

17 March 2021

By email: consultationreply@defra.gov.uk

Dear Martin Cannell

The regulation of genetic technologies

1. The Nuffield Council on Bioethics is an independent organisation that examines and reports on ethical questions raised by recent advances in biological and medical research. Over the past 30 years, the Council has achieved an international reputation for advising policy makers and stimulating debate in bioethics. We aim to inform policy through timely and thorough consideration of ethical implications, engaging a wide range of people in order to inform our deliberations, and help to ensure that the benefits of developments in medicine and the biosciences are realised in a way that is consistent with public values.

2. In 2016 we published a report, [Genome editing: an ethical review](#), that surveyed a range of applications for genome editing technologies and identified areas that required further examination. This led us to undertake a major inquiry into [genome editing in farmed animals](#), which will conclude later this year. Among all the applications of genome editing, applications in farmed animals are among the most advanced yet least discussed, despite the significant influence public attitudes have had on previous agricultural biotechnologies and the distinctive issues that are involved in their use in animals.

3. Our inquiry is being carried out by an expert, interdisciplinary working group. As the Council has not yet received or adopted their final report, we are not in a position to share any findings or recommendations, although we look forward to discussing these with you in due course. The present submission is therefore restricted to commenting on three points at which your current consultation (and wider review of biotechnology) specifically intersects with the work of the Council.

I. The importance of public views

4. The Council welcomes the publication of the present consultation as a first step in a policy process to review and (as the intention has been clearly signalled) to revise the framework for regulation of biotechnology products. Although the consultation may draw out the responses of existing stakeholders and committed individuals, it undoubtedly raises issues of broader public interest.

5. As part of the research informing our current project on genome editing and farmed animals, we commissioned a review of the literature on public attitudes towards genetically modified organisms (GMOs) and novel foods (Rowe and Watermeyer, forthcoming). Our aim was to understand how much is known about public attitudes and how much of what is known might be relevant to genome editing (rather than earlier generations of biotechnology) in farmed animals (as distinct from other organisms). The

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review found that attitudes were influenced by the interaction of multiple factors. Among the most salient of these, the review found that the purpose of the application was more important than the details of the technical processes involved, that attitudes were strongly linked to complexes of pre-existing values and that many were deeply entrenched, which limited the effectiveness of science communication. Nevertheless, the review could offer only tentative conjectures about what this would mean for public responses to prospective genome editing technologies. We have shared this review, in confidence, with officials at Defra.

6. Aware of the bearing that public opinion has had on earlier generations of biotechnology, the Council believes there are substantive and instrumental, as well as normative, reasons to engage the public (National Research Council, 1996). Furthermore, we believe that that a failure to do so in an earnest and open manner risks provoking damaging distrust. From the findings of our commissioned review, we can also anticipate that these consequences would be likely to carry across into other applications of biotechnology. There is an opportunity now, with the emergence of genome editing, to align public policy with the public interest for this next generation of biotechnologies, as well as for new applications of earlier technologies.

7. For this reason, we have been working with the Biotechnology and Biological Sciences Research Council and Sciencewise (the programme funded by UK Research and Innovation that aims to ensure policy is informed by the views and aspirations of the public) to develop a major public dialogue initiative on agricultural genome editing applications. Rather than simply surveying the weight of opinion on one side or the other, public dialogue offers the opportunity to explore how people from different perspectives engage with each other in response to a set of challenges that affect them collectively. It seeks common ground rather than driving people from it. It is a disappointment to us that this initiative has been held up by difficulties clearing funding, so that we are unable to report the outcome to you at this stage. We are hopeful, however, that we will be able to expedite this process so that it can contribute in a timely way to the current review.

II. The criterion of equivalence to ‘traditional breeding’

8. Part 1 of the consultation proposes, by amendment to the Environmental Protection Act 1990, to alter the definition of ‘Genetically Modified Organism’ and thereby to put organisms that ‘could have been produced by traditional breeding’ outside the regulatory regime of that Act and dependent provisions. The organisms thus exempted would include some, though not all, organisms produced using genome editing techniques.

9. Though the Council has not considered this specifically, it might reasonably be concluded that the risk of environmental and other harms from biotechnology products (for example, harms to the health of consumers) are adequately managed by existing provisions for the regulation of non-GMO products. Our concern, however, is that the framing of the consultation document obscures other equally relevant considerations. This is not helped by the assertion in the consultation document that: “Our position follows the science, which says that the safety of an organism is dependent on its characteristics and use rather than on how it was produced.” It is to be hoped that the invitations to supply evidence in support of responses will accommodate a range of different supporting considerations, not limited to quantitative information.

10. While we may ‘follow the science’ to estimate the likelihood of a harm occurring, science is necessarily silent about people’s appetite for risk, the relative importance they give to different harms, and the relative significance of those possible harms when considered alongside potential benefits. These are questions of value. This is why we believe there is a need for more nuanced understanding of the public interest to inform public policy.

11. The fact that traditional breeding in plants may involve the application of chemical mutagens and ionising radiation to produce random mutations is not well understood by non-specialist members of the public. This underlines the need to explore the nature of public interests other than through a stakeholder consultation. In farmed animals ‘traditional’ forms of selective breeding have resulted in breeds with a high frequency of congenital health problems (e.g. European Commission, 2016).

