REGULATION OF GENETIC TECHNOLOGIES

DEFRA Consultation Response
March 2021

A-LAW
UK Centre for Animal Law

Response to the public consultation on the regulation of genetic technologies submitted by the UK Centre for Animal Law (A-Law)

March 2021

Section 1 – about you

1. **Would you like your response to remain confidential?**

   No

2. **What is your name?**

   Paula Sparks

3. **What is your email address?**

   paula.sparks@alaw.org.uk

4. **Please tell us who you are responding as?**

   Non-governmental organisation – charity

5. **What is the name of your business / organisation?**

   UK Centre for Animal Law (A-Law)

6. **Which of the following areas are you interested in?**

   - Cultivation of crop plants
   - Breeding farmed animals **X**
   - Human food
   - Animal feed
   - Human and veterinary medicines
   - Other sectors/activities

7. **Where does your business / organisation operate?**

   England & Wales

A-Law – who we are

8. The UK Centre for Animal Law (A-Law) exists to promote knowledge and education about the law relating to animal protection, and the more effective enforcement of legislation relating to animals. We seek to be a source of objective, independent legal analysis on animal protection law issues. Whilst legal topics are often complex, it is our job to explain them as clearly as possible, so as to increase the effectiveness of UK animal protection organisations collectively, and to promote informed public debate. We are registered as a charity in England and Wales and are politically neutral.
9. In addition to publishing legal analyses to inform public debates, we provide animal protection organisations with access to high quality legal advice to assist their work. We also promote the teaching of animal law in UK universities.
10. A-Law is led by lawyers – predominantly practising solicitors and barristers – and works closely with legal academics. This present submission is the product of a working group made up of: Robyn Trigg, DPhil candidate at Magdalen College, University of Oxford and solicitor; Paula Sparks, non-practising barrister and Chairperson of A-Law; Rosalind English, academic consultant at 1 Crown Office Row; Natalie Harney, A-Law Farmed Animal Working Group co-chair; and Aerin Blood, undergraduate student at Trinity College, University of Oxford.
11. For further information about us, or to access our online resources, please see our website: www.alaw.org.uk.

Executive summary

12. This consultation on the regulation of genetic technologies (the Consultation) raises a number of issues which we shall address, specifically issues with respect to: the framing of the Consultation; animal welfare; tracing, monitoring, and labelling of gene edited organisms (GEOs) and any resultant products; the potential unintended consequences of gene editing; trading and imports; sustainability; and, patent law.

13. This response is predicated on the assumption that the practice of genome editing will continue to be legally permissible, on which we take no position for the purposes of this response. Our response is limited to considering the current legislative regime regulating the use of gene editing and the proposed deviation from that regime. We do not comment on the ethical acceptability of gene editing as a practice and no position should be assumed from this response.

14. This response will comment on the animal welfare concerns that are raised by the Consultation's proposals but we do not necessarily endorse the suitability of the existing animal welfare standards. We do not comment on the acceptability of using animals in the ways the Consultation envisages. No position in respect of these issues should be assumed.

The current regulatory regime

15. At present, all GEOs are considered to be genetically modified organisms (GMOs) and thus are dealt with under the same regulatory regime. This position was confirmed by the Court of Justice of the European Union (CJEU) in July 2018 when it held that all GEOs, including those achieved by mutagenesis (gene editing that does not involve the introduction of foreign DNA into the organism), are considered GMOs for the purposes of EU law, even if those mutagenesis techniques were developed after the introduction of the relevant EU law.[1]

16. This section will briefly set out the legislative provisions relevant to this response.

GMOs and their release

17. The principal piece of legislation dealing with GMOs in the UK is the Environmental Protection Act 1990 (EPA 1990), specifically Part VI, which sought to implement EU law. Part VI of the EPA 1990 has the purpose of 'ensuring that all appropriate measures are taken to avoid damage to the environment which may arise from the escape or release from human control of genetically modified organisms'.[2]

18. The EPA 1990 determines organisms to be 'genetically modified' if any of the genes or other genetic material of the organisms – 'a) have been artificially modified; or b) are inherited or otherwise derived, through any number of replications, from genes or other genetic material (from any source) which were so modified.'[3] Thus, it covers the organism that was initially genetically modified and any offspring.

