

# Genetic Technology (Precision Breeding) Bill

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[AS AMENDED ON REPORT]

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[AS AMENDED ON REPORT]

A

# B I L L

TO

Make provision about the release and marketing of, and risk assessments relating to, precision bred plants and animals, and the marketing of food and feed produced from such plants and animals; and for connected purposes.

**B**E IT ENACTED by the King’s most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

## PART 1

### PRECISION BREEDING: DEFINITIONS

#### 1 Precision bred organism

- (1) In this Act “precision bred organism” means a precision bred plant or a precision bred animal. 5
- (2) For the purposes of this Act an organism is “precision bred” if—
  - (a) any feature of its genome results from the application of modern biotechnology,
  - (b) every feature of its genome that results from the application of modern biotechnology is stable, 10
  - (c) every feature of its genome that results from the application of modern biotechnology could have resulted from traditional processes, whether or not in conjunction with selection techniques, alone, and
  - (d) its genome does not contain any feature that results from the application of any artificial modification technique other than modern biotechnology. 15
- (3) In this Act “modern biotechnology” means any technique mentioned in regulation 5(1)(a) or (b) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443).
- (4) A feature of an organism’s genome is “stable” if it is capable of being propagated whenever the organism is reproduced, whether by sexual or asexual reproduction. 20

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- (5) In determining whether a feature of an organism’s genome could have resulted from traditional processes, no account is to be taken of—
- (a) the copy number of the feature,
  - (b) its epigenetic status, or
  - (c) its location in the genome. 5
- (6) In this section “traditional processes” means—
- (a) in relation to plants—
    - (i) sexual fertilisation,
    - (ii) spontaneous mutation,
    - (iii) in vitro fertilisation, 10
    - (iv) polyploidy induction,
    - (v) embryo rescue,
    - (vi) grafting,
    - (vii) induced mutagenesis, or
    - (viii) somatic hybridisation or cell fusion of plant cells of organisms which are capable of exchanging genetic material by a process within sub-paragraphs (i) to (vii); 15
  - (b) in relation to animals—
    - (i) sexual fertilisation,
    - (ii) spontaneous mutation, 20
    - (iii) artificial insemination,
    - (iv) in vitro fertilisation,
    - (v) embryo transfer,
    - (vi) polyploidy induction, or
    - (vii) recovery and transfer of primordial germ cells. 25
- (7) 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).
- (8) If the category of techniques by which, or circumstances in which, genes or other genetic material are taken to be, or not to be, artificially modified for the purposes of Part 6 of the Environmental Protection Act 1990 changes by virtue of—
- (a) regulation 5 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443) being modified, or 35
  - (b) regulations being made under subsection (4B) or (4C) of section 106 of the Environmental Protection Act 1990,
- regulations may modify this section so as to make corresponding changes (with or without variation) to the definition of “modern biotechnology”.
- (9) Regulations under subsection (8) are subject to the affirmative procedure. 40
- (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.

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## 2 Meaning of “plant” and “animal”

- (1) In this Act “plant” means an organism in the taxonomic group—
- (a) Archaeplastida, or
  - (b) Phaeophyceae.
- (2) In this Act “animal” means an organism in the taxonomic group Metazoa, other than a human (or a human admixed embryo). 10
- (3) In subsections (1) and (2), references to an organism—
- (a) include an embryo and all subsequent developmental stages of the organism;
  - (b) in the case of a plant, also include a seed or a vegetative propagule; 15
  - (c) do not include a gamete.
- (4) In this Act “gamete”—
- (a) does not include an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo, but
  - (b) otherwise includes a mature germ cell capable of initiating fusion with a germ cell of the opposite sex. 20
- (5) In this section—
- “embryo” includes an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo;
  - “human” includes a human embryo and all subsequent developmental stages of a human; 25
  - “human admixed embryo” has the same meaning as it has in the Human Fertilisation and Embryology Act 1990 by virtue of section 4A(6) and (11) of that Act.

## PART 2

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### PRECISION BRED ORGANISMS: RELEASE, MARKETING AND RISK ASSESSMENTS

#### *Release*

## 3 Restrictions on release of precision bred organism in England

- (1) A person who has a precision bred organism under their control must not release the organism in England unless—
- (a) the following apply—
    - (i) the notification requirements are satisfied in relation to the release (see section 4),

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- (ii) the person is a person specified in the release notice under section 4(2), and
    - (iii) the release is carried out in accordance with the release notice, or
  - (b) the organism is—
    - (i) a marketable precision bred organism (see section 5(2)), or
    - (ii) the qualifying progeny of a marketable precision bred organism (see section 24).
- (2) For the purposes of this Act an organism is under a person’s “control” if the person keeps it contained by measures designed to—
  - (a) limit its contact with humans and the environment, and
  - (b) prevent or minimise the risk of adverse effects as regards the health of humans or the environment.
- (3) For the purposes of this section and section 4, a person “releases” an organism under their control by deliberately causing or permitting it to—
  - (a) cease to be under their control or the control of anyone else, and
  - (b) enter the environment.

#### 4 Release of precision bred organism: notification requirements

- (1) The notification requirements are satisfied in relation to the release of an organism if—
  - (a) a person has given a notice (a “release notice”) to the Secretary of State in relation to the release, accompanied by—
    - (i) any required information (see subsection (3)(b)), and
    - (ii) any fee required by regulations under section 39, and
  - (b) any minimum period prescribed by regulations has elapsed since paragraph (a) was satisfied.
- (2) A release notice must specify one or more persons, or descriptions of person, in relation to the release.
- (3) Regulations may—
  - (a) make provision about the form and content of a release notice (but subject to subsection (2));
  - (b) prescribe information which must accompany a release notice (“required information”).
- (4) Regulations under subsection (3) may, in particular, prescribe whom a person may specify under subsection (2) when giving a release notice.
- (5) For the meaning of “release” see section 3(3).
- (6) Regulations under subsection (1)(b) are subject to the negative procedure.
- (7) Regulations under subsection (3) are subject to the affirmative procedure.



*Marketing*

**5 Restrictions on marketing of precision bred organism in England**

- (1) A person must not market a precision bred organism in England unless –  
(a) it is a marketable precision bred organism, or  
(b) it is the qualifying progeny of a marketable precision bred organism. 5
- (2) In this Act “marketable precision bred organism” means a precision bred organism in respect of which –  
(a) a precision bred confirmation is in force, and  
(b) if it is a relevant animal, a precision bred animal marketing authorisation is in force. 10
- (3) For the purposes of this Act –  
(a) a precision bred organism is “marketed” by a person when products consisting of or including –  
(i) the precision bred organism, or  
(ii) its gametes, 15  
are made available to other persons, whether or not for consideration, and  
(b) the marketing occurs in England so far as those products are made available for delivery in England.
- (4) For provision about the following terms used in subsections (1) and (2) see – 20
- |   |                    |
|---|--------------------|
| qualifying progeny                            | section 24         |
| precision bred confirmation                   | section 8(1)(a)(i) |
| relevant animal                               | section 10         |
| precision bred animal marketing authorisation | section 13(1).     |
- 25
- (5) For the purposes of subsection (2), a precision bred confirmation or precision bred animal marketing authorisation is “in force” if it has been issued and not revoked, and, in the case of an authorisation, is not suspended.

