GM Freeze response to Defra Consultation on the Regulation of Genetic Technologies

Submitted by email to consultationreply@defra.gov.uk

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Section 1: About you

Our answers to the questions in this section of the consultation are as follows:

1. This response is not confidential and will be published at www.gmfreeze.org.
2. The author of this response is Liz O'Neill
3. You can contact us on liz@gmfreeze.org
4. This response is submitted on behalf of a non-governmental organisation
5. N/A
6. GM Freeze
7. GM Freeze is interested in the cultivation of crop plants, breeding farmed animals, human food, animal feed and other ways in which the use of genetic engineering may impact food and farming.
8. GM Freeze is a UK-wide organisation based in England.

GM Freeze is the UK umbrella campaign for a responsible, fair and sustainable food system, focused on concerns around the use of genetic engineering in food and farming. Our member organisations include large NGOs, scientists, farmers, retailers and grassroots campaign groups.

We are aware of many misconceptions around the role of single-issue campaigns and would like to stress that we exist because we are needed. GM Freeze member organisations and the thousands of individuals who support and follow our work, tell us that they find it difficult to follow issues around the use of genetic engineering in food and farming in detail. They ask us to keep up with the technical and political developments on their behalf and share what we learn in language that they can understand. We experience significant hostility from politicians, journalists and those working in various fields of genetic engineering, with our single-issue focus presented as a reason to discount and diminish our contribution to healthy debate. We trust that this attitude will not prevail in the analysis of responses to this consultation and look forward to ongoing respectful dialogue as a key stakeholder on this issue.

The conduct of this consultation is a matter of concern

This consultation is inadequate, and its purpose is ambiguous. The Secretary of State, George Eustice, and the department's Chief Scientific Adviser, Gideon Henderson, have been clear about their support for deregulation of gene editing techniques[1,2]. They have consistently given the impression in public appearances, media statements, briefings and meetings that key decisions have already been made. At the same time, when questioned about the evidence upon which these decisions have been built, they have declined to answer, suggesting that it is the responsibility of those responding to the consultation to consider matters such as what is meant by the phrase "could have been developed using traditional breeding methods".

If the Secretary of State wishes to use the UK's exit from the European Union to realise the Government's environmental[3] and animal welfare[4] ambitions, his department should be conducting a much more comprehensive process of enquiry and engagement that involves independent assessments of the scientific, economic, social, ethical and environmental impacts of different approaches to food and farming across the whole of the UK. Policy on potentially disruptive technologies should be developed with in-depth and properly supported input from citizens, stakeholders and civil society and this consultation falls far short of that standards. We offer more detail on two particular areas of concern below.

The consultation is confusing and misrepresents key issues
GM Freeze has received many enquiries from members of the public, including those employed in food and farming, who are confused by the phrasing and format of the questions. People are telling us that some of the questions feel like traps in which any answer they give will be used to justify what the government wants to do.

Promotion of gene editing focuses heavily on hypothetical, aspirational and early proof of concept applications of the technology that might be regarded as altruistic. There is a great deal of discussion about things that gene editing "could" or "might" do, but rarely even a mention of the first two commercialised uses of gene editing in agriculture – a herbicide tolerant oil seed rape[5] and a soya bean designed to produce frying oil for the fast-food industry[6]. This is not balanced and is likely to mislead people.

The consultation documents also present as fact a number of highly contested notions. For example, the need to increase productivity, when in fact we already produce more than enough food to feed the predicted peak world population[7] and a third of the world's food is lost or wasted[8]. Similarly, the idea that a permissive approach to gene editing will open up new markets rather than closing down key export routes and eliminating the GM-free and organic market premium.

Defra communications around the consultation have included the suggestion that regulation is the primary barrier to the extensive roll-out of gene editing in food and farming, but this is not the case. Gene editing techniques are subject to a comprehensive set of patents. The patent licensing landscape is complex[9] and, in the case of CRISPR, subject to a long running and global legal battle[10]. Intellectual property rights for these new techniques are relatively affordable for research and development purposes but escalate very sharply at the point of marketing or commercialisation. These costs and contractual complexities, alongside the low rate of translation from proof of concept to feasible real-world application, are a far greater barrier to commercialisation than the current regulatory landscape, especially for SMEs.

We have been particularly disappointed by the failure of Government ministers and advisors to challenge the misconception that gene editing is currently banned in the UK. Regulation is not a ban but a societal tool for managing risk and it is disingenuous for those holding high office to allow this key misconception to go unchallenged in the media and engagement events linked to this consultation.

