Title: Amendments to non-marketing standards for GMO plants **IA No:**	**Impact Assessment (IA)**
RPC Reference No:	**Date:** 25/10/2021
Lead department or agency: Department for Environment, Food and Rural Affairs	**Stage:** Options
Other departments or agencies: N/A	**Source of intervention:** Domestic
	Type of measure: Secondary legislation
	Contact for enquiries: Matthew Bardrick

Summary: Intervention and Options

RPC Opinion: Green

Cost of Preferred (or more likely) Option (in 2021 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
c. £1.2m	c. £1m	-c£0.1m	Non qualifying provision

What is the problem under consideration? Why is government action or intervention necessary?

The UK Government is committed to a regulatory regime which is proportionate to risk. The current Genetically Modified (GM) regulatory regime places disproportionate burdens on the companies conducting research into genetically modified (GM) plants, which are equivalent to those that could have been produced by traditional breeding methods.

There is some evidence that the GM regulatory system is blocking innovation in GE development in the UK, with very few GE plant products being trialled in the UK by a small number of research institutes (Rothamsted Research, the Sainsbury Laboratory and John Innes). Currently only 4.8% of world patents in CRISPR-related agriculture are held in the EU. This is driven by a European Court of Justice (CJEU) ruling that the definition of a Genetically Modified Organism (GMO) covers organisms produced by all forms of genetic technology, including those resulting from gene editing (GE) techniques that could also have been produced by traditional breeding methods.

What are the policy objectives of the action or intervention and the intended effects?

Removing regulatory burden for research and development trials involving those GE plants which could have been produced by traditional breeding methods will reduce the cost of trials. This will also send a signal that the UK Government wants to unleash the potential of these technologies and that this is the initial step of a wider reform programme. It will have a positive impact on investment to drive innovation and generate wider spill over benefits into the UK economy from this increased investment.

We have assessed this longlist of options against several critical success factors to develop our shortlist for appraisal:

- Intervention allows governance which is in proportion to current evidence of risks as based on the advice by ACRE without need for further technical assessment
- Intervention can be delivered in a timely manner which best capitalises on outcomes and maintains momentum for growth and innovation within the UK as an independent nation
- Intervention is sensitive to current consumer concerns without extensive need for further engagement (assessed during our stakeholder engagement sessions and consultation analysis)
- Societal benefit outweighs any cost
- Intervention does not challenge UK single market and devolved responsibilities.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

- Option 1 do nothing -Maintain the status quo

- Option 2 (preferred option)
  Remove current GM regulations for releasing qualifying plants (which could have been bred by traditional methods) for research and development not-marketing purposes (i.e., they will not get into the food chain without a full GMO authorisation) and replace with a light touch notification system.

- Option 3
  Remove current GM regulations for releasing qualifying plants (which could have been bred by traditional methods) for non-marketing purposes (and do not require light-touch notification)

- Alternatives to regulation

  It is not possible to achieve the outcomes using a non-regulatory approach. GM regulation is complex and interlinked across a range of legislation, both domestic and EU retained. It covers a wide range of technologies and products. It is necessary to amend this regulatory landscape but not remove it entirely to retain risk proportionality across the whole range of GM outcomes.

Will the policy be reviewed? It will be reviewed.will not

Is this measure likely to impact on international trade and investment?		NoNo		
Are any of these organisations in scope?	**Micro**Yes	**Small Y**Yes	**Med Y** Yes	**Large Y** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: Jo Churchill Date: 14/10/2021

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2020	PV Base Year 2021	Time Period Years: 10	Net Benefit (Present Value (PV)) (£m)		
			Low: £0.5m	**High:** £1.8m	**Best Estimate:** £1.1m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	10	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	£0.042124m		£0.00020625m	**£0.044m**

Description and scale of key monetised costs by 'main affected groups'

Defra and stakeholders do not foresee any significant costs to business. The policy intervention is deregulatory in nature and does not impose any new burdens on business intending to take qualifying GM plants to trial.

The main direct cost to business will be familiarisation costs for the amended regulations. Defra has conservatively estimated that all plant breeding firms in the UK (irrespective of whether they are engaged in GMO research for plant trials) will need to familiarise with the changes. There are approximately 65 plant breeders, and Defra have estimated this one-off cost to be £42,124 across the entire sector (based on anecdotal stakeholder feedback).

In addition, firms wishing to bring qualifying GM plants to field trial will need to submit a light touch notification to Defra. These costs are negligible as only an email notification will be required (around £206.25 per year) at a consistent rate of field trials yearly, as average current levels (two)).