*Precision bred confirmation*

**6 Application for precision bred confirmation**

- (1) A person (the “notifier”) may apply for a precision bred confirmation in relation to an organism by giving a notice (a “marketing notice”) to the Secretary of State. 30
- (2) Regulations may –  
(a) make provision about the form and content of a marketing notice, and 35

- (b) prescribe information which must accompany a marketing notice (“required information”).
- (3) As soon as practicable after receiving –
  - (a) a marketing notice,
  - (b) any required information, and 5
  - (c) any fee prescribed by regulations under section 39,
 the Secretary of State must refer the marketing notice to the advisory committee (see section 22(1)) by sending the committee the marketing notice and any required information that accompanied it.
- (4) Regulations under subsection (2) are subject to the affirmative procedure. 10

## 7 Report by advisory committee

- (1) This section applies where the Secretary of State refers a marketing notice to the advisory committee.
- (2) Within 90 days after the marketing notice is referred to it, the advisory committee must provide a report to the Secretary of State stating – 15
  - (a) whether it considers the organism to be precision bred, and
  - (b) its reasons for reaching that conclusion.
- (3) Before the end of that period, the committee may by notice (“an information notice”) request the notifier to provide further information to the committee.
- (4) The committee’s report to the Secretary of State must be accompanied by any information provided to the committee as the result of an information notice. 20
- (5) Subsection (2) is subject to regulations under section 23.

## 8 Issue of precision bred confirmation

- (1) As soon as practicable after receiving a report from the advisory committee under section 7(2), the Secretary of State must – 25
  - (a) if satisfied that the organism is precision bred –
    - (i) issue a statement to that effect (a “precision bred confirmation”), and
    - (ii) give notice of it to the notifier;
  - (b) if not satisfied, give notice to the notifier of that fact. 30
- (2) A notice under subsection (1)(b) must state the reasons for not issuing a precision bred confirmation.

## 9 Revocation of precision bred confirmation

- (1) Regulations may make provision conferring power on the Secretary of State to revoke a precision bred confirmation relating to an organism if the Secretary of State is no longer satisfied that the organism is precision bred. 35
- (2) Regulations made under this section must make provision –

- (a) for the procedure that is to be followed where the Secretary of State proposes to revoke a precision bred confirmation, which must include provision for –
    - (i) requiring notice of a proposal to revoke a precision bred confirmation to be published in any way that the Secretary of State considers appropriate to bring it to the attention of those affected by it, and 5
    - (ii) permitting persons affected by the proposal to make representations about it;
  - (b) about the consequences of revoking a precision bred confirmation; 10
  - (c) for prescribed information to be included in the register (see section 18).
- (3) Provision made by virtue of subsection (2)(b) must secure that the following are treated as revoked by the revocation of a precision bred confirmation relating to an organism – 15
- (a) a precision bred animal marketing authorisation relating to the organism;
  - (b) any marketing authorisation issued under regulations under Part 3 that was issued in reliance, for the purposes of any requirement imposed by virtue of section 26(3)(a), on the organism being a marketable precision bred organism. 20
- (4) Regulations under this section may confer a function on the advisory committee.
- (5) Regulations under this section are subject to the negative procedure.

*Relevant animals: precision bred animal marketing authorisation* 25

## 10 Meaning of “relevant animal”

- (1) In this Act “relevant animal” means an animal which is a vertebrate.
- (2) If the definition of “animal” in the Animal Welfare Act 2006 is extended for any purposes by virtue of section 1(3) of that Act to include invertebrates of any description, regulations may amend subsection (1) to extend the definition of “relevant animal” so as to include invertebrates of that description. 30
- (3) In this section, “vertebrate” and “invertebrate” have the meanings given by section 1(5) of the Animal Welfare Act 2006.
- (4) Regulations under subsection (2) are subject to the affirmative procedure.

## 11 Application for precision bred animal marketing authorisation 35

- (1) This section applies where a marketing notice is or has been given to the Secretary of State in relation to a relevant animal.
- (2) The notifier may apply to the Secretary of State for a precision bred animal marketing authorisation in relation to the relevant animal.

- (3) An application under this section must include a declaration that the notifier does not expect the health or welfare of the relevant animal or its qualifying progeny to be adversely affected (see section 25) by any precision bred trait (“an animal welfare declaration”).
- (4) An application under this section must be accompanied by – 5
- (a) an assessment of the risks to the health or welfare of the relevant animal or its qualifying progeny which could reasonably be expected to result from any precision bred trait,
  - (b) an explanation of the steps that the notifier has taken to identify the traits and risks mentioned in paragraph (a), 10
  - (c) any required information (see subsection (5)(b)), and
  - (d) any fee prescribed by regulations under section 39.
- (5) Regulations may –
- (a) make provision about the form and content of – 15
    - (i) an application under this section (but subject to subsection (3)),  
or
    - (ii) any document required under subsection (4)(a) or (b);
  - (b) prescribe any further information which must accompany the application (“the required information”).
- (6) After receiving an application under this section accompanied by everything required by subsection (4), the Secretary of State must refer the application to the welfare advisory body (see section 22(3)) by sending the body the application and the documents and information provided under subsection (4)(a) to (c). 20
- This is subject to subsection (8). 25
- (7) The Secretary of State must refer the application –
- (a) as soon as practicable, if a precision breeding confirmation has already been issued in relation to the relevant animal;
  - (b) otherwise, at any time before, or as soon as practicable after, such a confirmation is issued. 30
- (8) The duty to refer the application does not apply if, before referring it, the Secretary of State decides not to issue a precision breeding confirmation in relation to the relevant animal.
- (9) Regulations may prescribe circumstances in which an application for a precision bred animal marketing authorisation in relation to a relevant animal may be made by a person other than the notifier (and in those cases references to the notifier, in relation to the marketing authorisation and an application for it, are to be read as references to that person). 35
- (10) Regulations under subsection (5) are subject to the affirmative procedure.
- (11) Regulations under subsection (9) are subject to the negative procedure. 40

## 12 Report by welfare advisory body

- (1) This section applies where the Secretary of State refers an application for a precision bred animal marketing authorisation to the welfare advisory body.
- (2) Before the end of the reporting period, the welfare advisory body must provide a report to the Secretary of State stating—
  - (a) whether the notifier, in making the animal welfare declaration, has had regard to—
    - (i) the traits identified by the notifier as precision bred traits, and
    - (ii) the risks identified by the notifier as risks to the health or welfare of the animal or its qualifying progeny that could reasonably be expected to result from those traits,
  - (b) whether the notifier has taken reasonable steps to identify those traits and risks and has made an appropriate assessment of those risks, and
  - (c) the reasons for its conclusions on the matters referred to in paragraphs (a) and (b).
- (3) In this section, the “reporting period” means a period specified in regulations beginning with the day on which the application was referred to the body.
- (4) Before the end of the reporting period, the body may by notice (“an information notice”) request the notifier to provide further information to the body.
- (5) The body’s report to the Secretary of State must be accompanied by any information provided to the body as the result of an information notice.
- (6) Subsections (2) and (3) are subject to regulations under section 23.
- (7) Regulations under subsection (3) are subject to the negative procedure.

