Response ID ANON-HBYG-QUWG-E

Submitted to **The regulation of genetic technologies**
Submitted on **2021-03-12 12:34:00**

Introduction

1 Please provide your consent to participate in this consultation.

I consent to participate.

2 Would you like your response to remain confidential?

No

If you answered yes to this question, please give your reason.:

3 What is your name?

Full Name :
Miesbeth Knottenbelt

4 What is your email address?

Email:
miesbeth@nourishscotland.org.uk

5 Please tell us who you are responding as?

Non-governmental organisation - In an official capacity as the representative of a non-governmental organisation/ trade union/ other organisation.

About Your Business / Organisation

7 What is the name of your business/organisation?

Please state:
Nourish Scotland

8 Which of the following areas are you interested in? Please select all that apply.

Cultivation of crop plants, Breeding farmed animals, Human food, Animal feed, Human and veterinary medicines, Other sectors/activities

9 Where does your business/organisation operate? Please select all that apply.

Scotland

Please state:
Whilst our focus is Scotland, we maintain active relationships with UK organisations outside Scotland and internationally

Part 1: The regulation of GMOs which could have been developed using traditional breeding methods

10 Currently, organisms developed using genetic technologies such as GE are regulated as genetically modified organisms (GMOs) even if their genetic change(s) could have been produced through traditional breeding.Do you agree with this?

Yes – they should continue to be regulated as a GMO

Please explain your answer, providing specific evidence where appropriate. This may include suggestions for an alternative regulatory approach.:

Our overall position: Our response below is informed by a consultation with our membership which included scientists currently working with CRISPR techniques. Our general conclusions are unanimously that bioengineering is not in itself a bad thing to be avoided but that regulation around GMOs should be maintained because we know very little about safety risks and because previous introductions have shown significant negative impact in many ways, including destructive socio-economic effects.

Your question is misleading in that it states that genetic change(s) ‘could have been produced through traditional breeding’. This is an assumption that is unproven. We should not remove regulations and protections if the decision to do so is based on unproven theories.

Scientists confirm that science knows very little about GMOs behaviours and precise structures. They do know that gene-editing techniques produce errors and mutations (DNA damage) across the genome. This is why the results of bioengineering, especially gene-editing, are fundamentally different from naturally occurring genetic materials. This was confirmed by the European Court of Justice in 2018 and why we currently have process-based regulation in place.

Therefore our member scientists maintain strongly that process-based regulation is kept in place as an essential safety net that allows us to continue to monitor and track their introduction for safety.

11 Do organisms produced by GE or other genetic technologies pose a similar, lesser or greater risk of harm to human health or the environment compared with their traditionally bred counterparts as a result of how they were produced?

Greater

Please provide evidence to support your response including details of the genetic technology, the specific risks and why they do or do not differ. Please also state which applications/areas your answer relates to (for example: does it apply to the cultivation of crop plants, breeding of farmed animals, human food, animal feed, human and veterinary medicines, other applications/ areas). :

The scientists in our membership confirmed that a lab-based alteration to genetic material is 'genetic engineering' and results in 'GMOs', as recognised by the European Court of Justice in 2018. This is because the process of reproduction in a lab environment matters and is fundamentally different from a naturally occurring process, and by definition produces new genetic material. We ask: What new evidence allows this government to overrule the 2018 ECJ conclusions (around the need to maintain protective regulation) which were the result of a thorough review that took on board the most up to date science?

Traditional breeding has taken place over millennia, whereas genetic engineering, especially gene- editing, is a very recent intervention. GMOs pose a greater risk because we have no history to show what can happen.
Scientists know almost nothing about GMOs and ask very limited questions as part of their risk assessments in labs. Scientists working with these techniques conduct risk assessments that are entirely lab-based and ask only limited specific questions around 'risk to human health'.
This paper by IPES
http://www.ipes-food.org/_img/upload/files/Concentration_FullReport.pdf
raises further concerns about the narrowing scope of research and development in this area due to the increasing influence of concentrated private economic power on science. We cannot depend on science asking wider questions around risks.

When gene-editing is used to make new products, genetic materials are tweaked multiple times to achieve the desired effects. Every intervention introduces unintended effects, including off-target effects as the DNA repairs itself following a cut, which are a concern to scientists as they produce unpredictable effects often also on vital other functions in organisms. They do not test them against the effects of multiple interventions. They stated that we cannot therefore currently rely on scientists to pronounce these techniques safe without further wider risk assessments that ask much wider questions. This was also confirmed by the statement signed by a European network of scientists (ENSSER) in 2017 that maintained that strict regulation should be in place precisely because of their lack of knowledge around unintended errors.

