Response ID ANON-HBYG-QVBV-9

Submitted to **The regulation of genetic technologies**
Submitted on **2021-03-01 11:15:42**

Introduction

1 Please provide your consent to participate in this consultation.

I consent to participate.

2 Would you like your response to remain confidential?

No

If you answered yes to this question, please give your reason.:

3 What is your name?

Full Name :
Chris Platt

4 What is your email address?

Email:
info@conservativeanimalwelfarefoundation.org

5 Please tell us who you are responding as?

Non-governmental organisation - In an official capacity as the representative of a non-governmental organisation/ trade union/ other organisation.

About Your Business / Organisation

7 What is the name of your business/organisation?

Please state:
Conservative Animal Welfare Foundation

8 Which of the following areas are you interested in? Please select all that apply.

Breeding farmed animals, Human food, Animal feed

9 Where does your business/organisation operate? Please select all that apply.

Other (please state below)

Please state:
United Kingdom

Part 1: The regulation of GMOs which could have been developed using traditional breeding methods

10 Currently, organisms developed using genetic technologies such as GE are regulated as genetically modified organisms (GMOs) even if their genetic change(s) could have been produced through traditional breeding.Do you agree with this?

Yes – they should continue to be regulated as a GMO

Please explain your answer, providing specific evidence where appropriate. This may include suggestions for an alternative regulatory approach.:
We do not agree with the premise of the question. Gene edited organisms have not been produced by traditional breeding, so there is no basis for concluding that they “could have been” produced in this way. The entire purpose of expanding the use of gene editing in animals is to create animals that do not occur naturally, and that can be patented and used in industrial farming. This is likely leading to greater intensification of farming and more harm to animals.

There is no definition of what is meant by “could have been produced by traditional breeding".

There are many arguments why gene-edited GMOs are not the same as traditionally bred plants or animals. Gene edited crops are created in laboratories and patented on the basis that they are significantly different from organisms that exist in nature. They are the result of human decisions, including commercial interests, which may have adverse consequences.

11 Do organisms produced by GE 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?

Greater

Please provide evidence to support your response including details of the genetic technology, the specific risks and why they do or do not differ. Please also state which applications/areas your answer relates to (for example: does it apply to the cultivation of crop plants, breeding of farmed animals, human food, animal feed, human and veterinary medicines, other applications/ areas). :
There is no definition of what is meant by “could have been produced by traditional breeding". The proposal would exempt (at least some) gene edited GM organisms from the current requirements for health and environmental risk assessments and ongoing monitoring. This exemption would apply to imports as well as to gene edited GMOs produced, tested and/or marketed in England. There would be no means to track where these gene edited GMOs ended up, or to contain their spread.

12 Are there any non-safety issues to consider (e.g. impacts on trade, consumer choice, intellectual property, regulatory, animal welfare or others), if organisms produced by GE or other genetic technologies, which could have been produced naturally or through traditional breeding methods, were not regulated as GMOs?

Yes

Please provide evidence to support your response and expand on what these non-safety issues are.:
Gene-edited organisms are classed as genetically modified organisms (GMOs) in most countries in the world, including the EU, the devolved administrations (Wales, Scotland and Northern Ireland) and Parties to the Cartagena Protocol on Biosafety.(1)

The proposals therefore have major implications for consumer choice and for trade within the UK’s internal market, with the EU, and more globally. Since the whereabouts of gene edited organisms, in the food chain or the environment, will be unknown if they are deregulated, it would be impossible to comply with other countries’ labelling, traceability and monitoring requirements for GMOs. Businesses in the food, farming, aquaculture and fishing sectors will undoubtedly be impacted, but there are also many other sectors where gene edited organisms could be released, such as forestry and horse racing.

1. Why genome edited organisms are not excluded from the Cartagena Protocol on Biosafety. Third World Network and GeneWatch UK. December 2020. https://biosafety-info.net/wpcontent/uploads/2020/12/Genome-edited-BioBrief-Dec2020-Sirinathsinghji.pdf

13 What criteria should be used to determine whether an organism produced by gene editing or another genetic technology, could have been produced by traditional breeding or not?

