in seeds) that improve competitiveness and better meet consumer demands.

The successful development of the UK plant genetics sector requires a strong research base in both, the public and private sectors, access to elite germplasm and variety breeding and the availability of facilities to multiply and market the crop seed containing new traits. All these activities require a considerable number of highly qualified personnel and support services. Their employment creates initial wealth through salaries but also from expenditure on consumables and overheads.

This section examines the current/recent baseline relating to the plant genetics sector in the UK. The information presented draws on the findings of research conducted by the author in 2007/08 (*Brookes and Barfoot (2008) The impact on the UK economy of failure to embrace GM crop technology for the Department of Trade and Industry (DTI) – unpublished*) and data provided by representatives of both the public research bodies and private companies currently conducting plant genetic research in the UK. It also summarises the current EU regulatory baseline and the usage of crops/derivatives derived from relevant commercialised crop technology (GM technology).

2.2 Historic developments and the sector baseline

In the mid to late 1990s, the plant genetics sector was in effect the crop biotechnology sector[8]. This was generally a time of considerable business optimism about the potential future for the crop biotechnology sector in the UK. There was reasonable promise of GM crop products delivering high returns to industry and the main companies with interests in crop biotechnology began to invest more in crop biotechnology research in the UK, including collaborative research with the UK public sector. For example, Zeneca/Syngenta focused crop biotechnology research at Jealots Hill and established a specific cereals crop genetics research programme at the John Innes Centre. DuPont funded cereal crop genetics research at IACR-Rothamsted. In addition, Monsanto entered the UK market through the acquisition of PBI Unilever. New 'local' crop biotechnology companies such as Axis Genetics and Advanced Technologies Cambridge (ATC) also expanded. At that time, the number of GM crop traits was increasing, the regulatory requirements were being formulated and although opposition to the technology existed, it tended to have limited influence.

In the period to the mid 2000s, there was considerable rationalisation in the sector reflecting the general increasing cost of undertaking research and development, including the increasing application of regulatory hurdles for approval of new products and the cost of dealing with crop

[8] This being largely a combination of plant breeding/seed companies and agro-chemical companies

trial vandalism. The stalled, complex and costly (to comply with) regulatory approval process not only raised barriers to entry in the sector but contributed to delays and uncertainty for bringing crop biotechnology products to the EU market[9]. This resulted in much industry re-assessment of plant biotechnology research and product development activities in both UK-type crops and the location of such research. It led to significant exiting from both research and development into these crops *per se*, and from undertaking research in the UK. For example, Monsanto sold off its wheat breeding business to the French farmers co-operative RAGT, Syngenta's collaborative research with the John Innes Institute was run down and DuPont/Pioneer's funding of research at Rothamsted also came to an end. The UK-based company AXIS Genetics that was financing UK sourced technologies from universities and research institutes also closed down due to very poor investor sentiment towards GM crops. By 2006, there had been a virtual total disappearance of the commercial crop biotechnology sector from the UK, allied to considerable consolidation of the seed sector, in which most companies now have ownership from outside the UK and most of the crop biotechnology research was being undertaken in other countries.

In terms of expenditure on crop biotechnology in the UK, the UK private sector expenditure on employing about 475 staff to undertake research and development in crop biotechnology was about £45-50 million in about 1999/2000. This subsequently fell to very low levels of less than ten staff by 2006.

In 2018, UK private sector expenditure on plant genetics research and development had changed very little since 2006. The numbers employed in plant genetics research and development are about ten, with an annual expenditure at about £1.25 million. To place this in context, the UK accounts for under 0.1% of the total global private sector expenditure and employment on plant genetics research and development.

In the public sector, identifying what funding by the main public-sector funding bodies like BBSRC or DEFRA has been solely devoted to research and development that is focused on plant genetics type research is difficult. There is funding of general crop science and funding for plant science[10] that covers a range of potentially overlapping disciplines. Alternatively, identifying the plant genetics research and development expenditure and employment at individual research institutes (notably the John Innes Centre, Sainsbury Laboratory, Rothamsted Research, James Hutton Institute, Roslin Institute, Earlham Institute) and universities is equally difficult.

In the 2007 report for the DTI, the number employed by the main public-sector research bodies that were then undertaking crop-specific and broader plant biotechnology research with funding from the BBSRC was estimated to be about 860 scientists and 1,300 in total, inclusive of support staff. This had fallen by about a quarter relative to ten years previous to this (1996). At that time, much of the decline in public sector involvement in the sector was related to:

[9] Along with de facto moratoria of national approvals until EU regulations were established

[10] In the 2007 DTI report public sector plant science was defined as fundamental research into how plants function, including research into 'model' crops like Arabidopsis. Crop science is the application of plant science research to specific crops

- private sector withdrew/failure to renew or extend crop biotechnology collaborative research projects;
- the focus of public sector research having moved away from crop biotechnology to related areas such as model plants and applications such as microbes and yeasts that do not require field trials (that is of limited short-term value for industry until proof of concept in a commercial crop is demonstrated);
- a widespread perception that the UK funding bodies were reluctant to support research that required GM crop field trials.

In 2018, it is equally difficult to identify the current research and development expenditure and employment in the public sector associated with plant genetics crop research, especially as in the last 10-12 years, some research institutes conducting crop science research have changed affiliations and the way in which funding bodies such as the BBSRC present and break down expenditure has changed (making comparisons with 10-12 years ago difficult). Nevertheless, given the general application of strict, public expenditure controls in operation over the last ten years, it is likely that the current level of public sector expenditure and employment in crop-science related research is probably lower, or at best, about the same nominal level to 2008. However, in real terms, the 'buying power' of these budgets is significantly lower in 2018 than 2008.

A key point to note is that 10-12 years ago the UK plant genetics sector research/development sector was small, with the private sector having largely re-located all relevant research to locations outside the UK (and EU). The current sector is similarly very small, with little change in the private sector, and a likely smaller base in the public sector.

