

# BVA response to Defra consultation on the regulation of genetic technologies

## Who we are

- 1) The British Veterinary Association (BVA) is the national representative body for the veterinary profession in the United Kingdom. With over 18,000 members, our primary aim is to represent, support and champion the interests of the United Kingdom's veterinary profession. We therefore take a keen interest in all issues affecting the profession, including animal health, animal welfare, public health, regulatory issues and employment matters.

## Introduction

- 2) We welcome this opportunity to respond to Defra proposals on the regulation of genetic technologies. We agree that gene-editing has the potential to contribute to producing abundant, safe food and in doing so play a role in reducing the environmental impact of a growing global population.
- 3) Global consumption of animal-derived food is expected to double by 2050. There is increasing recognition that animal agriculture can be a significant contributor to environmental degradation, climate change, habitat loss, and waste. Changes in animal production and farming practices are necessary to increase the efficiency of agriculture and mitigate its environmental impact, and there is an important role for new technologies and innovation in sustainable animal agriculture<sup>1</sup>. Careful consideration should be given to how breeding and genetic modification can be used in an ethically responsible way to improve animal health and welfare, increase efficiency, and support sustainable agriculture.

## Background and scope

- 4) The consultation document as presented lacks clarity, particularly in relation to the terminology used and the phrasing of the questions, which are leading in places. For example, there is no definition of 'traditional breeding' although the term is used throughout the consultation and used to frame the arguments in support of deregulation of genetic technologies. There are a wide range of technological advancements which have become normal practice over the years, and it is unclear to what extent these are included or not in the interpretation of 'traditional breeding'. The process of cloning does not involve gene-editing but would be considered by most to be non-traditional. Selective breeding may or may not be considered 'traditional'. Clarity on the key terms used throughout the document is essential if the consultation is to elicit meaningful feedback for translation into appropriate and adequate legislation.
- 5) We consider that the introductory commentary of the consultation document is misleading in that it implies that gene-editing represents an improvement on 'traditional breeding' with regard to unintended genetic changes. The potential for unanticipated off-target effects with gene-editing is widely acknowledged (eg unanticipated somatic events<sup>2</sup>) including possible mutagenesis (Gupta et al. 2019)<sup>3</sup>. The consultation then goes on to partially contradict this inference by proposing deregulation based on the incorrect premise that 'traditional breeding' results in characteristics which can be assumed 'safe' and therefore gene-edited organisms which produce the same outcome are also 'safe'.

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<sup>1</sup> Sustainable animal agriculture is defined as animal agriculture carried out in a way that meets the needs of the present without compromising the ability to meet the needs of the future.

<sup>2</sup> Harrison, P. T. and Hart, S. (2018). A beginner's guide to gene editing.

<sup>3</sup> CRISPR-Cas9 system: A new-fangled dawn in gene editing. Life Sciences 232: 116636.

- 6) We consider that the stated basis of the proposals is fundamentally flawed. The technique of gene-editing can itself be unsafe as it can have deleterious 'off-target' effects on health and welfare. Depending on the type of genetic editing used, such deleterious effects can be passed down to future generations. These effects are unpredictable - just as a genetic mutation which might occur through 'traditional' breeding methods is unpredictable – and are currently unavoidable.
- 7) Consistent with societal and governmental attitudes about human use of animals, any use of gene-editing to increase the efficiency of food production must prioritise animal health and welfare. Given concern about off-target effects and a general lack of evidence base about the health consequences for animals produced by gene-editing, such prioritisation requires the implementation of a monitoring and reporting function on the health and welfare of gene-edited animals. This is analogous to the reporting function contained within the Human Fertilisation and Embryology Act (as amended in 2008) which facilitates data collection about the efficacy and safety of techniques and the health of children conceived using assisted reproductive technologies. It follows that animals produced using gene-editing should be regulated such that regulation can be used to require a reporting / monitoring function. In order to monitor and regulate current and future developments in genetic technologies, a regulatory body should be set up, similar to the Human Embryology and Fertilisation Authority, responsible for reviewing evidence and advising on ethical issues.
- 8) We strongly support retained EU law which requires that all gene-edited organisms are classified as genetically modified organisms. The EU regulates gene-edited organisms based on process, rather than outcome. This is in direct contrast to the countries cited in the consultation document, which regulate based on product, and where no safety or environmental assessments are required on gene-edited organisms, unless the organism contains foreign DNA<sup>4</sup>. A move away from highly regulated to a status of lightly regulated or even no unique regulations, would place England at odds with the EU, potentially jeopardising the relationship with a key trading partner. Alignment with the high standards of the EU must not be abandoned in pursuit of profitable trade deals with markets where animal welfare is a much lower priority. To do so represents a real risk of damage to our reputation in relation to animal welfare standards. Instead, as we take control of our trade policy, we should be assertive in spreading positive animal welfare norms via trade agreements.
- 9) We note that the proposals relate to England only. As outlined in our submission to the Department for Business, Energy, and Industrial Strategy on the UK Internal Market white paper, it is essential that there is ongoing cooperation and collaboration across the UK<sup>5</sup>. Deregulation of gene-editing in England is likely to create burdens within the UK, jeopardising the principle of mutual recognition which is necessary to support frictionless trade.