[1] C-528/16 – Confédération paysanne and Others. The CJEU considered whether organisms achieved by mutagenesis were GMOs for the purposes of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ 2001 L 106, p 1).
[2] Section 106(1), Part VI EPA 1990.
[3] Section 106(4), Part VI EPA 1990.

19. The EPA 1990 gives the Secretary of State scope to prescribe that genome alterations by certain techniques do not constitute artificial modification for the purposes of the definition of 'genetically modified' contained therein.[4]

20. The EPA defines the 'environment' to include 'land, air and water and living organisms supported by any of those media'.[5]

21. It further states that 'damage to the environment' 'is caused by the presence in the environment of genetically modified organisms which have (or of a single such organism which has) escaped or been released from a person's control and are (or is) capable of causing harm'.[6]

22. GMOs present in the environment are considered to be capable of causing harm if they individually or collectively in sufficient numbers are capable of causing harm or if they are able to produce descendants that are individually or collectively in sufficient numbers capable of causing harm.[7]

23. The EPA defines 'harm' to mean 'adverse effects as regards the health of humans or the environment'.[8]

24. Organisms of any kind are determined to be under the control of a person where they are 'contained by measures designed to limit their contact with humans and the environment and to prevent or minimise the risk of harm'.[9] An organism is 'released' from a person's control if the person 'deliberately causes or permits' the organism to stop being under their control or the control of another person and to enter the environment. An organism

[4] Section 106(4B), (4D), Part VI EPA 1990.
[5] Section 107(2), Part VI EPA 1990.
[6] Section 107(3), Part VI EPA 1990.
[7] Section 107(5), Part VI EPA 1990.
[8] Section 107(6), Part VI EPA 1990.
[9] Section 107(9), Part VI EPA 1990.

'escapes' if they stop being under a person's control and enters the environment, by means other than being released.[10]

25. GMOs are considered to be 'marketed' when 'products consisting of or including such organisms are placed on the market by being made available to other persons, whether or not for consideration'.[11]

26. The EPA 1990 sets up a system of risk assessments and specifies that notification must be given to the Secretary of State before GMOs can be imported, acquired, released or marketed.[12] Furthermore, consent may be required from the Secretary of State before GMOs can be imported, acquired, released or marketed.[13] The Genetically Modified Organisms (Deliberate Release) Regulations 2002 supplements the EPA 1990 and state that consent from the Secretary of State must be sought in all cases and circumstances in which GMOs are intended to be released (for purposes other than marketing) or marketed for the purposes of s 111(1)(a) EPA 1990.[14]

27. The Secretary of State must appoint a committee to provide them advice on their power of consent to import or acquire, release or market any GMOs.[15] This independent committee is known as the Advisory Committee on Releases to the Environment (ACRE).[16]

28. The Genetically Modified Organisms (Deliberate Release) Regulations 2002 provide mechanisms for safeguarding the environment[17], including prohibition notices, and the need to have a publicly available register of, *inter alia*, prohibition notices, applications for consent, and consents granted[18]. The publicly available register must include

[10] Section 107(10), Part VI EPA 1990.
[11] Section 107(11), Part VI EPA 1990.
[12] Section 108, Part VI EPA 1990.
[13] Section 108(8), 111, Part VI 1990.
[14] Sections 8, 14 Genetically Modified Organisms (Deliberate Release) Regulations 2002.
[15] Section 124(1), Part VI EPA 1990.
[16] https://www.gov.uk/government/organisations/advisory-committee-on-releases-to-the-environment.
[17] Section 32, Part VI Genetically Modified Organisms (Deliberate Release) Regulations 2002.
[18] Section 34, Part VIII Genetically Modified Organisms (Deliberate Release) Regulations 2002.

information relating to the location of the GMOs, notwithstanding the fact that this information might be commercially confidential.[19]

Labelling and tracing GMOs

29. There are clear rules regarding the labelling and traceability of foods consisting of or containing GMOs, including provisions for inspection and corrective measures for incorrectly labelled products.[20] For example, for pre-packaged products the label must indicate that the product contains GMOs[21] and for non-pre-packaged products offered to the final consumer, the display on or in connection with the product must indicate the product contains GMOs[22].

