POLICY &

REGULATION

OF NEW GENETIC TECHNOLOGIES

EDITING OR EVISCERATION?

Perspective and analysis by

A BIGGER CONVERSATION

Opening up the dialogue on food, farming & genetic engineering

What is the purpose of regulation? Is it just a dry set of rules and restrictions or is it 'living' policy that encompasses culture and engagement? Is it straightforward or is it complex? Does it serve everyone and everything – or just a select few individuals and interests?

Such questions have been brought to the fore in recent UK- and EU-wide discussions about whether and how to regulate plants and animals created using new genetic engineering technologies.

In the UK, post-Brexit, messaging around the regulation of these technologies suggest a market motive. More liberal regulations, we are told, will save or stimulate markets and the economy, and put 'Global Britain' at the vanguard of the Fourth Industrial Revolution.

But regulation is not an economic tool. Essentially its purpose is to protect individuals and/or the environment. It is also in part, an attempt to deal, at a societal level, with uncertainty. It grounds our big ideas in the real world of real people whose lives are affected by, for example, a given technology but who, because of in-built power disparities in society, have less say in its development, research, marketing and global spread.

Regulation, therefore, needs to be inclusive. 'Inconvenient' policy should not simply be abandoned or tweaked and decisions around these things should not be made without full, genuine and meaningful engagement with a wider group of stakeholders.

Yet this is what is happening in post-Brexit Britain where policy and regulations have been – some would say hastily and occasionally by stealth – rejigged, rewritten and in some cases substantially weakened.

Whatever one's views on Brexit itself, it is undeniable that UK policy making seems to be falling short of the Institute of Government's fundamentals of:

- Clarity on goals
- Open and evidence-based idea generation
- Rigorous policy design
- Responsive to external engagement
- Thorough appraisal
- Clarity on the role of central government and accountabilities
- Establishment of effective mechanisms for feedback and evaluation.

It also fails to follow the Institute's stricture that:

"*Policy-makers should see their role more as one of 'system stewardship', rather than delivering outcomes through top down control.*"

In our view, the current drive to deregulate genome editing in the UK, is a process that pays no heed to of the fundamentals of good policy-making and would hollow out 20 years of substantial and carefully constructed policy.

But we are also aware that this process is part of a larger strategy. On the day before the UK consultation on deregulating genome editing was announced, 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 U.K. 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.*"

Policymakers should see their role more as one of 'system stewardship', rather than delivering outcomes through top down control

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.

Editing or evisceration?

It is within the context of the government's 'bonfire of the regulations' that the UK's Department for Environment, Food and Rural Affairs (Defra) launched a public Consultation on the Regulation of Genetic Technologies, which ran between and January and March 2021. It too had a chaotic and badgering tone, demanding from the lay public not just opinion but specific ideas on policy and suggestions for how to liberate genetic technologies. A report on its findings is imminent.

In the EU, a less ostensibly dramatic but nonetheless similar, push for deregulation is underway. At the

request of the European Council, the Commission undertook a "study" "on the status of new genomic techniques [NGTs] under Union law" – which included an element of stakeholder consultation (albeit by invitation only) – throughout 2019 and 2020. That report has just been published.

At first glance a compare-and-contrast of these two exercises suggests 'chalk and cheese' differences. The UK exercise was poorly conceived and executed; it was fast and dirty and a bit embarrassing. The European process has taken longer, has been more involved, and appears to be more considered and careful. But in both cases the underlying themes and dynamics are the same and both follow the same basic script.

The focus of both is editing – not just gene editing but the 'editing' of existing regulations. The underlying goal, however, is evisceration. To clear the way for gene editing and other new genetic engineering techniques, the regulation and policies relating to these technologies are to have their 'internal organs' removed, leaving behind a hollowed-out, packaged carcass that serves only as taxidermic window dressing.

