



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

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—

Changes to legislation: There are currently no known outstanding effects for the Genetic Technology (Precision Breeding) Act 2023, Section 11. (See end of Document for details)

- (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.

Commencement Information

II S. 11 in force at Royal Assent for specified purposes, see **s. 48(3)(a)**

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