Gene editing in animals

30. The Animals (Scientific Procedures) Act 1986 (ASPA 1986) regulates the circumstances in which animals can be used for experimental or other scientific purposes and therefore applies to gene editing in protected animals.

31. Post-Brexit animal sentience is no longer explicitly recognised in UK law. ASPA 1986 implicitly acknowledges that the animals to which it applies are sentient by virtue of recognising that they can experience pain, suffering, distress, and lasting harm.

32. ASPA 1986 applies to 'protected animals', namely living vertebrates other than humans and living cephalopods.[23] Any such vertebrate in 'foetal, larval or embryonic form' is

[19] See s 33(1)(a), s 34(2)(c), s 34(3)(c) Genetically Modified Organisms (Deliberate Release) Regulations 2002.
[20] See EU Regulation (EC) No 1829/2003 on genetically modified food and feed, Regulation (EC) No. 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, The Genetically Modified Food (England) Regulations 2004, The Genetically Modified Organisms (Traceability and Labelling) (England) Regulations 2004.
[21] Article 6(a) Regulation (EC) No. 1830/2003.
[22] Article 6(b) Regulation (EC) No. 1830/2003.
[23] Section 1(1) ASPA 1986.

protected: a) in the case of mammals, birds or reptiles, when two-thirds of the gestation or incubation period for the relevant species has elapsed; and b) in any other case, the animal becomes capable of independent feeding.[24] Living cephalopods in their embryonic form are not protected.[25]

33. Section 2(1) ASPA 1986 sets out what constitutes a 'regulated procedure' for its purposes. A 'regulated procedure' means a procedure applied to a protected animal for a 'qualifying purpose' which 'may have the effect of causing the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.'[26]

34. A procedure is applied for a qualifying purpose if it is for an experimental or other scientific purpose (whether or not the outcome is known) or for educational purposes.[27] A procedure carried out for a qualifying purpose is also considered to be a regulated procedure if the relevant animal has not attained the stage of development to be a protected animal, the animal will be allowed to live until after it attains the relevant stage of development, and the procedure is likely to have the effect set out in s 2(1) ASPA 1986.[28]

35. Modifying an animal's genes can be a regulated procedure. It is a regulated procedure if the animal is a protected animal and the modification may have the effect set out in s 2(1) ASPA 1986, or the animal will be allowed to live until after the relevant stage of development to become a protected animal is reached and the modification may have the effect set out in s 2(1) ASPA 1986.[29]

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[24] Section 1(2) ASPA 1986.
[25] Section 1(2A) ASPA 1986.
[26] Section 2(1) ASPA 1986.
[27] Section 2(1A) ASPA 1986.
[28] Section 2(2A) ASPA 1986.
[29] Section 2(3A) ASPA 1986.

36. Moreover, breeding an animal can be a regulated procedure if: a) an animal is bred from an animal whose genes have mutated or been modified or from the descendant of such an animal; b) the animal is allowed to live past the relevant stage of development to become a protected animal; and c) after this stage of development has been reached, the animal may experience pain, suffering, distress or lasting harm of a level set out in s 2(1) ASPA 1986 as a result of the mutation or modification in a).[30]

37. 'Non-experimental agricultural practices' are not considered to be regulated procedures.[31] 'Non-experimental' is not further defined in ASPA.

38. The Secretary of State must exercise their functions under ASPA 1986 in accordance with 'the 3 Rs' – the principles of replacement, reduction, and refinement.[32]

39. ASPA sets up a system of licensing, whereby relevant licences must be obtained in order to undertake regulated procedures.[33] The relevant licences are: i) undertaking licences[34]; ii) personal licences[35]; iii) project licences[36].