Other key non-monetised costs by 'main affected groups'

N/A

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	10	Optional	**£0.5m**
High	Optional		Optional	**£1.8m**
Best Estimate				**£1.2m**

Description and scale of key monetised benefits by 'main affected groups'

Direct benefits to business.

Businesses will benefit from savings compared to the status quo from reduced regulatory burdens. For firms bringing qualifying GM plants to field trial these are due to the removal of requirements for trial applications, in-trial monitoring, post-trial monitoring, and security measures. These are permissive savings that are ongoing and proportionate to the level of field trial activity. Assuming a consistent rate of field trials yearly as average current levels (two) these equate to a benefit to business of a minimum NPV of £1m over 10 years.

Other key non-monetised benefits by 'main affected groups'

Increased R&D investment and associated spill overs

By reducing regulatory burdens for the qualifying GM trials, and by providing a signal to plant breeding firms that HMG intends to commit to a regulatory environment proportionate to risk, we intend this will unlock future private investment in the sector. This will result in an increase in research activities and field trials. Subsequently, this will create more jobs in GM R&D in the UK within plant breeding and further spill overs.

The resulting benefits are impossible to quantify at this stage and of course are not wholly attributable to this regulatory change alone. Therefore, they are not evaluated quantitatively here.

Key assumptions/sensitivities/risks	**Discount rate (%)**	3.5

- Key assumption- Level of GE field trial activity remain constant

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			**Score for Business Impact Target (qualifying provisions only) £m: N/A**
Costs: £0.0m	**Benefits: £0.1m**	**Net: -£**0.1m	The proposal is a non-qualifying regulatory provision (NQRP) with overall business impact less than the threshold. It therefore does not affect the BIT.

Evidence Base

Supporting evidence

1. The policy issue and rationale for Government intervention

The UK Government recognises the potential of new genetic technologies, including gene editing (GE) to help address future challenges in agriculture, and would like the UK to be a leader in developing possible applications of these technologies, building on the excellence of our scientific research base.

The current regulatory regime applies to all genetically modified organisms (GMO) which covers organisms developed using a range of techniques, including gene editing. This regulatory environment was clarified in a 2018 ruling by the Court of Justice of the European Union (CJEU[1]), which ruled that organisms produced by these techniques would be classified as GMOs.

The UK Government is committed to a regulatory regime which is proportionate to risk. Scientific advice is that the use of GM (Genetically Modified) plant breeding techniques which result in plants that could occur naturally and/or through traditional breeding results in no greater risk. However, as the current regime does not differentiate between different GMOs it places a disproportionate regulatory burden on the research of this subset of GM plants which could have been produced by traditional breeding methods. This deters research and the development of plant products made using these genetic technologies in the UK.

Both UK and EU innovation in this space has stalled under the current regulatory regime compared to world leaders; only 4.8% of world patents in CRISPR-related agriculture are held in the EU[2]. For example, Argentina, which began to regulate genetically edited organisms more proportionately to risk in 2015, have approved twenty-two new breeding technology (NBT) products between 2016-2019, most of which were plants[3]. In contrast, only one gene edited plant passed regulatory approval between 2017-2020 in the UK[4].

The current GMO legislation[5] requires that each GM organism is assessed and authorised on a case-by-case basis before it can be used in field trials. This involves a risk assessment, a public consultation, and the publication of details of when and where its research trial will take place which do not apply to plants bred traditionally. HMG would like to amend its regulation to be based on the

[1] Judgment of the Court (Grand Chamber) of 25 July 2018

[2] Frontiers | The Economics of Regulating New Plant Breeding Technologies - Implications for the Bioeconomy Illustrated by a Survey Among Dutch Plant Breeders | Plant Science (frontiersin.org)

[3] Frontiers | Gene Editing Regulation and Innovation Economics | Bioengineering and Biotechnology (frontiersin.org)

[4] Genome-edited plants in the field - ScienceDirect

[5] Genetically Modified Organisms (Deliberate Release) Regulations 2002 (legislation.gov.uk)

scientific advice[6] for the subset of GM plants, which could have been produced using traditional breeding techniques. Therefore, the regulatory approach applied to that subset should be more like the approach for traditionally bred organisms. Imposing burdens on their research and development compared to traditional breeding is inefficient and disproportionate.

