



Genetic Technology (Precision Breeding) Act 2023

2023 CHAPTER 6

PART 2

PRECISION BRED ORGANISMS: RELEASE, MARKETING AND RISK ASSESSMENTS

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.
- (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”).

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- (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

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- (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.