40. A project licence can be granted if the specified programme of research relates to 'the improvement of the welfare of animals or the production conditions for animals reared for agricultural purposes'.[37]

41. A licensee under ASPA 1986 must not set free or re-home a protected animal without the consent of the Secretary of State.[38] The Secretary of State must not consent to a protected animal being set free or re-homed unless satisfied that: a) the animal's health allows for them to be set free or re-homed; b) the setting free or re-homing poses no danger to public health, animal health, or the environment; c) there is an adequate scheme

[30] Section 2(3B) ASPA 1986.
[31] Section 2(8) ASPA 1986.
[32] Section 2A ASPA 1986.
[33] Section 2B et seq ASPA 1986.
[34] Section 2C ASPA 1986.
[35] Section 4 ASPA 1986.
[36] Section 5 ASPA 1986.
[37] Section 5C(3)(b)(iii) ASPA 1986.
[38] Section 17A(1), (2) ASPA 1986.

in place to ensure the socialisation of the animal on being set free or re-homed; and d) appropriate measures have been taken to safeguard the animal's well-being upon being set free or re-homed.[39]

The welfare of gene edited animals

42. The welfare of animals falling under the scope of ASPA 1986 is regulated by ASPA 1986 itself.[40]

43. The Animal Welfare Act 2006 (AWA 2006) does not apply to anything done lawfully under ASPA 1986.[41] Section 9 AWA 2006 (the duty of person responsible for an animal to ensure the needs of the animal are met) does not apply to animals being kept under a granted section 2C licence (undertaking licence) under ASPA 1986 where: regulated procedures are being applied to protected animals; protected animals are being bred with a view to being used in regulated procedures or their tissues or organs are going to be used for scientific purposes; or protected animals who have been bred elsewhere are being kept with a view to using them in regulated procedures or using their tissues or organs for scientific purposes, as set out in s 2B(2) ASPA 1986.[42]

44. The Welfare of Farmed Animals (England) Regulations 2007 (FA(E)R 2007) apply to 'farmed animals'.[43] For the purposes of those Regulations 'farmed animal' means 'an animal bred or kept for the production of food, wool or skin or other farming purposes' but does not include 'experimental or laboratory' animals.[44]

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[39] Section 17A(3) ASPA 1986.
[40] Schedule 2C sets out conditions which must be contained in section 2C licences, e.g. relating to having an Animal Welfare and Ethical Review Body (s 6(1), Schedule 2C), recording keeping with respect to the animals (s 8 et seq, Schedule 2C), and other provisions relating to the 'general care and accommodation of protected animals' (s 11, Schedule 2C).
[41] Section 58 AWA 2006.
[42] Section 58(3) AWA 2006. Also see s 2B(2) ASPA 1986.
[43] Regulation 3(1) FA(E)R 2007.
[44] Regulation 3(2) FA(E)R 2007.

45. Regulation 28 FA(E)R 2007 states that 'natural or artificial breeding or breeding practices which cause, or are likely to cause, suffering or injury to any of the animals concerned, must not be practised'.

Issues with the framing of the Consultation

46. We note the absence of ethical considerations within the scope of the Consultation. The Consultation Document does not seek to canvas views as to the ethical acceptability of the practice of gene editing in either plants or animals. The lack of ethical considerations severely narrows the scope of the Consultation. It is a relevant consideration in the decision to potentially expand the scale of gene editing and increase the availability of gene edited products.

47. Furthermore, in Section 2 of the Consultation Document, Question 2 is framed to consider the potential risks of producing organisms by gene editing or other genetic technologies on 'human health or the environment'. There is no explicit reference to what the potential impact for animals might be. Regulation 1829/2003 explicitly states that the objective of the Regulation is to ensure a high level of protection of '…human life and health, *animal health and welfare*, environment and consumer interests in relation to genetically modified food and feed…'.[45] And, as noted at paragraph [20] above, the definition of 'environment' in the EPA 1990 includes living organisms who are supported by land, air, and water.[46]

48. It is clear that animal health and welfare are explicit considerations under the current legislation governing the use of GMOs for food and feed. It is also clear that consideration of the environment should include consideration of the interests of living

[45] Article 1(a) EU Regulation (EC) No 1829/2003 on genetically modified food and feed.
[46] Section 107(2), Part VI EPA 1990.

organisms that rely on the environment. The scope of Question 2 is therefore overly narrow, which is perhaps illustrative of an implicit bias in deprioritising issues of animal health and welfare in the framing of the Consultation. This de-prioritising of animal health and welfare is also illustrated in the framing of Question 3, Section 2 where 'animal welfare' is explicitly referred to as a 'non-safety issue'.

