



Genetic Technology (Precision Breeding) Act 2023

2023 CHAPTER 6

PART 2

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),
 - (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—

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- (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.
- (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.
- (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,
 are made available to other persons, whether or not for consideration, and

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- (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—

qualifying progeny	section 24
precision bred confirmation	section 8(1)(a)(i)
relevant animal	section 10
precision bred animal marketing authorisation	section 13(1).

- (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.
- (2) Regulations may—
- make provision about the form and content of a marketing notice, and
 - prescribe information which must accompany a marketing notice (“required information”).
- (3) As soon as practicable after receiving—
- a marketing notice,
 - any required information, and
 - 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.

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—
- whether it considers the organism to be precision bred, and
 - 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.
- (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—
 - (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.
- (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.
- (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
 - (ii) permitting persons affected by the proposal to make representations about it;
 - (b) about the consequences of revoking a precision bred confirmation;
 - (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—
 - (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.
- (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

10 Meaning of “relevant animal”

- (1) In this Act “relevant animal” means an animal which is a vertebrate.

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- (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.
- (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

- (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—
 - (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),
 - (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—
 - (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).

This is subject to subsection (8).

- (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.

- (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).
- (10) Regulations under subsection (5) are subject to the affirmative procedure.
- (11) Regulations under subsection (9) are subject to the negative procedure.

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—

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- (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.

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);
 - (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
 - (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
 - (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
 - (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;

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- (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);
 - (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.
- (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—
 - (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;
 - (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.
- (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.

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)—
- (a) secure that any person prescribed by the regulations may—
 - (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—
 - (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;

- (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—
- (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.

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—
- (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.
- (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;
 - (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.
- (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;
 - (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.

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));
 - (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));
 - (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));
 - (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).
- (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).
- (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);
 - (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.
- (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.

- (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.

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—
 - (a) conferring powers on inspectors—
 - (i) to enter premises;
 - (ii) to inspect and search premises;
 - (iii) to take copies of documents;
 - (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—
 - (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;
 - (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—
 - (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.
- (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
 - (b) by a compliance notice or stop notice issued in connection with a requirement imposed by or under this Part,

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including, in particular, a requirement imposed by an inspector in exercise of the inspector's functions.

- (2) The following are not Part 2 obligations—
 - (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—
 - (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.
- (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.
- (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).
- (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
 - (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).
- (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.

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;
 - (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—
- “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—
 - (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
 - (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.

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.