Please provide evidence to support your response.:
We do not agree with the premise of the question. Gene edited organisms have not been produced by traditional breeding, so there is no basis for concluding that they “could have been” produced in this way. The entire purpose of expanding the use of gene editing in animals is to create animals that do not occur naturally, and that can be patented and used in industrial farming. This is likely leading to greater intensification of farming and more harm to animals.

For gene edited animals, the following issues and evidence are important.

(i) Production of gene edited animals requires the use of other techniques in order to reproduce animals with altered DNA. These processes are not comparable to anything that can occur naturally. The DNA of a mammal for example, can be gene edited in a non-reproductive cell (such as a skin cell), but to reproduce the animal, the nucleus of this cell (which contains the altered DNA) then needs to be fused into an egg from the same species, and implanted into a female animal to produce gene edited offspring: this is known as reproductive cloning. This process is highly inefficient and it leads to numerous adverse effects on animal welfare. Cloning can be avoided in some cases by injecting the altered DNA directly into reproductive cells, but this process still results in multiple failures and often the cells of the gene edited animal do not all contain the required gene edits: thus, cloning is still the preferred method of producing gene edited mammals. A single gene edited animal typically requires hundreds (or sometimes thousands) of embryo transfers to create one gene edited mammal (Tan et al., 2016). Adverse effects on animals include: the effects of egg harvesting procedures on egg donor animals; effects of hormone injections and surgery on surrogate mother animals; miscarriages, stillbirths, deformities and deaths associated with the numerous unsuccessful pregnancies; slaughter of live animals which do not carry the required genome edits; adverse effects of cloning which may occur in surviving animals (Kirkden & Broom, 2012). Cloning of one or two animals may be sufficient for experimental animals, but commercial applications would require these techniques to be applied on a far larger scale. For example, one paper proposes that multiple bulls would need to be gene edited and cloned over many generations to create a commercially viable herd of gene edited dairy cows (Mueller et al., 2019);
(ii) Gene editing in animals has proven unintended effects, including ‘off-target’ effects (gene edits in the wrong place) and ‘on-target’ effects, including unwanted integration of DNA from other species (Norris et al., 2020). Thus, the process of gene editing gives rise to changes in the DNA of an animal that would not occur using conventional breeding;
(iii) Gene edits may be made intentionally in ways that do not give sufficient weight to the welfare of animals. For example, many ‘super-muscly’ gene edited animals have been created which suffer adverse health effects (Rana and Cramer, 2018). In general, attempts to use gene editing to increase production are likely to have adverse effects. Whilst some such animals can be created using conventional breeding, this would likely occur on much larger scale, and in more species/breeds, with the use of gene editing. Thus, the scale of the anticipated problems for animal welfare is not something that “could” occur naturally.
(iv) Even for potentially desirable traits, such as disease resistance, gene editing can create problems that do not occur naturally. These include narrowing the gene pool (reducing diversity) due to using a small number of (usually cloned) founder gene edited animals, and potentially creating silent reservoirs of disease (if animals become infected without showing symptoms), or speeding up the evolution of pathogens (viruses, fungi or bacteria) in response to the gene edits in the animal (EFSA, 2013). Further, the purpose of such gene editing is to allow more animals to be more tightly packed into industrial-scale farms. Again, this could considerably exacerbate problems for animals beyond what “could” occur naturally.