We therefore seek to remove the need for researchers to submit a risk assessment and seek consent from the Secretary of State for the Environment before they can carry out a field trial (in England) involving GM plants that could have been produced by traditional breeding. This will enable our bioscience sector to further test the benefits and safety of the new products, without the burden of disproportionate regulatory requirements.

Assessing the risks of GMOs which could have been bred by traditional means

The Advisory Committee on Releases to the Environment (ACRE) has advised on the safety aspects associated with organisms produced by gene editing and other techniques which result in plant varieties that could have been produced by traditional breeding methods. ACRE's role is to provide statutory advice to ministers on the risks to human health and the environment from the release of GMOs.

ACRE's view is that an organism produced by gene editing (and similar techniques) would not pose a greater safety risk than a traditionally bred or naturally occurring version of that organism because of how it was produced. Therefore, where genetic alterations and combinations are of the type that are selected in traditional breeding, any associated health and environmental risks would be comparable. In this way, ACRE believes that the environmental release of these organisms should not be regulated in the same way as the environmental release of GMOs. The view is supported by the Royal Society

Rationale and evidence to justify the level of analysis used in the IA

The level of analysis in this assessment is proportionate to the potential costs to business which are minimal. The measures fall below the de-minimus threshold for an IA therefore it represents a non-qualifying regulatory provision (NQRP). However wider public and NGO interest in GMO regulation is high so Defra has developed an assessment of the impacts in accordance with this heightened policy environment.

[6] See box below "Assessing the risks of GMOs which could have been bred by traditional means"

2. Policy objectives and intended effects

Amending the legislation that applies to the release of GM plants for non-marketing purposes, which could have been produced by traditional breeding methods, intends to remove a disproportionate burden placed on research involving plants produced using these new breeding techniques. We seek to encourage research and development activity to further test the benefits and safety of the new products, without the burden of disproportionate regulation.

This is the first step in reforming the regulations that apply to organisms produced by genetic technologies such as gene editing. It will send a wider signal that HMG would like to create a regulatory environment in England that is proportionate to scientific risk and drives innovation.

Further, reducing regulation on R&D could lead to increased inward investment into the UK. Survey evidence7, asking plant breeding SMEs about investment decisions suggests that the 2018 CJEU ruling led to significant research and product development flight outside of the EU. This is to areas with less burdensome regulatory environments *(Jorasch, 2020*8*)*. Around 40% of the SMEs and 33% of large companies stopped or reduced their new breeding technique related R&D activities after the ECJ ruling[8]. These companies who have major markets outside of the EU moved the focus of their product development on new breeding techniques to markets outside the EU. Rebalancing regulatory burdens will increase inward investment.

In practice, this means removing the need for each field trial to be authorised in accordance with GM rules in England and the associated administrative costs this incurs both in seeking authorisation and in managing the trial site.

We expect this first step will give UK and international businesses the confidence and commercial appetite to invest in the near future. The paragraphs below describe, in detail, the current regulatory environment.

Current Regulatory Process for GM field trials (as part of GMO regulation)

Regulatory costs for a given GM field trial may differ from one trial to the next. However, through stakeholder engagement with plant breeders (Rothamsted Research, The Sainsbury Laboratory & John Innes Centre), we have derived illustrative estimates of the average costs or equivalent labour hours required to complete different stages of each plant trial. The paragraphs below set out in detail the regulatory processes, timelines and costs associated with engaging in qualifying GM trials under the current regulatory framework.

[7] Frontiers | Potential, Challenges, and Threats for the Application of New Breeding Techniques by the Private Plant Breeding Sector in the EU | Plant Science (frontiersin.org)

[8] Frontiers | Potential, Challenges, and Threats for the Application of New Breeding Techniques by the Private Plant Breeding Sector in the EU | Plant Science (frontiersin.org)

1) Submitting a trial application

- *Drafting application*

Labour hours are required to draft and complete an application. This labour requirement to complete a proposal, decreases with subsequent applications. Stakeholder engagement suggests that the labour days required to produce an application is between 10-14 days. This includes time for meetings with the GM Inspectorate (GMI) who are responsible for overseeing GM regulation.

- *Admin fee*

Researchers are obliged to pay an admin fee of £5,000 to Defra. This is an admin fee associated with processing an application.

- *Publication and Communications activities*

Subsequently, institutes looking to undertake trials are obliged to publicise their intent to go to trial, this may come in the form of publishing an advert in a national newspaper. Stakeholder engagement suggest that the monetary cost associated with advertising in a high-profile newspaper is between £3,000 - £5,000. This cost is subject to the given choice of newspaper, hence the figures provided represent the upper limit of the cost of publishing.