## 13 Issue of precision bred animal marketing authorisation

- (1) As soon as practicable after receiving a report from the welfare advisory body under section 12(2) in relation to a relevant animal, the Secretary of State must—
  - (a) decide whether to issue a precision bred animal marketing authorisation in respect of the relevant animal,
  - (b) issue the authorisation if the decision is to do so, and
  - (c) notify the notifier—
    - (i) of the decision, and
    - (ii) if the decision is not to issue an authorisation, of the reasons for the decision.
- (2) The Secretary of State may issue a precision bred animal marketing authorisation only if satisfied—
  - (a) that the notifier, in making the animal welfare declaration, has had regard to—
    - (i) the traits identified by the notifier as precision bred traits, and

- (ii) the risks identified by the notifier as risks to the health or welfare of the animal or its qualifying progeny that could reasonably be expected to result from those traits, and
- (b) that the notifier has taken reasonable steps to identify those traits and risks and has made an appropriate assessment of those risks.

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*Protection of relevant animals following issue of marketing authorisation*

#### **14 Precision bred animal marketing authorisations: reporting obligations**

- (1) Regulations may make provision for requiring the notifier or any other prescribed person—
  - (a) to provide the Secretary of State with prescribed information about the health or welfare of any animal within subsection (2); 10
  - (b) to take prescribed steps, in connection with supplying such an animal to another person, to secure that prescribed information about the subsequent health or welfare of—
    - (i) that animal, or 15
    - (ii) any of its progeny within subsection (2),
 is provided by, or can be collected from, that other person.
- (2) An animal is within this subsection if it is—
  - (a) a relevant animal to which a precision bred animal marketing authorisation relates, or 20
  - (b) its qualifying progeny.
- (3) Regulations under this section may provide for requirements to apply to information about the health or welfare of a relevant animal or its qualifying progeny during periods—
  - (a) prescribed by the regulations, or 25
  - (b) determined by the Secretary of State in particular cases.
- (4) Regulations under this section are subject to the affirmative procedure.

#### **15 Suspension and revocation of precision bred animal marketing authorisation**

- (1) Regulations may make provision for the Secretary of State—
  - (a) to suspend a precision bred animal marketing authorisation where the Secretary of State receives information (whether by virtue of section 14 or otherwise) relating to the health or welfare of the relevant animal or its qualifying progeny; 30
  - (b) to revoke a precision bred animal marketing authorisation where, in consequence of such information, the Secretary of State considers the health or welfare of the relevant animal or its qualifying progeny likely to be adversely affected by precision bred traits (see section 25); 35
  - (c) to suspend or revoke a precision bred animal marketing authorisation where there has been a failure by any person to comply with regulations under section 14. 40

- (2) Regulations made under this section must make provision—
- (a) for the procedure to be followed where the Secretary of State proposes to suspend or revoke a precision bred animal marketing authorisation, which must include provision for the following, except in urgent cases—5
    - (i) requiring notice of the proposal to be published in any way that the Secretary of State considers appropriate to bring it to the attention of those affected by it;
    - (ii) permitting persons affected by the proposal to make representations about it;10
  - (b) about the consequences of suspending or revoking a precision bred animal marketing authorisation;
  - (c) for prescribed information to be included in the register (see section 18).
- (3) Regulations under this section may confer a function on the welfare advisory body.15
- (4) Nothing in this section affects the power for regulations under Part 4 to make provision in relation to a failure to comply with regulations under section 14.
- (5) Regulations under this section are subject to the negative procedure.20

*Reviews and appeals relating to Part 2*

**16 Reviews and appeals relating to Part 2**

- (1) Regulations must make provision for reviews of and appeals against decisions under this Part.
- (2) The regulations must, in particular, in relation to each of the decisions mentioned in subsection (3)—25
- (a) secure that any person prescribed by the regulations may—30
    - (i) require the Secretary of State to review the decision, and
    - (ii) if not satisfied with the outcome of any such review, appeal against the decision,
  - (b) secure that the grounds on which a review may be required or an appeal brought include the following—35
    - (i) that the decision was based on an error of fact,
    - (ii) that the decision was wrong in law, and
    - (iii) that the decision was unreasonable for any reason, and
  - (c) make provision for such an appeal to be brought in the First-tier Tribunal.
- (3) Those decisions are—
- (a) a decision under section 8 not to issue a precision bred confirmation;
  - (b) a decision under section 9 to revoke a precision bred confirmation;40

- (c) a decision under section 13 not to issue a precision bred animal marketing authorisation;
  - (d) a decision under section 15 to suspend or revoke a precision bred animal marketing authorisation.
- (4) Regulations may make provision as to— 5
- (a) the Secretary of State’s functions on a review of a decision under this Part;
  - (b) the powers of the First-tier Tribunal on an appeal by virtue of this section.
- (5) Regulations under this section are subject to the negative procedure. 10

#### *Risk assessments*

### **17 Restrictions on importation and acquisition of precision bred organisms in England**

- (1) Regulations may make provision for requiring a person to carry out an environmental risk assessment before— 15
- (a) importing a precision bred organism where its destination is in England;
  - (b) acquiring a precision bred organism which is in England.
- (2) In subsection (1), an “environmental risk assessment” means an assessment of the risks of damage to the environment being caused as result of the person importing or acquiring the organism. 20
- (3) Regulations under subsection (1) may, in particular, make provision—
- (a) prescribing how risk assessments are to be carried out;
  - (b) prescribing matters which must be taken into account, investigated or assessed by persons carrying out risk assessments; 25
  - (c) requiring risk assessments to be kept under review;
  - (d) requiring records to be kept of risk assessments and for those records to be provided to the Secretary of State.
- (4) Provision that may be made by virtue of subsection (3) includes provision requiring persons carrying out risk assessments to obtain advice from prescribed persons. 30
- (5) For the purposes of this section—
- (a) “acquire”, in relation to precision bred organisms, includes any method by which such organisms may come to be in a person’s possession, other than by their being imported; 35
  - (b) “damage to the environment” is caused by the presence in the environment of a precision bred organism which is no longer under anyone’s control (see section 3(2)) and is capable of causing adverse effects as regards the health of humans or the environment.
- (6) Regulations under this section are subject to the negative procedure. 40



