
DRAFT STATUTORY INSTRUMENTS

2024 No.

ENVIRONMENTAL PROTECTION, ENGLAND

FOOD, ENGLAND

**The Genetic Technology (Precision Breeding) (England)
Regulations 2024**

Made - - - -

Coming into force - -

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 4(3) and (4), 6(2), 9(1), (2) and (4), 16(1), (2) and (4), 17(1) and (3), 18(6), 20(1), (2) and (3), 21(3), 23(1), 26(1), (2), (3), (4), (7) and (8), 27(1) and (2), 28(1) and (3), 29(4), 31(3), 32(1) and (2), 33(2), 34(2), 35(3) and (4), 36(1) and (3), 37, 38(1), (4), (5) and (7), 40(1), 42(1) and (2), 43(3) and (6) of the Genetic Technology (Precision Breeding) Act 2023^(a).

The Secretary of State has carried out the consultation required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety^(b)

In accordance with section 43(4) of the Act, a draft of this instrument has been laid before, and approved by a resolution of, each House of Parliament.

PART 1

Introduction

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the Genetic Technology (Precision Breeding) (England) Regulations 2024 and come into force [].

^(a) 2023 c.6.

^(b) OJ No. L31, 1.2.2002, p.1, last amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 (OJ No. L231, 6.9.2019, p. 1-28).

(2) Subject to paragraph (3), this Part and regulation 45 of, and Schedule 5 to, these Regulations extend to the United Kingdom.

(3) An amendment to a provision has the same extent as the provision being amended.

(4) Otherwise, these Regulations extend to England and Wales but apply in England only.

Interpretation

2. In these Regulations —

“the Act” means the Genetic Technology (Precision Breeding Act) 2023^(a);

“the advisory committee” has the meaning in section 22(1) of the Act;

“the Food and Feed Register” means the register containing particulars relating to food and feed marketing authorisations established and maintained in accordance with section 27(1) of the Act and regulation 27 of these Regulations;

“precision bred organism” means a precision bred plant^(b);

“the Precision Breeding Register” means the register of precision bred organisms established and maintained in accordance with section 18 of the Act and regulations 10 and 11 of these Regulations;

PART 2

Release of Precision Bred Organisms

Notification requirement for release of precision bred organisms in England

3.—(1) This regulation applies in relation to the release^(c) of a precision bred organism in England by a person in accordance with section 3(1) of the Act.

(2) The release notice must specify the following persons in relation to the release—

- (a) the person who is proposing to release the precision bred organism from under their control;
- (b) if the person in paragraph (a) is a legal person, a natural person who is an employee or agent of the legal person who may be contacted in relation to the release notice;
- (c) a general description of other persons who may assist in the release.

(3) A person to whom paragraph (2)(a) applies must—

- (a) give the release notice to the Secretary of State at least 20 days before the day on which the organism is to be released beginning with the day the release notice is received by the Secretary of State^(d);
- (b) ensure the release notice contains the information required in Schedule 1 to these Regulations.

(4) The release notice may contain any other information that the person giving the notice considers relevant.

(5) More than one precision bred organism may be notified in a single release notice provided that—

^(a) 2023 c. 6.

^(b) “plant” is defined in section 2(1) of the Act.

^(c) “release” has the meaning in section 3(3) of the Act.

^(d) See regulation 43 of these Regulations.

- (a) the precision bred organisms are from the same species; and
- (b) the organisms contain only the changes, or combinations of those changes, described in the release notice in accordance with paragraph 4 of Schedule 1, and paragraph 2 of Schedule 3, to these Regulations.

Transitional provisions for release

4.—(1) When the circumstances in paragraph (2) apply, the procedure in paragraph (3) must be followed.

(2) The circumstances referred to in paragraph (1) are—

- (a) a notifier has given the Secretary of State a notification to release Qualifying Higher Plants pursuant to the Genetically Modified Organisms (Deliberate Release)(Amendment)(England) Regulations 2022 (a) before the coming into force of these Regulations; and
- (b) the Qualifying Higher Plants covered by the notification in sub-paragraph (a) include plants which—
 - (i) will be undergoing field trials after the coming into force of these Regulations, and
 - (ii) have not been released before the coming into force of these Regulations.