2) In-trial monitoring

Institutes are required to monitor their trials. This implies labour hours spent to monitor crops and attend meetings with GMI. The costs estimated by those contacted for labour commitments associated with this stage is approximately 6 working days.

3) Post-trial monitoring

This stage of the trial comprises crop disposal, meetings with the GMI and reporting. Taken together, estimates show that the associated labour days required for completion at this stage is between 3 – 8 days.

In addition to this, land used to grow GMO crops is left fallow along with further monitoring to ensure GM material does not enter the food chain, which can be given as stipulated conditions as part of post-trial monitoring. The opportunity cost of this will depend on field size, however, it represents a significant cost, as in some cases land must be left fallow for up to 2 years post-trial. Assuming the gross margin on the alternative use for that land (for

example wheat) as a worst case this could result in an opportunity cost of up to £1000/ Ha per year[9].

4) Site security

Lastly, because details of trial site locations must be published under GM rules, research institutes install fencing around field crops to protect them from vandalism. Depending on the size of the field, the associated cost of purchasing fencing and other security measures has been estimated to be between £30,000-£70,000 depending on whether they are taking place on new or existing sites.

3. Policy options considered, including alternatives to regulation

There are a range of potential interventions to deliver the policy objective to allow field trials for qualifying GM plants while ensuring that regulation is proportionate to risk.

Long list options:

- Status Quo – maintain current regulation.
- Change the definition of GMO to exclude GM materials which could have been produced by traditional breeding; *an entire overhaul of the definition of GMO, to exclude organisms that could have been generated by traditional breeding methods. Amending the definition would exclude these techniques from a burdensome regulatory framework all the way to commercialisation.*
- Change the definition of GMO to exclude plants which could have been produced by traditional breeding; *an overhaul of the definition of GMO, to exclude GE plants. Amending the definition would exclude plant products produced by these techniques from a burdensome regulatory framework all the way to commercialisation.*
- Remove current GM regulations for releasing qualifying plants (which could have been bred by traditional methods) for non-marketing purposes and replace with a light touch notification system
- Remove current GM regulations for releasing qualifying plants (which could have been bred by traditional methods) for non-marketing purposes (and do not require light-touch notification)

We have assessed this longlist of options against several critical success factors outlined below to develop our shortlist for appraisal:

[9] Wheat remains top of the crops in 2020 Gross Margins (AHDB)

- Intervention allows governance which is in proportion to current evidence of risks as based on the advice by ACRE without need for further technical assessment
- Intervention can be delivered in a timely manner which best capitalises on outcomes and maintains momentum for growth and innovation within the UK as an independent nation
- Intervention is sensitive to current consumer concerns without extensive need for further engagement (assessed during our stakeholder engagement sessions and consultation analysis)
- Societal benefit outweighs any cost
- Intervention does not challenge UK single market and devolved responsibilities

	Risk Proportionality	Timely deliverable	Meets consumer concern tests	Value for Money	Minimal Internal Market distortions
Status Quo	-	-	-	-	-
Change in definition to exclude all qualifying GM materials from GMO	X	X	X	Determined at appraisal	X
Change in definition to exclude qualifying GM plants from GMO	✓	X	✓	Determined at appraisal	X
Amend non marketing regulations for qualifying GM Plants (Light-touch notification)	✓	✓	✓	Determined at appraisal	✓
Amend non marketing regulations for qualifying GM Plants (No notification)	✓	✓	✓	Determined at appraisal	✓

Only those options which were judged to meet all the critical success factors were taken forward for value for monetary appraisal.

<u>Alternatives to regulation</u>

The regulation of Genetically Modified Organisms (GMOs) in the UK derives from a combination of the UK's international obligations under treaty, retained EU law, and domestic legislation[10]. It is necessary to work with and amend this legislation to achieve the policy objective; ensuring that for qualifying plants, business activities and responsibilities placed upon them are proportionate to the risks they pose at field trial stage.

Given the complexity of legislative frameworks for GMOs, an entirely non regulatory solution (i.e., achieving this outcome by repealing all relevant regulation) is not feasible and would not be sufficiently targeted to maintain proportionate safeguards for all GMO activities the regulations pertain to.

Therefore, we still need a regulatory solution, albeit more proportionate to risk and underpinned by the latest scientific developments.

Policy Options (Shortlist)

The narrative below sets out the policy options appraised.