2.2 Regulatory baseline

Currently, the EU regulatory framework for crop biotechnology applies to the UK. This means that all GMOs must receive EU level authorisation before entering the EU market. The authorisation rules regulating GMOs cover separately 'live' GMOs (ie, seed) and products made from, containing or derived from GMOs that are 'not live' (eg, soybean oil, maize starch).
The main pieces of legislation affecting GMOs are:

- **Directive 2001/18 which addresses deliberate release of GMOs into the environment**. This directive deals with authorisation of 'live' GMOs, and all GMOs for planting 'as seed' in the EU, or which may be imported in seed form (that are viable and could grow in the EU), are subject to authorisation under this directive. Thus, imports of unprocessed grains and oilseeds, even if not destined for planting purposes in the EU, are subject to authorisation under this directive. Non-viable products of GMOs (eg, oils and meals from oilseeds) are, however, not subject to this directive. The main focus of this directive is impact on the environment and humans. Although a GMO may receive authorisation for EU cultivation under this Directive, Directive 2015/412 allows member states to restrict or ban the cultivation in their territories for non-scientific reasons. Eighteen-member states, and four regions, in two countries (Wallonia in Belgium, Northern Ireland, Scotland and Wales in the UK) have used this opt out to ban the cultivation of the only currently approved and commercially available GM crop (GM insect resistant maize);

- **Regulation on GM Food and Feed (Regulation 1829/2003)**. This regulation covers all food and feed made from GMOs (including both 'live' GMOs such as sweet corn, whole soybeans) and 'non-live' processed products such as oils and meals of oilseeds and processed derivatives of grains (eg, starches, glutens). This legislation focuses on issues of health, safety and labelling;
- **Labelling (Regulation 1830/2003) - all food 'produced from' GMOs** irrespective of whether there is detectible DNA or protein of GM origin in the final product, including feed, is required to be labelled (eg, refined oil produced from a GMO crop). Products produced with the aid of GMO products, but not directly derived from GMOs, do not have to be labelled as from GMOs. For example, meat, eggs and dairy products derived from animals that have consumed feed containing GMOs. Products produced with the aid of GMOs (notably produced using genetically modified micro organisms) also do not require labelling;
- **Labelling threshold –** all approved products with more than 0.9% GMO material have to be labelled as containing or derived from GMOs. This threshold for the presence of GMOs specifically allows for the accidental presence of approved GMOs (eg, by pollen drift or from GMO residues left in transport or processing equipment that has previously used GM-derived material), but operators must have the evidence to prove that the presence was unavoidable given the trading/technical conditions;
- **Products containing GMOs that are not approved in the EU**. The Regulation operates a zero tolerance for the presence of unapproved GMOs in any product sold in the EU for food use, although since June 2011, a tolerance threshold of 0.1% has been adopted relating to the presence of unapproved events (that are nevertheless entered into the EU regulatory approval process) in feed;
- **Traceability (Regulation 1830/2003)**. All operators/stakeholders in the food and feed supply chains must keep records and documentation that allows for traceability of GMOs. All operators in a supply chain (eg, producers, suppliers and retailers) are required to inform customers if GMOs were used in their products.

GMO authorisations are valid for 10 years, after which applicants have to re-submit for authorisation.

In relation to the operation of EU legislation on GMOs, the authorisation process has consistently failed to operate in the manner originally intended[11]. The approval time laid down in the legislation is twelve months (six months for the European Food Safety Authority (EFSA) to undertake scientific assessments and approximately six months for the 'comitology' processes). The EU regulatory process relating to scientific assessments is similar to international norms, as in countries such as the Australia, Argentina, Brazil, Canada, Japan and the USA. The EU process includes two parts; a risk assessment phase managed by the European Food Safety Authority

[11] Acknowledged by the EU Commission in its document 'Reviewing the decision-making process for GMOs', Com 2015, 176 final and by the European Ombudsman which recorded on 19 January 2016 (case 1582/2014/php) that the Commission's previous delays in authorising safety-assessed import applications for GM food and feed "reflected a systemic problem" and constituted maladministration. The Ombudsman confirmed that, between 2012 and 2014, the Commission regularly failed to comply with the existing legal requirements for putting GM products to vote within the specified time frame, and also waited too long - three and a half months on average - to grant authorisation following the Appeal Committee stage

(EFSA), followed by a risk management phase comprising a political review by EU member states of products receiving a positive risk assessment from EFSA. Whilst 12 months is the expected time for approval, the average time taken to complete authorisations has invariably been significantly longer (typically more than 3 years). Advice and assessments of GMOs on scientific criteria are undertaken by the European Food Safety Authority (EFSA) which eventually issues opinions on GMOs submitted for either authorisation for deliberate release and/or for use in food and feed. Despite EFSA being the executive arm of the EU Commission charged with providing scientific advice, its opinions are not binding and consequently, EFSA opinions are frequently ignored by EU policy makers[12], with politics rather than science determining decisions on GMO authorisation. Some member state governments consistently vote against authorisation of GMOs on political grounds and this contributes to further delays in the authorisation process.

The time taken to come to decisions on authorisation means the EU regulatory approval procedures takes significantly longer (more than 3 years) than the approval procedures in some of the major agricultural commodity trading partners of the EU (typically less than one year). As a result, GMOs tend to be approved for commercial use in food and feed products in countries such as the US and countries in South America before approval is granted in the EU. This 'asynchronous authorisation' process has and continues to result in trade disruption (see below), where agricultural commodities and derivatives that may contain GMOs approved in an exporting country are exported to the EU before the EU grants authorisation for importation and use. Of crucial importance to whether trade disruption occurs is the zero-tolerance rule relating to adventitious (or accidental) presence of not yet EU approved GMOs in consignments or shipments of agricultural commodities and derivatives exported to the EU. As it is practically impossible to supply (outside a laboratory) a crop commodity with 100% purity, the zero-tolerance rule has, and continues to cause, disruption to the supply of agricultural commodities and derivatives which may have low level presence (LLP) of GMOs not yet approved in the EU. The 'technical solution' of allowing detection of 0.1% for the maximum permitted presence of EU unapproved material in supplies of commodities and derivatives imported into the EU for use in the animal feed sector represents a limited attempt to overcome the problem but it fails to address the issue in supplies used in the food sector, especially when supplies enter the EU with no specific 'food' or 'feed' based customer or if the imports include GMOS that are approved in exporting countries but have not been entered into the EU regulatory approval system.

