Beyond GM/A Bigger Conversation response to

BEIS consultation on Reforming the Framework for Better Regulation

This document is our response to the above consultation and we consent to it being made public.

Beyond GM/A Bigger Conversation is a UK-based civil society organisation. Its aim is to raise the level of the discussion around genetic engineering in food and farming to make it more intelligent and more inclusive. To this end we undertake a range of activities from public-facing engagements and publications (Beyond GM) to more structured and formal events aimed at deep-dive discussions with all sides of the debate (A Bigger Conversation).

Our speciality is agricultural genome editing. Whilst this is the subject of a separate regulatory review, many of the points we made in our response to the Defra consultation on the Regulation of Genetic Technologies are also germane to this consultation. In particular those relating to the purpose and scope of regulation, the need for clear definitions and criteria and, the importance of earlier citizen/public involvement and assessment of benefits.

Questions about the potential benefits and risks of 'light touch' regulation, or indeed outright deregulation are of particular importance when it comes to so-called 'disruptive technologies'. These are a focus of this government's economic strategy and therefore of real-world relevance to this consultation document.

The government's proposed 'bonfire' of deregulation, is vitally important to all citizens yet this consultation seems designed to discourage citizen participation. It assumes a level of knowledge and engagement that may not exist in the general population and which cannot be acquired or developed over the all-too-short consultation period of 12 weeks.

Whist there are some thought-provoking proposals within the consultation document, we envisage that following through, with what will be a complex and difficult task, will be time-consuming and costly and, in the end, may yield very little in terms of those putative business wins.

This consultation presents a near fait accompli which will leave many people feeling it is already too late to make a difference to the government's thinking and planning. Without meaningful input from citizens, moves to deregulate or have light touch regulation of large sections of UK industries will be treated with mistrust, suspicion and a profound sense of disempowerment. We urge the government to engage in a separate, citizen-friendly dialogues before any move towards widespread deregulation is put in place.

As a framework for our selected responses below we would like to make the following observations:

Using Regulation to build markets is fraught with uncertainty and risk

In seeking to use regulation, or more specifically deregulation, as a market tool to promote competition and innovation the government doesn't just redefine the purpose of regulation, it sets aside or downgrades its responsibility to safeguard its citizens, protect environment, provide a

framework for fair, transparent and equitable business and trade and to ensure that those who inflict harm are held to account.

Placing a burden of facilitating market growth on regulators brings a new set of challenges. Balancing those with a poorly defined but residual 'safeguarding' of responsibilities is full of uncertainty which, if not acknowledged and worked through, could result in greater adverse impact and more complex regulation down the line.

Regulation should not be presented as a burden

There are many references to regulatory 'burden' in this consultation and yet the BEIS Business Perceptions Survey 2020 found that 51% of businesses said most regulations are fair and proportionate and almost two thirds of businesses (64%) agreed that the purpose of regulation was clear.

It also included results from a smaller parallel survey that assessed the impact of alternative wording of the questions asked in the main survey. This found that by removing the words "burden" and "obstacle" and using "impact" and "amount of work," attitudes towards regulation were less negative.

This gives us cause to question the excessive use of the word burden in this consultation.

Regulation is a safeguarding framework, not a burden. Its purpose is to protect individuals, the environment, and individual businesses and sectors. Regulation is also a societal tool for dealing with uncertainties such as gaps in scientific knowledge and can be a guarantee of fair competition and trade – not a hindrance.

Those uncertainties multiply in the face of new and/or disruptive technologies such as artificial intelligence, mass surveillance, driverless cars, 3-D printing and genetic technologies used for the purposes of re-engineering humans, animals, plants and microbes. These technologies cut across multiple sociological, environmental, economic, scientific and regulatory areas. Effective and rational regulation is only possible when the complexity which these technologies bring to the regulatory discussion is acknowledged and evidence from all impacted disciplines and stakeholders and citizens – including those who too often fall outside a narrow definition of 'stakeholder'– is included.

We are also aware of much theoretical discourse on how to remove regulatory burden (e.g. Nesta's Renewing Regulation: Anticipatory Regulation in an Age of Disruption and Deloitte's The Regulator's New Toolkit).

