The Genetic Technologies (Precision Breeding Techniques) Bill

Lead department	Department for Environment, Food and Rural Affairs
Summary of proposal	The Government proposes to introduce legislation to enable the regulatory requirements for genetically modified organism (GMO) plants to reflect the level of associated risk. The proposal would reform existing regulation of genetic technologies, through introducing a new category of organisms (in England only) and put further provisions in place to create a more proportionate risk-based regulatory environment.
Submission type	Impact assessment (IA) – 11 March 2022
Legislation type	Primary legislation
Implementation date	2023
Policy stage	Final
RPC reference	RPC-DEFRA-5170(1)
Opinion type	Formal
Date of issue	16 June 2022

RPC opinion

Rating[1]	**RPC opinion**
Not fit for purpose	The Department has sufficiently addressed the concerns raised by the RPC in its initial review notice. However, the policy as described in the revised IA, now presents as a change of policy from what was discussed previously, and which does not sufficiently consider the potential additional impacts of creating a new category, to allow validation by the RPC. Therefore, the RPC is unable to certify that the IA is fit for purpose.

[1] The RPC opinion rating is based only on the robustness of the EANDCB and quality of the SaMBA, as set out in the Better Regulation Framework. RPC ratings are fit for purpose or not fit for purpose.

Business impact target assessment

	Department assessment	RPC validated
Classification	Qualifying regulatory provision	Qualifying regulatory provision
Equivalent annual net direct cost to business (EANDCB)	£0.05 million (initial IA estimate) £-10.3 million (final IA estimate)	Unable to validate
Business impact target (BIT) score	£-51.5 million	
Business net present value	£89.03 million	
Overall net present value	£89.03 million	

RPC summary

Category	Quality[2]	RPC comments
EANDCB	**Red**	The IA establishes the current level of industry activity and the process for bringing a GMO product to market. It identifies a range of impacts, of both primary and secondary legislation proposals, including an EANDCB for the revised impact arising due to the primary legislation. As a result of the further clarification of the policy with the Department, the IA has not adequately considered and discussed the full range of potential impacts arising from the creation of a new category.
Small and micro business assessment (SaMBA)	**Red**	The IA notes that the current regulation has a disproportionate impact on SMBs and, as a result, SMBs would gain more than larger businesses from its removal. However, as with the identification of the impacts in general, the Department has not sufficiently considered and discussed the full range of impacts upon SMBs. Furthermore, the IA would benefit from discussing what actions could be taken to support SMBs that may enter the new market.
Rationale and options	**Weak**	The IA cites that the current regulation is not proportionate to the level of risk linked to the products. However, the IA needs to explain more clearly how the introduction of a new category will not undermine the policy intention of reduced regulatory burden. The IA establishes why a non-regulatory option is not feasible. In addition, the IA needs to include greater discussion of the impacts arising from labelling and traceability, to distinguish better the two regulatory options considered.
Cost-benefit analysis	**Weak**	The calculations in the IA, utilises evidence gathered from stakeholders. The methodological approach, for the impacts that are considered, is now sufficiently clear. The IA needs to be improved by revisiting the assumption relating to the devolved administrations (DAs) and what impact this will have on the number of trials across the various scenarios.
Wider impacts	**Weak**	The IA includes discussion across a range of wider impacts, including trade, investment, innovation and environmental. It needs to be strengthened through incorporating some of the narrative included in the wider impacts section into the main

[2] The RPC quality ratings are used to indicate the quality and robustness of the evidence used to support different analytical areas. Please find the definitions of the RPC quality ratings here.

		section of the IA, as well as including a detailed assessment of the competition, innovation, consumer and environmental impacts.
Monitoring and evaluation plan	**Good**	While the Department does not make a formal review commitment, there is a clear M&E plan in place. The IA discusses both process and impact evaluations and the Department has a clear understanding of what will be used to determine if the policy is working effectively and successfully.