The consultation has come at the wrong time

This consultation was launched seven days after the end of the Brexit transition period, at a time when food and farming businesses are adjusting to huge changes. It has run while we are in the depths of the biggest public health emergency for many generations and people across the country report that they have very limited capacity to engage with anything beyond their own and their family's immediate needs.

This consultation period has overlapped significantly with the consultation on Defra's Draft National Action Plan for Sustainable Use of Pesticides[11]. Citizens, organisations and businesses impacted by pesticides are often also concerned about genetic engineering, but few will have the capacity to engage fully with two complex technical consultations in the same time period.

A number of highly relevant explorative processes are ongoing. The Department for Business, Energy and Industrial Strategy's Better Regulation Executive are exploring alternative regulatory approaches to genetic technologies[12]. We understand that the Food Standards Agency are conducting research on public views around the use of genetic engineering in our food. The Nuffield Council on Bioethics are exploring the issue in depth[13] and are in the process of developing a structured public dialogue. It is difficult to understand why Defra has not waited for the conclusion of these processes and the publication of their findings before drawing up plans for a wholesale change.

Section 2 – Part 1: the regulation of GMOs which could have been developed using traditional breeding methods.

The framing of this part of the consultation is highly problematic because the phrase "could have been developed using traditional breeding methods" makes no scientific sense. The possibility that gene editing can produce organisms that are identical to those produced naturally or by traditional breeding is entirely theoretical.

As noted above, Defra does not appear to have an agreed position on what this designation means. In the introduction to the consultation[14] we are told that "This proposal does not apply to organisms which introduce genetic material from other species" but does this mean the intentional addition of genes sourced from another species (transgenesis) or all genetic engineering processes that employ genetic material originated outside the target organism (a far greater range of techniques). Indeed, some statements and materials suggest it could apply just to SDN-1 techniques but the Secretary of State's comments at the National Farmers Union conference[15] suggest that his interpretation includes all techniques short of intentional transgenesis. It seems extraordinary that Defra has launched a flagship policy of deregulation without any plan for how it will be applied.

Even if one accepts that a definition of "could have been developed using traditional breeding methods" will eventually emerge, there has been no clarity on whether Defra intends to remove all process-triggered regulation from the gene editing events covered (treating them as if they were traditional breeding methods with a history of safe use) or develop some alternative regulatory process. Ambiguity in this area means that it will be impossible to know what assumptions consultation respondents have made in expressing their support or objection to Defra's plans.

We are often told, by politicians and those working (and often owning patents) in the field, that regulation of genetic technologies should enable and support innovation, but regulation exists to protect society and innovation is not an end in itself. Even where there is an identified need for new ideas and new thinking, new technology is only one possible answer. The field of agroecology yields numerous inspiring projects and innovative ways of both working and sharing lessons learnt but it does not benefit from the kind of financial or political support that is being ploughed into genetic technologies.

Question 1: 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 we agree that all organisms developed using genetic technologies such as gene editing should be regulated as GMOs.

As noted above we have significant concerns about the phrasing of this question. However, we include the following points as evidence of why all uses of genetic engineering in food and farming should be properly regulated. In addition, we urge decision makers to consider the claims that are being made for gene editing. If it is as disruptive and powerful as we are told, that is reason enough to take care and regulate in ways that ensure that it is used safely, responsibly and transparently.

The European Court of Justice ruling that gene editing produces GMOs is valid and important
The proposal to deregulate some (undefined) forms of genetic engineering involves disapplying a 2018 ruling of the European Court of Justice (ECJ)[16]. The UK Government made its dissatisfaction with that ruling known at the time but public debate in the UK has significantly misrepresented the nature of the ruling, which followed an in-depth two-year analysis of a wide range of scientific evidence. What the ECJ said was that, legally and scientifically, all organisms obtained by mutagenesis are GMOs and must be regulated as such.

Discussion of the ECJ ruling often appears to rest on a feeling that effective regulation of gene editing is unfair. Comparisons are frequently made with the potential harms that could be wrought by chemical or radiation mutagenesis which is exempt from GM regulation on the basis that it has a history of safe use. Random mutagenesis techniques are outside the scope of GM Freeze's expertise, but we are struck by the importance of levelling up, rather than down. If current understanding of the impacts of random mutagenesis calls into question its regulatory status the appropriate response would be to review the regulation of these techniques, rather than to abandon public protections on gene editing.

