Genetic Technology (Precision Breeding) Bill

MARSHALLED LIST OF AMENDMENTS TO BE MOVED ON REPORT

[Amendments marked ★ are new or have been altered]

Amendment No.

Clause 1

BARONESS BENNETT OF MANOR CASTLE

1★ Clause 1, page 1, line 4, leave out "or a precision bred animal"

Member's explanatory statement

This amendment is intended to remove animals from the scope of the Bill.

BARONESS BENNETT OF MANOR CASTLE

2★ Clause 1, page 1, line 5, at end insert "used for food production"

LORD BENYON

Clause 1, page 1, line 11, leave out from "genome" to end of line 14 and insert "that results from the application of modern biotechnology could have resulted from traditional processes, whether or not in conjunction with selection techniques, alone,"

Member's explanatory statement

This amendment would limit the test in Clause 1(2)(c) to features of a precision bred organism's genome that result from the application of modern biotechnology and would require them to be capable of resulting just from traditional processes (whether or not in conjunction with selection techniques).

LORD KREBS

4 Clause 1, page 1, line 11, after "could" insert "in principle"

HL Bill 83-I 58/3

Member's explanatory statement

This amendment recognises that, although a particular genetic change resulting from precision breeding could, in principle, have arisen through traditional breeding processes, in practice this might be extremely difficult to achieve. Examples include overcoming the effects of linkage drag and selecting simultaneously for changes in several recessive genes.

LORD BENYON

- 5 Clause 1, page 1, line 14, at end insert "and
 - (d) its genome does not contain any feature that results from the application of any artificial modification technique other than modern biotechnology."

Member's explanatory statement

This amendment would introduce a new requirement to ensure that the genome of a precision bred organism could not contain features that result from artificial modification techniques that are not modern biotechnology within the meaning of the Bill.

LORD BENYON

6 Clause 1, page 2, line 3, leave out subsection (6)

Member's explanatory statement

This amendment would omit Clause 1(6), which defines "natural transformation". It is consequential on the Minister's first amendment to Clause 1 which would remove Clause 1(2)(c)(ii).

LORD KREBS

7 Clause 1, page 2, line 5, leave out "functional protein" and insert "change in the phenotype"

Member's explanatory statement

This amendment tightens the restrictions on any residual exogenous DNA that might result from gene editing.

LORD BENYON

- 8 Clause 1, page 2, line 25, at end insert
 - "(7A) An "artificial modification technique" means any technique by which genes or other genetic material can be artificially modified within the meaning of Part 6 of the Environmental Protection Act 1990 (as it has effect from time to time)."

Member's explanatory statement

This amendment would define artificial modification techniques in line with Part 6 of the Environmental Protection Act 1990 (which deals with genetically modified organisms).

LORD BENYON

9 Clause 1, page 2, line 26, leave out "an organism is" and insert "genes or other genetic material are"

Member's explanatory statement

This amendment is a technical amendment so that subsection (8) reflects the language of the definition of "artificially modified" in the Genetically Modified Organisms (Deliberate Release) Regulations 2002, which is expressed in relation to genes or other genetic material, rather than the organisms. It would not make a substantive change.

LORD BENYON

- 10 Clause 1, page 2, line 35, at end insert
 - "(10) An organism to which subsection (11) applies does not fail to be precision bred merely because it does not meet the condition in subsection (2)(d).
 - (11) This subsection applies to an organism which, for the purposes of Part 6 of the Environmental Protection Act 1990, is to be taken not to be a genetically modified organism by virtue of
 - (a) paragraph (3) of the regulation referred to in subsection (8)(a), or
 - (b) regulations under subsection (4C) of section 106 of that Act."

Member's explanatory statement

This amendment would ensure that an organism will not fail to be a precision bred organism by reason only of the new test introduced by the Minister's second amendment to Clause 1 if it is to be taken not to be a genetically modified organism by virtue of the provisions referred to in subsection (11)(a) and (b).

Clause 3

BARONESS HAYMAN OF ULLOCK BARONESS PARMINTER

Clause 3, page 3, line 24, after "unless" insert ", in relation to a precision bred animal, the date condition in section (*Entry into force of provisions relating to animals*) has been met, and unless"

Member's explanatory statement

This amendment would prevent a precision bred animal from being released unless the date condition in a later Clause in the name of Baroness Hayman of Ullock has been met. Taken collectively, these amendments would ensure a phasing in of the animal provisions in the Bill.

BARONESS BENNETT OF MANOR CASTLE

- 12★ Clause 3, page 3, line 30, at end insert
 - "(iv) the details of the gene editing event, and the record of the whole genome sequence of the qualifying organism, are recorded in a publicly available register established by regulations,"

BARONESS BENNETT OF MANOR CASTLE

- 13★ Clause 3, page 4, line 4, at end insert
 - "(4) Regulations under this section are subject to the affirmative procedure."

Clause 4

LORD BENYON

Clause 4, page 4, line 24, leave out "this section" and insert "subsection (1)(b)"

Member's explanatory statement

This amendment is consequential on the Minister's next amendment to Clause 4.