(3) A notifier must give to the Secretary of State a release notice covering those Qualifying Higher Plants notified under the regulations referred to in paragraph (2)(a) in accordance with regulation 3 of these Regulations within 3 months beginning with the date these Regulations come into force.

PART 3

Marketing of Precision Bred Organisms

Application for precision bred confirmation

5.—(1) This regulation applies in relation to the giving of a marketing notice under section 6(1) of the Act.

(2) A marketing notice under paragraph (1) must contain the information required in Schedule 2 to these Regulations.

(3) The marketing notice may contain any other information that the notifier considers relevant.

(4) A marketing notice may include more than one precision bred organism provided the precision bred organisms comply with paragraph 7 of Schedule 2 to these Regulations.

(5) The notifier may withdraw a marketing notice at any time before the Secretary of State makes a decision under section 8(1) of the Act by giving a request to the Secretary of State.

The advisory committee - reporting period etc

6.—(1) Subject to paragraph (2), where the Secretary of State has referred a marketing notice to the advisory committee under section 6(3) of the Act and the advisory committee subsequently requests further information from the notifier under section 7(3) of the Act, the reporting period does not run from the date of the information notice requesting the further information until receipt by the advisory committee of the further information requested.

(a) S.I. 2022/347.

(2) If the information requested in the information notice is not provided within 60 days of the date of the information notice, the marketing notice may be treated as withdrawn.

Revocation of precision bred confirmation

7.—(1) The Secretary of State may revoke a precision bred confirmation if the Secretary of State is no longer satisfied that the organism is precision bred in any of the following circumstances—

- (a) the notifier or other person named in the marketing notice notifies the Secretary of State directly or indirectly that the organism is not precision bred;
- (b) the Secretary of State reasonably suspects that a notifier or other person named in a marketing notice has provided false or misleading information in the marketing notice;
- (c) the Secretary of State is provided with new genetic information about an organism with precision bred confirmation.

(2) Where reasonable evidence is made available to the Secretary of State under paragraph (1) by a person other than the notifier, the Secretary of State must give notice to the notifier that information has been provided to the Secretary of State under paragraph (1).

(3) A notice under paragraph (2) must include—

- (a) the information provided under paragraph (1) that indicates why the organism may not be precision bred;
- (b) the date by which the notifier must respond to the notice.

(4) Where the Secretary of State proposes to revoke a precision bred confirmation, the Secretary of State must—

- (a) publish notice of the proposal to revoke the precision bred confirmation in any way that the Secretary of State considers appropriate to bring it to the attention of those affected by it;
- (b) invite those affected by the proposal to make representations to the Secretary of State about it.

(5) The Secretary of State may request a report from the advisory committee considering whether the precision bred organism should be revoked where the Secretary of State has—

- (a) provided to the advisory committee the documentation available under paragraph (1) and any response from the notifier provided following a notice under paragraph (2);
- (b) agreed the time period within which the advisory committee will provide its report.

(6) As soon as practicable after completion of the steps in paragraphs (2), (4) and (5), the Secretary of State must—

- (a) if satisfied that the organism is not precision bred—
 - (i) issue a revocation notice, and
 - (ii) give notice of it to the notifier;
- (b) If satisfied that the organism is precision bred, give notice to the notifier of that fact.

(7) A revocation notice under paragraph (6)(a)(i) must include the following—

- (a) notice that the precision bred confirmation is being revoked;
- (b) the date of the revocation;
- (c) the reasons for the revocation;
- (d) circumstances in which the revocation notice may be reviewed and appealed;
- (e) the procedure for the review or appeal;

- (f) the steps to be taken by the notifier following receipt of the revocation notice.
- (8) Following the revocation of a precision bred organism, the Secretary of State may—
 - (a) direct that a precision bred organism, or food or feed produced from a precision bred organism^(a), be recalled or withdrawn from the market;
 - (b) require the publication of details of the revocation in any way that the Secretary of State considers appropriate to bring it to the attention of those that may be affected by it;
 - (c) direct appropriate steps to identify purchasers or users of the precision bred organism in order to notify them of the revocation and the consequences for the regulation of the organism.
- (9) The Secretary of State must update the Precision Breeding Register with details of the revocation in accordance with regulation 11 of these Regulations.
- (10) Revocation of a precision bred confirmation under this regulation has the effect that any food and feed marketing authorisation issued under regulation 23 of these Regulations in reliance on the organism being a marketable precision bred organism for the purposes of any requirement imposed by virtue of section 26(3)(a) of the Act must also be treated as revoked and the Secretary of State must accordingly—
 - (a) notify the Food Standards Agency that the precision bred confirmation has been revoked; and
 - (b) supply a copy of the revocation notice issued under paragraph (6)(a)(i) to the Food Standards Agency to enable the Food and Feed Register to be updated with notice of the revocation.