49. Despite this narrow focus with respect to issues of 'safety', the Consultation is also overly broad in other respects. This makes assessing the potential impact on animal welfare particularly difficult. For example, the Consultation Document refers to 'gene editing' and 'other genetic technology' which may be capable of 'making changes that could have been produced by traditional breeding methods'.[47] It is not clear which technologies might actually be permitted under any change in legislation. It is also unclear how such a decision to include or exclude certain technologies would be made, by whom, and on what basis. It is uncertain how the number of technologies allowed to be regulated outside of the present GMO regulations could change and be monitored over time.

50. Moreover, there is no indication of how 'traditional breeding methods' will be defined. The Consultation canvasses views on what criteria should be used to determine whether an organism produced by gene editing or other genetic technologies could have been produced by traditional breeding. The answer to this question may itself pose animal welfare concerns, which, of course, cannot be identified at this stage. However, if gene editing or other genetic technologies are going to be used to 'speed up' the breeding process[48], how can we assess whether the organism could have been produced by traditional breeding methods? It is a logical corollary that no gene edited animal will in

[47] See for example, page 5 and footnote 2 of the Consultation Document.
[48] As indicated on page 4 of the Consultation Document.

fact have been produced by traditional breeding methods else there would be no desire or need to gene edit in the first place.

Animal welfare concerns

51. At page 4 of the Consultation Document, gene editing is described as '…a range of technologies that can achieve genetic changes of the type that are selected for in traditional breeding, such as insertions, deletions and, occasionally, translocations of genetic material.' Later, at page 5, the Consultation Document states that the Consultation 'focuses on research and marketing of gene edited organisms (GEOs) and GMOs that take place outside of the laboratory…'. It is not clear what exactly this means or how some of the intended effects might be achieved outside of a laboratory setting. It is unclear whether this indicates an intention to move the type of gene editing envisaged to be within the scope of this Consultation outside of the scope of ASPA 1986.
52. If gene editing (and breeding from gene edited animals) will not take place in a laboratory where will it take place and how will those premises be inspected and monitored? As it currently stands, gene editing and breeding from gene edited animals can be regulated procedures for the purposes of ASPA 1986. Is it intended that the licensing regime contained within ASPA 1986 continues to apply in relation to the activities captured by the Consultation?
53. Once the genome edits have been made, how will the production of animals be increased to a commercial scale for agricultural purposes? Where will such breeding take place and how will that be regulated and monitored?
54. ASPA 1986 currently states that 'non-experimental agricultural practices' are not regulated procedures.[49] 'Non-experimental' is not further defined but it is hard to see

[49] Section 2(8) ASPA 1986.

how the envisaged practices could be considered non-experimental. As noted above at paragraph [45], FA(E)R 2007 does not apply to 'experimental or laboratory' animals.[50] It is unclear, therefore, exactly how the welfare of any gene edited animals would be regulated and monitored.

55. Given the lack of clarity around exactly how animal welfare needs will be regulated and monitored, a number of further questions arise. These will be set out in the remainder of this section.

56. Will there be a closed list of the specific genome changes that are permissible? How will the types of changes that are permissible be selected and by whom? Will animal welfare scientists and other animal welfare groups be consulted during any decision-making process? How will the long-term effects of specific modifications be monitored? How will the health and welfare needs of each gene edited animal be assessed? How frequently will any such assessment be carried out? Will an assessment that a certain genome modification has resulted in unacceptable welfare implications for the animal result in a reconsideration of the acceptability of that edit? What would be the procedure for challenging the acceptability of a specific edit?