The combination of slow (asynchronous) approvals and the LLP problems relating to unapproved events has created major problems for trade in commodities and their derivatives and has led to important changes in trade in the last 15 years. Up to the mid 2000s, the EU used to annually import about 4-5 million tonnes of maize, 2.5-3 million tonnes of corn gluten feed (maize processing by-product) and about 1 million tonnes of dried distillers' grain (maize processing by-product) from the US. Due to the increasing number of (mostly stacked) biotech events adopted by maize growers in the US, which were taking a long time to complete passage through the EU regulatory system, US export trade in maize fell dramatically, virtually ceasing in some years (eg, 2006-2008 and again in 2011-2013). US maize exports to the EU were initially replaced with supplies from Argentina, where until about 2009, only EU approved maize biotech

[12] EU policy makers essentially refers to members of national member state authorities who vote on authorisation

events were approved for planting and latterly by Brazil, which did not permit commercial planting of GM maize until 2008. However, both these countries have subsequently abandoned any policy of only approving new GMO traits in maize (and soybeans) for planting once the EU had approved the traits for importation and use, with GM maize going on to dominate domestic production (accounting for 85% and 87% respectively of total production in Argentina and Brazil in 2016). Ukraine is now the main source of supply for maize imports into the EU (officially a non-GM producer, though some small areas of the crop are reported to be (illegally) planted to GM-traited varieties[13]).

A similar pattern has occurred in respect of EU imports of corn gluten feed and distillers' grain. From import volumes of 2.5-3 million tonnes of corn gluten feed and 1 million tonnes of distillers' grain (from the US), this has fallen to annual between 0.25 million tonnes and 0.85 million tonnes (combined total).

In all cases, a primary reason for these changes in sources of supply (away from mainly GM supplying countries) and/or away from GM-derived feed ingredients (distillers' grain and corn gluten feed) has been uncertainty and risk associated with having import shipments rejected for presence of EU unapproved GMO traits.

2.3 GM crop planting and production

The only GM crop/trait approved and available for commercial planting in the EU is insect resistant maize (event Mon 810), of which 131,260 ha (equal to 1.5% of the EU grain maize area) were planted to varieties containing this trait in 2017. These plantings are found only in Spain (95% of the total area) and Portugal. No commercial GM crops are, or have been, planted in the UK – grain maize is small crop in the UK (about 20,000 ha, which is mostly used on-farm for feed) and the target of the GM trait is not a problem pest in the UK, hence no agronomic need to consider use of this technology or for plant breeders to incorporate the trait in varieties suitable for planting in the UK.

2.4 Experimental planting of GM crops in the UK

As indicated above, UK publicly-funded research and development into crop traits from GM and new breeding techniques has been, and continues to be, limited. Most research is of a fundamental basis and therefore largely of a confined nature. The extension of this largely laboratory-based research crop development to field trial level has been/is likely to be limited in the next few years to GM omega-3 oil in camelina and photosynthesis-enhanced (higher yielding) wheat at Rothamsted and GM late blight resistant (plus reduced acrylamide and bruising) potatoes at the Sainsbury Laboratory. The latter technology has been licenced to the Simplot company in the USA, where commercial development of the technology began in 2015. This is providing a small licencing fee to the technology developers in the UK (which may increase depending on the level of commercial planting). In addition, Rothamsted has approval to undertake a crop trial of modified (using an NBT), high oleic camelina.

[13] Source: Brookes G and Blume Y (2012) The potential economic and environmental impact of using GM traits in Ukraine arable crop production. Report for Croplife International, available at www.pgeconomics.co.uk

2.5 UK crop and derivative usage (of crops where GM technology is widely used)

2.5.1Trade and usage of soybeans and derivatives

The UK use of soybeans and derivatives is summarised in Table 3. This shows that about 0.7 million tonnes of soybeans were imported for crushing in the UK. This crush produced about 0.137 million tonnes of soy oil and 0.561 million tonnes of soymeal. In addition, 2.09 million tonnes of soymeal were imported to meet total domestic usage of 2.587 million tonnes.

Table 3: UK soybean and main derivative use 2016 (million tonnes)

	Beans	Oil	Meal
Domestic production (or crush for oil and including from imported beans)	Negligible	0.137	0.561
Imports	0.700	0.155	2.092
Domestic use	0.690 (crushed to oil and meal)	0.266	2.587
Exports	0.1	0.02	0.06

Source: derived from Oil World

Note: There is a small domestic soybean crop in the UK, which is mostly fed directly to animals, without entering the traditional processing system

In terms of origins, the primary sources of supply were:

- For beans: Brazil, USA and Argentina, dominated UK sources of supply accounting for 52%, 32% and 13% respectively of total UK imports (these shares probably understate the shares of these sources of supply because of intra EU imports – 2% of UK soybean imports came from other EU countries, of which most came from the Netherlands and therefore probably originally derived from these three non-EU countries of origin);
- For oil: 47% of soy oil supplies in the UK derives from domestically crushed soybeans, with the balance of 53% imported. Of the oil imported, three-quarters comes from other EU member states, (mostly the Netherlands), based on the crushing of imported soybeans;
- For meal, 20% of meal used in the UK derives from the soybeans crushed in the UK, with the majority (80%) imported. Of the direct imports from soybean growing and exporting countries, 47% was from Argentina, 14% from Paraguay and 9% from Brazil in 2016. About a quarter of imports come from other EU member states, which is either from soybeans, crushed in the EU, or soymeal imports into ports such as Rotterdam that are transhipped to the UK.

In value terms, in 2016, total imports of soybeans and its derivatives of oil and meal were about £942 million of which beans, oil and meal accounted for 24%,10% and 66% respectively of the total. At least 90% of this contained or was derived from GM sources of supply.

2.5.2 Trade and usage of maize and derivatives

In relation to the maize market, the UK uses about 1.76 million tonnes, of which two-thirds is used as animal feed (either in compound feed or fed direct to animals) and the rest used in human and industrial uses. Within the food sector about 0.15 million tonnes is flint maize imported for the manufacture of cornflakes. About half of maize supplies entering the UK derive from other EU member states (mainly France) and half from countries outside the EU. The UK's flint maize requirements mostly derive from Argentina.

The UK has also traditionally used significant volumes of maize gluten in the animal feed sector. This is essentially a by-product of starch manufacture and derives from a combination of UK and EU (maize) starch manufacture plus imports from outside the EU. In the early 2000s, usage of maize gluten in the feed sector was between 0.7 and 0.8 million tonnes. This fell back to just under half a million tonnes in 2006 and to 0.15 million tonnes in 2007. This historically low level of use has continued over the last 10 years, with imports of about 0.15 million tonnes in 2016 – 35% of these imports are from the USA.

The UK also imports annually about 0.4 million tonnes of dried distillers' grain (DDGS), of which 50% is from other EU member states and just over 40% is from the USA. As with soybean and soymeal imports, the EU origin DDGS is a mix of grains processed by the brewing and distilling sectors in the EU and some transhipment of third country imports from ports such as Rotterdam.