References:
EFSA. (2013). Guidance on the environmental risk assessment of genetically modified animals. EFSA Journal, 11(5), 3200. https://doi.org/10.2903/j.efsa.2013.3200

Craymer, P. R. and L. (2018, December 14). Big Tongues and Extra Vertebrae: The Unintended Consequences of Animal Gene Editing. Wall Street Journal. https://www.wsj.com/articles/deformities-alarm-scientists-racing-to-rewrite-animal-dna-11544808779

Kirkden, R. D., & Broom, D. M. (2012). Welfare of Genetically Modified and Cloned Animals Used for Food. Available on: https://www.ciwf.org.uk/media/4237869/welfare_of_genetically_modified_and_cloned_animals_used_in_food.pdf

Mueller, M. L., Cole, J. B., Sonstegard, T. S., & Van Eenennaam, A. L. (2019). Comparison of gene editing versus conventional breeding to introgress the POLLED allele into the US dairy cattle population. Journal of Dairy Science, 102(5), 4215–4226. https://doi.org/10.3168/jds.2018-15892

Norris, A. L., Lee, S. S., Greenlees, K. J., Tadesse, D. A., Miller, M. F., & Lombardi, H. A. (2020). Template plasmid integration in germline genome-edited cattle. Nature Biotechnology, 38(2), 163–164. https://doi.org/10.1038/s41587-019-0394-6

Tan, W., Proudfoot, C., Lillico, S. G., & Whitelaw, C. B. A. (2016). Gene targeting, genome editing: from Dolly to editors. Transgenic Research, 25(3), 273–287. https://doi.org/10.1007/s11248-016-9932-x

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

14 There are a number of existing, non-GM regulations that control the use of organisms and/or products derived from them. The GMO legislation applies additional controls when the organism or product has been developed using particular technologies.Do you think existing, non-GM legislation is sufficient to deal with all organisms irrespective of the way that they were produced or is additional legislation needed? Please indicate in the table whether, yes, the existing non-GMO legislation is sufficient, or no, existing non-GMO legislation is insufficient and additional governance measures (regulatory or non-regulatory) are needed.Please answer Y/N for each of the following sectors/activities:

Gov_Sufficiency - Yes (sufficient governance):

Gov_Sufficiency - No (insufficient governance):
Cultivation of crop plants, Breeding farmed animals, Human food, Animal feed, Other sectors/activities

Please provide evidence to support your response.:
Non-GM legislation covers some aspects of food safety, but this does not cover our principal concerns regarding the welfare of animals outside laboratory settings (on farms or fish farms, or in the wild). Nor does non-GM legislation cover environmental impacts.

GM legislation requires the traceability, monitoring and labelling of genetically modified organisms (GMOs) from farm (or sea) to fork. This is important because:
(i) The welfare of gene-edited farm animals is not addressed by non-GM legislation;
(ii) Consumers have a right to know what they are eating;
(iii) Consumers, retailers, regulators, importers/exporters and even producers/farmers will not know whether gene edited animals are present in products/supplies (including imports) unless gene edited animals, and associated reproductive material (sperm, eggs etc.) are tracked and labelled from farm to fork;
(iv) Since gene edited animals are living organisms, assessment of food safety and environmental risks will need to include interactions with their environment (on the farm, for example).

In contrast, non-GM food safety laws would at best consider the safety of specific ingredients, which are typically produced in a uniform quality assured factory-based production process. Treating gene edited meat, milk or dairy products simply as ingredients would neglect and consideration of their existence as living animals on farms.

Gene edited wild animals could also be created and their welfare and wider impacts on the environment and human health would not be considered under non-GM laws, nor would it be possible to track and monitor them if they were exempt from GM laws.

15 Where you have answered no (existing, non-GMO legislation is insufficient to deal with organisms produced by genetic technologies), please describe what additional regulatory or non-regulatory measures you think are required to address this insufficiency, including any changes you think need to be made to existing non-GMO legislation. Please explain how any additional measures you identify should be triggered (for example: novelty, risk, other factors).

Please provide evidence to support your response.:
We support the international definitions of genetically modified organisms (GMOs) which include gene edited organisms. Regulating gene edited animals as GMOs requires risk assessments, monitoring, labelling and traceability. This is consistent with the approach taken under the Cartagena Protocol on Biosafety to the UN Conventional on Biological Diversity and in most other countries (including the EU).