In both the UK and the EU, we see politicians obsessed with the notion of a technological nirvana as the centrepiece of a spurious "knowledge-based economy". Others, less evangelical but supportive of revision rather than the sweeping away of regulation, are still part of a policy push that has little space and time for responsible discourse.

Complexity and uncertainty

Beneath the surface of all this, it is possible to perceive an emerging hesitancy and a greater degree of caution, more nuanced thinking and less clear-cut positions across the spectrum of opinion than has been assumed. This is evident from a number of responses to the UK consultation, which

THE REALITY OF 'SCIENTIFIC CONSENSUS'

At present the current policy and political narrative is dishonest – a major obstacle to the development of sound governance and public good.

Politicians – whether from the research establishment or from the political parties – and the media claim that there is a scientific consensus about the safety, risks and potential of these technologies. They dismiss critical or questioning voices as being akin to "climate change deniers".

What is not acknowledged is that amongst the ranks of genetic technology adherents, there are considerable differences in view about significant aspects of the technology; so much so, that is hard to find "consensus" or coherence amongst this group on pivotal issues such issues as:

- Whether gene editing should be defined and regulated as GMOs at all or only in part.
- Where lines would be drawn with any scientific credence; how, scientifically, can genome editing technologies be defined as "natural" or "akin to nature".
- Where can lines be drawn with any scientific coherence between "traditional breeding", "conventional breeding" and genome editing.
- How can levels of risk assessment and evaluations be identified and implemented on coherent scientific criteria and how/by whom would "trigger points" be invoked.
- How can patents be invoked with gene editing methods which wholly or in part involve an organism's own repair mechanism.
- How can significantly different ethical and values considerations and technical methods between genome editing techniques relating to crops and livestock be resolved scientifically.
- Should scientific considerations alone be the criteria for risk/impact assessments? If not, who decides and how other considerations are invoked and weighted.

Over several years our on- and off-the-record discussions with genome editing researchers and developers, has led us to conclude that at present there is no consensus amongst pro-gene editing scientists on these questions.

That is not to say that one cannot or will not emerge, but it will take time – something which is not being given in the political and policy rush to deregulate.

are already in the public domain. It remains to be seen whether this nuance will be reflected in Defra's report.

Similarly, the EC study is threaded through with references to complexity, contested positions, differing perspectives and considerable uncertainty about definition, science, appropriate regulation, public engagement, ethics and rights.

Whilst it concludes that current EU GMO legislation has "*implementation challenges and requires contentious legal interpretation to address new techniques and applications*", it is far from the absolutist, black and white manifesto for the deregulation of genome editing that much of the media and commentators would have us believe.

Stakeholders on all parts of the spectrum of opinion are in a process of reassessment and unexpected views are emerging

The concluding paragraph states:

"*There are strong **indications** that [current EU GMO regulations] are not fit for purpose for **some** NGTs and their products, and that it needs to be **adapted** to scientific and technological progress. The follow up to this study should confirm **whether adaptation** is needed and, **if so, what form** it should take and which policy instruments should be used in order for the legislation to be resilient, future-proof and uniformly applied as well as contribute to a sustainable agri-food system* [***emphasis is ours***]."

This conclusion highlights several key issues:

- The conclusion that the current situation is not "fit for purpose" is not definitive – possibly because the study is very sketchy on how alternative regulatory approaches could work in a way that is actually an overall improvement.
- The current regulation may not be "fit for purpose" for only some NGTs, implying that it is for most, which presumably is why...
- ...they are talking about adaptation not wholesale scrapping and/or replacing.

The final part of the concluding paragraph also implies a realisation that society now requires a more coherent, broad and sustainable approach to regulating and managing new technologies (especially disruptive ones) than in the past.
It could – and likely will – be argued that this is taking an overly optimistic or naive view of the study's conclusions; that moves to deregulate are industry-driven, that diplomatic wording disguises the usual cynical, power plays of policy and politics. Based on the framing of the Discussion section of the report and the Commissions' a covering letter to the Portuguese presidency, there are certainly grounds for this argument.