LORD BENYON

- Clause 4, page 4, line 24, at end insert
 - "(7) Regulations under subsection (3) are subject to the affirmative procedure."

Member's explanatory statement

This amendment would provide for regulations under Clause 4(3) to be subject to the affirmative procedure.

Clause 6

LORD BENYON

Clause 6, page 5, line 31, leave out "negative" and insert "affirmative"

Member's explanatory statement

This amendment would provide for regulations under Clause 6(2) to be subject to the affirmative procedure.

Clause 11

LORD BENYON

17 Clause 11, page 8, line 24, at end insert –

"(9A) Regulations under subsection (5) are subject to the affirmative procedure."

Member's explanatory statement

This amendment would provide for regulations under Clause 11(5) to be subject to the affirmative procedure.

LORD BENYON

18 Clause 11, page 8, line 25, leave out "this section" and insert "subsection (9)"

Member's explanatory statement

This amendment is consequential on the Minister's previous amendment to Clause 11.

Clause 12

BARONESS JONES OF WHITCHURCH BARONESS BAKEWELL OF HARDINGTON MANDEVILLE LORD CAMERON OF DILLINGTON

- Clause 12, page 8, line 30, at end insert
 - "(za) whether the welfare advisory body is satisfied that the notifier has a record of acting in a manner which is consistent with the requirements applicable to the notifier which are laid out in
 - (i) the Human Fertilisation and Embryology Act 1990,
 - (ii) the Animal Welfare Act 2006, and
 - (iii) any other enactment which the welfare advisory body deems relevant,"

Member's explanatory statement

This amendment makes clear that in addition to considering information submitted by the notifier, the welfare advisory body should satisfy itself that the notifier has a record of acting in a manner which is consistent with research and animal welfare requirements outlined in various other Acts of Parliament.

BARONESS JONES OF WHITCHURCH BARONESS BAKEWELL OF HARDINGTON MANDEVILLE

Clause 12, page 8, line 39, after "paragraphs" insert "(za),"

Member's explanatory statement

This amendment is consequential on a previous amendment in the name of Baroness Jones of Whitchurch, and ensures the welfare advisory body provides reasons for any advice offered to the Secretary of State under that amendment.

After Clause 12

BARONESS JONES OF WHITCHURCH

21 After Clause 12, insert the following new Clause –

"Additional factors to be considered in relation to a precision bred animal marketing authorisation

- (1) When producing a report under section 12, the welfare advisory body may choose to consider the factors listed in subsection (3).
- (2) In the event that a report of the welfare advisory body does not consider the factors listed in subsection (3), the Secretary of State must do so prior to making a decision under section 13(1) regarding the issuing of a precision bred animal marketing authorisation.
- (3) The additional factors to be considered in relation to a precision bred animal marketing authorisation are—
 - (a) whether the precision bred traits will have a direct or indirect adverse effect on the health or welfare of the relevant animal or its qualifying progeny,
 - (b) whether the relevant animal or its qualifying progeny are likely to experience pain, suffering or lasting harm arising from or connected with precision bred traits that aim to produce increased yields, faster growth or any other increase in productivity, and
 - (c) whether the precision bred traits may facilitate the keeping of the relevant animal or its qualifying progeny in conditions that are likely to have an adverse effect on animal health or welfare."

Member's explanatory statement

This new Clause would introduce a small number of additional animal welfare factors to be considered by the welfare advisory body or Secretary of State prior to the granting of a precision bred animal marketing authorisation.

Clause 14

BARONESS PARMINTER LORD TREES BARONESS HAYMAN OF ULLOCK BARONESS BAKEWELL OF HARDINGTON MANDEVILLE

22★ Leave out Clause 14 and insert the following new Clause –

"Precision bred animal marketing authorisations: reporting obligations

- (1) Before issuing a precision bred marketing authorisation for the first time, the Secretary of State must establish a monitoring system for the reporting of potential adverse effects on the health or welfare of such animals or their progeny which must enable
 - (a) the voluntary reporting to the Secretary of State by keepers of animals, animal health and veterinary professionals, or others, of adverse effects,
 - (b) the mandatory reporting to the Secretary of State by the marketing authorisation holder of adverse effects, and
 - (c) relevant information to be available to support future research.
- (2) Regulations under subsection (1) may
 - (a) define what is meant by adverse effects on health and welfare,
 - (b) prescribe information to be required from the notifier for reporting adverse effects to the Secretary of State,
 - (c) make provision for requiring the recipient of marketing authorisation to take prescribed steps, in connection with supplying such an animal to another person, to secure that prescribed information about the subsequent health and welfare of that animal or its progeny, is provided by, or can be collected from that other person, and
 - (d) determine the period after marketing authorisation that such reporting of adverse effects on the health and welfare of animals or their progeny of a given precision bred technique is to be required.
- (3) Regulations under this section are subject to the affirmative procedure."