Option 0: "do nothing"

Under the status quo, plants developed using GMO techniques which could have evolved naturally continue to fall under the definition of GMO and are subject to GMO regulation. The regulations in retained EU law relating to GMO remain in place. Companies, research institutes and consortia cannot engage in GM trials, without adhering to the existing regulations designed for GMO trials.

Option 1: Remove current GM regulations for releasing qualifying plants for non-marketing purposes and replace with a light touch notification system (preferred option):

This option would remove the requirements for carrying out a risk assessment and seeking consent from the SoS, *for non-marketing purposes of such plants*. This applies to plants developed by these technologies, that could have been produced by traditional breeding methods, being replaced with a mandatory but

[10] Environmental Protection Act 1990 (legislation.gov.uk)
Genetically Modified Organisms (Deliberate Release) Regulations 2002 (legislation.gov.uk)
Text of the Cartagena Protocol on Biosafety (cbd.int)
Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (legislation.gov.uk)

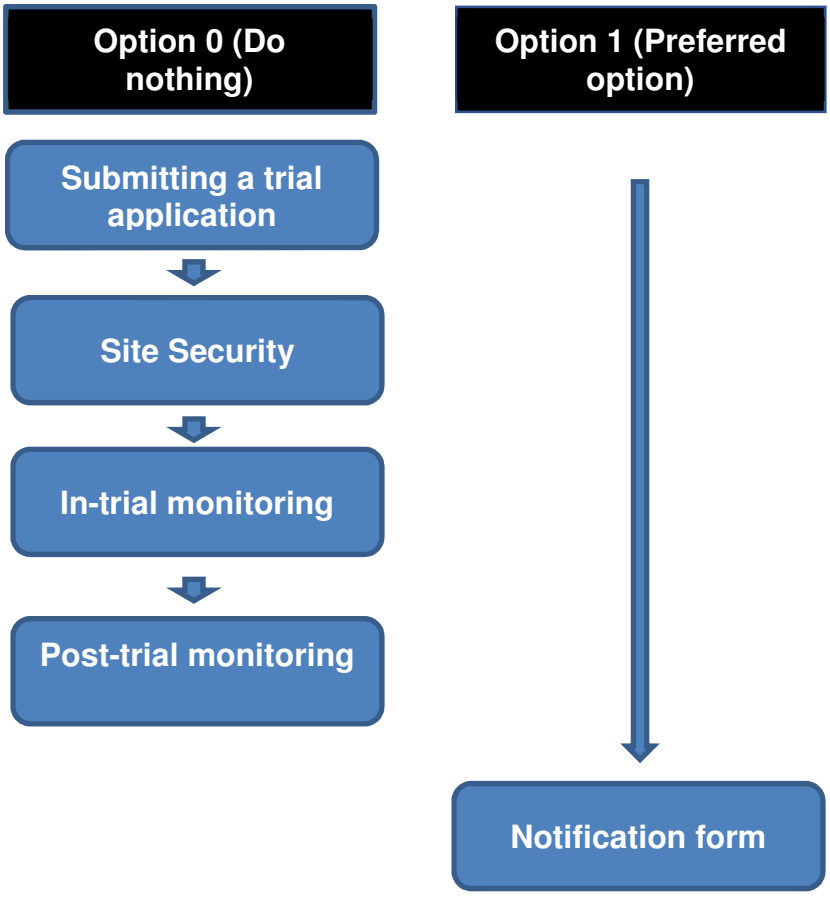
“light-touch” notification for the intent to carry out field trials, which would involve the following:

An individual or organisation intending to release certain types of genetically modified plant for any other purpose than placing on the market, should submit a ‘Notice of intent – GM crop release. Such a notice should be submitted to Defra before seed / other propagating plant material is placed into the ground for germination / onward growth. The notice of intent will comprise a pro-forma requesting the following information:

- name, address, telephone number and e-mail address (person responsible plus affiliation)
- species of plant being used
- trait being investigated and aim of the research project
- confirmation that the notifier has checked that the organisms to be released do not contain any extraneous genetic material
- expected start date and duration of the release

The pro-forma would be submitted to Defra by e-mail and/or web-based process. As there is no need for approval, Defra would acknowledge receipt of the notice and publish on a gov.uk web page / the public register.

Figure 1: Different options of regulatory process for releasing qualifying plants for non-marketing purposes



Recognising that these products have the same risk as the traditionally bred ones[11], this will reduce the regulatory burdens on releasing these plants for non-marketing purposes, instead driving R&D and attracting investment opportunities. Maintaining a light touch notification system will allow government to monitor the growth of the sector and evaluate the impact of the policy change with minimum burden to business or the exchequer.