2.5.3 Trade and usage of rapeseed and derivatives

The UK use of rapeseed and derivatives is summarised in Table 4. This shows 1.725 million tonnes of rapeseed were used for crushing in the UK. This crush produced about 0.741 million tonnes of rapeseed oil and 0.988 million tonnes of rapemeal. Domestic use of rapemeal was just over 1 million tonnes.

Table 4: UK rapeseed and main derivative use 2016 (million tonnes)

	Beans	Oil	Meal
Domestic production (or crush for oil and including from imported beans)	1,771	0.741	0.988
Imports	0.06	0.115	0.180
Domestic use	1,725 (crushed to oil and meal)	0.742	1.048
Exports	Negligible	0.126	0.120

Source: derived from Oil World

In relation to the origin of supplies, the majority comes from domestic production, with almost all imports of oil and meal coming from other EU member states.

2.5.4 Use of GM crops and derivatives in the UK

The data presented above for soybean/derivative imports highlights the dominance of supplies from countries where GM soybeans account for almost all of production (90% plus of the total area planted to soybeans in the USA, Argentina, Paraguay and Brazil). A market for certified conventional (non-GM) supplies exists and is concentrated in the human food sector, where soy-based derivatives are used in a wide range of food products; often at fairly low (less than 1%)

incorporation rates. Some parts in the livestock production sectors, have also required the use of certified conventional soy oil and meal in livestock rations (notably the fresh poultry and egg sectors). Overall, the current proportion of total soybean and derivative use required to be certified as conventional is probably similar to the proportions in the EU market. Almost all of the soy oil derivatives (eg, lecithin) and soy protein derivatives used by the food sector are probably required to be certified as derived from conventional soybeans. Of the 0.15-0.25 million tonnes of soy oil, annually used by the food sector, the majority is not required to be certified as derived from conventional soybeans (about 0.1 million tonnes is used by the food service sector, the vast majority of which is not required to be certified as derived from conventional soybeans). Soy oil use by the UK feed sector is fairly limited (probably less than 30,000 tonnes), largely reflecting soy oil's lack of price competitiveness relative to other oils (eg, palm oil). Also, where the feed sector has a requirement for mainstream soy ingredients to be certified as being derived from conventional soybeans or other oilseeds, the feed sector has largely replaced soy oil with alternative oils rather than pursuing a certified conventional (soy oil) strategy with its attendant complications, costs and risks.

In relation to soymeal, almost all of the 2.6 million tonnes used in 2016/17 goes into animal feed. The current (annual) demand for certified conventional soymeal probably amounts to between 0.2 and 0.3 million tonnes. The poultry sector (mostly broilers/poultrymeat but also some egg producers) probably accounts for the highest usage of certified conventional soymeal.

The requirement for, and use of, certified conventional maize in the UK is similar to soybeans in that most usage in human food and starch has a requirement for certified conventional maize, whilst most maize used in the feed sector has no such requirement. As the majority of supplies come from other EU countries (notably France), these are typically non-GM.

The use and origins of maize derivatives such as maize gluten feed in the UK has followed a similar path to that referred to above for the EU. The UK used to import significant volumes of maize gluten feed and distillers' grain and these have fallen tenfold since the early/mid 2000s to annual volumes of between 0.25 million tonnes and 0.85 million tonnes (combined total). A primary reason for these changes in sources of supply (away from mainly GM supplying countries) and/or away from GM-derived feed ingredients (distillers' grain and corn gluten feed) has been uncertainty and risk associated with having import shipments rejected for presence of EU unapproved GMO traits.

In relation to use of rapeseed and derivatives, these are mostly supplied from domestic production and/or from other EU member states. As no GM crop technology is used in the EU rapeseed crop, all of these supplies are non-GM and no distinct GM versus non-GM rapeseed/derivative market has developed in the UK/EU.

2.5.5 Summary of current baseline

The current UK plant genetics sector research/development sector is small, with the private sector having largely re-located all relevant research to locations outside the UK (and EU) some 15-20 years ago. This small base largely reflects the unfavourable environment towards the commercialisation of new seed developed from crop biotechnology in the EU and the systematic failings of its regulatory approval system. Against this background, it is not surprising that no commercial seed derived from GM or NB techniques have been developed and made available for use by UK farmers, although one UK-based innovation (GM blight resistant potatoes) has been recently licenced for commercial application in the USA.

Whilst the current research and development base is small, the UK annually uses significant volumes of imported food and feed ingredients produced using these technologies – for example, the UK imported in 2016, soybeans and its primary derivatives of oil and meal from GM sources of supply, equal to about £850 million. A small market for certified non-GM raw materials and ingredients exists, found mostly in the food use sector.

2.5.6 Relevance of size and importance of the plant genetics sector to the UK

As indicated above (section 2.1), the development and exploitation of plant genetics in seeds is important because it contributes to the creation of income and employment in the economy via research and development and provides UK agriculture with better seed that can contribute to improved competitiveness and better meeting consumer demands.

The small size of the UK plant genetics sector and the lack of seed innovations derived from GM/NBTs has resulted in economic costs or foregone benefits to the UK economy over the last 20-25 years:

- Employment in the sector is low (private sector = about 10 FTEs in 2018). This compares with about 475 FTEs in the mid 1990s. These were primarily high value-added research scientist jobs;

- A more crop-biotechnology/NBT friendly regulatory & market environment would most likely have led to job creation, rather than job losses over that period. The 2008 PG Economics paper for the DTI, referred to earlier, estimated that in the ten-year period 1996-2006, if UK employment trends in the sector had followed trends in the USA, where crop biotechnology was widely adopted, there could have been +900 additional crop-biotechnology scientist FTEs created in the UK, generating additional annual income (salaries) of up to £77 million;

- There has been a UK crop trait research and development 'gap' for some 20 years which may have constrained the potential commercial development of new crop biotechnology traits with specific applicability to UK arable crops. The blight resistant potato case study example in Appendix one is one such example of a technology that could be made available to UK potato farmers. This could be providing annual farm income benefits equal to £343/ha to potato farmers or between £3 million and £21 million at the national level. Currently, this UK-developed innovation is being exploited commercially only for the benefit of US potato farmers and consumers. In addition, the 2008 PG Economics report referred to above highlighted that commercialised GM technology suitable for adoption in the UK at that time (and still widely used in other countries, eg, herbicide tolerant sugar beet and oilseed rape) could have been adopted in the UK, if the regulatory and market environment in the EU had been more technology-friendly. This report estimated that UK agriculture had foregone between £428 million and £534 million in farm income benefits between 1996 and 2006 and was continuing to forego between