Taken as a whole, however, the European study acknowledges complexity, differences and problems that are not amenable to simple, regulatory solutions. In large part this is because, even amongst supporters of regulatory change, there is no agreement about what that change should be and no coherent perspective on purpose and goals, even on narrow technological questions.

It may be hard to discern it, but underneath the noise of politicians, the research establishment and members of the media banging the drum for deregulation, it is possible to detect conflicting sub-themes, counter dynamics, internal contradictions and simple misunderstandings, confusion and uncertainty.

Liberating technology or sound governance?

It has been clear for some time that stakeholders on all parts of the spectrum of opinion are in a process of reassessment and unexpected views are emerging.

There is a recognition that true sustainability in farming and food goes beyond narrow science and technology perspectives and encompasses, not just environment, but food and nutritional security, ethical and values-based supply chains, social and cultural aspects as well simple economics.

These considerations have not been reflected in the comments and statements coming from the UK government – before or during the Defra consultation – nor from the European Commission, whose covering letter to its study ignores the 'if and whether' change is needed questions in the study's conclusions in order to launch a "policy action on plants" aimed at reducing or removing the 'if'.

The presumptive narrative of "liberating" science and technology is profoundly inappropriate at a time where the power of technology to cause harm is as great or greater than its potential to do good.

It ignores a society waking up to the fact that equity, ethics, values, democracy, transparency, boundaries and limits are as much a part of sustainability as is technological efficiency.

The issue of gene editing and associated technologies is hugely important in its own right. But more than that, it is one of the crucial testing grounds for how society's relationship with technology develops in the future.

If a genuine, open and constructive discussion can be nurtured, rather than the stage managed stakeholder engagement beloved of vested interests of all sides, then there is a chance that an eviscerated regulation that serves no-one and will not be sustainable over the longer term can be avoided in both the UK and the EU.

Attempts in the 1990s to develop co-existence regulation or codes failed to find agreement of proportionality and equity

For this to happen, we believe the following factors need to be considered and honestly addressed by all sides.

The dynamic for regulatory change

For several years now A Bigger Conversation has been discussing this issue, publicly and privately, with a range of people – genetic engineers, farmers, breeders, ethicists, NGOs, researchers, retailers and others – in their professional roles and as citizens.

We have found that whilst there is a strong strand of opinion that the GMO regulatory structures in farming and food, should be revised, few people want wholesale deregulation and no-one wants to follow the incoherent, illogical US model – not even some US biotechnology companies.

However, because there is no consensus on why, where and how any revision of regulation should take place, and no constructive and transparent discussion on this, the risk is that something totemic but ill-considered and ultimately damaging to all sides could be forced through.

This is most likely in the UK. In fact, it is unclear why the UK government is pushing for a change in the legal status of genome editing. Post-Brexit changes to UK statutes have removed the political obstacles to marketing GMOs in the EU by giving Ministers – not Parliament – the sole power of approval. Certain advisory bodies must give opinions but these are unlikely to put up objections. The Advisory Committee on Releases into the Environment (ACRE) has, in the last couple of years, given the green light to all proposed field trails of gene edited crops. The UK Food Standards Agency (FSA), is likely to continue in the vein of the European Food Standards Agency (EFSA) in approving GMOs on a case by case basis. Whilst the monitoring required by the UK's Advisory Committee on Novel Foods is far from onerous.

In other words, under post-Brexit changes it is feasible for gene edited crops and livestock to be commercialised in the UK under existing GMO regulations. They would have to be labelled but the UK already requires labelling of GMO products (for now mostly imports of US food products) and if labelled, genome edited products produced in the UK could apply for market approval in the EU.

We are left with the assumption, therefore, that the push to deregulate gene editing is part of a broader ongoing plan to remove all regulatory constraints on all future genetic-based technologies, such as synthetic biology, alongside the removal of transparency and labelling requirements. Indeed, Part 2 of the UK consultation suggests the most likely trajectory is the deregulation of all agricultural genetic technologies bar older style transgenesis.