Option 2: Remove regulation for qualifying GM Plants for field trials with no notification

Remove the requirements for risk assessments, consents, and notification prior to field trials for plant varieties developed via genetic technologies as above. Institutes looking to go to trial would *not* need to inform Defra.

This option would provide benefits of aligning regulatory burdens proportionate to risk as outlined above but would provide HMG no information on the location, and development in current trials.

4. Expected level of business impact

We present the impacts of our preferred option 1 "Remove current GM regulations for releasing qualifying plants for non-marketing purposes and replace with a light touch notification system" against a baseline of do nothing (option 0).

Costs and benefits of the preferred option - *Remove current GM regulations for releasing qualifying plants for non-marketing purposes and replace with a light touch notification system*

The monetised costs and benefits presented below are based on assumptions tested with stakeholders. These stakeholders were chosen as representatives of the relatively small number of operators directly affected by this regulatory change. We expect the impact to fall on UK plant breeders, both commercial and research institutes (not-for-profit organisations) who are currently undertaking GMO and GE field trials under burdensome regulatory conditions.

Costs to business - Direct Costs

We do not foresee any significant costs to business. The policy intervention is deregulatory in nature and does not impose any new burdens on businesses that intend to take qualifying GM plants to trial.

[11] As noted above, this is based on the scientific advice provided to the government by the Advisory Committee on Releases to the Environment (ACRE) and is supported by the Royal Society and the Food Standards Agency's Advisory Committee on Novel Foods and Processes (ACNFP).

Familiarisation costs for business

The main direct cost to business resulting from the reduction in regulatory burdens on qualifying GM plant field trials, are familiarisation costs. Companies with an interest in genetic editing and related technology will need to get acquainted with the new approach to regulating such field trials and disseminate this information across their organizations—a one-off cost. We do not foresee that firms will require additional staff training, nor updating of internal/IT systems to account for the newly created regulatory environment.[12]

Based on past assessments of the sector and internal Defra estimates, around 65 UK plant breeders may potentially incur these costs. This is likely to be an overestimate however, as many of these breeders will not be using non-traditional development techniques. Defra and stakholders have conservatively estimated each firm will require one individual—with professional legal qualifications—2 working days (*16 hours*), to distil how the new approach to regulating GM will affect them and communicate the implications this has for their business. At current mean wages (*£33.2*) for legal professionals[13], this represents £650 imposed on the average firm, and approximately £42,000 across the entire sector. The working calculations are provided below.

[Wage + non-wage cost[14]] x time taken x companies affected = sectoral impact of familiarisation costs

[33.2 + 0.22(33.2)] x 16 x 65 = £42,124 = £0.042124m

Light-touch notification cost

Research Institutes intending to take qualifying GM plants to trial, will be obliged to complete a one-page application form to inform Defra of their intent to do so. This means, that whilst Defra will no longer receive the £5,000 admin fee to cover the existing process, this new approach will mean HMG will only incur costs on processing 1-2 forms per year (based on the number of current GM trials). This minimal cost will be covered within existing Departmental resource.

The costs incurred by research institutes and companies will also be neglilgible too. This is because all information included in the notification (contact details, species details, research aim etc.) will already be held within research institutions so will require no additional systems or checks in place to generate or record these.

[12] This is supported by stakeholder consultation. Rothamsted Research, The Sainsbury Laboratory & John Innes Centre,

13 Annual Survey of Hours and Earnings (ASHE). Taken from "Table 14.5a "Hourly pay – Gross (£) – 2021" for "Legal professionals" – Occupation code 241. Legal profession assumed deemed most appropriate to comprehend and effectively communicate regulatory change.

[14] A 22% non-wage cost is added to the overall hourly wage costs, as per RPC guidance.

These costs will be recurring but permissive, that is, they will only be incurred if businesses choose to take qualifying plants to field trial. The calculation below assumes the level of activity remains at current levels. In the event of significant increases in research activity, the costs will increase marginally with the level of increasing activity. However, the total aggregated costs imposed on the sector will remain negligible over the long term. This is due to the current low number of GM trials (1-2 per year), and the relative simplicity of the new notification form (as set out above on p9). Defra and stakholders do not expect for this cost to be more than 1 working day (8 hours) of time (£14.1[15]), for a scientific administrator to complete and check the application[16] (based on anecdotal stakeholder information).