*Register*

**18 Precision breeding register**

- (1) The Secretary of State must establish and maintain a register (“the register”) containing prescribed information about –
  - (a) release notices and any required information (see section 4(1)(a)); 5
  - (b) marketing notices and any required information (see section 6(1) and (2));
  - (c) reports provided by the advisory committee to the Secretary of State under section 7(2);
  - (d) information provided to the advisory committee in accordance with an information notice given by the committee (see section 7(3)); 10
  - (e) notices given by the Secretary of State under section 8(1);
  - (f) reports provided by the welfare advisory body to the Secretary of State under section 12(2);
  - (g) information provided to welfare advisory body in accordance with an information notice given by the body (see section 12(4)); 15
  - (h) notices given by the Secretary of State under section 13(1);
  - (i) enforcement notices (see section 32(3));
  - (j) such other matters relating to this Act as may be prescribed.
- (2) The Secretary of State must not include information in the register if, on request by a person, the Secretary of State determines that the information is for the time being commercially confidential in relation to that person. This is subject to subsection (4). 20
- (3) Subsection (2) ceases to apply if the Secretary of State determines that the information is no longer commercially confidential (whether or not on request by a person). 25
- (4) For the purposes of subsections (2) and (3), the following information is not to be regarded as commercially confidential –
  - (a) the name of any person giving the notices and required information mentioned in subsection (1)(a) and (b); 30
  - (b) a general description of any precision bred organism.
- (5) The Secretary of State must ensure that the register is accessible to the public free of charge by electronic means.
- (6) Regulations may make provision for the keeping of the register.
- (7) Regulations under subsection (1) are subject to the affirmative procedure. 35
- (8) Regulations under subsection (6) are subject to the negative procedure.

*Monitoring and inspection***19 Inspectors**

- (1) The Secretary of State may appoint inspectors for the purposes of this Part.
- (2) An inspector appointed under this section is not liable in any civil or criminal proceedings for anything done in the purported exercise of the inspector's functions under section 20 or Part 4 if the court is satisfied that the act was done in good faith and that there were reasonable grounds for doing it. 5
- (3) Relief from liability of an inspector under subsection (2) does not affect any liability of any other person in respect of the inspector's act.
- (4) In this Part "inspector" means an inspector appointed under this section. 10

**20 Monitoring and inspection of Part 2 obligations**

- (1) Regulations may make provision for –
  - (a) monitoring compliance with Part 2 obligations, and
  - (b) investigating suspected failures to comply with Part 2 obligations.
- (2) Subject to subsection (3), regulations under this section may, in particular, make provision – 15
  - (a) conferring powers on inspectors –
    - (i) to enter premises;
    - (ii) to inspect and search premises;
    - (iii) to take copies of documents; 20
    - (iv) to take photographs and samples;
    - (v) to require the provision of information;
  - (b) for allowing inspectors, in carrying out their functions, to be accompanied by other persons;
  - (c) for treating matters as relevant breaches (see section 31), including – 25
    - (i) obstructing an inspector;
    - (ii) providing false information to an inspector;
    - (iii) impersonating an inspector.
- (3) Regulations under this section –
  - (a) may not create criminal offences; 30
  - (b) may not authorise an inspector to enter a private dwelling without the consent of the occupier except in exercise of a warrant issued by a justice of the peace;
  - (c) may not authorise the use of force to enter premises;
  - (d) must contain provision to prohibit information obtained by inspectors under the regulations being used or disclosed otherwise than – 35
    - (i) for the purposes of this Part or Part 6 of the Environmental Protection Act 1990, or
    - (ii) for prescribed purposes relating to safeguarding the health and welfare of animals. 40

- (4) Regulations under this section are subject to the affirmative procedure.

## 21 Meaning of “Part 2 obligation”

- (1) In this Act “Part 2 obligation” means any requirement, other than one within subsection (2), imposed –
- (a) by or under this Part, or 5
  - (b) by a compliance notice or stop notice issued in connection with a requirement imposed by or under this Part, including, in particular, a requirement imposed by an inspector in exercise of the inspector’s functions.
- (2) The following are not Part 2 obligations – 10
- (a) a request made in an information notice (within the meaning of section 23) given by an advisory body, or
  - (b) any obligation of the Secretary of State, an advisory body or an inspector.
- (3) Regulations may provide for references to a failure to comply with a Part 2 obligation to include references to providing or recording information, or making a statement, that is false or misleading – 15
- (a) in purported compliance with a Part 2 obligation, or
  - (b) in connection with any application or review, or any proposal to suspend or revoke a confirmation or authorisation, under this Part. 20
- (4) For the purposes of this section “requirement” includes “prohibition”.
- (5) Regulations under subsection (3) are subject to the affirmative procedure.

### *Release and marketing: general provisions*

## 22 Advisory bodies

- (1) References in this Act to the advisory committee are to the committee appointed by the Secretary of State under section 124(1) of the Environmental Protection Act 1990. 25
- (2) The advisory committee must, at the request of the Secretary of State, provide advice on any matter relevant to the Secretary of State’s functions under sections 6 to 9 (precision bred confirmation). 30
- (3) References in this Act to the welfare advisory body are to such committee or other body as may be designated by regulations.
- (4) A body designated by regulations under subsection (3) may be –
- (a) a committee appointed by the Secretary of State for the purposes of this Part, or 35
  - (b) a body –
    - (i) established by or under any other Act, or
    - (ii) which otherwise exercises functions of a public nature.

- (5) The welfare advisory body must, at the request of the Secretary of State, provide advice on any matter relevant to the Secretary of State’s functions under sections 11 to 15 (precision bred animal marketing authorisation).
- (6) Subsections (7) and (8) apply to any committee appointed by the Secretary of State under subsection (4)(a). 5
- (7) Members of the committee are to hold and vacate office in accordance with the terms of their appointment.
- (8) The Secretary of State may pay to members of the committee such remuneration and allowances as the Secretary of State may determine.
- (9) Regulations under subsection (3) are subject to the affirmative procedure. 10

### 23 Advisory bodies: time limits etc

- (1) Regulations may –
- (a) make provision for a reporting period relating to an organism not to run while the information requested by any information notice given in relation to the organism has not been provided; 15
- (b) make provision for a relevant application relating to an organism to be treated as withdrawn if the information requested by any information notice given in relation to the organism is not provided within a prescribed period.
- (2) In this section – 20
- “information notice” means an information notice under section 7 (report by advisory committee) or 12 (report by welfare advisory body);
- “relevant application” means a marketing notice or an application for a precision bred animal marketing authorisation;
- “reporting period” means – 25
- (a) a 90 day period mentioned in section 7(2), or
- (b) a reporting period within the meaning of section 12.
- (3) For the purposes of this section –
- (a) an information notice is given in relation to an organism if it is given in connection with a relevant application relating to the organism, and 30
- (b) a reporting period relates to an organism if it applies for the purposes of a relevant application relating to the organism.
- (4) Regulations under subsection (1) are subject to the negative procedure.