£65 million and £82 million on an annual basis. Whilst these potential 'lost farm income benefits' were forecasts made 11 years ago, the consistent evidence available in peer reviewed literature in 2018 confirms that important farm income benefits have been foregone over this 11-year period. For example, the average farm income benefit from using herbicide tolerant sugar beet (in the USA and Canada from 2008) and herbicide tolerant canola in the USA, Canada and Australia[14]) were £90/ha and £44/ha respectively[15];

- It is possible that the trading uncertainty for traders and processors/users of imported agricultural commodities like maize and their derivatives may have contributed to the loss of income (salaries), value added and employment generated in the UK-based crop user/processing sectors, if they re-located or focused, more of their businesses in countries/regions where greater regulatory clarity and access to more flexible and competitive sources of raw materials are available;

- Whilst some economic gains are available from supplying the market that requires certified non-GM raw materials and ingredients, as indicated above in section 2.5.4, this market is relatively small. Therefore, these economic gains are likely to have been, and are, limited relative to the significantly larger economic losses/loss of competitiveness associated with not using GM technology in production sectors servicing markets that express no preference for non-GM status supplies.

[14] From 1996 in Canada, 1999 in the USA and 2008 in Australia

[15] Source: Brookes G and Barfoot P (2018) Farm income and production impacts of using GM crop technology 1996-2018, GM Crops and Food, 2018. DOI: 10.1080/21645698.1464866)

3. Plant genetics sector development post Brexit

This sub-section examines the potential for developing the UK plant genetics sector under a number of post-Brexit regulatory arrangements.

3.1 Regulatory scenario one: The status quo – continued alignment with EU regulation

For the UK plant genetics sector these regulatory arrangements are assumed to mean:

- UK regulation of crop biotechnology changes in line with EU regulatory developments, with UK approvals and authorisation of GM traits for planting, importation and use only made once the EU has authorised. Member States and devolved governments (Northern Ireland, Scotland and Wales) would be able to continue with their 'bans' on the planting of GM crops, even if a crop/trait combination suitable for growing in the UK had been granted EU-level approval;
- UK regulation of new breeding techniques remains aligned with EU decisions. At the time of writing (September 2018), EU regulation of NBTs is to be based on the recent (July 2018) Court of Justice of the European Union (CJEU) decision, relating to mutagenesis techniques developed since the adoption of the GMO Directive 2001/18/EC. This means that many plant breeding innovations derived from NBTs (notably site directed nucleases like Zinc-Fingers, TALEN and CRISPR) will be subject to the current EU regulations applicable to GMOs. It is, however, possible that the EU Commission or some member states' 'competent authorities' may decide to propose revisions be made to the GMO Directive 2001/18/EC, for example, amendments to the Annex 1B list of techniques excluded from the Directive. In sum, many NBTs are assumed to now be subject to the GMO regulatory requirements, although some degree of uncertainty will continue as to whether the Commission or some 'competent authorities' in member states will request changes to the GMO directive.

Under this regulatory option, negative economic consequences relative to the current position are to be expected:

a) Decisions to grant approval for GM traits contained in crops and derivatives for importation and use (in the UK) will continue to be dictated by the EU regulatory and comitology procedures. Uncertainty relating to the timing of approvals will continue, causing trading difficulties for the user sectors of imported commodities and their derivatives (mainly in the animal feed and livestock production sectors, but also the food manufacturing sector). 'GM avoidance' trading policies will continue to operate (which focus on sourcing imports from countries where only GM traits approved for importation and use in the EU are grown or using feed ingredients derived from crops/derivatives where GM technology is not currently commercially used (such as wheat). These trading policies/practices have added, and continue to add, costs to the UK supply chain - the author is not aware of any publicly available estimate of this cost having been made, though operators in the supply chain have held a consistent view over the last 15 years that this has increased their costs;
b) The current low level of GM crop-related research and development is unlikely to change, with only limited income opportunities arising from the existing licencing UK-

developed research to businesses located outside the EU (as in the current licencing arrangement between the Sainsbury Laboratory and the Simplot Potato Company in the US). This reflects a continuation of the highly unfavourable environment for the research, development and commercialisation of the technology;

c) With the regulatory position of many NBTs assumed to be the same as for GMOs, there is likely to be:

- A further reduction in the current (relatively small) level of private and public sector commitment to/involvement in NBT crop-related research and development. Whilst, basic research and a limited number of confined trials (and possibly field trials) may occur, these are unlikely to move towards commercialisation because of the high cost of regulatory compliance relative to plant breeding innovations not subject to GMO-type regulations;
- The categorisation of NBTs as GMOs for regulatory purposes has the potential to cause significant (and new) trade disruption for the food, feed and livestock production sectors. In particular, if the main grain/oilseed crop producing countries (eg, US, Brazil, Argentina) and major importers (eg, China, Japan) decide these techniques do not merit GMO-style regulatory approval for cultivation, importation and use, the EU will have problems accessing imported food and feed ingredients if significant volumes are derived from crops using these techniques[16]. This has the (increasing) potential to create short term raw material shortages, together with possible higher prices/costs of production to the agri-food/feed supply chains (and consumers), and additional, longer term losses of competitiveness, jobs and value-added in the UK (and EU) agri-ingredient processing sectors;
- The categorisation of most NBTs as GMOs for regulatory purposes also has the potential to add to the loss of competitiveness for UK and EU agriculture. As indicated above, few businesses/organisations will be able to afford (or be prepared to incur) the high costs of meeting the (GMO) regulatory requirements in the EU, especially if other countries/regions do not follow the EU's regulatory approach for NBTs. With reduced plant genetics sector presence in the EU, and the focus of its NBT-related innovations likely to be on crop traits of benefit to farmers outside the EU, UK/EU farmers can be expected to miss out on access to both GMO and most NBT-derived new/improved crop varieties.

Overall, under regulatory scenario one additional negative economic consequences are to be expected.