[Wage + non-wage cost[17]] x time taken x number of applications = sectoral impact of light touch notification costs

[14.1 + 0.22(14.1)] x 8 x 1.5 = £206.25 = £0.00020625m

Note that both assumptions around the time needed for familiarisation and the time necessary to send the light-touch notification form were gathered from stakeholders. Several proposed potential approaches for the legislative change were presented, and their response of a best estimate was used for the time it would take under each approach.

Also, note that any cost additions here are linked to associated savings from removing previous burdens discussed in the next section. Any increase in costs due to increasing activity will equally have associated benefit increases from avoiding current regulatory burdens. Businesses will only choose to increase activity levels if the net benefit of doing so is positive.

Direct benefits **to business**

In comparison to the status quo, the preferred policy option would remove direct and indirect *regulatory costs*, including *labour commitments* for developers seeking to engage in GM trials for plants. Companies or Research Institutes seeking to perform such trials will no longer bear the following categories of regulatory costs:

- Trial application, including the admin fee for processing, labour to develop the application and cost of required marketing and communications activity.
- In-trial monitoring
- Post-trial monitoring

[15] Annual Survey of Hours and Earnings (ASHE). Taken from "Table 14.5a "Hourly pay – Gross (£) – 2021 – for "Administrative occupations" – Occupation code 41. Administrative occupation chosen as most representative of the scientific administrator completing the notification form.

[16] Based on anecdotal stakeholder information.

[17] A 22% non-wage cost is added to the overall hourly wage costs, as per RPC guidance.

- Security measures (as trial location will be no longer made public)[18]

Researchers would only need to inform Defra of their intention of going to trial. Removing the regulatory stages, would significantly reduce the costs of engaging in qualifying GM trials compared to the status quo.

The regulatory costs of GM field experiments differ from trial to trial. This is due to several factors such as field size, meetings with GM Inspectorate and field security commitments. Through Defra's engagement with wider stakeholders, and plant breeders, we estimate that average regulatory costs of qualifying GM plant trials are between £54,000 – £107,000 (low and high estimates provided by research institutes). We have presented these as a high and low-cost scenario.

Table 1: Sensitivities for field trial regulatory cost assumptions, and respective NPV Benefit (based on stakeholder engagement).

	Assumed Regulatory cost per trial	
Avoided Cost	Low-cost scenario (£)	High-cost scenario (£)
Trial application	*15,500*	*20,500*
In trial monitoring	*4,500*	*7,000*
Post-trial monitoring	*2,250*	*6,000*
Fallow land	*2,000*	*3,000*
Security	*30,000*	*70,000*
TOTAL benefit per trial	*c.54,250*	*c.106,500*
*Ten-year benefit (net present value)	*0.5m*	*0.9m*

*See annex for detail

We assume that under the status-quo, the current level of two field trials yearly, will be maintained thereafter, until appraisal end. For a 10-year appraisal period, if this trend were to continue, the result of incurred costs savings for plant developers, no longer having to adhere to regulatory stages, would have a present value of £0.9m in the low-estimate scenario and £1.8m in the high estimate scenario (see Annex).

The above estimates in Table 1, are based on a fixed level of qualifying GM trials (two yearly) over the next 10 years[19] this reflects the current historic level of activity. If we were to assume an upward trend in qualifying GM field trials, under the status quo scenario, this could result in significantly higher business

[18] Through consultation with stakeholders, we have confirmed that businesses will no longer expect to face all costs mentioned above.

[19] The costs to develop these crops are subject to commercial sensitivities, but anecdotal evidence and some studies suggest the development of GE crops to trial implementation for example are just over $10m and takes 6 years. In both the high and low case scenario therefore the removal of the proposed regulatory costs is unlikely to be a significant factor to increase the number of trials (representing only 0.7-1.4% of these research and development costs).

benefits as they are directly proportionate to this activity. Businesses will only choose to increase their activity if it is beneficial for them.

Indirect benefits

Increased R&D investment and associated spill overs

Typically, at the aggregate sector level, previous estimates suggest that the UK Plant breeding sector spends 20% of annual turnover (*Jorasch, 2020*[20]*)* on R&D activities. Estimates suggest that this represents £30-40 million per annum at the sector level. The number of researchers employed in this R&D is approximately 400 (*Barnes, 2016*[21]*).*

By reducing regulatory burdens for the qualifying GM trials, and by providing a signal to plant breeding firms that HMG intends to commit to a regulatory environment proportionate to risk, we expect this to unlock future private investment in the sector. This will result in an increase in research activities and field trials. Subsequently, this will create more jobs in GM R&D in the UK within plant breeding and further spill overs.