Gene editing encompasses a wide range of processes and risks
Despite the misleading depictions of DNA microsurgery and over-simplistic metaphors like "genetic scissors", the term gene editing encompasses a vast array of complex molecular modification processes, each with significant capacity for error and unintended outcomes.

The most celebrated genetic engineering tool, CRISPR, is used to create a genetic injury by cutting an organism's DNA at a targeted location and activating the cell's own repair mechanism. With SDN-1 techniques, the organism is allowed to repair itself; with SDN-2 a template is provided to try and control how the DNA is repaired; with SDN-3 a template for repair is provided and genes from another organism (usually a completely different species) are inserted. Whichever techniques are used, the modified organism then undergoes cell culture and replication stages, just as with older GM techniques.

Each stage in the creation of a genetically engineered organism carries risks of both molecular errors (DNA changes that were not intended) and unexpected impacts (a desired change causing something other than, or in addition to, the desired effect). It does not matter how small the intended, or unintended, changes may be as even miniscule DNA errors can have profound impacts. In addition, a scientific review showed that gene editing can make changes in parts of the genome that would, with traditional breeding methods, be protected from mutations.[17]

Process-based regulation is the way in which Governments discharge their responsibility for public safety and environmental protection. The clamour for "trait based" or "product based" regulation requires us to take the genetic engineer's word for it that the only impacts of their lab work are those which were intended and reported. The replicable nature of DNA changes makes it simply unacceptable to allow those with a vested interest in product approval the authority to mark their own homework.

"Foreign DNA" plays a significant role in gene editing
Protest banners and newspaper headlines in the 1990s often featured slogans focused on the insertion of "foreign" genes but people's concerns about genetic engineering have always been much more nuanced and deeply understood than this might be assumed to imply. Nonetheless regulators have implied that the inclusion of DNA from another species is a matter of particular concern. It is, therefore, important to recognise that genetic material from a range of sources is used in gene editing processes and the uptake of trans genes does not only happen when intended.

A 2019 a study by the US Food and Drug Administration (FDA)[18] found that antibiotic resistance genes had been accidentally added to the DNA of gene-edited 'hornless' cattle. The FDA said that its findings "demonstrate that there is good reason for regulators to analyse data on intentional genomic alterations in animals to determine whether there are any unintended results, either on- or off-target and, if so, to determine whether they present any cause for regulatory concern."[19]

Question 2: 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?

Organisms created by all forms of genetic engineering pose a **GREATER** risk of harm to human health or the environment, compared with their traditionally bred counterparts as a result of how they were produced. This is because they have no history of safe use, they are prone to unintended effects and they are likely to be used in ways that will cause harm.

Gene editing has no history of safe use

Traditional breeding is generally accepted to have a history of safe use stretching back millennia. In stark contrast, genetic engineering (and especially gene editing) is so new that we are only just beginning to understand its potential consequences.

Releasing genetically novel organisms into the environment disrupts the delicate balance of nature and risks a range of unpredictable harms. The ambitious claims made for gene editing's potential suggest that these techniques are particularly disruptive. Altered genes can spread to wild relatives, changing the natural ecosystem in ways that are very difficult to predict, control or repair. Therefore, even where the intention of those developing new crops or animals is altruistic, risk assessments, post-release monitoring and full traceability are the minimum requirements to protect society and the ecosystem from potentially disastrous unexpected outcomes. With an ecological crisis enfolding we should be taking more care, not rushing to adopt technofixes without proper safeguards.

In 2017 a statement published by the European Network of Scientists for Social and Environmental Responsibility (ENSSER) was signed by scientists throughout the world[20]. It recommended that, because of our lack of knowledge and the possibility of unintended errors, the products of new genetic modification techniques should be strictly regulated as GMOs.

It is, at best, premature to consider relaxing genetic engineering safeguards that were created to protect people, animals and the environment.

Unintended effects are a key concern

Claims that gene editing only produces small or very few changes in the genome ignore the reality of how these techniques can and will be used.

Gene editing is not a single process but a collection of varied techniques. For example, it can include Agrobacterium insertion of the gene-editing tool, the use of plasmids containing genes from a wide range of other species[21], encoding the gene-editing tool, tissue culture[22], and the use of antibiotic marker genes. Each of these processes can produce unintended changes or genetic errors so each must be evaluated on a case-by-case basis for the specific risks that it entails.