It is worth noting, however, that regulations are not always pre-emptive and don't exist in a vacuum. More often than not – and here chemical and pharmaceutical regulations are good examples – they are a response to something that's gone badly wrong at some point in the past causing harm to businesses, people or the environment (or all three).

We note that the BEIS research paper Regulator Approaches to Facilitate, Support and Enable Innovation acknowledges that little robust analysis has been carried out around the impacts of removing this so-called burden. Such analysis must be done on a case by case, industry by industry and across industry/society basis before we begin a deregulatory free-for-all.

Regulation does not limit innovation

In the context of this consultation, we feel it is also important to challenge the notion, promoted by the Government, that regulation is a limiting factor for progress and innovation.

It is often argued, for example, that regulation in the field of biotechnology has hindered R&D innovation. Yet, according to the EU's Joint Research Centre (JRC) – a body which includes leading UK researchers – Europe, which has some of the most comprehensive regulations on genetic engineering technologies in the world, has carried out almost 50% of the global research in this field. The simplistic claim that regulation shackles R&D innovation is, therefore, open to challenge.

Our own research, suggests that several factors – other than regulation – have played a part in placing or influencing limits on genetic engineering approaches to agricultural products, including:

- Differing values and worldviews.
- Differing perspectives about causes and priorities relating to environmental concerns.
- Differing perspectives on the desirability and scope of biological limits.
- A lack of consensus regarding the importance and scope of conceptual and ethical factors.
- Power concentration and monopolisation within industry.
- Economic factors including uncertainty of return on investment for various players.
- Time pressures within the context of changes in the market and supply chains.
- Inconsistent and variable public acceptance.
- The presence of viable non-tech or low-tech alternatives.

It can be argued that collectively these factors, more than regulation, have constituted a limitation to the roll-out and expansion of genetic engineering technology. But they are not a limit to innovation itself; rather they are the real-world context in which innovative ideas must grow, thrive and prove their worth.

If government feels that progress and innovation are being stifled, it should first look to these other factors as causative before attempting to remove essential regulatory safeguards.

'British' regulation must still work within an international regulatory context

An isolated approach to regulation – however flexible and proportionate simply will not work in the real world.

Regulatory flexibility does not exist in a vacuum. It exists within the global legal context of sometimes significantly different jurisdictions.

Recently, after consulting thousands of its members, the Confederation of British Industry (CBI), the UK's biggest business organization, called for "ongoing convergence" with EU rules for goods, services, and digital standards. The scale of the accessible market is immensely important to growth prospects.

Regulation must also work within a context of environmental and societal change

Given the plethora of environmental problems faced by society – notably but not limited to climate change – it is no longer enough to 'do no harm' or even 'do no significant harm' when considering our regulatory choices. Citizens today – but future generations even more so- rightly and urgently expect a paradigm shift at the level of sustainability and stability. Such a shift demands that issues of climate breakdown, human dignity and civic rights, right to food, right to work, equal access to technology, land ownership and use, cultural identity and social inclusion are fully integrated into regulatory thinking and processes in early-stage evaluations.

These longer-term considerations will reshape our marketplaces as much as – and likely more than – a narrow, falsely competitive view of regulation. An appropriate regulatory approach is one that takes these factors into account.

Invention is not the same innovation

Whilst resilience and recovery do require a commitment to innovation, the government makes a fatal error in confusing invention with innovation. Indeed, while the word innovation is used liberally throughout the consultation, it is never defined.

Innovation evokes the concept of use and, in particular, use that is of benefit to the greatest number of people. The benefit of every proposed innovation must be assessed against a clear set of criteria that indicates the possibility of real, rather than assumed, benefit before it is widely released. Such criteria form the basis of socially responsible innovation. If the government believes that deregulated disruptive innovation is better than socially responsible regulated innovation it must clearly state its evidence for this path.

The need for a 'balanced' regulation encompasses strengthening as well as weakening
Whilst there is a case for regulatory change, it is important to consider whether there are areas where we might need stronger regulation and to set out criteria for assessing this.

