GM Freeze response to Department for Business, Energy & Industrial Strategy consultation:

Reforming the framework for better regulation

Submitted by email to BRframeworkreview@beis.gov.uk

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Introduction

This response is submitted by Liz O'Neill – <u>liz@gmfreeze.org</u> – on behalf of GM Freeze. It is not confidential and will be published on our website at https://www.gmfreeze.org/publication-category/consultation-responses/.

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. Below, we respond with general comments and answers to the questions relevant to our role as an expert civil society body. Our member organisations hold a variety of views on broader issues on the reform of regulation and some may submit these to the consultation separately.

General comments

The consultation document states that "We welcome views from businesses, the community and voluntary bodies" but the content is extremely inaccessible to anyone other than a policy or regulation specialist. We anticipate that, despite the profound potential impact of any changes made along the lines proposed and the broadly evidenced public support for a robust regulatory approach¹, few ordinary citizens will respond. We urge the Minsters to instead commission a consultative dialogue that will allow business and civil society representatives to engage more deeply with citizens and explore what the proposals would mean in practice before offering their views on the Government's proposals.

The consultation document proudly declares that "we will not compromise on public safety" while paragraph 1.4 states that "the Government's response to Grenfell will continue to be excluded from the framework, regulatory offsetting, and any deregulatory targets." The juxtaposition of these two statements suggests that the circumstances surrounding the catastrophic Grenfell Tower fire are assumed to be exceptional. We would suggest, instead, that all involved in deciding the future direction for UK regulation consider the devastating fire as indicative of the potential outcome of treating regulation as a burden rather than a tool to protect society and support public policy objectives. It is vital that the public and environmental safety implications of removing or amending any existing regulation are reviewed with full consideration for what can, and indeed might, go wrong.

Response to selected questions posed in the consultation document

Question 3: Are there any areas of law where the Government should be cautious about adopting this [less codified, more common law-focused] approach?

Genetic technologies

Question 4: Please provide an explanation for any answers given.

The regulation of genetic technologies needs to be clearly codified for the following reasons.

DNA is self-replicating so any problems associated with its release into the environment are extremely difficult to put right after the fact. For example, on three separate occasions GM wheat was discovered in the USA between eight and 15 years after the conclusion of the field trials from which it escaped. This raises environmental and food safety concerns, of course, but it also caused significant economic disruption. Some countries halted purchase of US wheat altogether² and there were broader market concerns for US farmers and traders. Investigations by APHIS (United States Department of Agriculture – Animal and Plant Health Inspection Service)³ failed to find the route of contamination in any of these cases.

The operation of intellectual property rights linked to genetic technologies is complex with legal battles ongoing over the ownership of patents relating to the CRISPR gene editing tool⁴. A common-law approach is not compatible with this legal environment and compromise not just UK users of genetic technologies but also those who choose not to use them but are still impacted through their presence in the food chain and wider environment.

The UK Department for Environment Food and Rural Affairs (Defra) consulted earlier this year on plans to amend the regulation of genetic technologies. GM Freeze does not support these plans⁵ and it is clear from the Summary of responses⁶ that there is significant public objection to deregulatory proposals as well as a wide variety of views around the science, the application and the potential impacts of newer genetic engineering techniques. In this unsettled context it falls to the Government to provide certainty through clear and unambiguous regulation.

Political divergence across the nations of the United Kingdom is also a concern when considering the prospect of less codified regulation of genetic technologies. Food and agriculture are devolved areas of competency. Scotland, Wales and Northern Ireland have all adopted policy positions that are significantly more sceptical about the use of genetic engineering in food and farming than that taken by the UK Government in Westminster. In 2015, Scotland, Wales and Northern Ireland all used EU Directive 2015/412 to preclude the cultivation of specific genetically engineered crops on their territory⁷ and all three nations continue to favour policy alignment with the European Union.

The small size of the UK, the complex integration of supply chains across Great Britain in particular, and the tendency of both pollen and seed to spread freely over large geographical areas mean that a "suck it and see" approach by the UK Government simply will not work when it comes to the use of genetic technologies in food and farming. Similarly, a common law approach to the regulation of genetic technologies would close key export routes and eliminate the valuable GM-free and organic market premium.

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Looking more widely at all food and farming regulations, we note that the impacts of the COVID 19 pandemic, the HGV driver shortage and other recent events have highlighted the vulnerability of the food supply chain. What farmers, food producers and retailers need now is certainty. Protracted litigation to establish case law could put our food supply at risky while lack of transparency or wider consultation could lead to poor decision-making based on the particulars of whichever case happens to be "first out of the blocks".