The opportunity for gene editing tools to make more 'precise' cuts in DNA is highly publicised but precision does not equate to accuracy – after all a stopped clock is very precise but is only accurate twice a day. Even if the DNA injury occurs in the desired location, the subsequent repair is carried out by the organism's own cellular processes and can result in many genetic errors.[23] As gene editing can be used to target several genes at once, each additional edit multiplies the risk of unintended effects.

Gene Editing is likely to be used in ways that will cause harm

The ambitious claims made for gene editing's potential mirror closely the unfulfilled promises made for the first generation of GM crops. In practice, only two gene-edited crops are being grown commercially anywhere in the world: Cibus's herbicide-tolerant oilseed rape (SU Canola[24]) and Calyxt's soybean with an altered oil profile[25].

If plants or animals are genetically altered to make them resistant to pests or diseases, it does not take long for those pests or diseases to evolve in response. This has been widely seen with herbicide-tolerant and insect-killing GM crops around the world: weeds and pests have quickly adapted and new problems of herbicide-resistant weeds[26] and insecticide-resistant pests[27] have emerged. Cibus's oilseed rape, therefore, brings with it the same risks from increased herbicide use as the older-style GM herbicide-tolerant crops, including biodiversity reduction and the evolution of herbicide-tolerant 'superweeds'.

Calyxt's soybean oil is largely intended for use in fast food restaurants where, according to the manufacturers, it gives a 3-fold greater fry life compared to conventional soybean oil.[28] The growth of the fast-food sector represents a direct threat to human health and this early example of gene-editing roll out suggests that commercial advantage will take precedence over any potential gains for society, animals or the environment.

Question 3: 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 there are a large number of non-safety issues that need to be considered before any decision is made to change the regulation of organisms produced through gene editing or other genetic technologies. These include consumer rejection, trade with the EU, devolution, animal welfare, coexistence, social and ethical concerns.

UK Citizens do not support deregulation of gene editing

The views of the general public must be valued and respected. A wide range of surveys and in-depth studies have shown that there is significant public concern about growing or eating genetically engineered crops and no public support for deregulation.

When Food Standards Scotland carried out a survey in October 2020[29], it found that genetically engineered food was a top issue of concern (second only to chlorinated chicken which had been in the news for months ahead of the survey) and that only one in ten was likely to buy GM food, even if it was significantly cheaper. Another 2020 study conducted by the National Centre for Social Research[30] found that 59% wish to maintain restrictions on genetically engineered crops. A 2021 survey by the UK's National Economic and Social Research Council[31] found that 64% of those who took part were opposed to the cultivation of genetically engineered food.

Consumers support clear and consistent labelling of all food produced with genetic engineering. The right to choose what we want to buy and eat is highly valued and many consumers make choices based on a complex mix of ethical, social and environmental factors, as well as concerns about food safety and animal welfare.

Deregulation of gene editing would damage trade and could undermine the EU-UK Trade and Cooperation Agreement

No European Union country will accept food products, commodities, seed or other imports from the UK that might include unauthorised GMOs. If gene edited organisms are not regulated as GMOs in England, English farmers, food producers and exporters will not know whether or not they are using GMOs. It will be impossible for them to prove that their goods are acceptable for import into the EU or, indeed, the majority of international territories that impose restrictions on the use and sale of gene edited organisms.

Even where GMOs are approved for import into the EU, they must be labelled (making them traceable) and subjected to post-market monitoring to check for any problems and allow for unsafe products to be recalled. When GMOs are used in foods for human consumption the end products must be labelled. If gene edited organisms (that will retain their classification as GMOs in the EU) are not regulated as GMOs in England**,** English farmers, food producers and exporters will not be able to meet these requirements.

It is likely that removing any form of genetic engineering from the scope of GM regulation will be considered a breach of EU-UK Trade and Cooperation Agreement (TCA) principle of non-regression, which states: "A Party shall not weaken or reduce, in a manner affecting trade or investment between the Parties, its labour and social levels of protection below the levels in place at the end of the transition period, including by failing to effectively enforce its law and standards." (Article 6:2, Clause 2)[32]. This raises particular concerns for Northern Ireland.

It also worth noting that, even outside the EU, only a few territories are taking a permissive approach to gene editing regulation and none has adopted the proposed distinction between gene edited organisms that "could" and "could not" have been produced through traditional breeding. Also, while there are significant markets for certified non-GM products, there is no specific demand for genetically engineered food or commodities.