### 24 Meaning of “qualifying progeny”

In this Act “qualifying progeny”, in relation to a marketable precision bred organism, means any progeny of the organism whose genome does not contain any feature resulting from the application of modern biotechnology, apart from features inherited from that or any other marketable precision bred organism. 35

## 25 Precision bred animal marketing authorisation: adverse effects

- (1) Regulations may prescribe circumstances in which the health or welfare of a relevant animal or its qualifying progeny is, or is not, to be regarded for the purposes of—
  - (a) section 11(3), or
  - (b) section 15(1)(b),as being adversely affected by any precision bred trait.
- (2) Regulations under this section are subject to the affirmative procedure.

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### PART 3

#### FOOD AND FEED PRODUCED FROM PRECISION BRED ORGANISMS

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## 26 Regulation of food and feed produced from precision bred organisms

- (1) Regulations may make provision for regulating the placing on the market in England of food and feed produced from precision bred organisms.
- (2) Regulations under subsection (1) may, in particular—
  - (a) prohibit any person from placing food or feed produced from a precision bred organism on the market in England except in accordance with a marketing authorisation issued by the Secretary of State under the regulations in relation to the organism, and
  - (b) impose requirements for the purpose of securing traceability in relation to food or feed produced from precision bred organisms that is placed on the market in England.
- (3) Regulations made by virtue of subsection (2)(a) may, in particular, prescribe requirements that must be satisfied in order for the Secretary of State to issue a food and feed marketing authorisation in relation to a precision bred organism which may include requirements—
  - (a) that the precision bred organism—
    - (i) is a marketable precision bred organism, or
    - (ii) is the qualifying progeny of a marketable precision bred organism;
  - (b) for securing that—
    - (i) any food or feed produced from the organism and covered by the authorisation will not have adverse effects on human or animal health;
    - (ii) the way in which any such food or feed will be placed on the market will not mislead consumers;
    - (iii) the production of any such food or feed will not have adverse effects on the environment;
    - (iv) consuming any such food or feed in place of other food or feed that it might reasonably be expected to replace will not be nutritionally disadvantageous to humans or animals.

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- (4) Regulations made by virtue of subsection (2)(a) may also make provision, in particular –
- (a) about the procedure for determining applications for food and feed marketing authorisations;
  - (b) for food and feed marketing authorisations to be issued subject to conditions and limitations; 5
  - (c) for varying or cancelling conditions or limitations that apply to food and feed marketing authorisations, or imposing new ones;
  - (d) about revocation of food and feed marketing authorisations;
  - (e) about publication of information relating to applications for food and feed marketing authorisations. 10
- (5) In subsection (4), references to applications for food and feed marketing authorisations include references to applications to vary or cancel conditions or limitations that apply to marketing authorisations.
- (6) Provision that may be made by virtue of subsection (4) includes provision conferring functions on the Food Standards Agency, which may include provision – 15
- (a) for requiring the Food Standards Agency, in carrying out a function conferred by the regulations –
    - (i) to obtain advice or information from, or consult, persons of prescribed descriptions; 20
    - (ii) to carry out risk assessments;
  - (b) relating to any risk assessment required by the regulations.
- (7) Regulations which, by virtue of subsection (6)(a)(i), impose an obligation on any person other than the Food Standards Agency may provide that the obligation is not a Part 3 obligation (see section 29). 25
- (8) Regulations made by virtue of subsection (2)(a) –
- (a) may prescribe who is authorised to place food and feed on the market by virtue of a food and feed marketing authorisation, which may, in particular, be – 30
    - (i) only the person who applied for the authorisation,
    - (ii) any person, or
    - (iii) any person of a prescribed description, and
  - (b) may provide for any provision made by virtue of paragraph (a) to be subject, in the case of a particular food and feed marketing authorisation, to any limitation to which the authorisation is subject. 35
- (9) Regulations under this section are subject to the affirmative procedure.

## 27 Food and feed marketing authorisations: register

- (1) Regulations may make provision for requiring the Food Standards Agency to establish and maintain a public register containing prescribed particulars relating to food and feed marketing authorisations (the “food and feed register”). 40

- (2) Regulations under subsection (1) may provide for information provided to the Secretary of State or the Food Standards Agency in connection with food and feed marketing authorisations or applications for them, or with applications to vary or cancel conditions or limitations, to be included in the food and feed register. 5
- (3) The particulars prescribed under subsection (1) in relation to a food and feed marketing authorisation may include, in particular, particulars of any confirmation or authorisation issued under Part 2 that may be required in connection with the authorisation by virtue of section 26(3)(a).
- (4) Regulations under subsection (1) are subject to the affirmative procedure. 10

## 28 Monitoring and inspection of Part 3 obligations

- (1) Regulations may make provision for designating one or more bodies within subsection (2) as enforcement authorities with functions of—
  - (a) monitoring compliance with Part 3 obligations, and
  - (b) investigating suspected failures to comply with Part 3 obligations. 15
- (2) A body is within this subsection if it—
  - (a) is established by or under any other Act, or
  - (b) otherwise exercises functions of a public nature.
- (3) Subject to subsection (4), regulations under this section may, in particular, make provision—
  - (a) conferring powers on enforcement authorities to appoint inspectors to carry out functions under the regulations;
  - (b) conferring functions on an inspector, including—
    - (i) powers of entry, inspection, examination, search and seizure;
    - (ii) powers to take copies of documents, photographs and samples; 25
    - (iii) powers to impose requirements;
    - (iv) powers to require the provision of information;
  - (c) for allowing inspectors, in carrying out their functions, to be accompanied by other persons;
  - (d) for treating matters as relevant breaches, including—
    - (i) obstructing an inspector;
    - (ii) providing false information to an inspector;
    - (iii) impersonating an inspector; 30
  - (e) for relief for inspectors from criminal or civil liability for acts done in good faith in the purported exercise of their functions; 35
  - (f) corresponding to, or applying (with or without modifications), any provision made by or under—
    - (i) the Food Safety Act 1990;
    - (ii) section 67 of the Agriculture Act 1970.
- (4) Regulations under this section—
  - (a) may not create criminal offences; 40

- (b) may not authorise an inspector to enter a private dwelling without the consent of the occupier except in exercise of a warrant issued by a justice of the peace.

- (5) Regulations under this section are subject to the affirmative procedure.