57. Would there be changes to the welfare standards applicable to certain animals on the basis of certain genome edits and the eventual outcomes they produce? For example, if a genome edit has the effect of making an animal more resistant to a particular disease that is spread by overcrowding, will it be permissible to reduce the amount of space each animal is housed in?

58. Moreover, it is possible that if animals are genetically edited to increase disease resistance, they may, in fact, become reservoirs or carriers for particular pathogens. For example, an alteration of an animal's genetic sequence may instruct the production of

[50] Regulation 3(2) FA(E)R 2007.

altered receptors which do not allow binding by a disease-causing toxin (as we understand by virtue of the Pfizer mRNA Covid-19 vaccine). However, this might mean an animal becomes a carrier for that particular pathogen without being affected themselves but which may increase levels of longer-term exposure of other susceptible organisms without such genomic edits. Moreover, such edits leading to disease resistance might also lead to overproduction of natural antibodies, which may result in an overactive immune system in the gene edited animal.

59. Gene edits intending to result in faster growth rates or greater productivity might lead to reduced immunity in gene edited animals as too few bodily resources are allocated to their immune systems. Such edits might result in changes to the production of certain metabolites, which can be used as a substrate (e.g. mucus etc) by pathogens. How is it intended that any such changes will be monitored and assessed? Changes to animals' metabolites might also impact their products of metabolism (e.g. urine and faeces), which can reach other organisms by, for example, run-off. It is not clear how or if at all any such changes would be monitored and assessed.

60. Will gene edited animals need to be confined in a particular way to decrease potential contact with humans, other animals, and the environment? Given that there is a high risk that if gene edited animals were released or escaped from any such confinement that they might hybridise with non-gene edited animals, it seems inevitable that the management practices concerning gene edited animals will have a heavy emphasis on confinement. How will the health and welfare impacts of any such confinement be assessed and monitored? Will there be any direct comparisons between the welfare implications of 'traditional' breeding methods and gene editing?

61. Will there be any regulation relating to how many animals can be 'sacrificed' in the process of making the 'right' gene edits? How will this be regulated and monitored? How will the 3 Rs inform the decision making with respect to gene editing animals?

62. It should also be noted that the very 'traditional' breeding techniques that breeders may seek to replicate through gene editing are not without controversy. These concerns have been raised not only by animal advocacy groups, but also scientific bodies tasked with advising the Government and international institutions. For example, the European Food Safety Authority highlighted welfare detriments arising from genetic selection of cows bred for high milk yields.[51] In the UK, the Farm Animal Welfare Council (now the Animal Welfare Committee) which advises Defra about the welfare of farmed animals has highlighted osteoporosis as a consequence of selectively breeding hens for high egg production.[52]

63. Perhaps, one of the most controversial areas has been the genetic selection of fast growing 'broiler' chickens, with well documented concerns about welfare problems such as lameness, due to their fast growth rates.[53] In a recent report for the animal protection organisation, Open Cages ('A British Pandemic – The Cruelty and Danger of Supermarket Chicken') scientists attribute 'severe welfare problems' to rapid growth rates in selectively bred chickens.[54]

[51] Scientific Opinion of the Panel on Animal Health and Welfare on a request from European Commission on welfare of dairy cows. The EFSA Journal (2009) 1143, 1-38.
[52] Farm Animal Welfare Council, 2010. Opinion on Osteoporosis and Bone Fractures in Laying Hens – https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/325043/FAWC_opinion_on_osteoporosis_and_bone_fractures_in_laying_hens.pdf.
[53] Knowles et al, 2008. Leg disorders in broiler chickens: prevalence, risk factors and prevention. Plos one 3 (2): e1545. doi: 10.1371/journal.pone.0001545.
[54] https://www.afisapr.org.br/attachments/article/2020/A%20British%20Pandemic_%20The%20Cruelty%20and%20Danger%20of%20Supermarket%20Chicken.pdf.