The proposed deregulation will undermine the legitimate authority of UK's devolved nations

Food and agriculture are devolved areas of competency, meaning that Scotland, Wales and Northern Ireland are responsible for GM regulation in their own countries. All three of the UK's devolved countries have sceptical policies on GM and in 2015 all three used EU Directive 2015/412 to preclude the cultivation of specific GM crops on their territory[33].

Although the consultation asks about changes that would take effect in England, any changes to the English definition of a GMO would significantly impact Scotland, Wales and Northern Ireland. The Internal Market Act could force Scotland and Wales to allow English food producers to sell unchecked, unlabelled gene edited foods, whatever the rules at home. Food businesses in Northern Ireland could be prevented from selling or handling any food produced in England because it might include GMOs that breach EU rules.

Rather than pursuing English deregulation Defra should be working collaborative with its counterparts in Scotland, Wales and Northern Ireland to develop a four-nations approach.

There are significant concerns about the impact of gene editing on animal welfare
It is well recognised that conventional breeding has resulted in poor welfare outcomes for farmed animals, pets, and animals used in some sports. As these result from the commodification of animals, rather than any deficiency in the process of sexual reproduction, it is reasonable to assume that super-charging the ability to "design" animals will only lead to greater suffering.

Even where gene editing is proposed as a solution to welfare concerns, for example with disease resistant pigs or hornless cattle, closer inspection suggests that its use could in fact perpetuate poor husbandry and intensive farming operations. Rather than creating abuse-tolerant animals, we should address the poor hygiene, overcrowding and lack of genetic diversity that make farmed animals so vulnerable to disease, deformity, and aggressive behaviour. It is also vital to consider the potential that gene-edited disease-resistant animals will either drive the evolution of pathogens or become asymptomatic carriers of infection.

Regardless of outcome, the process of genetically engineering animals causes significant harm. Gene editing of animals usually includes cloning which, according to the RSPCA[34] and Compassion in World Farming[35], inflicts very severe or lasting pain on animals, violates their integrity and reduces them to a mere instrument or tool. Cloning is typically only successful 10-25% of the time[36], meaning that most embryos transferred into hosts' wombs do not result in a full-term pregnancy and are aborted. For those cloned animals that survive, birth defects are common[37]. Defects include premature death, pneumonia, liver failure and obesity. For example, a study on cloned mice found that up to 4% of the genes were malfunctioning during pregnancy[38]. Microinjection can be used instead of cloning, but this requires a large number of animals to act as surrogates for the implantation of genetically engineered embryos. On average, 24 embryos are needed to produce one gene-edited pig.[39]

Genetic errors created by the gene-editing process can occur as an unintended consequence of genetic engineering, even if new genes are not inserted into the animal. For example, gene editing for super-muscly animals resulted in rabbits, pigs and goats with enlarged tongues and pigs having an extra spinal vertebra, even though no DNA had been inserted[40].

Deregulation of gene editing would destroy any possibility of coexistence between different farming systems
Most farming in the UK – and most of the food produced and sold here – does not involve the use of genetic engineering. The right to choose is a long-established part of UK farming and food policy and it is widely understood that conventional, organic and genetically engineered crops and animals can only coexist if one system of production does not negatively impact on the others, for example through contamination or pesticide drift.

Farmers and others in the food chain, have the right to make the decisions that are best for their business and an obligation to meet the needs of their customers. Non-GM farmers, processors and producers will lose their right to choose if gene edited crops are released without proper measures to prevent cross-contamination through pollen, seed or inadequate segregation along the food chain. Detailed rules on practical enforcement, traceability, liability and redress are all required for fair coexistence, but recent email exchanges with the GM team at Defra indicate that work has not yet begun on developing such measures.

Gene editing raises significant social and ethical concerns
All technological advances bring new risks and raise ethical questions, such as, "Why are we doing this?", "How will it be used?" and "What will its impact on society be?". This is particularly true with gene editing, where what is being created could outlast us and be passed on to future generations. In addition to assessing risk to health and the environment, the government has a duty to consider and assess, on a case-by-case basis, the value and ethics of adopting each new application of gene editing. This kind of assessment should take place as early as possible in the research and development phase.

The operation of intellectual property rights raises ethical concerns with all forms of genetic engineering but is particularly troubling in the case of gene editing. The legal ownership of the patents relating to the CRISPR gene editing tool is the subject of a bitter legal battle[41] and the cost of commercial production licenses will only further embed global market concentration.