[16] As it is virtually impossible to detect the use of some NBT if no new foreign DNA/protein has been transferred into a plant, enforcement of the GMO regulations in respect of preventing unapproved NBT traits entering the EU will prove difficult and likely necessitate a 'paper trail' approach (as applies in respect of the existing traceability requirements for some derivatives like oils derived from GM crops). Such systems are inherently prone to abuse. In addition, traders may try to avoid using crops/derivatives where the use of EU unapproved NBTs is widespread in order to minimise risks associated with import shipments being rejected. This course of action often results in higher cost raw materials being used because the GMO/NBT derived crops are typically cheaper to produce than the non-GM/NBT ones

3.2 Regulatory scenario two: improved implementation and some change - operating EU regulation of GMOs 'as originally intended' and not treating some NBTs 'as GMOs' for regulatory purposes

These regulatory arrangements for GMOs are assumed to maintain the objectives and processes of risk assessment inherent in the EU legislation but avoid the comitology failings acknowledged by the EU Commission and identified by the European Ombudsman. Specifically:

- UK approvals for GMOs for importation and use take place within the original 12 months' maximum timeframe originally intended in EU legislation, or as soon as EFSA risk assessment opinions have been made, rather than waiting for the formal EU regulatory approval process, inclusive of the time-consuming comitology procedures, to be completed (the entire process typically taking in excess of three years);
- The flexibility provisions relating to the scientific data requirements provided for in implementing Regulation 503/2013 are applied (where relevant)[17];
- UK regulation of crop biotechnology for planting would also, in principle, take place within the same maximum 12 months' timeframe originally intended in EU legislation, or as soon as EFSA risk assessments have been completed. However, the principles of Directive 2015/412 that allows member states to restrict or ban the cultivation of GM crop traits approved for planting in their territories for non-scientific reasons is assumed to apply in the UK, allowing Northern Ireland, Scotland and Wales to continue to use this opt out to ban the cultivation of any approved and commercially available GM crop.

In addition, UK regulation of NBTs diverges from the ECJ ruling that NBTs using mutagenesis techniques developed since 2001 are to be treated as GMOs for regulatory purposes in the EU. This scenario assumes that the UK permits some plant breeding innovations derived from NBTs (notably those that amend/alter plant DNA but do not add new DNA from other plants/species) are to be exempt from GMO regulations[18].

Under this option:

- With greater clarity on the timing and granting of approvals for importation and use, uncertainty will be reduced for traders and users of imported commodities and their derivatives. The application of the flexibility provisions relating to the scientific data requirements provided for in Regulation 503/2013 will also provide for both cost and time savings to the GMO approval process. These changes will offer greater flexibility and a wider choice of feed ingredients and may result in lower cost of raw materials to the livestock production sector. In turn, this may improve the competitiveness of the UK livestock production sector;
- The unfavourable environment for conducting research/development and commercialisation of GM crop technology will continue, with no significant change to the

[17] Currently these are not applied by EFSA

[18] In line with the decision of the Advisory Committee on Releases to the Environment (ACRE) of 2011, when providing an Opinion on an herbicide tolerant oilseed rape developed by Cibus LLC developed using cisgenics (classified as form of mutagenesis) and DEFRA's recent decision to permit the pilot trial of gene-edited camelina with high oleic acid content at Rothamsted, without subjecting it GMO regulatory procedures

current low level of GM crop-related research and development, concentrated in the public sector. No significant change to the level of income and employment generated by the sector is expected;

- With some types of NBT (eg, site directed nucleases like CRISPR) not being subject to GMO-style regulations in the UK, this is likely to create a more positive environment for the research and development of crops derived from these technologies. This is in contrast to the likely negative economic impacts that may arise under scenario one. Commitments to fund NBT-related research and development in crops suitable for growing in the UK are more likely from private sector plant genetics companies, together with increased interest in collaborative research and development with the UK public research community. New UK-based private sector investment in research expenditure and employment could be forthcoming, that may, in the longer-term lead to the commercial development of new crop traits for UK farmers and food processors. These may offer a range of benefits from improved agronomic performance, reduced cost of new seed and higher quality products such as altered grains and oilseeds (see appendix 1).

Overall, a commitment to make the existing regulations applicable to importation and use of GMOs operate 'as intended' plus divergence from the CJEU decision relating to the regulation of some NBTs, has the potential to deliver economic gains from a combination of improvement in the competitiveness of the agricultural commodity user sectors and from new plant genetics sector investment in NBT research and development. It also avoids the likely negative economic consequences of scenario one.

3.3 Regulatory scenario three: The UK sets its own path – diverging from EU GMO regulations

For the UK plant genetics sector these regulatory arrangements are assumed to mean:

- The UK authorities responsible for approval of GMOs (DEFRA and the FSA) set their own science-based regulations and guidelines in line with international norms (eg, in line with Canada or Australia). Approval for planting crops derived/containing GMOs and the importation and use of crops/derivatives derived from/containing GMOs are based on timely risk assessment advice/recommendations only and granted as soon as the scientific recommendations are made by the relevant competent UK authorities;
- As in scenario two, some plant breeding innovations derived from NBTs are not subject to GMO style regulations, provided there is no enhancement/addition of new DNA – as scenario two.

Under this option:

- As under scenario two, uncertainty will be reduced for traders and users of imported commodities and their derivatives. This will offer greater flexibility and a wider choice of feed ingredients and may result in lower cost of raw materials to the livestock production sector. In turn, this may lead to an improvement in the competitiveness of the UK livestock production sector;

- A move to GMO (and NBT) regulation based on international norms, where approval for planting is based on scientific risk assessment only and with no linkage to the EU approval process/decisions will represent a more favourable environment for the commercialisation of GM crop technology. Commitment to fund research and development of GM crops suitable for growing in the UK is more likely from private sector plant genetics companies, together with increased interest in collaborative research and development with the UK public research community. An indication of potential benefits that may accrue from these potential developments are provided in the GM crop case study example (blight resistant potatoes) presented in Appendix 1. This technology, if widely adopted, could lead to farm level economic benefits associated with higher yields and lower costs of production, supply chain and consumer benefits of better-quality potatoes, less wastage and reduced health risks (lower exposure to acrylamide in cooked potato products) and environmental gains from reduced fungicide application and carbon dioxide emission savings;
- As under regulatory scenario two, with some plant breeding innovations derived from NBTs not being subject to GMO-style regulations, this is likely to create a positive environment for the development of crops derived from these technologies. Commitment to fund NBT-related research and development of crops suitable for growing in the UK may be put in place by private sector plant genetics companies, together with increased interest in collaborative research and development with the UK public research community. New UK-based private sector investment in research expenditure and employment could be forthcoming, that may, in the longer-term lead to the commercial development of new crop traits for UK farmers and food processors. These may offer a range of benefits from improved agronomic performance, reduced cost of new seed and higher quality products such as altered grains and oilseeds (see appendix 1).

The potential long-term economic gains to the UK economy are likely to be highest under regulatory scenario three. With a regulatory environment favourable to both NBTs and GM techniques, this is likely to result in higher levels of UK-based plant genetics sector research expenditure and employment than under scenario two. It may also lead to the commercial development of more new crop traits based on NBTs or GMOs becoming available to UK farmers and food processors than under scenario two. These may offer a range of benefits from improved agronomic performance, reduced cost of new seed and higher quality products (see appendix 1).