Member's explanatory statement

This amendment requires that, before precision bred animals are marketed, there be mechanisms established for reporting possible adverse effects on the animals' health and welfare or that of their progeny. Regulations shall define adverse effects, details of the information required, and the time period over which it is required for any given precision breeding technique and application.

Clause 18

BARONESS PARMINTER LORD TREES BARONESS HAYMAN OF ULLOCK BARONESS BAKEWELL OF HARDINGTON MANDEVILLE

- 23★ Clause 18, page 12, line 28, at end insert
 - "(aa) records of clinical outcomes, and adverse effects and outcomes, of the precision bred animals and their qualifying progeny (see section 14(1)(c));"

LORD BENYON

- 24 Clause 18, page 13, line 16, at end insert
 - "(6A) Regulations under subsection (1) are subject to the affirmative procedure."

Member's explanatory statement

This amendment would provide for regulations under Clause 18(1) to be subject to the affirmative procedure.

LORD BENYON

25 Clause 18, page 13, line 17, leave out "this section" and insert "subsection (6)"

Member's explanatory statement

This amendment is consequential on the Minister's previous amendment to Clause 18.

Clause 22

LORD BENYON

Clause 22, page 15, line 27, leave out "negative" and insert "affirmative"

Member's explanatory statement

This amendment would provide for regulations under Clause 22(3) to be subject to the affirmative procedure.

After Clause 47

BARONESS HAYMAN OF ULLOCK BARONESS PARMINTER LORD WINSTON

27 After Clause 47, insert the following new Clause –

"Entry into force of provisions relating to animals

- (1) The Secretary of State may not make regulations relating to animals using powers contained in Parts 2 to 4 of this Act unless the date condition has been met and the guidance and evidence condition has been met.
- (2) The date condition is that, in relation to farm animals, the date is no earlier than 1 January 2026, and, in relation to other animals, the date is no earlier than 1 January 2028.
- (3) The guidance and evidence condition is that the Secretary of State has laid before each House of Parliament a statement confirming that, in the Secretary of State's view
 - (a) all necessary guidance for persons making applications under sections 6 and 11 has been published, and
 - (b) scientific evidence supports the extension of those application processes to animals.
- (4) The Secretary of State may, by regulations, amend the dates listed in subsection (2) if the requirement under subsection (3) is met before the dates originally stated in subsection (2).
- (5) Regulations under subsection (4) are subject to the affirmative procedure."

Member's explanatory statement

This new Clause would prevent regulations that bring into force the ability to release and market precision bred animals from being made before specified dates. Before commencing the relevant provisions, the Secretary of State would have to lay a statement confirming that (1) relevant guidance has been published, and (2) they are satisfied that their approach is supported by scientific evidence. The timetable could be accelerated should scientific opinion support this.

Clause 48

BARONESS BENNETT OF MANOR CASTLE

- $28\star$ Clause 48, page 30, line 22, leave out subsections (2) to (5) and insert
 - "(2) This section comes into force on the day on which this Act is passed.
 - (3) The rest of this Act comes into force on such day as regulations may appoint.
 - (4) Regulations under this section may not be made until the Secretary of State has laid a Priority Setting Partnership Report before both Houses of Parliament.

- (5) The Priority Setting Partnership Report shall be drafted by a Priority Setting Partnership established and funded by the Secretary of State, and include a response from the Secretary of State.
- (6) The Priority Setting Partnership shall—
 - (a) identify evidence uncertainties in relation to precision breeding which cannot be answered by existing research,
 - (b) produce a list of research priorities in relation to precision breeding, and
 - (c) make comments on this Act in relation to issues identified in respect of paragraphs (a) and (b).
- (7) The Priority Setting Partnership shall have a membership comprising
 - (a) scientists and academics with expertise in the field of genetics, agriculture, and ecology,
 - (b) lay members of the public,
 - (c) representatives of animal welfare organisations, and
 - (d) other interested parties."

Member's explanatory statement

This amendment would require a report to be published identifying gaps in scientific evidence relating to precision breeding before the Act can come into force.

BARONESS HAYMAN OF ULLOCK BARONESS PARMINTER

29 Clause 48, page 30, line 25, after "regulations" insert "relating to plants"

Member's explanatory statement

This amendment is consequential on a new Clause in the name of Baroness Hayman of Ullock. It makes clear that the regulation-making powers under Parts 2 to 4 of the Bill which come into force on the day the Act is passed only apply in relation to plants.

BARONESS HAYMAN OF ULLOCK BARONESS PARMINTER

- Clause 48, page 30, line 25, at end insert
 - "(aa) so far as necessary to enable the exercise of any power to make regulations relating to animals, in accordance with the date condition and guidance and evidence condition set out in section (*Entry into force of provisions relating to animals*);"

Member's explanatory statement

This amendment is consequential on a new Clause in the name of Baroness Hayman of Ullock. It makes clear that the regulation-making powers under Parts 2 to 4 of the Bill which relate to animals may only be exercised once the conditions in the new Clause have been met.

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