Question 5: Should a proportionality principle be mandated at the heart of all UK regulation? Question 6: Should a proportionality principle be designed to 1) ensure that regulations are proportionate with the level of risk being addressed and 2) focus on reaching the right outcome? Question 7: If no, please explain alternative suggestions.

We are answering these questions together because we do not support the mandating of a proportionality principle within UK regulation. Rather, the UK should uphold the well-established precautionary principle in relation to genetic technologies and much else.

The precautionary principle is often misrepresented by those with a financial or other interest in the rapid uptake of emerging technologies. The precautionary principle protects society and the environment when potentially devastating hazards are identified but the likelihood of their occurrence is uncertain. When we know that something could go very badly wrong but are not yet able to measure how likely it is to happen, we cannot calculate risk. The only proportionate response to an identified, but incalculable risk, is precaution.

Contrary to the view expressed in the consultation document, precaution encourages innovation. By guarding against damage that could be caused by new products or processes it fires the drive to develop safer, better products and processes.

The consultation document appears to apply a double standard to the role of precaution in environmental protection. Paragraph 3.1.13 of the consultation document recognises the value of the precautionary principle in prompting action on the climate emergency while at the same time criticising its application to emerging technologies. Emerging technologies are novel by definition. Their new and untested nature is precisely the reason why we must take care before releasing them. Public and environmental protection are core Governmental responsibilities, and the UK needs a regulatory framework that enshrines this in law. We draw the Ministers' attention here to the concerns noted in the Interim Office for Environmental Protection's *Advice on the Draft Environmental Principles Policy Statement* which urges Government to "avoid the sort of narrow approach to precaution that can limit the principle's effectiveness in practice"⁸.

Question 16: Should regulators be invited to survey those they regulate regarding options for regulatory reform and changes to the regulator's approach?

We can see the value of regulators seeking input from those whose activities are regulated but it is important that they also consider wider societal views and perspectives. Input from consumers, citizens, civil society, and businesses working in other parts of the relevant supply or value chains must be considered with equal weight. This means actively engaging relevant stakeholders, in a form that will allow them to fully understand and contribute to decision making.

Question 23: Are there any other changes you would suggest to improve impact assessments?

Impact assessments should consider the societal impact of both regulation and lack of regulation. For example, the potential impact of an unregulated activity causing harm to people, animals or the environment should be assessed alongside any operational impacts on regulated businesses.

Question 24: What impacts should be captured in the Better Regulation framework? Select all which apply:

Environmental, health and wider societal impacts should be captured in the Better Regulation Framework. Privileging innovation, growth, competition and investment over these key societal benefits denies the core purpose of regulation – to safeguard citizens and the world in which we live. Regulatory reviews should include an independent assessment of the impact that different regulatory approaches could have on the environment, including the benefits of regulation and the risks of deregulation.

Question 30: Should the One-in, X-out approach be reintroduced in the UK? Question 32: What do you think are the disadvantages of this approach?

We do not support a One-in, X-out approach or, indeed, any approach to regulatory review that relies on measuring the "amount" of regulation. Any such measure is intrinsically arbitrary and unlikely to capture the social and environmental impacts of removing key safeguards. Regulations are not playing cards to be swapped and traded, they are a societal tool to protect people, animals, and the environment.

The consultation document states that regulations pertaining to building and fire safety are out of scope "in order to ensure that key public safety regulatory provisions are retained". The application of the precautionary principle to emerging technologies, particularly self-replicating genetic technologies, is a key public safety provision and should be afforded the same status.

We also urge the Ministers to consider the views of citizens. Public support for retaining the UK's high food standards has been clear in a wide range of campaigns since the UK voted to leave the European Union. In 2020 Unchecked UK reported a high level of support for regulations among younger Leave voters, with the majority of respondents expressing a preference for maintaining or increasing regulations across diverse areas of public life.⁹

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² Fox, JL, 2013. Volunteer GM wheat, mischief or carelessness? Nature Biotechnology 31: 669-670.

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⁴ Cynober, February 2019. CRISPR: One Patent to Rule Them All, Labiotech.eu https://www.labiotech.eu/in-depth/crispr-patent-dispute-licensing/

⁵ GM Freeze, March 2021. Submission to Defra's Consultation on the Regulation of Genetic Technologies https://www.gmfreeze.org/publications/defra-regulation-of-genetic-technologies/

⁶ Defra, September 2021. Summary of responses to a consultation on the regulation of genetic technologieshttps://assets.publishing.service.gov.uk/government/uploads/system/uploads/attach ment data/file/1021309/genetic-technologies-regulation-summary-of-responses.pdf

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