The catch-all of light touch alongside the deregulation drive fails to recognise that different industries require different approaches in order to achieve appropriate regulation. In some cases, stronger regulation is both necessary and appropriate. There is no one-size-fits all approach that will work.

There are already very few limits on the development and implementation of some very risky and invasive technologies (e.g. facial recognition, artificial intelligence, data collection). Stronger regulation will ensure that the development of these technologies is proportionate to society's needs and does not inflict harm or negatively affect related sectors.

ANSWERS TO SPECIFIC QUESTIONS

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

Any technology that is described (or describes itself) as disruptive or even 'transformative' or which seeks to blur the lines between the natural/living and artificial/technological requires a much more cautious and comprehensive approach to regulation.

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

Any regulatory reform which proposes lessening or removing regulatory oversight should be approached with caution.

The lessons of the 2007/2008 global financial crisis demonstrate how a creep of deregulation coupled with an unchecked desire to stoke unfettered growth in the financial markets led to a devastating global collapse of the financial markets, causing untold misery for citizens and

businesses. The New Economics Foundation describes it as "a textbook illustration of the catastrophic effects of deregulation." It is not at all clear that lessons learned have been retained.

The catastrophic fire at Grenfell Tower is another clear result of long-standing and systemic regulatory failure.

For the purposes of this consultation, however, we are particularly concerned about proposals for light touch regulation around so-called disruptive technologies – a category which encompasses our speciality of agricultural genetic technologies.

We are aware of the current enthusiasm for disruption and the seemingly growing acceptance within government and quasi-government circles that disruptive technologies like gene editing are "blurring the lines between the physical, digital and biological worlds".

Yet we've seen no discussion at government level – and certainly not with citizens – about what this blurring means in a regulatory context.

By their very nature, disruptive technologies – e.g. driverless cars, social media and AI – cut across multiple areas of concern and have wide ranging implications for accepted narratives around things like food and food systems, impacts on environment, trade, informed consumer choice and health. Because of this, they require more comprehensive and carefully considered regulation (and a much stronger code of ethics) underpinning them. They are more complex to regulate because of both known and unknown (as noted in our response to Q24) risks.

It is our contention that changing either the definition of regulation or, in the case of disruptive technologies, removing the regulation itself is likely to be a high impact action that a) affects a large number of businesses and individuals; b) introduces a radical change to existing regulations; c) requires government to acknowledge a high degree of uncertainty and a large number of factors which need to be considered to estimate the impact of such an action; d) likely to have disproportionate impact on one group of businesses (such as small businesses, or businesses in one sector) and e) is novel and contentious and may not, in the end, meet stated objectives.

Whilst opinions are likely to differ on the scale and frequency of risk, it is surely unarguable that a technology hailed as disruptive and transformative will also pose new elements and levels of risk that must be taken into account.

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 have observed a trend of euphemisms such as 'enabling', 'proportionate' and 'flexible' creeping into the regulatory discourse – including the Government White Paper, Regulation for the Fourth Industrial Revolution.

Whilst it may be intuitively appealing, the notion of a so-called 'Proportionality Principle' is not defined in law, nor is this principle, or the mechanism for how it will work, well defined within the consultation document, nor in the recent TIGRR report.

Aligned to this, the consultation document provides no evidence that regulation inhibits innovation or markets, nor that the Precautionary Principle, upon which much European (and currently, by

extension, UK) regulation is based, has ever been taken too far or been responsible for societal detriment, either in the EU or the UK.

The emphasis on flexibility and enablement also begs the questions – unspoken, but also unanswered in the consultation document – Proportionate for whose needs? Enabling for whom? and Flexible for the benefit of whom?

Absent any real evidence of harm caused by a precautionary regulatory regime, we propose that the UK continues to embrace the Precautionary Principle which provides a pathway for regulators to take action the face of a possible threat to health or the environment, particularly where scientific data is not able to provide a complete evaluation of the risk.

The Precautionary Principle, which can be applied to a phenomenon, product or process, is not a risk analysis tool but can be invoked as part of a formal decision-making process. The European Commission's approach, which was set out in 2000 and has not changed since then, notes that "the precautionary principle is neither a politicisation of science or the acceptance of zero-risk but that it provides a basis for action when science is unable to give a clear answer."