Review of a precision bred confirmation or revocation decision

- 8.—**(1) A notifier who receives a notice under—
- (a) section 8(1)(b) of the Act (decision not to issue a precision bred confirmation); or
 - (b) regulation 7(6)(a) of these Regulations (a decision to revoke a precision bred confirmation)
- may require the Secretary of State to review the decision to issue the notice.
- (2) A person with an interest in a notice issued under regulation 7(6)(a) may require the Secretary of State to review the decision to issue the notice.
- (3) A request for a review under paragraphs (1) or (2) must be made within 28 days of the date of receipt of the relevant notice.
- (4) The grounds for a review are—
- (a) that the decision was based on an error of fact;
 - (b) that the decision was wrong in law;
 - (c) that the decision was unreasonable for any reason.
- (5) As part of the review, the Secretary of State may give due regard to any additional information or evidence provided to it.
- (6) Upon reviewing a decision under this regulation, the Secretary of State must—
- (a) decide whether to confirm, vary or withdraw the notice;
 - (b) give notice to the notifier, and any person with an interest who has requested a review under paragraph (2), setting out—
 - (i) the Secretary of State's decision,

(a) food or feed produced “from” a precision bred organism has the meaning in section 30(2) of the Act.

- (ii) the reasons for that decision;
 - (c) inform the notifier, and any person with an interest who has requested a review under paragraph (2), of the right to appeal to the First-tier Tribunal.
- (7) The Secretary of State may suspend the operation of a revocation notice to which the review relates pending the outcome of the review.

Appeal to the First-tier Tribunal

9.—(1) A notifier, or person with an interest in a notice, who requested a review under regulation 8(1) and is not satisfied with the outcome of the review under that regulation may appeal to the First-tier Tribunal.

(2) An appeal to the First-tier Tribunal under paragraph (1) must be made within 28 days of the date of notification of the review decision under regulation 8.

(3) The grounds for appeal are—

- (a) that the decision was based on an error of fact;
- (b) that the decision was wrong in law;
- (c) that the decision was unreasonable for any reason.

(4) The First-tier Tribunal may give due regard to any additional information or evidence provided to it.

(5) Upon consideration of any appeal under this regulation, the First-tier Tribunal, may—

- (a) withdraw the notice;
- (b) confirm the notice;
- (c) vary the notice;
- (d) take such steps as the Secretary of State could take in relation to the notice;
- (e) remit the decision whether to confirm the notice, or any matter relating to that decision, to the Secretary of State.

(6) The First-tier Tribunal may suspend the operation of a notice to which the review relates pending the outcome of the appeal.

PART 4

The Precision Breeding Register

Information to be included in the Precision Breeding Register

10.—(1) The Precision Breeding Register must contain the particulars set out in paragraphs (3) to (5).

(2) Paragraphs (3) to (5) are subject to section 18(2) of the Act (commercially confidential information).

(3) The Secretary of State must add the following information about a release notice to the Precision Breeding Register—

- (a) the name and address of the person proposing to release the precision bred organism from under their control;
- (b) a description of other persons who may assist in the release of the precision bred organism;