## **29 Meaning of “Part 3 obligation”** 5

- (1) In this Act “Part 3 obligation” means any requirement, other than one within subsection (3), imposed –
  - (a) by or under this Part, or
  - (b) by a compliance notice or stop notice issued in connection with a requirement imposed by or under this Part. 10
- (2) Part 3 obligations include, in particular –
  - (a) where a food and feed marketing authorisation is subject to conditions, the obligation to comply with those conditions;
  - (b) any requirement imposed by an inspector in exercise of the inspector’s functions. 15
- (3) The following are not Part 3 obligations –
  - (a) an obligation of the Secretary of State, the Food Standards Agency or an inspector;
  - (b) any obligation that is not a Part 3 obligation by virtue of provision made under section 26(7). 20
- (4) Regulations may provide for references to a failure to comply with a Part 3 obligation to include references to providing or recording information, or making a statement, that is false or misleading –
  - (a) in purported compliance with a Part 3 obligation, or
  - (b) in connection with any application or review, or any proposal to suspend or revoke an authorisation or to vary, revoke or impose conditions or limitations, under this Part. 25
- (5) For the purposes of this section “requirement” includes “prohibition”.
- (6) Regulations under subsection (4) are subject to the affirmative procedure.

## **30 Interpretation of Part 3** 30

- (1) In this Part –
  - “feed” has the meaning given by Article 3(4) of the Food Regulation;
  - “food” has the same meaning as in the Food Regulation (see Article 2 of that Regulation);
  - “food and feed marketing authorisation” means a marketing authorisation issued under regulations under section 26 in relation to a precision bred organism; 35
  - “the Food Regulation” means Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing 40



the European Food Safety Authority and laying down procedures in matters of food safety;

“inspector” means a person appointed as such under regulations under section 28;

“traceability”, in relation to food or feed produced from a precision bred organism, means the ability to trace and follow the organism and the food or feed through all stages of production, processing and distribution. 5

(2) For the purposes of this Part, food or feed is produced “from” a precision bred organism if it contains or consists of, or is otherwise derived from, the precision bred organism. 10

(3) References in this Part to food or feed being placed on the market are to be read in accordance with Article 3(8) of the Food Regulation.

#### PART 4

#### ENFORCEMENT 15

##### *Enforcement of relevant breaches: general provisions*

### 31 Meaning of “relevant breach” etc

(1) In this Act “relevant breach”, in relation to a person, means a failure by the person to comply with a relevant obligation, but—

(a) in relation to an inspector appointed under section 19, means a failure to comply with a Part 2 obligation; 20

(b) in relation to an inspector appointed under regulations under section 28, means a failure to comply with a Part 3 obligation.

(2) In this Part—

(a) “inspector” means an inspector appointed under section 19 or under regulations under section 28; 25

(b) “relevant obligation” means a Part 2 obligation or a Part 3 obligation.

(3) Regulations may make provision for—

(a) persons to be treated as having failed to comply with a Part 3 obligation in circumstances corresponding or similar to those in which section 20 of the Food Safety Act 1990 provides for persons to be guilty of an offence under that section; 30

(b) a failure to comply with a Part 3 obligation not to be regarded as a relevant breach in circumstances corresponding or similar to those in which sections 21 and 22 of the Food Safety Act 1990 provide for defences to offences under that Act. 35

(4) Regulations under subsection (3) are subject to the affirmative procedure.

**32 Enforcement**

- (1) Regulations may make provision for –
- (a) an inspector to issue either of the following –
    - (i) a compliance notice (see section 33);
    - (ii) a stop notice (see section 34); 5
  - (b) the Secretary of State or an inspector to issue a monetary penalty notice (see section 35);
- to a person in relation to a relevant breach.
- (2) Regulations may provide for a requirement imposed by a stop notice to be enforceable, on the application of the Secretary of State, by injunction. 10  
This does not affect the enforcement of the requirement (or power to make provision for its enforcement) in any other way (whether by monetary penalty notice or otherwise).
- (3) In this Act “enforcement notice” means – 15
- (a) a compliance notice,
  - (b) a stop notice, or
  - (c) a monetary penalty notice.
- (4) Regulations under this section are subject to the affirmative procedure.

*Enforcement notices***33 Compliance notices** 20

- (1) In this Act “compliance notice” means a notice requiring the person to whom it is issued to take specified steps within a specified period.
- (2) Regulations which provide for the issue of a compliance notice must secure –
- (a) that a compliance notice may be issued only where the inspector issuing the notice is satisfied that the person to whom it is issued has committed or is committing a relevant breach, 25
  - (b) that the steps specified under subsection (1) are steps that the inspector considers will ensure that the relevant breach does not continue or recur, and
  - (c) that the period specified under subsection (1) is not less than 14 days beginning with the day on which the notice is received. 30
- (3) Sections 36 and 37 make further provision about compliance notices.
- (4) In this section “specified”, in relation to a compliance notice, means specified in the notice.

**34 Stop notices** 35

- (1) In this Act “stop notice” means a notice prohibiting the person to whom it is issued –
- (a) from carrying on a specified activity, or

- (b) from doing so until the person has taken specified steps.
- (2) Regulations which provide for the issue of a stop notice must secure –
  - (a) that a stop notice may be issued to a person only where the inspector issuing the notice reasonably believes that the person to whom it is issued has committed or is likely to commit a relevant breach, and 5
  - (b) that the steps specified under subsection (1)(b) are steps that the inspector issuing the notice considers will ensure that the specified activity will be carried on in a way that does not involve the person committing a relevant breach.
- (3) Sections 36 and 37 make further provision about stop notices. 10
- (4) In this section “specified”, in relation to a stop notice, means specified in the notice.

### 35 Monetary penalty notices

- (1) In this Act “monetary penalty notice” means a notice requiring the person to whom it is issued to pay a sum specified in the notice (a “monetary penalty”) to the appropriate authority. 15
- (2) In this section “appropriate authority” means –
  - (a) in relation to a Part 2 obligation, the Secretary of State;
  - (b) in relation to a Part 3 obligation, an enforcement authority.
- (3) Regulations which provide for the issue of a monetary penalty notice must secure that the Secretary of State or an inspector may issue a monetary penalty notice only where satisfied that the person to whom it is issued has committed a relevant breach. 20
- (4) Regulations which provide for the issue of a monetary penalty notice must require the notice to state – 25
  - (a) how payment may be made,
  - (b) the period within which payment must be made, and
  - (c) the consequences of late payment or failure to pay.
- (5) Regulations which provide for the issue of a monetary penalty notice may make provision – 30
  - (a) for the payment of interest on late payment;
  - (b) as to how any amounts payable by virtue of the regulations are to be recoverable.