Gene editing is a distraction from key sustainability issues
Gene editing is promoted with a long list of boasts and promises that have almost no foundation in science. Many of the same claims were made for the first generation of GMOs when they emerged in the 1990s and yet these older style GMOs have not resulted in higher yields, lower pesticide use, better profits for farmers, or lower seed prices. GMOs have also failed to 'feed the world'. Around 40% of GM crops are turned into biofuels, the rest are used as animal feed or as ingredients – mostly oils and sugars from corn, soya and cottonseed – for ultra-processed food.

An understanding of genetics can greatly assist plant and animal breeding. Nevertheless, it is widely recognised that there are limits to what can be achieved solely through genetics as complex problems such as hunger, malnutrition and ecological collapse require systemic solutions. To frame gene editing as the answer to all farming's problems is not just unproven and misleading, it distracts attention from meaningful actions which are likely to have a greater and more immediate beneficial impact. Instead of deregulating gene editing the government should be addressing the real problems, such as soil health and waste in the food system.

Question 4: 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?

We are not aware of any criteria that could determine whether an organism produced by gene editing or another genetic technology could have been produced by traditional breeding other than to actually produce a genetically identical organism through traditional breeding. The molecular match between the two organisms would need to be verified on a case-by-case basis through full genome sequencing and analysis of the detailed composition of both organisms.

As noted on page 3 (above), the designation "could have been produced by traditional breeding" does not make any scientific or legal sense so it is not a sound basis on which to develop regulations.

Section 3 – Part 2: Questions on broad reform of legislation governing organisms produced using genetic technologies

The questions in this section of the consultation significantly widen the scope of the discussion and their status is ambiguous. While GM Freeze welcomes the principle of public consultation, the inclusion of such broad-reaching questions in a consultation that is already rushed, poorly timed and heavily focused on a confusing proposition for deregulation, is inappropriate and unhelpful.

Question 1: 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?

We would like to register a particular concern about the presentation of this question, which does not define or even describe relevant non-GM legislation. It is counter intuitive as it requires that respondents answer "no" if they wish to retain the status quo. We have heard from supporters who found this question particularly confusing and were reluctant to complete the consultation on the basis that they did not understand what they were being asked. We have, nonetheless, offered our own answers below.

a) Cultivation of crop plants

No - existing non-GM legislation is NOT sufficient to deal with organisms produced by genetic technologies.

b) Breeding farmed animals

No - existing non-GM legislation is NOT sufficient to deal with organisms produced by genetic technologies.

c) Human food

No - existing non-GM legislation is NOT sufficient to deal with organisms produced by genetic technologies.

d) Animal feed

No - existing non-GM legislation is NOT sufficient to deal with organisms produced by genetic technologies.

e) Human and veterinary medicines

This is not our area of expertise.

f) Other sectors/activities

This could include almost anything so no - existing non-GM legislation is NOT sufficient to deal with the potential use of organisms produced by genetic technologies in a wide range of fields and applications.

Question 2: 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 measured should be triggered.

Specialist GMO regulation must be retained

Laws designed to prevent the adulteration of foodstuffs, the incidence of food poisoning or the sale of poor-performing seed cannot be repurposed to adequately assess the potential impacts of technologies that alter organisms at a genetic level. Genetic engineering raises unique risks due to inheritance and replicability of the changes being made. The only way to safeguard our food, our farms and the natural environment is through specialist GMO regulations the encompass individual risk assessments, post-release monitoring, traceability and clear consumer labelling that supports both individual choice and the opportunity for recall.

GMO regulation can be improved

Although existing GM regulations provide vital protections for people, animals and the environment, they could be improved. We would suggest that Defra explores options for:

- Formal consideration of the social, ethical and economic context for the release of any genetically engineered organism.
- Greater independence in the assessment of scientific data.
- Independent assessments of the need for the proposed new organism and any alternative approaches that might achieve the desired outcome with less risk, lower financial investment and greater opportunities for equitable roll-out. These assessments should begin by identifying the nature and causes of the problem that a proposed new genetically engineered organism is purported to solve.
- Assessments of the impact of commercial roll out, including the effect that intellectual property rights will have on farmers and others in the food chain.
- Improved ongoing safety assessments including the use of whole genome sequencing to identify any unintended alterations.
- The use of citizen panels and assemblies.

References

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