3.4 Conclusions

In terms of the overall potential economic and wider societal impact of these three regulatory scenarios, scenario one is likely to deliver negative economic impacts (primarily due to the ECJ decision in respect of the regulation of NBTs derived from mutagenesis techniques), with scenarios two and three, providing for more plant genetics friendly regulatory environments, offering the potential for additional economic and wider societal gains. Scenario three is likely to offer the highest level of long-term benefit to the UK economy in terms of value-added, employment generation and contribution to improved competitiveness of the plant breeding, crop and livestock production and agri-product processing sectors.

Appendix 1: Technology examples/case studies

Case study: GM technology – late blight resistant potatoes

Technology

Developed at the Sainsbury Laboratory, this GM technology conveys resistance to late blight in potatoes and offers traits that improve potato quality in terms of reduced bruising and browning, lower acrylamide levels and lower levels of reducing sugars. Late blight is the major disease of potatoes in the UK and can significantly impair yields and even destroy entire crops.

Current status

Undergoing field trials in UK and licenced for commercial cultivation in the USA (Innate potatoes from Simplot).

Potential farm level economic impacts of commercial use in the UK

The potential economic impact at the farm level of the late blight resistant component of the technology is summarised in Table 5 below. This is based on the following:

- Yield impact: currently potato growers experience some degree of yield loss from blight damage, even if they systematically apply a regime of fungal treatments to their crops. This is because for complete control of blight timing of application is critical (and it is not always possible to get optimal timing of application) and fungicides are not necessarily 100% effective (eg, because of development of tolerance/resistance to them). A yield gain of +2.5% has been assumed, based on industry assessment that up to 5% of yield potential may be lost each year;
- Cost saving: the main cost saving is associated with reduced use of fungicides. Fungal treatments on potato farms in England (source: UK Pesticide Usage Survey2016) show that the average number of applications was about twelve, although some farms may make between fifteen and twenty applications per crop. It is assumed that a 60% saving on fungicide costs is likely to arise if this seed technology was used, allowing farmers to significantly reduce usage (targeted at non-blight fungal problems);
- Cost of technology: based on industry views, a seed premium of +£190/hectare has been assumed.

Overall, this suggests that, based on 2016/17 returns, use of the technology in England would likely lead to be a 6.3% increase in profitability (+£343/ha), arising from a combination of fungicide cost/application savings and higher yields.

Table 5: Possible farm level economic impact of GM fungal resistant (to late blight) potatoes in the UK: 2016/17 baseline

	Conventional	GM fungal resistant	Assumptions
Price (£/tonne)	180	180	
Yield (tonnes/ha)	41.8	42.84	**Existing crops are assumed to lose up to 5% of yield on average to late blight: a 2.5% yield gain has been assumed**
Sales revenue	7,524	7,711	**+£187 (+2.5%)**

Variable costs			
Seed	760	950	**Seed premium for technology estimated at £190/ha**
Fertiliser	379	379	
Crop protection	577	231	**Savings on fungicide cost (blight control) = 60% of total crop protection costs**
Other variable costs	404	404	
Total variable costs	2,120	1,964	**-£156 (-7.3%)**
Gross margin	**5,404**	**5,747**	**+343 (+6.3%)**

Source: conventional margin based on Cambridge University Farm Business Survey for East of England region 2016/17, advice on potential impact of GM fungal resistant potatoes, PG Economics (2007)

Potential economic benefits in aggregate (national level)

Building on the analysis presented above, the possible aggregated economic impact of using a GM blight resistant potato in the UK, will depend on the (assumed) adoption level. Adoption levels will be determined by such factors as the farm income benefit (initially perceived) obtained by farmers, which is mainly affected by yield effect and fungicide cost savings. It will also be influenced by the availability (or otherwise) of the trait in leading potato varieties. This latter point is of key importance, given the high cost of getting the desired traits into each tuber variety (this has to be undertaken individually for each variety in potatoes, as distinct from crops like cereals and oilseeds, where it is possible to relatively easily backcross a GM trait into numerous varieties).

The largest planted variety in the UK in 2017 was Maris Piper which accounted for about 14% of the total planted area (16,800 ha). Starting from this base, a range of possible adoption scenarios are presented in Table 6. These point to a significant level of aggregate farm level benefit equal between £2.88 million and £20.58 million being possible.

Table 6: Potential aggregate farm income impact from adoption of GM blight resistant potatoes (£ million)

Adoption scenario	Assumed area of adoption (ha)	Aggregate farm income gain
50% of Maris Piper area	8,400	2.88
100% of Maris Piper area	16,800	5.76
Maris Piper share of total plantings increases to 25% of total	30,000	10.29
Maris Piper area increases to 50% of total plantings or technology approved and commercialised in one or two other leading varieties that have a combined area = 50% of UK planting	60,000	20.58

The quality traits available in this GM potato (reduced bruising and browning, lower acrylamide levels and lower levels of reducing sugars) also offer important economic and consumer benefits. Reduced bruising and browning have the potential to deliver better quality potatoes and reduce waste throughout the supply chain of fresh potatoes from farm to end consumer. Exposure to acrylamide from cooked foods, including chips and crisps, represents a human health risk as it may be carcinogenic to humans. Guidance measures on how to reduce human exposure to acrylamide in cooked foods (eg, FDA (2013)) includes focusing on varieties of potatoes that are more resistant to cold-induced sweetening and lower levels of sugars or asparagine. GM low acrylamide potatoes, that deliver between 78% and 85% less acrylamide in chips (French fries) offer an important route to addressing the risk of exposure to acrylamide via the consumption of processed potato products.