### 36 Content of enforcement notices: further provision

- (1) Regulations which provide for the issue of an enforcement notice to a person must require the notice to state – 35
  - (a) the grounds for issuing the notice,
  - (b) the person’s rights to require a review of or appeal against the notice, and

- (c) the consequences of failure to comply with the notice.
- (2) The statement required by virtue of subsection (1)(a) must include information specifying –
  - (a) the relevant obligation to which the relevant breach relates, and
  - (b) the matters which, in the opinion of the inspector or Secretary of State issuing the notice, constitute the failure to comply with that obligation. 5
- (3) Regulations which provide for the issue of an enforcement notice may provide for the variation or revocation of the notice –
  - (a) by the Secretary of State, in the case of a monetary penalty notice issued by the Secretary of State; 10
  - (b) by an inspector, in any other case.

### 37 Enforcement notices: reviews and appeals

- (1) Regulations which provide for the issue of an enforcement notice to a person must –
  - (a) secure that the person to whom it is issued may – 15
    - (i) require the Secretary of State to review the decision to issue the notice, and
    - (ii) if not satisfied with the outcome of any such review, appeal against that decision;
  - (b) secure that the grounds on which a review may be required or an appeal brought include the following – 20
    - (i) that the decision was based on an error of fact,
    - (ii) that the decision was wrong in law,
    - (iii) that any steps specified in the notice were unreasonable,
    - (iv) in the case of a stop notice, that the person to whom it was issued had not committed the relevant breach and would not have done so had the notice not been issued, 25
    - (v) in the case of a monetary penalty notice, that the amount of the penalty was unreasonable, and
    - (vi) that the decision was unreasonable for any other reason, 30
  - (c) make provision for such an appeal to be brought in the First-tier Tribunal, and
  - (d) make provision for suspending the operation of a compliance notice or monetary penalty notice where an appeal is brought under the regulations in relation to the notice pending the outcome of the appeal. 35
- (2) Regulations which provide for the issue of an enforcement notice may make provision as to –
  - (a) the Secretary of State’s functions on a review of a decision to issue an enforcement notice, or
  - (b) the powers of the First-tier Tribunal on an appeal by virtue of this section. 40

Costs

**38 Costs**

- (1) Regulations may make provision for an appropriate authority, by notice (a “costs notice”) to require a person to pay the costs incurred by the authority in relation to an enforcement notice up to the time of its issue. 5
- (2) In this section, “appropriate authority”, in relation to an enforcement notice, means –
  - (a) in relation to a Part 2 obligation, the Secretary of State;
  - (b) in relation to a Part 3 obligation, an enforcement authority.
- (3) In subsection (1), “costs” includes, in particular – 10
  - (a) investigation costs;
  - (b) administration costs;
  - (c) costs of obtaining expert advice (including legal advice).
- (4) Regulations which provide for the issue of a costs notice to a person must secure that – 15
  - (a) the notice specifies the amount required to be paid,
  - (b) the person to whom the notice is issued may require the person issuing it to provide a detailed breakdown of the amount,
  - (c) the person to whom the costs notice is issued is not liable to pay any costs which that person shows to have been unnecessarily incurred, 20
  - (d) the person to whom the notice is issued may –
    - (i) require the Secretary of State to review a relevant decision, and
    - (ii) if not satisfied with the outcome of any such review, appeal against that decision, and
  - (e) the grounds on which a review may be required or an appeal brought include – 25
    - (i) in the case of a decision as to the amount of the costs, that the amount includes any amount referable to any costs unnecessarily incurred,
    - (ii) that the decision was based on an error of fact, 30
    - (iii) that the decision was wrong in law, and
    - (iv) that the decision was unreasonable for any other reason.
- (5) Regulations which provide for the issue of a costs notice to a person must also make provision –
  - (a) for an appeal under the regulations to be brought in the First-tier Tribunal, and 35
  - (b) for suspending the operation of a costs notice where an appeal is brought under the regulations pending the outcome of the appeal.
- (6) In subsection (4), “relevant decision”, in relation to a costs notice, means – 40
  - (a) the decision to issue the notice, or
  - (b) the decision as to the amount of the costs.

- (7) Regulations which provide for the issue of a costs notice may make provision—
- (a) for the payment of interest on late payment;
  - (b) as to how any amounts payable by virtue of the regulations are to be recoverable.
- (8) Regulations under this section are subject to the affirmative procedure.

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## PART 5

### GENERAL

#### 39 Fees

- (1) Regulations may make provision requiring a fee to be paid to the appropriate authority in respect of the exercise of any function conferred by or under Part 2 or Part 3. 10
- (2) In this section “appropriate authority” means—
- (a) in relation to a function conferred by or under Part 2, the Secretary of State; 15
  - (b) in relation to a function conferred by or under under Part 3, the Food Standards Agency.
- (3) Regulations which require the payment of a fee must prescribe—
- (a) the amount of the fee, or
  - (b) how the amount of the fee is to be calculated. 20
- (4) In prescribing the amount of a fee in respect of a function (or any other amount by reference to which the fee is to be calculated) the Secretary of State may have regard to the desirability of securing that, as far as practicable and taking one year with another, the following are equal—
- (a) income of the appropriate authority from fees referable to the function, and 25
  - (b) expenditure incurred by—
    - (i) the Secretary of State, in the case of a function conferred by or under Part 2, or
    - (ii) the Secretary of State, the Food Standards Agency or enforcement authorities, in the case of a function conferred by or under Part 3, 30
 in exercising the function (including a reasonable share of expenditure which is referable only partly or indirectly to the exercise of that function). 35
- (5) Regulations under this section are subject to the affirmative procedure.

#### 40 Notices and documents

- (1) Regulations may make provision about—

- (a) how a notice or other document may be issued or given under this Act;
  - (b) when such a notice or document is to be treated as being received.
- (2) Regulations under this section are subject to the negative procedure.

**41 Consequential amendments of the Environmental Protection Act 1990** 5

- (1) The Environmental Protection Act 1990 is amended as follows.
- (2) After section 106 insert –

**“106A Exclusion of precision bred organisms from English application of Part**

- (1) In this Part as it applies in relation to England, references to genetically modified organisms (except in this section and section 127) – 10
- (a) do not include references to precision bred organisms;
  - (b) so far as they relate to marketing, also do not include references to gametes of precision bred organisms.
- (2) For the purposes of subsection (1), this Part applies in relation to England so far as it applies in relation to – 15
- (a) importing genetically modified organisms where their destination is in England;
  - (b) acquiring genetically modified organisms which are in England;
  - (c) keeping or releasing genetically modified organisms in England; 20
  - (d) marketing a genetically modified organism so far as the organism (or, where the organism is marketed by virtue of a product consisting of or including the organism being made available to other persons, that product) is made available for delivery in England. 25
- (3) In this section “precision bred organism” and “gamete” have the same meanings as in the Genetic Technology (Precision Breeding) Act 2022.”
- (3) In section 124 (advisory committee for purposes of Part 6), in subsection (1), at the end insert –
- “For other functions of the committee, see Part 2 of the Genetic Technology (Precision Breeding) Act 2022.” 30

**42 Power to make consequential provision**

- (1) Regulations may make supplementary, incidental or consequential provision in connection with any provision of or made under this Act.
- (2) Regulations under this section may modify legislation. 35
- (3) Regulations under this section which contain provision modifying primary legislation (with or without other provision) are subject to the affirmative procedure.