Response to initial review

As originally submitted, the IA was not fit for purpose, due to insufficient consideration of the likely impacts arising from expected, related secondary legislation; failing to support some assumptions in the cost-benefit analysis (CBA) with appropriate evidence; and including insufficient detail of how supporting evidence was used to estimate costs.

The Department has now reframed its position on the expected secondary legislation, providing clarity of the current sector and discusses how the policy is expected to unlock future potential of a nascent sector. In addition, the IA now provides an acceptable justification for the key assumptions made and includes greater clarity on the evidence that supports the calculations in the IA, that were highlighted in the initial review.

In addition to the changes made in response to the initial review, in the revised IA, the Department has revised the preferred policy option, from what was seen previously by the RPC. The collective alterations, both in response to the points made by the RPC in the initial review and a shift in the Department's expectation of what the best estimate position[3], have resulted in the EANDCB reducing from £0.04 million to £-10.3 million. Therefore, the policy is now presented as having a net benefit to business, after previously representing a small net cost.

However, as discussed in the summary of this opinion, while the Department has adequately addressed the issues that were raised in the initial review, due to further clarification provided by the Department in relation to the intent of the policy, the RPC has now identified further areas of concern, which has led to the determination of the IA not being fit for purpose. As such, the RPC is unable to validate the EANDCB on the basis of insufficient evidence of the expected impacts.

Summary of proposal

The Government proposes to reform the existing regulation of genetic technologies for plants, as well as revise the current definition of what is classified as GMO. These proposals would apply in England only. They would also put in place further provisions to create a more proportionate risk-based regulatory environment. The IA sets out three options:

[3] The EANDCB presented for validation at this time, is equivalent to the high scenario from the Department's initial submission. This change in position has been sufficiently clarified and explained by the Department.

- Option 1 - the do-nothing baseline, where the current regulatory requirements are retained.
- Option 3a - the preferred option, where there would be the creation of a new category of organisms, known as Precision Bred Organisms (PBOs), for which current GMO requirements would be removed, then replaced with requirements proportionate to the level of risk.
- Option 4 - which in addition to the actions of the preferred option 3a, would introduce labelling requirements for certain PBO products.

The IA identifies the expected costs arising from the introduction of the proposed primary legislation to be the familiarisation costs for businesses in the affected sector, the costs to business of completing a newly introduced Advisory Committee on Releases to the Environment (ACRE) notification form, the cost to government of setting up a new notification system, and the costs to government of processing incoming notifications. Meanwhile, the benefits are discussed as being the retention of costs, which, otherwise, would have occurred under the current requirements for GMOs, as well as the wider societal benefits (un-monetised) from the future adoption of genome editing (GE) technology.

EANDCB

Identification of impact(s)

The IA includes an assessment of the full expected impact of these measures, in line with scenario 2 of the RPC guidance[4] on primary legislation IAs.

In the revised IA, submitted in response to the initial review notice (IRN) issued by the RPC, the preferred policy option now clarifies that there will be the creation of a new category of organisms. The Department has not sufficiently considered and discussed what additional impacts may arise as a result of the creation of a new category. The creation of the PBO category would mean that businesses, research firms and other interested parties, would have three distinct classifications to be aware of and use, as opposed to simply two (i.e. GMO and non-GMO) as is currently the case.

This will add further complexity to the market and potentially lead further costs, such as additional transitional costs to establish new systems, as well as those for new processes to handle this new category. While the RPC may accept that businesses (and other key affected stakeholders), would not face any further impacts due to the introduction of this new category, the Department does not sufficiently consider what areas of impact there may be and subsequently discuss whether they would exist, or why business would not face them. In particular the IA needs to have considered whether:

- this will create potential burdens and risks for businesses, and farmers, in cases where an organism turns out not to qualify for this new category or, leads to adverse effects that could be said not to be plausible from traditionally bred organisms;

[4] https://www.gov.uk/government/publications/rpc-case-histories-primary-legislation-ias-august-2019

- activities for organisms and businesses in the new category are the same as those in the 'traditional' or unregulated category; and
- the category does not create new markets, where different organisations have significant power, or where existing organisations gain or lose significant market power.