Citizens in EU countries are much better placed than those in the UK to resist this. These issues carry much more weight in political, policy and research circles in EU countries than in the UK. However, one noteworthy point from our dialogues with pro-gene editing researchers and developers in the UK, is that they are not universally averse to labelling and transparency.

This is an example of how a realignment of interest groups could bring about more effective regulation.

Co-existence

Since we began our A Bigger Conversation dialogues we have pressed the point that – like it or not – co-existence of different farming and food systems is a fundamental given in policy and law throughout the world.

This is especially true in the EU (and the UK when it was part of the EU) where it has been specifically set out, if not adequately described in policy. This means that all farming approaches – but specifically

organic, non-GM conventional and GM – can be followed by farmers; and that consumers should be able to purchase products from whichever farming system they choose.

It is also implied, but has never been formally set out in either codes or law, that no approach should harm, interfere with or impinge on the lawful operation of any other; and that consumers are able to clearly distinguish between products from these differing approaches.

In practice, on the ground, and in the marketplace, there are many areas of potential impingement and interference. Some of these have been dealt with by, for example, organic regulations but others such as GMO incursion and/or contamination haven't.

Attempts in the 1990s to develop co-existence regulation or codes failed to find agreement of proportionality and equity.

The emergence of gene editing and its seemingly ubiquitous potential brings these questions back into focus. It is not just a matter of physical cropping distances and gene flow, supply chain integrity at all levels, information transparency and labelling and ongoing monitoring are other key considerations.

To move forward, all sides have to recognise and accept the policy imperative that the others have an equitable right to exist.

So, for example, the proponents of GMOs and new genetic techniques, will have to accept that a significant number – and in many countries a majority – of people do not want to have anything to do with farming and products created via those methods and that comprehensive labelling and transparency, equitably paid for, is required.

On the other hand, opponents of the technology, whatever their doubts and scepticism about its potential and the sustainability of its uses, will have to accept that significant, in some cases highly significant, numbers of people support at least some of its implementation. This means accepting a regulatory system that is not a de facto and, possibly undemocratic, blocking mechanism.

At the moment calls for proportionate regulation dominate the argument put forward by the biotech establishment. But actual co-existence means all players, across the spectrum, have to accept the perspective of equity and proportion, in their work, their positions and their discourse. This means amending value judgements and world views accordingly.

We have seen signs of willingness to do this in some places – though not in the discourses coming out of government in London, Brussels and Washington.

Definitions and scope

One criticism of existing GMO regulations is that they lack clarity in relation to new technologies. It is hard to see how any attempts to constructively revise regulations will fare any better in the current context.

It is clear that some key aspects of the claims made by policymakers and politicians do not sit easily with a number of people in the pro-genetic engineering science community. In particular, the narrative that genome editing and other novel genomic techniques are not genetic engineering methods in the way that "old style" GMOs are, is problematic for some.

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They do not agree that there is a fundamental difference and therefore struggle – conceptually and technologically – to find coherent ways of differentially regulating genome editing methods, other than by referencing contested grounds of risk assessment and public opinion.

For this reason, assertions that regulatory revision should be "science based" made by some in the research establishment, seem hollow and uncomfortable to others.

Many across the spectrum of opinion find the glib proposals that some types of gene editing are "akin to nature" or "just tweaking natural processes" or have the same impact as "natural processes" and/or "traditional breeding" to be woefully inadequate when looked at critically – or scientifically.

The European Commission study recognised that "molecular characterisation" would be needed to demonstrate similarity or differences and that:

"*NGTs and NGT products vary considerably (the same technique can be used in various ways to achieve various results and products), so it is not possible to draw generalised conclusions as to their safety*".

In other words, more clarity than currently exists is needed on definitions of gene editing, "traditional breeding", scope and boundaries and trigger points for differing regulatory treatments, and, especially important, the interface between gene editing and the ill-defined term and largely unregulated area of synthetic biology.