Potential environmental impacts of commercial use in the UK

a) Environmental impacts associated with fungicide use

Significant environmental benefits associated with less fungicide use with GM blight resistant potatoes can be expected. The GM potato will allow farmers that currently apply fungicides (the most used active ingredients are cyazofamid, cymoxanil, fluazinam, mancozeb, propamocarb hydrochloride, fluopicolide and mandipropamid) targeted at late blight to stop using these fungicides. Based on the 2016 UK Pesticide Usage Survey, this will result in saving of about 7.63 kg of fungicide active ingredient use per ha and a field EIQ[19]/ha saving of 219.81units/ha. This represents a 67% reduction in the total amount of fungicide active ingredient used per hectare and a 69% reduction in the field EIQ/ha value associated with fungicide use on potatoes. The aggregate annual saving in fungicide active ingredient use will depend on the proportion of the crop adopting GM late blight resistant potato technology. If the technology was initially available in the leading variety Maris Paper and 50% of this crop, this would result in a saving of 128,250 kg of fungicide active ingredient (10% of the current total use) and a 10% reduction in the environmental impact associated with fungicide use on the potato crop. If in the longer term, varieties containing the GM trait ended up being planted on 50% of the total crop area, this would result in about a 35% reduction in total fungicide active ingredient used on potatoes (460,000 kg ai) and a 36% reduction in the environmental load associated with fungicide use on potatoes in the UK.

b) Environmental impacts associated reduced carbon dioxide emissions

These may arise from:

- Reduced fuel use associated with (less) fungicide application. Based on the quantity of energy/fuel required to apply fungicide being approximately 0.84 litres/ha (assuming use of a 50-foot boom sprayer: Lazarus, (2015), this means that each litre of tractor diesel consumed contributes an estimated 2.67 kg of carbon dioxide into the atmosphere, so 1 less application reduces carbon dioxide emissions by 2.24 kg/ha. If the use of GM fungal resistant potatoes results in an average of twelve less fungicide spray runs per ha, this potentially saves 26.88 kg of carbon dioxide per ha. At an adoption level equal to 50% of the current Maris Piper area, this aggregates to a saving of 225,792 kgs of carbon dioxide. If the adoption level rose to 50% of the total potato area (60,000 ha), the carbon dioxide saving would be 1.61 million kg of carbon dioxide, or the equivalent to taking 193 cars off the road each year;
- Reduced use (manufacture) of fungicides. Drawing on analysis by Audsley et al (2009), that estimated the energy use for fungicide manufacture used on potatoes to be equal to about 201 kg of carbon dioxide per ha, the potential saving at an adoption level equal to 50% of the current Maris Piper potato area would be equal to 1.69 million kgs carbon dioxide (equal to taking about 1,440 cars off the road for a year), rising to 12.06 million

[19] As measured by Cornell University's Environmental Impact Quotient (EIQ) indicator

kgs of carbon dioxide saving (equal to taking about 10,320 cars off the road for a year), if 50% of the UK potato crop used this technology.

Case study: New breeding techniques – Crispr technology

Example one: High oleic camelina
Under research and development at Rothamsted Research, gene-edited camelina oilseed offers a high oleic acid oil plant. Camelina is a high yielding oilseed crop, commonly grown in North America and parts of Eastern Europe for its edible oil. Researchers at Rothamsted have used gene-editing to alter the genetic code of this plant so that it has the capacity to make higher levels of oleic acid.

Current status
Field trials have recently been approved in the UK and are expected to start in 2018/19. At present, these are intended to be 'proof of concept' type trials and any potential commercial application is several years away. In this context, it should be noted that high oleic acid oilseed rape varieties are already commercially available in the UK and any new high oleic oilseed (in camelina or developed in a more widely grown crop like oilseed rape) would have to perform better than these varieties in terms of factors such as crop yield, oleic oil content and/or cost of production before there is a reasonable chance of such a seed innovation coming to the market. Part of the process of evaluation will also include the impact of using GE techniques on the time taken to bring a new (high oleic) oilseed to market. If the time taken to market is reduced via GE techniques, as is expected in the waxy corn example referred to above, this may prove commercially attractive to plant breeders/seed companies and may result in more choice of seed varieties to farmers, at potentially lower prices than are currently available.

Example two: waxy maize
Developed by DuPont Pioneer, this is likely to be one of the first commercially developed crop traits using a gene editing technique (to delete a target gene). The CRISPR technology offers a new and improved waxy maize variety. Waxy maize contains about 97% amylopectin, compared to 75% amylopectin and 25% amylase in the commonly grown dent maize. Waxy maize, with its very low amylase content, produces starches that have higher viscosity and less rigidity than starches derived from dent maize and are therefore valued for some food and industrial uses (eg, some desserts and adhesives). Traditionally waxy maize varieties have been developed using conventional plant breeding techniques and have typically had between a 3% and 10% yield penalty compared to average yields obtained from dent maize varieties. As a result, in order to encourage farmers to grow waxy maize varieties, starch manufacturers have had to pay price premia to offset this yield penalty, together with the additional costs involved in keeping this maize segregated on-farm, in storage and transportation to maize millers. Table 7 summarises the volume of maize affected and additional costs that the yield penalty associated with waxy maize varieties costs the US maize processing/starch sector, with the annual cost in a range of between $2.35 million to $52.2 million.

Table 7: Conventional waxy maize: yield penalty and price premium

	Yield (tonnes/ha)	Price ($/tonne)
Baseline for crop	10.52	146.0
3% to 10% yield drag	0.316 to 1.052	

Price premium required to offset yield drag		4.38 to 14.6
Volume of waxy maize (million tonnes)	0.536 to 3.577	
Extra cost to maize processing sector for securing product (million $)		2.35 to 52.2

Source: derived from USDA

Notes:

1. Yields and prices based on averages for the last three years USA
2. Area of waxy maize in the US: 1.7 million ha to 3.4 million ha
3. Additional cost to maize processing sector relates only to higher prices paid to farmers to offset yield drag. There would also be a need to pay an additional premium for segregation of the crop from dent maize on-farm and in transportation to a maize processing mill

Current status

Field trials in the US expected in 2019, with commercial launch in 2020.

Potential economic impacts of commercial use in the US

The potential economic impacts include the following:

- Yield impact: the yield penalty referred to in Table 7 of -3% to -10% would be eliminated;
- Cost saving: the starch sector would no longer have to pay farmers a price premium to compensate for the yield drag, resulting in an annual saving to the sector of between $2.35 million and $52 million. Whilst, some of this aggregate gain would be required to pay a seed premium to the technology developer for the new seed, based on typical pricing models for new seed, it is likely that between two-thirds and three-quarters of the aggregate gains referred to above, would be available to the processing sector, some of which are likely to be passed on down the supply chain in the form of lower prices for the relevant starch-based food ingredients and industrial raw materials;
- Cost saving to the plant breeder/seed companies. Currently, conventional breeding of waxy maize varieties takes approximately 2-3 years longer to bring a new variety to market than the time taken to develop a conventional dent maize variety. The CRISPR technology will reduce the time taken to bring new waxy maize varieties to market to a similar time taken for dent maize varieties. By shortening this time for new variety development, it reduces the cost of new variety development.