In addition, the IA should have considered the potential 'retention of costs which the IA assumes will be removed (such as current labelling and traceability costs), that affected firms already face and for which they already have systems in place to undertake. Those firms who may wish to distinguish themselves from competitors, and seek to display best-practice, may choose to continue to undertake some of these processes even if not required by regulations.

Counterfactual/baseline

The IA clearly establishes the current regulatory requirements for GMO plant products and the associated costs of bringing products to the market, noting that the GMO market for animals does not yet exist, due to the regulatory barriers in place. The IA, in its discussion of the likely impacts of secondary legislation, would benefit from considering whether the move towards the creation of PBO plants, may kick-start the growth of similar research in animals.

Un-monetised impacts

The traceability and labelling costs, the primary benefit for the preferred option and which differentiates the two regulatory options considered, is not quantified. As this is the main difference between the two regulatory options, the Department needs to provide some quantification of the scale of the potential impact from this change.

SaMBA

The IA highlights that SMBs account for around 42 per cent of plant breeders in the UK. As the policy is deregulatory in nature, it argues that the current regulatory requirements have a disproportionate impact on SMBs and, therefore, SMBs stand to gain more from their removal than their larger counterparts. It also discusses the potential disproportionate costs that SMBs would face as a result of the proposed changes. However, as with the identification and discussion of impacts more generally, the IA does not adequately address the impacts arising as a result of the creation of a new category for SMBs. The IA needs to discuss whether SMBs will face additional impacts, and if this is the case, whether they are disproportionate and whether

While an SMB exemption for this policy would not make sense due to its deregulatory nature, the IA would still benefit from considering what mitigating actions could be taken to support SMBs in this new and evolving market, particularly as there may be some transitional costs that limit their ability to take advantage of the new reduced regulatory framework.

Rationale and options

Rationale

The IA make the case that the current regulatory framework is not proportionate to the risk posed by the organisms, that will be allowed to be designated PBOs. The Department, in their discussion of the relative risks state that "*The current regime focusses entirely on the process behind how a product was made. This places a disproportionate regulatory burden on research and marketing of organisms produced by genetic technologies where the end-product could have been produced by traditional breeding methods, and therefore has the same associated risks*". If this statement is accepted, then it would seem to undermine the case for a third category. The Department needs to clearly illustrate how creating a new third classification for organisms, does not undermine the intended reduction in regulatory burden that the policy wishes to achieve.

Furthermore, much of the evidence regarding risk discussed in the IA, is drawn from interested parties, or based on scientific trials, that do not replicate real-world conditions (including farmers' behaviour). Such a narrative could, in turn, impede research, development and evaluation of an important new technology. The Department should have considered independent evaluations of the safety and environmental impact of using CRISPR technology in agriculture and food. This could take the form of farm-scale studies of gene-edited crops, similar to those that DEFRA's predecessor Department carried out in the late 1990s on GM crops.

Options

The IA discusses the process used to develop and narrow down the list of options that have been considered. This includes establishing clearly why a non-regulatory option is not feasible and would not deliver the desired policy outcomes and objectives. Three options have been carried forward for consideration in the IA.

The primary difference between the preferred option and the other regulatory option considered in the IA, is the requirement for traceability and labelling. However, as this aspect is un-monetised (as noted above) it means that the two options presented for consideration share the same EANDCB and NPV figures respectively.

As this is the main difference between the two regulatory options, the IA needs to include greater discussion of this requirement to provide a clearer understanding of the difference between the impacts of the options. Furthermore, the IA notes that stakeholders have indicated a preference for option 4, and so, the IA should expand on why the preferred option is the most appropriate.