Health and safety issues

There are considerable disagreements over the significance of the health implications of different methods that fall under the catch-all term of "new (or novel) genetic techniques". The scientific literature documenting unexpected off- and on-target effects is mounting but its significance is contested, denied or ignored.

For example, the European Commission study repeatedly references the European Food Safety Agency's opinion of November 2020, which concludes that the risks from some gene editing methods (SDN-1 and SDN-2) are similar to conventional plant breeding.

Complex patterns of genetic change go beyond what has been achieved in genetic engineering and conventional breeding thus far

However, it totally ignores EFSA's February 2021 report, which cites an example of SDN-1 wheat where "*complex patterns of genetic change go beyond what has been achieved in genetic engineering and conventional breeding thus far*."

EFSA concludes in this case that "*risk assessment should take issues such as molecular changes, gene expression and the potential impact on health and the environment into account*."

Many in the research and scientific community show considerable confidence about the extent of knowledge regarding health risks in relation to plants. But as this example shows, this is a new and emerging technology and others would like to see a more cautious approach.

It is notable that until relatively recently it was widely asserted that gene editing of livestock was precise, safe and known. In the wake of a US experience with gene edited cattle, the European Commission study concedes that that scientific knowledge about the use of gene editing in livestock is too inadequate to liberalise regulations at this time.

Differing attitudes as to "known unknowns" and "unknown unknowns" and their potential impacts are to be expected. The Precautionary Principle has been developed to resolve these differences into a workable framework, but in the case of genome editing technology, the Precautionary Principle seems to have been applied in an inconsistent and inadequately transparent way.

In the above example, the treatment, referencing and framework of the two EFSA reports in the Commission study, appears to be especially egregious.

Similarly, the UK consultation document, driven by policy imperatives that have little to do with farming, environment, food or health, dishonestly fails to mention any evidence relating to the possibility of health and safety risks.

Such manipulation of information should have no place in responsible governance in a civilised society. Reconciliation of divergent views and the emergence of a workable consensus on this technology will only come about if all parties commit to responsible and responsive governance.

Risk assessment scope and methods

As there are significantly divergent views on the potential health and safety impacts of these technologies, so there are a range of views about risk assessment scope and methods.

However, it is worth reiterating that in over three years of talking to people and institutions from across the spectrum of opinion, we have found few, if any, opposed to regulation of some kind. Whether that baseline consensus can be built on is debatable but doing so would require consideration of, at a minimum, the following:

Process vs product assessment

This is usually presented as an either-or and, as such, misrepresents views at both ends of the stakeholder spectrum.

As a recent paper by Van Der Meer *et al* points out,

the EU GMO Directive and the Cartagena Protocol requires consideration of both process and product, but there is a lack of clarity about weighting, scope and triggers that should be addressed. Clarity on these issues is necessary whether existing regulations are scrapped, marginally revised or substantially amended.

Differentiated/tiered risk assessment

The argument that more proportionality should be employed in risk assessment has merit. After all, in all aspects of life people constantly weigh risks against benefits. This, and the above point, suggests that "case by case" assessment might be appropriate and should at least be considered.

But as the examples from EFSA quoted above show, line-drawing that excludes or includes some applications is a precarious exercise with novel and emerging technologies.

More definition and descriptions of criteria, process and protocol is needed before citizens can have confidence in differentiated regulatory revision. But this should be possible to achieve.

Issues of scale

In a recent paper, Heinemann and colleagues have considered the risks associated with increasing scale and frequency of new genetic technologies. In summary Heinemann further argues:

"*As you increase the number of practitioners, and the number of species that can be manipulated and kinds of genes that can be targeted and the rate at which multiple changes can be made in an individual, the sum of unintended and potentially adverse changes increases at an exponential rate*."

Whilst opinions are likely to differ on the extent and frequency of risk, it is surely unarguable that a technology hailed as "transformative" and "disruptive" will also pose new elements and levels of risk.