- (c) a general description of the precision bred organism covered by the release notice in accordance with Schedule 3 to these Regulations;
 - (d) the confirmations provided in accordance with paragraph 5 of Schedule 1 to these Regulations.
- (4) The Secretary of State must add the following information about a marketing notice to the Precision Breeding Register—
- (a) the name and address of the person with overall responsibility for marketing the precision bred organism;
 - (b) a general description of the precision bred organism covered by the marketing notice in accordance with Schedule 3 to these Regulations;
 - (c) a description of the intended use of the precision bred organism covered by the marketing notice;
 - (d) a description of the changes made to the precision bred organism covered by the marketing notice;
 - (e) a description of how the genetic changes were introduced into the precision bred organism;
 - (f) A description of the analysis and procedures that have been undertaken to—
 - (i) minimise the potential for unintended genetic changes,
 - (ii) identify any unintended genetic changes likely to have resulted from the use of modern biotechnology^(a);
 - (g) If the marketing notice covers more than one precision bred organism, a summary of those precision bred organisms;
 - (h) a summary of any advice the Secretary of State has received from the advisory committee as to whether the organism covered by the marketing notice is precision bred and either—
 - (i) whether the advisory committee considers the organism to be precision bred, or
 - (ii) a summary of the scientific reasoning why the advisory committee has advised that the organism is not precision bred;
 - (i) any information provided to the advisory committee in accordance with an information notice given by the committee;
 - (j) information relating to a withdrawal of a marketing notice.
- (5) The Secretary of State must add the following information about a precision bred confirmation—
- (a) a copy of the precision bred confirmation and a reference to the marketing notice in respect of which it was issued;
 - (b) the fact that a precision bred confirmation has been revoked and the contents of the notice by which the confirmation was revoked;
 - (c) any advice received from the advisory committee as to whether a precision bred confirmation should be revoked;
 - (d) a summary of any enforcement notices issued relating to the precision bred confirmation.

Keeping of the precision breeding register

11.—(1) The information prescribed in regulation 10(3) must be added to the Precision Breeding Register within 20 days of the date of receipt of the release notice by the Secretary of State.

^(a) “Modern biotechnology” is defined in section 1(3) of the Act.

(2) The information prescribed in regulation 10(4)(a) to (i) and 10(5)(a) must be added to the Precision Breeding Register as soon as reasonably practicable after the Secretary of State has made a decision under section 8(1) of the Act.

(3) The information prescribed in regulation 10(4)(j) must be added to the Precision Breeding Register as soon as reasonably practicable after the marketing notice has been withdrawn.

(4) The information prescribed in regulation 10(5)(b) and (c) must be added to the Precision Breeding Register as soon as reasonably practicable after the revocation of the precision bred confirmation by the Secretary of State under regulation 7(6).

(5) The information prescribed in regulation 10(5)(d) must be added to the Precision Breeding Register as soon as reasonably practicable after the enforcement notice has been served on the notifier.

PART 5

Risk Assessment

Risk assessment for precision bred organisms in contained use

12.—(1) [Placeholder - This regulation will provide for restrictions on importation and acquisition of precision bred plants in contained use conditions by maintaining the existing requirements placed on genetically modified organisms and precision bred plants in those conditions.]

PART 6

Monitoring and Inspection of Release and Marketing

Inspectors

13.—(1) In this Part “inspector” means an inspector appointed by the Secretary of State under section 19 of the Act.

(2) An inspector under paragraph (1) has the following functions—

- (a) monitoring compliance with Part 2 obligations;
- (b) investigating suspected failures to comply with Part 2 obligations.

Meaning of “Part 2 obligations”

14. For the purposes of the Act and these Regulations(a), references to a failure to comply with a Part 2 obligation 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;
- (b) in connection with any application or review, or any proposal to revoke a precision bred organism under Part 2 of the Act.

Inspection

15.—(1) For the purposes of carrying out their functions, inspectors may—

(a) See section 21 of the Act as regards the meaning of Part 2 obligation.

- (a) on producing, if so required, some duly authenticated document confirming the inspector's authority;
 - (b) at any reasonable hour;
 - (c) enter any land or premises, other than a private dwelling.
- (2) Inspectors must inform the owner or occupier or person who has control of the land or premises of the purpose of the proposed inspection and, where possible, agree a suitable date and time for that inspection.
- (3) Where it is not possible to agree a suitable date and time, the inspector must notify the owner or occupier or person who has control of the land or premises of the purpose of the inspection and the date and time at least 48 hours in advance of that inspection.