Argument that the Precautionary Principle and/or the EU's stated approach to its application are limiting and inflexible ignores the fact, enshrined in the regulation that: "Measures should be periodically reviewed in the light of scientific progress, and amended as necessary." We, therefore, fail to see how this sensible approach – which acknowledges that we don't know everything and provides guidance for assessment in the face of scientific uncertainty, ambiguity or ignorance – can be described as lacking in flexibility.

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

To answer this question fully requires a clear idea of what "survey" means. This is not defined in the consultation.

Government has already surveyed many businesses on this point. In January 2021 business news outlet Bloomberg reported that Prime Minister Boris Johnson had:

"…asked business leaders to help him decide which regulations should be ripped up now that the UK has completed its divorce from the European Union. The premier made the offer in a call Wednesday afternoon with some 250 corporate leaders, according to four people with knowledge of the matter. He asked what red tape could be cut to make life easier for Britain's companies to operate after Brexit."

Businesses reported being "badgered" by the government for ideas, suggesting that although it desired reform, it had little idea about what reform looked like or what its impact might be.

Other surveys of business suggest that good regulatory delivery is also good for business. Research conducted by the OECD in partnership with the European Commission in 2010 suggested that a positive regulatory environment can contribute significantly to economic development and sustainable growth, improving the openness of international markets and creating a less constricted business environment for innovation and entrepreneurship. It can protect compliant businesses by enabling fair competition and promoting a level playing field and provide businesses with the confidence to invest, grow and create new jobs. We believe these findings hold true today.

In addition, it is not enough to simply ask UK businesses which regulations they would like removed, nor is it the exclusive purview of businesses to decide what regulations the country as a whole needs or does not need. The views of individual businesses will necessarily be limited by and to their field of operation. Consequently, the long history of global environmental pollution and degradation, has shown many businesses have no idea of their global impact or where they fit into the bigger picture of the living world and of ecological disaster.

For this reason, surveys should seek the opinions of a wider group of stakeholders, including citizens, to better understand their views on regulatory reform and changes to the regulator's approach.

Such surveys would reveal that, for citizens, regulation remains an important safety net. In 2020, for example, 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.

With regard to genetic technologies the recent FSA consumer dialogue likewise noted that "consumers wanted thorough regulation and transparent labelling if GE foods reach the UK market".

Likewise in the recent Nuffield Council on Bioethics public dialogue on genome edited animals, regulations were seen as important for maintaining food standards for consumers as well as guaranteeing animal welfare.

These concerns have a long history. Data from the 2010 OECD report Regulatory Policy and the Road to Sustainable Growth showed that amongst the EU 15 most supported "smart regulation (not necessarily deregulation), and in particular, that citizens and consumers are keen to pursue high social welfare and environmental performance standards."

Question 18: Do you think that the early scrutiny of policy proposals will encourage alternatives to regulation to be considered?
Question 20: Should the consideration of standards as an alternative or complement to regulation be embedded into this early scrutiny process?
Question 23: Are there any other changes you would suggest to improve impact assessments?

Impact assessments (IAs) can vary in quality and scope. To ensure a high standard and greater coherence we believe there must be more consistent standards and criteria for the kind of data collected and considered in order to justify policy changes or different policy options.

There also needs to be greater clarity and transparency on how much weight the consulting body gives to the views expressed by different groups of stakeholders. Our particular concern is that the views of citizens are too often downgraded in comparison to those of businesses and lobbyists even though citizens bear the brunt of an inadequate or uncertain regulatory landscape.

When such swingeing changes are being considered it would greatly improve the pre-consultation and consultation stages for the consulting body to engage in earlier and wider public stakeholder meetings and workshops to engage in even-handed, non-prejudicial discussion about the options that are being considered. The views of citizens must also be given equal weight to those of business.