- (4) Other regulations under this section are subject to the negative procedure.

### 43 Regulations

- (1) This section applies to regulations under this Act other than regulations under section 48 (commencement regulations).
- (2) Regulations are to be made by statutory instrument. 5
- (3) A power to make regulations includes power –
- (a) to make –
    - (i) different provision for different purposes;
    - (ii) transitional, transitory or saving provision;
  - (b) to confer a function involving the exercise of a discretion. 10
- (See section 42(1) for power to make consequential, incidental and supplemental provision.)
- (4) Where regulations under this Act are subject to the affirmative procedure, the regulations may not be made unless a draft of the statutory instrument containing them has been laid before, and approved by a resolution of, each House of Parliament. 15
- (5) Where regulations under this Act are subject to the negative procedure, the statutory instrument containing them is subject to annulment in pursuance of a resolution of either House of Parliament.
- (6) Any provision that may be made by regulations under this Act subject to the negative procedure may be made in regulations subject to the affirmative procedure. 20

### 44 Interpretation

- In this Act the following terms have the following meanings –
- “advisory body” means the advisory committee or welfare advisory body; 25
  - “the advisory committee” has the meaning given by section 22(1);
  - “the affirmative procedure” has the meaning given by section 43(4);
  - “animal” has the meaning given by section section 2(2);
  - “compliance notice” has the meaning given by section 33(1);
  - “control” is to be read in accordance with section 3(2); 30
  - “enforcement authority” means a body designated as such under section 28(1);
  - “enforcement notice” has the meaning given by section 32(3);
  - “the environment” includes land, air, water and living organisms supported by any of those media; 35
  - “gamete” has the meaning given by section 2(4);
  - “legislation” means –
    - (a) primary legislation,
    - (b) retained direct EU legislation, or



- (c) subordinate legislation;
- “marketable precision bred organism” has the meaning given by section 5(2);
- “marketing notice” has the meaning given by section 6(1);
- “modern biotechnology” has the meaning given by section 1(3); 5
- “modify”, in relation to legislation, includes amend, repeal or revoke (and related terms are to be read accordingly);
- “monetary penalty notice” has the meaning given by section 35(1);
- “the negative procedure” has the meaning given by section 43(5);
- “notifier”, in relation to a marketing notice, has the meaning given by section 6(1) (but see section 11(9)); 10
- “organism” (except in section 2) means plant or animal;
- “Part 2 obligation” has the meaning given by section 21;
- “Part 3 obligation” has the meaning given by section 29;
- “plant” has the meaning given by section 2(1); 15
- “precision bred” has the meaning given by section 1;
- “precision bred animal marketing authorisation” means a marketing authorisation issued under section 13(1);
- “precision bred confirmation” has the meaning given by section 8(1)(a)(i);
- “precision bred organism” has the meaning given by section 1(1); 20
- “precision bred trait”, in relation to a relevant animal, means a trait of the animal which results from a feature of the animal’s genome that results from the application of modern biotechnology;
- “prescribed” means prescribed by regulations;
- “primary legislation” means – 25
- (a) an Act,
  - (b) an Act of the Scottish Parliament,
  - (c) an Act or Measure of Senedd Cymru, or
  - (d) Northern Ireland legislation;
- “progeny”, in relation to a precision bred organism, includes any progeny of the organism, whether resulting from sexual or asexual reproduction; 30
- “qualifying progeny” has the meaning given by section 24;
- “the register” has the meaning given by section 18;
- “regulations” means regulations made by the Secretary of State;
- “relevant animal” has the meaning given by section 10; 35
- “relevant breach” has the meaning given by section 31(1);
- “stop notice” has the meaning given by section 34(1);
- “subordinate legislation” means an instrument made under primary legislation or under retained direct EU legislation;
- “the welfare advisory body” has the meaning given by section 22(3). 40

## 45 Financial provisions

The following are to be paid out of money provided by Parliament –

- (a) any expenditure incurred under or by virtue of this Act by the Secretary of State or the Food Standards Agency, and
- (b) sums payable out of money so provided under any other Act.

#### **46 Crown application**

- (1) This Act binds the Crown. 5
- (2) If the Secretary of State certifies that it appears to the Secretary of State appropriate in the interests of national security that powers of entry conferred under this Act should not be exercisable in relation to Crown premises specified in the certificate, those powers are not exercisable in relation to those premises. 10
- (3) In subsection (2), “Crown premises” means premises held, or used, by or on behalf of the Crown.
- (4) No power of entry conferred under this Act may be exercised in relation to land belonging to His Majesty in right of His private estates.
- (5) In subsection (4), the reference to His Majesty’s private estates is to be construed in accordance with section 1 of the Crown Private Estates Act 1862. 15

#### **47 Extent and application to sea areas**

- (1) Subject as follows, this Act extends to England and Wales only.
- (2) Part 1 and section 41 extend to England and Wales and Scotland only.
- (3) Sections 42 to 46, this section and section 48 extend to England and Wales, Scotland and Northern Ireland. 20
- (4) This Act—
  - (a) applies to the territorial sea adjacent to England as it applies in England;
  - (b) applies to any area for the time being designated under section 1(7) of the Continental Shelf Act 1964 as it applies in England. 25

#### **48 Short title and commencement**

- (1) This Act may be cited as the Genetic Technology (Precision Breeding) Act 2023.
- (2) Part 1 comes into force on the day on which this Act is passed. 30
- (3) Parts 2 to 4 and sections 39 and 40 come into force—
  - (a) so far as necessary to enable the exercise of any power to make regulations, on the day on which this Act is passed;
  - (b) for remaining purposes, on such day as regulations may appoint.
- (4) Section 41 comes into force on such day as regulations may appoint. 35
- (5) The rest of this Part comes into force on the day on which this Act is passed.

- (6) Regulations under this section may appoint different days for different purposes.
- (7) Regulations may make transitional, transitory or saving provision in connection with the coming into force of any provision of this Act.
- (8) Regulations under this section are to be made by statutory instrument.

# Genetic Technology (Precision Breeding) Bill

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[AS AMENDED ON REPORT]

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## B I L L

TO

Make provision about the release and marketing of, and risk assessments relating to, precision bred plants and animals, and the marketing of food and feed produced from such plants and animals; and for connected purposes.

*Brought from the Commons on 1st November 2022*

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Ordered to be Printed, 25th January 2023.

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