## Section 2 – Part 1: the regulation of GMOs

- 10) Currently, organisms developed using gene-editing are regulated as genetically modified organisms. This section of the consultation invites views on whether this should continue to be the case “...*even if their genetic change(s) could have been produced through traditional breeding.*” As already mentioned above, the definition of the term ‘traditional breeding’ in this context is unclear, and the question is leading.
- 11) We consider that gene-edited organisms should continue to be regulated based on process, rather than outcome, for animal welfare reasons, as already outlined. Gene-editing can result in off-target effects, and lack of regulation will mean a missed opportunity to gather data. The UK should be looking to become a world leader in the regulation of gene-edited organisms and focus on this as its trade USP.
- 12) The consultation goes on to ask whether organisms produced by gene-editing or other genetic technologies pose a similar, lesser or greater risk of harm to human health or the environment compared with their traditionally bred counterparts as a result of how they were produced.

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<sup>4</sup> Global gene-editing regulation tracker <https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/japan-animals/>

<sup>5</sup> <https://www.bva.co.uk/media/3681/bva-submission-to-the-beis-white-paper-uk-internal-market-final.pdf>

- 13) As gene-editing is still a relatively new process we consider that the risks are currently difficult to quantify, which is why it is essential that regulation and transparent reporting of data continues such that an evidence base can be built. If gene-editing is deregulated then the opportunity to gather data, continually improve on techniques, and achieve better outcomes, will be lost.
- 14) Regarding the so-called 'non-safety issues' which should be considered in the event of deregulation, the consultation document rightly identifies animal welfare as one example. Animal welfare should be given greater prominence in the debate over gene-editing and any legislative reform should, as an ethical imperative, ensure that animal welfare is protected, recognising its key role in achieving sustainability objectives and fostering international trading relationships.
- 15) Transparency and consumer choice in relation to food labelling is also an important consideration. Consumers should value quality animal-derived products. This means good animal health and welfare, food safety, environmental protection, and fair returns for producers. To support this, we have produced a position on farm assurance schemes<sup>6</sup> with seven guiding principles to assist our members and the wider public to understand how farm assurance schemes promote higher animal health and welfare, as well as the BVA #ChooseAssured: UK Farm Assurance Schemes Infographic<sup>7</sup> to aid the public in their purchasing choices of high health and welfare products. De-regulation would mean that gene-edited products were not identifiable, and that consumers were unable to make informed choices in relation to gene-edited food products, a retrograde step for 'Brand Britain'.
- 16) The final question in this section is based on an assumed and unclear definition of 'traditional breeding' which renders it impossible to answer. As such we can offer no criteria and urge Defra to reconsider and clarify the fundamental assumptions of the proposals before redrafting and reissuing the consultation.

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

- 17) As already stated, we strongly support retained EU law which requires that all gene-edited organisms are classified as genetically modified organisms. For the reasons outlined above we do not support deregulation in this area. Although we understand this part of the consultation is presented as the start of a process of evidence gathering to inform approaches to regulating novel organisms in the longer term, we are concerned by the apparent haste with which part one of this consultation has been put together and would strongly oppose a similar degree of haste being applied to wider legislative reform. The subject area is extremely complex and there are significant potential consequences for animal health and welfare, food safety, trade, and the environment if reform is expedited to facilitate the production of cheap food.

### **Conclusion**

- 18) The proposals as presented are leading, misleading, poorly defined, and likely driven by industry and the desire to save costs. Gene-editing and other genetic technologies have an important role to play in promoting efficiency and supporting sustainable food production for a growing population. To realise the benefits of this relatively new and rapidly evolving area of science, transparent monitoring and reporting is critical, and as such the development of organisms using gene-editing must be regulated.

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<sup>6</sup> <https://www.bva.co.uk/media/3113/bva-policy-position-on-farm-assurance-schemes-31519.pdf>

<sup>7</sup> <https://www.bva.co.uk/media/3768/bva-uk-farm-assurance-schemes-choose-assured-infographic-october-2020-for-web.png>