The scientists in our membership also confirmed that they know very little about how new genetic material behaves in wider and different environments, e.g. after ingestion. There is evidence that mutations in crop plants can cause new toxins and allergens and can become a threat to people and planet (as animals ingest these and introduce them into their ecosystems). They must be assessed for these potential new risks.

Our scientists maintain therefore that a thorough assessment and public report of what it is that scientists know is essential before we make decisions about dropping protective regulations.

Monocultures, biodiversity and resilience: newly introduced GMOs disrupt the delicate balance of ecosystems and has destroyed regional biodiversity, diminishing natural resilience and causing often unintended damage to regional species. We have witnessed the introduction of GM seeds and breeds introducing monocultures and narrowing global and regional genetic variety. This in itself poses wider long-term risk, especially in the face of climate change. Preserving genetic variety is already a challenge we are facing
See IPBES Biodiversity loss reports here: https://www.ipbes.net/
Yet biodiversity is also understood to be key to our capacity to survive during times of unpredictable environmental change.
This paper by the FAO: http://www.fao.org/documents/card/en/c/ca3129en/
explores the worrying decline of the world's biodiversity for food and agriculture, linking this directly to the negative impact of powerful mega-companies and the concentration of power in the agri-food economy. It includes a discussion on genetic improving of cattle breeds, showing that there is evidence of these negative effects in all sectors.

Specific to animal GM:
Given how little we know about resulting GMOs, before deregulation is considered, we need to establish answers to questions about unintended negative effects on animals including the bringing about of pain and illness, and the increase and proliferation of dangerous zoonotic diseases.

Since our science does not fully understand the behaviour of GMOs in any particular area, the risks apply to genetic engineering in all areas, including cultivation of crop plants, breeding of farmed animals, human food, animal feed, human and veterinary medicines, other applications/ areas.

12 Are there any non-safety issues to consider (e.g. impacts on trade, consumer choice, intellectual property, regulatory, animal welfare or others), if organisms produced by GE or other genetic technologies, which could have been produced naturally or through traditional breeding methods, were not regulated as GMOs?

Yes

Please provide evidence to support your response and expand on what these non-safety issues are.:

Contamination into the currently growing market for organic produce is inevitable and deregulation will result in destroying this market as it disables possibilities around containment and tracing.

The introduction of unregulated GMOs is highly likely to negatively affect UK export markets to the EU as strict regulation will remain in place there. This will affect not only the market for GM products but the effects are likely to be on a much wider scale because of the lack of traceability and high risk of contamination across all produce in the case of regulation being lifted.

The introduction of GMOs into the English market will have the same negative impacts on Scotland and other devolved nations as they risk contamination around border areas and in any case, the devolved nations will not be able to stop the spread of unlabelled and unchecked GM foods under the Internal Market Act restrictions.

Establishment of further market monopolies: Bioengineering techniques are developed by large private companies for private gain. They rely on patents to maximise their profits and establish powerful monopolies that result in forcing farmers to buy their seed, forbidding them to save it, as they have always done traditionally. This is not only contrary to farmers' human rights, it has also resulted in widespread negative economic impact that has been widely documented.

It has also been shown that excessive regulation is not a main barrier for companies entering the gene-editing market.
https://www.euractiv.com/section/agriculture-food/news/gene-editing-regulation-not-the-biggest-hurdle-for-smes-in-eu-says-academic/
This argument, that is used widely in favour of de-regulation, has no grounds.

Ability to retain choice, as a fundamental human right: Deregulation removes customers', retailers' and farmers' ability to make choices about how they want to engage with GMs. Labelling laws are essential in that they fundamentally protect individuals' rights to decide on how they want to live with GMOs in their environment and this requires the development and implementation of effective coexistence rules.

Specific to animal GM:
Given how little we know about resulting GMOs there are deep ethical questions to be asked and red lines to be drawn. Even traditional breeding for profit gain has led to poor animal welfare concerns. GM increases potential for using animals purely as instruments for profit and gain, and will produce inevitable unintended negative effects on animals including their quality of life.

Furthermore, we do not believe that encouraging bioengineering by de-regulating this practice is the solution to the challenges the food system faces. On the contrary, the evidence shows that it is a distraction from the sustainability challenges we face and often exacerbates these challenges. There is much evidence to show that GM has not resulted in higher yields or profits for farmers, lower pesticide or fertiliser use, or lower seed prices. GM foods are not increasing our ability 'to feed the world'.