Those arguing for proportional regulation and case by case assessment need to offer a way to evaluate and incorporate issues of scale and frequency.

Parameters of 'safe use'

Critics of current GMO regulations highlight the illogicality of defining random mutagenesis as a GMO method, and then exempting it from regulation on the basis of a 'history of safe use' – especially when criteria of 'safe use' is not defined and the parameters of "history" are not described.

It seems reasonable to ask if methods of so-called targeted mutagenesis could be treated in the same

Sustainability means what?

Both the UK consultation and the European Commission study suggest that – freed from burdensome regulation – new genomic techniques can make a massive contribution to sustainable development. Yet neither focus adequately on the UN's Sustainable Development Goals, which the UK and EU are signed up to.

In the EC study there is implicit reference in sentences such as "Sustainability in the food system goes beyond the environment and can involve seed and food security, safety, nutrition, competitiveness and social aspects".

But the UK barely nods in the direction of anything more than safety, competitiveness and related issues wrapped up in the shambolic notion of sustainable intensification.

This production focussed, compartmentalised approach simply misses the crucial interactions of issues, institutions, people, culture and values involved in bringing about a truly sustainable farming and food system.

The sustainability case for genomic technologies can only be properly judged from the perspective of these interactions. This is now widely recognised, but even when the EU study looks in that direction there is no apparent understanding of what this means or how it should be done.

However, from our dialogues we believe there is a heightened awareness of the need, not to simplify or tweak, but to develop a context and structure for this technology which recognises the extent and interaction of issues beyond a narrow production focus.

Moreover, we feel there is a willingness to try new co-operation across the 'pro' and 'anti' barriers in order to pressure institutions, policy makers and governments to put equitable and citizen responsive policies and regulations in place.

way. If so, what criteria and parameters would have to be met to qualify for the exemption?

More to the point, any regulatory revision that removes or 'tiers' some types of gene editing and not others from oversight must be based on clear criteria of 'safe use', including the time period over which 'safe use' has been demonstrated, or will be monitored.

As it stands neither the UK nor the European consultations have adequately addressed any of these points. With goodwill, a discussion between stakeholders on these points might facilitate the emergence of a more broadly based consensus than currently exists.

Transparency and labelling issues

Whilst it is not possible to say there is a universal "buy-in" of transparency and labelling, there is widespread acknowledgement that it is required, even by many on the pro-genomic technologies part of the opinion spectrum.

In our discussions we have found that, whilst there are differing views regarding purpose, extent and value of labelling, the principle of greater transparency, more public access to information throughout the production process and end product has a surprisingly high level of support.

There is also a world of difference between token transparency and a meaningful, empowering system

Of course, the devil is in the detail. But it has been encouraging to hear genetic engineers/ developers suggest the possibility of a publicly accessible register of gene editing events, even if that event can't be determined solely by analysis.

One interesting point made for this, is that such a register would facilitate product and market development for small and medium-sized enterprises (SMEs) as well as, potentially, greater citizen acceptance of the technology.

The European Commission study clearly highlights the rights and concerns of organic and non-GMO producers and citizens. Transparency and labelling are an essential pre-requisite of "co-existence" and the fact that pro-technology stakeholders are more accepting of the view that it is the right of citizens is a source of optimism.

Nonetheless, transparency and labelling are controversial issues in relation to trade and so-called "non-tariff barriers". There is also a world of difference between token transparency and a meaningful, empowering system. But we are encouraged that at least there is the possibility of discussion.

Detection

How fruitful any discussion is, depends in part on how blinkered or imaginative approaches are taken on the issue of detection.

Both the UK and the European Commission study use the difficulty of having a "science-based" form of detection as a justification for deregulation.

It's a spurious argument given how much in the farming and food marketplace (and how many commercial claims) is based on declaration, voluntary codes, so-called "goodwill" and audit trails.