Tracing, monitoring, and labelling

64. The Consultation does not provide any information on how gene editing and GEOs might be regulated if removed from the scope of the present GMO regulations. This raises a number of initial questions with respect to tracing, monitoring, and labelling. These shall be set out in this section. However, we note that additional questions may arise if a more fulsome consultation takes place.
65. How will gene edited animals be traced and monitored?
66. How will the eventual products consisting of or containing GEOs be traced and labelled?
67. Will any additional safety checks be carried out before any products consisting of or containing GEOs can be put on the market and what risk assessments will be carried out before GEO products are released or put on the market?
68. Will there continue to be a register of GEOs and their location? Will there be a register of products consisting of or containing GEOs that are on the market?

Potentially unintended consequences of gene editing

69. How will potentially unintended consequences be monitored and assessed? This includes with respect to the health and welfare needs of gene edited animals themselves and the potential impacts on humans, other animals (wildlife and other non-gene edited animals), and the environment more broadly caused by any release, escape, or marketing of GEOs and any products consisting of or containing GEOs.
70. Given the relative newness of modern gene editing techniques and the speed at which the technology is advancing, how can we know what any long-term unintended consequences might be? If measures around tracing, monitoring, and labelling GEOs

and any resultant products are relaxed, how will potentially unintended consequences be monitored?

Trading and imports

71. It is not clear from the Consultation what, if any, implications the removal of GEOs from the current GMO regulatory regime would have on trading and imports. Would a relaxation of rules relating to products consisting of or containing GEOs mean we are bound to accept imports from countries employing the same genome editing techniques but with potentially lower animal welfare, and health and safety requirements? Conversely, will some countries or trading blocs be unwilling to accept imports of GEO products based on health and safety or animal welfare concerns?

Sustainability

72. The Consultation Document states that the Government is focused on achieving the UN's Sustainability Development Goals (SDGs) to 'address food security challenges, tackle climate change and biodiversity loss'.[55]

73. Scientific evidence suggests that plant-based agriculture has the lowest environmental impact – the animal products with the lowest environmental impacts typically exceed the impacts of vegetable substitutes.[56] If the Government's focus is on future sustainability, why is it not seeking to create a dietary shift by concentrating on plant-based agriculture rather than animal agriculture with gene edited animals?

[55] Page 6 of the Consultation Document.
[56] J. Poore & T. Nemecek, 2018, Reducing food's environmental impacts through producers and consumers. Science 01 Jun 2018: Vol. 360, Issue 6392, pp. 987-992; DOI: 10.1126/science.aaq0216 – https://science.sciencemag.org/content/360/6392/987.

74. Moreover, given the Consultation Document includes tackling biodiversity loss as part the SDGs[57], how will the long-term impacts on biodiversity be measured and monitored? Who will undertake this task and how frequently will such checks be carried out?[58]

75. In considering the impacts of gene editing on biodiversity loss, it is also essential to consider the impacts any edits might have on an animal's gut microfauna. Gene edits can affect the gut microorganisms inside a gene edited animal, which can consequently impact the composition of microorganisms in their faeces. If such faeces are used as manure, this can affect the distribution, abundance, and species diversity of certain groups of organisms (for example, pollinator insects) within a landscape or region. It is not clear if or how any such potentially unforeseen changes might be monitored and assessed.

Interaction with patent law

76. Again, it is not clear from the Consultation Document how any changes to the regulation of GEOs would interact with patent law? Would the limitation of gene editing to organisms that could have been produced by traditional breeding methods affect the patentability of the gene editing processes and resultant organisms (products)? Would such a limitation mean that the processes and products are considered to be 'essentially biological' for the purposes of the Patents Act 1977 and therefore unpatentable?

77. If the envisaged techniques and resultant products are capable of being patented, how will this affect price and consumer choice of agricultural products?

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[57] Page 6 Consultation Document.
[58] Chatham House (2021) 'Food System Impacts on Biodiversity Loss' – https://www.chathamhouse.org/2021/02/food-system-impacts-biodiversity-loss.

78. We would be happy to help further, if required.

17.03.2021

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