The objective of the policy is to foster expansion of this important and highly innovative sector to deliver economic growth and high-quality jobs, with benefits to consumers and the environment. The resulting benefits are impossible to quantify at this stage and of course are not wholly attributable to this regulatory change alone. Therefore, they are not evaluated quantitatively here.

Assessment of Costs and Benefits of Option 2 (*Remove regulation for qualifying GM field trials Plants only with no notification*)

This policy intervention would remove all regulatory stages for qualifying GM field trials for plants only. In addition, institutes intending to go to trial would not need to notify Defra. This approach is the least onerous of the policy options, hence would involve a marginally greater saving in costs to business, as researchers would not need to notify Defra, of their intent of going to trial whatsoever.

Nonetheless, this option would still impose the same level of refamiliarization costs on the wider sector, as the preferred option. Additionally, Defra would have no knowledge of concurrent qualifying GM trials and would not gather any information on progress in the sector. To evaluate the policy, Defra would incur additional post implementation monitoring costs to the exchequer which it is

[20] Frontiers | Potential, Challenges, and Threats for the Application of New Breeding Techniques by the Private Plant Breeding Sector in the EU | Plant Science (frontiersin.org)

[21] The UK Plant Breeding Sector and Innovation (publishing.service.gov.uk)

reasonable to assume would be higher than the negligible cost to business for light touch notification. This would also be viewed negatively by the public and NGOs as this would leave qualifying GM developments without any form of government oversight, something that was noted by some respondents to the Gene Editing Consultation earlier this year[22].

Small businesses Impact

Drawing on previous analysis of domestic plant breeding (*Barnes et. al., 2016)*, firms operating in this area in the UK range from micro to medium sized business. Given the relatively small financial burden associated with the current regulations, any savings would disproportionately benefit the smallest companies in the market, as these costs will represent a much higher proportion of overall business costs. Hence it is clear that savings in regulatory costs will predominantly benefit Small and Micro Businesses (SMBs).

A summary of the potential trade implications of measure

The measure only amends the regulatory requirements for non-marketing purposes and not for organisms entering the food and feed supply chain. We, therefore, do not expect this measure to have any direct impact on trade.

However, as this is only the first step in HMG's commitment to a regulatory environment proportionate to risk, we might expect this signal to lead to increased pre-emptive investment in UK GE product development. This could lead to tangible private market gains once, as is the intention, the UK has amended GMO regulatory requirements for marketing purposes in future. This will likely, have direct tangible impacts on trade and we will provide a full Regulatory Impact Assessment for this primary legislation at the time which will cover these impacts.

Monitoring and evaluation

This is a deregulatory measure, which removes burdens on businesses. Through the light touch notification process component of our preferred policy option, we will monitor the impact of the measure on activity in the sector. The Government is also currently developing policy on wider reforms in the sector. Through this process we will continue an open dialogue with key stakeholders and the public and continue to develop key insights into the GE market. Irrespective of the path of these reforms will continue to stay in contact with stakeholders in case there are any unintended consequences.

[22] The regulation of genetic technologies - Defra - Citizen Space

Annex

Calculations for Cost savings under new regulatory system

Figure 1: GE trial scenarios over 10 period.

	0	1	2	3	4	5	6	7	8	9
No. GE trials: low	1	1	1	1	1	1	1	1	1	1
No. GE trials: high	2	2	2	2	2	2	2	2	2	2

Tables 1 and 2: provide the present value of projected cost savings in regulatory costs, over 10 year (high and low-cost estimate based on stakeholder intelligence).

Table 1- Cost Savings for in the low-cost scenario

Appraisal year	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**PV Total**
Low (single trial)	£54,250	£54,250	£54,250	£54,250	£54,250	£54,250	£54,250	£54,250	£54,250	£54,250	£466,967
High (Two trials)	£108,500	£108,500	£108,500	£108,500	£108,500	£108,500	£108,500	£108,500	£108,500	£108,500	£933,934

Table 2- Cost Savings in the high-cost scenario

Appraisal year	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**PV Total**
Low (single trial)	£106,500	£106,500	£106,500	£106,500	£106,500	£106,500	£106,500	£106,500	£106,500	£106,500	£916718.60
High (Two trials)	£213,000	£213,000	£213,000	£213,000	£213,000	£213,000	£213,000	£213,000	£213,000	£213,000	£1,833,437.20