13 What criteria should be used to determine whether an organism produced by gene editing or another genetic technology, could have been produced by traditional breeding or not?

Please provide evidence to support your response.:

The government should not be downplaying the nature of gene-editing by using flawed comparisons with traditional breeding.

The evidence is that the general public generally does not want GM and remains at a minimum weary of the unknown risks involved.
https://www.gmfreeme.org/gmos-in-the-uk-where-are-we-now/
It is clear that with introducing new genetic material, we are stepping into making fundamental changes to our world which concerns all people and planet. The public needs to be brought on board with this.

As to what criteria should be used:
If anyone is going to be persuaded of the potential benefits of this new technology, this will need full engagement and transparency around what is known/remains unknown, trusted and full safety assessments of wider questions (and including assessments conducted outside lab environments), wide efforts into education around all the issues concerned, a large democratic and representative/inclusive consultation, and public reporting of government's next intended steps and mechanisms around these.
In preparation for this, science and social science need to be funded to develop their criteria and assessments, and a range of effective engagement and other suitable tools will need to be developed for engagement with the wider public. Before introduction, mechanisms for monitoring and keeping audit trails have to be developed, piloted and established.
This activity will also need to include discussion and engagement around values and wider ethical questions.

By comparison, rather than a hasty 10-week consultation, in Norway a panel is in the midst of an 18-month long review. This is an independent, broad and democratic assessment involving civil society, individuals representing a range of special interests and expertise and members of the public.
The process encompasses 5 'pillars': health, environment, ethics, sustainability and economics.

At the very least, a serious inquiry should be conducted UK-wide– not just in England - as the Internal Market Act renders devolution on this matter a red herring.

Part 2: Questions on broad reform of legislation governing organisms produced using genetic technologies

14 There are a number of existing, non-GM regulations that control the use of organisms and/or products derived from them. The GMO legislation applies additional controls when the organism or product has been developed using particular technologies.Do you think existing, non-GM legislation is sufficient to deal with all organisms irrespective of the way that they were produced or is additional legislation needed? Please indicate in the table whether, yes, the existing non-GMO legislation is sufficient, or no, existing non-GMO legislation is insufficient and additional governance measures (regulatory or non-regulatory) are needed.Please answer Y/N for each of the following sectors/activities:

Gov_Sufficiency - Yes (sufficient governance):

Gov_Sufficiency - No (insufficient governance):
Cultivation of crop plants, Breeding farmed animals, Human food, Animal feed, Human and veterinary medicines, Other sectors/activities

Please provide evidence to support your response.:

This question in particular is really only addressed to specialists and not fit-for-purpose in a consultation that is addressed to the general public.

We maintain that non-GM regulations cannot be sufficient for controlling the introduction of GM products including those resulting from gene-editing, as GM products have been fundamentally altered through lab intervention and are therefore different. Evidence tells us so, and therefore they require separate regulation and monitoring, across all sectors and activities.

The current legislation around GM products is generated by bodies that are not adequately independent, transparent nor consult with the wider public (e.g. the FSA is appointed by UK government Ministers).
They do not allow for systematic wider discussion or input of alternative views, nor consideration of non-technical and non-commercial justification for any decisions made.

15 Where you have answered no (existing, non-GMO legislation is insufficient to deal with organisms produced by genetic technologies), please describe what additional regulatory or non-regulatory measures you think are required to address this insufficiency, including any changes you think need to be made to existing non-GMO legislation. Please explain how any additional measures you identify should be triggered (for example: novelty, risk, other factors).

Please provide evidence to support your response.:

Since the public is in no position to decide on the technical aspects of this exercise, there should be a fit-for-purpose and thorough independent assessment followed by publicly scrutinised reports into the science and safety aspects.
There should also be an independent review of the social and ethical as well as the economic (including trade) aspects, conducted by specialists and with costings/modelling of different future scenarios for UK agriculture.
There should also be an independent review of the different regulatory frameworks, assessed for transparency, labelling and co-existence with other agricultural approaches.
There should be a wide range of public discussion events (both government, stakeholder and grassroots initiated and organised) that would be recorded and reported in a transparent manner.
The results of this kind or process could usefully lead to a Green Paper, in which the government sets out its proposals for the regulatory system, including all aspects (environment and food safety, market transparency and co-existence).

These assessments and processes should be standardised, and adapted and implemented at defined future instances where new developments in this technology and new scenarios of introductions emerge.