We note that the Regulatory Policy Committee makes a strong case for earlier scrutiny of IAs. It notes:

> "Since 2018 it has been optional for departments to submit IAs at pre-consultation stage (while the policy is being developed). Currently, only around a third of IAs are submitted for RPC review at this point, compared to those submitted at the final stage where RPC scrutiny is mandatory.
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> "While scrutiny of final stage IAs still allows the RPC to question the estimated impact of proposed measures on businesses, it does not inform the decision-making process – since the decision has already been made. Earlier scrutiny – before consultation – also allows gaps in the evidence and analysis to be addressed as part of the consultation to better inform the final policy decision. Put simply, earlier scrutiny helps policy-makers and ministers to make better and more effective regulation."

Whilst there is a role for technical scrutiny, conducted by independent experts, in order to support and strengthen a democratic approach to regulation, the scope and scrutiny of IAs should also take a values-based approach, encompassing sociological, environmental and economic concerns.

There is certainly a role for standards as complementary to regulation and as an aid to creating understanding of the aims and terms of regulation. It is less clear where and how standards might in some circumstances replace regulation. This should be considered in the context of "appropriate regulation" outlined in our comments above.

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

The list of four options in this question is wholly inadequate given the potential scope of potential light touch regulation and or outright deregulation.

Innovation, Trade and Investment, Competition and Environment are all part of the larger picture of regulatory assessment. But so are socioeconomic and ethical concerns, safety, long-term sustainability and a range of known and unknown 'unknowns'.

For example in the 2017 My Science Inquiry, Professor John Finney of the British Pugwash Group (a membership organisation that brings together scientists and others concerned with international affairs and disarmament) highlighted the challenges of pre-emptive regulation of emerging and converging technologies with regard to "attempting to regulate new technologies whose implications or potential civil and military applications may not yet be fully understood."

As noted in our introductory remarks, terms like innovation are greatly misused in the context of this consultation. To determine if an invention is innovative requires an assessment of how it will be used in a societal context and whether it brings benefit and improvement (something that could be done as part of an early impact assessment. The mere fact of a new invention or a new way of doing this does not *de facto* make it 'innovative'.

We are dismayed that Environment seems something of an afterthought at the end of a list of market-based considerations which, at face value, seem to be given equal status.

We would argue that, under current global circumstances, environment carries much greater weight and that the current over-focus on creating markets and trade links ignores the reality of the world we currently inhabit: a world of accelerating climate breakdown and environmental degradation.

We would also like to point out that there is a broad assumption that newer technologies are more productive than before, use fewer resource inputs and emit less pollution. Regulation demands proof that this is the case.

Question 30: Should the One-in, X-out approach be reintroduced in the UK?
Question 31: What do you think are the advantages of this approach?
Question 32: What do you think are the disadvantages of this approach?

The notion of "one-in, x-out" is fundamentally at odds with any considered approach to regulation – whether focussed on achieving light touch, balance, or even deregulation. Reducing regulatory reform to a superficial numbers game is the antipathy of good governance.

We note that a proposal of one-in-three-out, by the previous government, the intention of which was to remove three pieces of regulation for every new piece brought in post Brexit, was highly contested and never pursued.

In relation to the environmental considerations raised in our introductory remarks and in Q24, we note that the Environmental Audit Committee (EAC), in particular, took exception to the proposal in relation to environmental regulations post-Brexit and published three letters (here, here and here) sent to Government Ministers, saying that the rule should not apply to environmental regulations after the UK leaves the EU.

Given that environmental and social benefits are often apparent only over longer periods of time, we are not supportive of any approach to regulatory revision that relies wholly or substantially on the crude, short-term tool of quantifying regulation.

In the real-world example included in the consultation (p39), the cost to business of reducing the maximum stake in gaming machines from £100 to £2 was around £450m pa – a cost which the Department for Digital, Culture, Media and Sport (DCMS) said it expected could be offset by significant benefits to society, including reduced government expenditure in areas linked to gambling-related harm such as healthcare or the criminal justice system. In the end these benefits could not be monetised or accurately quantified and, as noted, had 'one-in, X-out' applied it would have made it very difficult to introduce this policy change.

It is not clear how the proposed offsetting of regulatory costs stemming from new regulations by reducing the existing regulatory stock would be judged. An obvious problem, as the example above suggests, is that it is likely to exclude all of the regulation's indirect benefits and non-monetised benefits such as environmental and social benefits. This, we believe, is unacceptable.