These outcomes are arguably not well controlled by existing non-GMO regulation, albeit that aggravating (or ameliorating) them by the use of biotechnology may be coincidentally forestalled by the GMO regime.

12. For this reason, although the Council does not wish to mount an argument in defence of the regime established by European Directive 2001/18, we submit that any revision of the law in this area should be informed by a more thoroughgoing review of the use of biotechnologies in food and farming systems, and for related purposes, rather than piecemeal revision of existing legislation to facilitate particular technologies. In the case of livestock and aquaculture, this should include consideration of measures to secure the welfare of farmed animals and manage long term impacts on the environment and biodiversity, alongside removing redundant regulation and ensuring the safety of products for human consumption.

13. We acknowledge that breeders have introduced 'balanced' breeding programmes that take into account guidance, including guidance from Defra under the Animal Welfare Act 2006, that highlights the need to address welfare and environmental outcomes. We remain concerned, however, that breeding strategies should not be used to mitigate or mask the adverse health effects of unsatisfactory husbandry practices while leaving animals in conditions of poor welfare. Our forthcoming report will examine this in more detail.

III. The distinction between parts 1 and 2 of the review of biotechnology regulation

14. The proposed distinction between genome editing that mimics the possible outcomes of 'traditional' breeding and more radical genetic modification (which may also be accomplished by genome editing) has intuitive appeal. This appeal is mainly due to the privileged framing being that of product safety (on the assumption that genome editing offers more precise control of well characterised interventions than other techniques). However, we are not convinced that this is either the most proper or most popular framing.

15. We recall here our commissioned research on public attitudes to genetic modification and novel foods found that members of the public seem to care less about the technical aspects of the process used than about the nature of the application (Rowe and Watermeyer, forthcoming). One way to make people care about the distinction between the techniques, however, would be to invest this distinction with regulatory significance. If, as a result, public acceptance polarises around this distinction, this is likely to be to the detriment of applications, many of them potentially offering significant public benefits, that could not have come about by 'traditional breeding' (for example, those involving transgenic modifications).

16. Most importantly, however, the concerns about breeding to which we have drawn attention above apply equally to organisms that might be produced by 'traditional' breeding (albeit that they may actually be produced by genome editing) and to organisms that could not be produced in this way (for example, transgenic organisms). In relation to these concerns, the significance of the distinction becomes nugatory and the two parts of the consultation fall into one another. This, again, argues for a more thoroughgoing review of biotechnology regulation rather than the piecemeal facilitation of particular technologies.

Conclusion

17. The scope of considerations that are engaged by the facilitation of new technological pathways is much broader than product safety or risks of environmental escape. Most of these apply across different techniques of breeding. If the UK wishes to present itself as a global leader in protecting animal welfare and the environment, the review should give consideration to measures that will increase confidence that the application of biotechnology will ameliorate rather than aggravate these challenges. This requires a more thoroughgoing review of the biotechnology regulation than is proposed in part 1 of the current consultation.

18. We remain at your disposal if you would like us to amplify any points made in this submission. We look forward to engaging with Defra as this review proceeds and, in particular, in relation to our forthcoming report.

Yours sincerely,

A handwritten signature in black ink that reads "Pete Mills". The signature is written in a cursive style with a horizontal line underneath the name.

Pete Mills
(Assistant Director, Nuffield Council on Bioethics)

* References and responses to specific questions follow.

References

- Nuffield Council on Bioethics (2016) *Genome editing: an ethical review* (<https://www.nuffieldbioethics.org/publications/genome-editing-an-ethical-review>)
- Nuffield Council on Bioethics (forthcoming 2021) *Genome Editing and Farmed Animals* – Project page (<https://www.nuffieldbioethics.org/publications/genome-editing-and-farmed-animals/>)
- Rowe and Watermeyer (forthcoming 2021) – apply to Nuffield Council on Bioethics
- European Commission (2016) Report from the Commission to the European Parliament and the Council on the impact of genetic selection on the welfare of chickens kept for meat production COM(2016) 182 final (<https://ec.europa.eu/transparency/regdoc/rep/1/2016/EN/1-2016-182-EN-F1-1.PDF>)
- National Research Council (1996) *Understanding Risk: Informing Decisions in a Democratic Society*. (<https://doi.org/10.17226/5138>).

Responses to specific consultation questions

Section 1 – About you

1. Would you like your response to remain confidential? b. No
2. What is your name? Nuffield Council on Bioethics
3. What is your email address? bioethics@nuffieldbioethics.org
4. Please tell us who you are responding as? b. Non-governmental organisation – In an official capacity as the representative of another organisation.
5. Where do you live? a. England
6. What is the name of your business/ organisation? Nuffield Council on Bioethics
7. Which of the following areas are you interested in? Please select all that apply. Cultivation of crop plants, Breeding farmed animals, Human food, Animal feed, Human and veterinary medicines, Other sectors/activities
8. Where does your business/organisation operate? e. Other (please state) The Nuffield Council on Bioethics is an independent organisation based in the UK but with a global reach.

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

1. Please see paragraphs 14–16 above.
2. Please see paragraphs 9–10 above.
3. Please see paragraphs 5 and 12 above.
4. Please see paragraphs 14–16 above.

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

1. Please see paragraphs 11–13 above.
2. Please see paragraph 12 above.