Provenance' is massively important in the food market and at all levels of supply chains. This is largely determined by audit trail and increasingly by blockchain information technology, all of which rely on sharing of information not end-product analysis.

Criticism that this is inadequate and leaves large loopholes for fraudulent behaviour is curious. Does this mean that companies and institutions promoting and using gene technologies are less trustworthy, and more likely to pursue dishonest behaviour than others in the farming and food supply chain?

In this area new ideas will eventually emerge and methods will improve.

Detection through analysis is, in fact, already possible, though it is currently not straightforward. Analysis is made significantly easier if the genome editing 'event' is known, declared and registered.

Projects like Norway's FOODPRINT are working on technically and economically feasible options for gene-editing detection in the context of traceability and labelling of genetically modified (GM) products throughout the food chain.

However, an accessible, transparent register has implications for commercial confidentiality and intellectual property.

Intellectual property rights

Intellectual property rights (IPR) in the form of patents have been an essential element in the development and implementation of genetic engineering in food and farming.

The regulatory system and commercial application of GMOs have been built around the ownership of patents and licences. This is undeniable but also highly controversial, since IPR has facilitated corporate centralisation of farming and food and severely limited transparency in regulatory and commercial processes.

The most obvious indication that gene editing and other new genomic techniques are of the same order and genus as the previous generation is that the pioneers of gene editing technology have been locked into a long-running and global legal battle over ownership of the patents to the technology, with no end in sight.

They – and others – have formed numerous companies to exploit the IPR of these approaches in many fields and notably in crops and animals.

By definition, patents are granted for novel, man-made inventions. From this perspective it is hard to view efforts to frame gene editing as a 'natural process' or the same as 'traditional breeding' – neither of which is subject to patents – as anything other than disingenuous.

Through our outreach we have found that a number of researchers and developers using gene editing technology agree with this. There is also a recognition that liberating the technology and making it more widely available (for example to SMEs) requires greater transparency and revised notions of commercial confidentiality then currently exists.

What this means in practice and extent is unclear. One suggestion for crop breeding is that those types of gene editing said to be akin to 'traditional' plant breeding could operate under a similar system to the existing Plant Breeders' Rights system.

This would require expanding crop registration to cover gene editing events and provide royalty payments but would also allow farmers to save seed and use it for growing and breeding.

Neither the UK consultation nor the European study offered any real ideas on these issues.

Towards equitable co-existence

Genome editing remains an experimental technology. Looked at politically, economically, scientifically or democratically simply removing regulations from plants and animals created using this technology makes no sense. Nevertheless, this may be where we are heading.

Even if the eventual destination ends up being revised regulations, this needs to be done for a rational purpose and to the highest standards.

We believe there is a fragile and emerging new awareness and willingness amongst people on opposing sides of the genome editing debate to work together. This belief is not based on an illusion that good will can simply melt all differences away.

Some of these differences are rooted in fundamentally different values and world views. Some, however, relate to technological priorities, risk/benefit balance, precaution and innovation, assessment methodologies, degree/method of transparency that are substantial but may, in time, either be resolved or reconciled.

There is now, widespread concern that our society is in such peril that 'business as usual' – and the 'conversation as usual' that accompanies it – is not an option. Indeed, for us, one of the most dispiriting aspects of the Defra process was how 'old school' it was and how it seemed designed to play on fears and reinforce divisions.

Concern for where we are all heading is so profound, that some people at least are willing to step outside of their customary mindsets in order to explore workable options for the greater good.

Crucially, this stepping outside will have to be done on all sides and be accompanied by a new narrative of equity, pluriformity, transparency, broad societal goals beyond production and an overt recognition of the rights and responsibilities of all parties.

If that can be achieved, then we might begin to shift the impasse that has plagued the agricultural genetic engineering debate for far too long and avoid the regulatory evisceration that can only lead to problems further down the line.

Only by breaking that impasse can we find ways of communicating, ways of working and structures that places technology in the service of an equitable and civilised society.

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