Cost-benefit analysis

Evidence and data

The Department has engaged with various stakeholders across the affected industry, to both shape the policy and to understand better the expected impacts of proposed legislation. The Department needs to include more detail of the findings from this engagement, in particular more detailed discussion of current industry practices, to enable the identification and consideration of the full range of impacts associated with the introduction of the new PBO category. The IA draws upon evidence from the engagement with industry and prior consultation to support the cost estimates included. Following initial review, the IA now provides sufficient clarity over the methodological approach taken for the calculations that have been included and what specific evidence has informed each calculation.

Assumptions, risk and uncertainty

The IA uses a range of assumptions, that are now given appropriate justification and are supported by evidence.

The IA notes that "*Whilst this legislative change will only take effect in England, the mutual recognition element of the United Kingdom Internal Market (UKIM) Act means that products entering the market in England would also be marketable in both Scotland and Wales. Thus, there would be no tangible barrier to PBOs entering the market across GB. However, in the unlikely event that this does become a barrier to market, we have captured the Net Present Value of such a scenario in our overall "low estimate" with 0 trials per year*." However, the Department needs to address whether this is an accurate assumption to be made and whether the Bill may create an internal market barrier, e.g., given that PBOs will still be able to be sold in the English market, it does not seem reasonable to treat this as '0 trials'.

The methods taken (and thus organisms produced) within scope of the policy, remain largely undefined, and the IA does not present a concrete definition of what is captured by this policy. The Department should consider the impacts to the policy, from the potential risk that due to the usage of the terms "*occurred naturally*" that more organisms could stake a claim to be PBOs than currently is expected.

Wider impacts

The IA addresses the likely EU position on gene-edited products, as well as considering the trade impact more widely, citing the potential export markets for UK-based producers. The IA includes a good discussion on the potential benefits to innovation and the environment, as part of its wider impacts section. The IA could be strengthened by incorporating these qualitative discussions into the main consideration of the impacts of the policy options in the IA.

Consumers
The Department presents the concerns that the public may have with gene edited products, as being driven by misinformation or worse, saying it intends to "(*S)end a signal to address the information asymmetries between public perception and true risk which is hindering development that could support the wider public good*". However, the IA should consider the relationship between public attitudes and public acceptance, with the former typically driving the latter. Consumer sentiment towards gene edited products has real cost implications, even if only as risk to the policy fully realising the benefits, that should be discussed further.

Innovation
The IA does include discussion of the innovation impacts and how the removal of these barriers should lead to the unlocking of the sectors potential. However, the introduction of the light-touch notification system, may lead to a shift in the direction of research and development (R&D), towards methods such as gene editing, over both traditional breeding (as they are seen to be slower and more costly) and other methods of GM.

Competition
The IA only briefly addresses the potential competition impacts, noting that domestics producers could face increased pressure from countries. However, the IA should develop its consideration of the competition impacts, in particular whether there are specific businesses/sectors which are better positioned to take advantage of the reduced regulatory barriers than other competitors.

Environmental
The IA briefly mentions organic farmers as having been involved during the consultation process, however the Department should have discussed whether there were any concerns raised about the potential for cross-pollination and if so, how these would be addressed.

Monitoring and evaluation plan

The Department has not included a review commitment for this policy. However, the IA describes how the new mandatory notification scheme will help support the Department's M&E plan.

The IA states the intent to conduct both a process and impact evaluation, to understand how the policy is being implemented and how successful it is in achieving its objectives, respectively. It provides detail of both types of evaluation and includes a theory of change, which the Department will use to shape the direction of its M&E. The IA also addresses how success of the policy will be determined, as well as touching upon the consideration of what might be done, if the policy is judged not to be working effectively.

The IA notes that the lack of uptake of new technologies, is a risk to assessing the impact. Given this risk, the dependence on the notification system for M&E, and the time lag due to long lead-times for R&D processes, the Department discusses how it will undertake interim stakeholder engagement to monitor progress.

Regulatory Policy Committee

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