Powers of entry

16.—(1) An inspector may, at any reasonable hour, enter any land or premises, other than a private dwelling, without notice, if—

- (a) there is a reasonable suspicion of—
 - (i) a failure to comply with a Part 2 obligation,
 - (ii) an offence having been committed under any other legislation insofar as it is relevant to a Part 2 obligation;
 - (b) the inspector produces, if so required, a duly authenticated document confirming the inspector's authority; and
 - (c) one of the conditions in paragraph (4) is met.
- (2) An inspector may, at any reasonable hour, enter any private dwelling without notice if a warrant has been obtained in accordance with paragraph (3).
- (3) A justice of the peace may, by signed warrant, permit an inspector to enter any private dwelling, if the justice on sworn information in writing is satisfied that—
- (a) there is a reasonable basis for the suspicion under paragraph (1)(a);
 - (b) one or more of the conditions in paragraph (4) is met; and
 - (c) if only the condition in paragraph (4)(a) is met—
 - (i) notice of intention to apply for a warrant has been served on the owner or occupier or other person with control of the property, or
 - (ii) such notice has not been served because serving such a notice would interfere with the purpose or effectiveness of the entry.
- (4) The conditions are that—
- (a) entry to the land or premises has been refused or the Secretary of State has reasonable grounds to suspect that entry is likely to be refused;
 - (b) entry is required urgently;
 - (c) the land or premises are unoccupied or the occupier is temporarily absent.
- (5) A warrant signed in accordance with paragraph (3) is valid for one month from the date of the signature.
- (6) An inspector who enters any land or premises which are unoccupied or from which the occupier is temporarily absent must leave them as effectively secured as they were before entry.

Powers of inspection

17.—(1) An inspector who carries out an inspection of premises in accordance with regulations 15 or 16, may—

- (a) inspect and search premises;
- (b) take copies of documents;
- (c) take photographs and samples;
- (d) require the provision of information.

(2) Information obtained under paragraph (1)(d) must not be used or disclosed otherwise than for the purposes of Part 2 of the Act or Part 6 of the Environmental Protection Act 1990(a).

(3) Inspectors may be accompanied by such other persons as the inspector considers necessary in carrying out their functions under this Part.

(4) The owner or occupier of the premises or such other person with control of the premises, or the employee or agent of that person must give the inspector such assistance as the authorised person may reasonably request.

PART 7

Food and Feed produced from Precision Bred Organisms

Interpretation in this Part

18.—(1) In this Part—

“applicant” means a person who applies for a food and feed marketing authorisation(b);

“authorisation-holder” means a person who has been granted a food and feed marketing authorisation under this Part;

“Food Standards Advisory Committee” means the Advisory Committee on Novel Foods and Processes or any other advisory committee appointed under section 5(3) of the Food Standards Act 1999(c);

“a marketing authorisation” means a food and feed marketing authorisation;

“representative” means the representative of the applicant established in Great Britain (if the applicant is not established in Great Britain). A reference to an applicant includes their representative.

Marketing of food and feed produced from precision bred organisms

19.—(1) No person may place on the market(d) in England food or feed produced from precision bred organisms unless—

- (a) a marketing authorisation in respect of the food or feed has been issued by the Secretary of State in accordance with this Part;
- (b) any conditions or limitations attaching to the marketing authorisation are satisfied; and
- (c) the marketing authorisation has not been revoked.

(2) A precision bred organism under this Part must be—

(a) 1990 c. 43.

(b) “Food and feed marketing authorisation” is defined in section 30(1) of the Act.

(c) 1999 c.28.

(d) “place on the market” has the meaning in section 30(3) of the Act.

- (a) a marketable precision bred organism^(a); or
 - (b) the qualifying progeny^(b) of a marketable precision bred organism.
- (3) Before the Secretary of State can issue a marketing authorisation under this Part, the following requirements must be satisfied—
- (a) any food or feed produced from the organism and covered by the marketing authorisation will not have adverse effects on animal or human health;
 - (b) the way in which any such food or feed will be placed on the market will not mislead consumers;
 - (c) the production of any such food or feed in place of other food or feed will not have adverse effects on the environment;
 - (d) 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.
- (4) An application for a marketing authorisation under this Part may include more than one precision bred organism if all the precision bred organisms are covered by the same precision bred confirmation^(c).
- (5) An applicant must apply for a marketing authorisation under the process set out in regulation 21 (“Tier 2”) if—
- (a) the criteria set out in regulation 20(1)(c) are not met; or
 - (b) the applicant is uncertain whether the criteria are met.
- (6) If the criteria in regulation 20(1)(c) are met, an application may be made under the process set out in regulation 20 (“Tier 1”).
- (7) An applicant may withdraw an application for a marketing authorisation at any time by giving a request to the Food Standards Agency.
- (8) Subject to regulation 26, the Food Standards Agency must publish on its website marketing authorisation applications which have been verified in accordance with—
- (a) regulation 20(5)(c) for a Tier 1 marketing authorisation application; or
 - (b) regulation 22(1)(c) for a Tier 2 marketing authorisation application.
- (9) For the purposes of this Part, the following functions are conferred on the Food Standards Agency—
- (a) the review of marketing authorisation applications;
 - (b) the publication of marketing authorisation applications;
 - (c) the determination of commercially confidential information under regulation 26;
 - (d) the performance of risk assessments and risk management assessments;
 - (e) making requests for additional information under regulation 22;
 - (f) the preparation of a report for the Secretary of State under regulation 22;
 - (g) the obtaining of advice from a Food Standards Advisory Committee or such other persons with the relevant expertise;
 - (h) the communication of the Secretary of State’s decision to the applicant under regulation 23.

(a) “marketable precision bred organism” is defined in section 5(2) of the Act.
 (b) “qualifying progeny” is defined in section 24 of the Act.
 (c) see section 8 of the Act.

Application for a Tier 1 food and feed marketing authorisation

- 20.—(1) An applicant may apply for a Tier 1 marketing authorisation in circumstances where—
- (a) the precision bred organism has a precision bred confirmation issued by the Secretary of State under section 8 of the Act;
 - (b) the applicant is able to demonstrate, if asked to do so, that the requirements in regulation 19(3) are satisfied; and
 - (c) the applicant is able to demonstrate that the relevant precision bred organism—
 - (i) is from a species that has a significant prior history of safe consumption in the UK or EU,
 - (ii) does not introduce significant changes to the nutritional quality of the organism currently consumed that are likely to be disadvantageous to the consumer,
 - (iii) does not introduce significant changes that are expected to elevate the toxicity of any food or feed produced from the precision bred organism,
 - (iv) does not introduce significant changes that are expected to alter the allergenicity of any food or feed produced from the precision bred organism, and
 - (v) does not have any additional features that cause food or feed safety concerns.
- (2) An applicant may apply for a Tier 1 marketing authorisation by giving the Food Standards Agency a marketing authorisation application.
- (3) The marketing authorisation application must contain the information required in paragraph 1 of Schedule 4 to these Regulations.
- (4) The information required in paragraph (3) must be given to the extent and level of detail that such information is appropriate to the nature and scale of the application.
- (5) Upon receipt of a marketing authorisation application under paragraph (2), the Food Standards Agency must, as soon as reasonably practicable—
- (a) acknowledge receipt of the marketing authorisation application;
 - (b) allocate a unique reference number to the marketing authorisation application;
 - (c) verify that the requirements of paragraph (3) are met.
- (6) Where the requirements of paragraph (3) are not met, the Food Standards Agency must advise the applicant that the application is invalid.
- (7) The Food Standards Agency may request the applicant provide additional information, including evidence, in support of their application, if required.
- (8) Where the Food Standards Agency has requested additional information under paragraph (7), the applicant must provide that information within any time period specified by the Food Standards Agency.
- (9) If the additional information requested under paragraph (7) is not supplied within the time period in paragraph (8), the application will be treated as withdrawn.
- (10) Where the application has been completed in compliance with the requirements of paragraph (3), the Food Standards Agency must report to the Secretary of State —
- (a) that it considers that a marketing authorisation should be issued;
 - (b) any other relevant matters.
- (11) Upon receipt of a report from the Food Standards Agency under paragraph (10), the Secretary of State must follow the authorisation process set out in regulation 23.

Application for a Tier 2 food and feed marketing authorisation

- 21.—**(1) An applicant may apply for a Tier 2 marketing authorisation in circumstances where—
- (a) the precision bred organism has a precision bred confirmation issued by the Secretary of State under section 8 of the Act;
 - (b) the applicant is able to demonstrate, if asked to do so, that the requirements in regulation 19(3) are satisfied;
 - (c) the applicant reasonably concludes that any of the criteria set out in paragraph 20(1)(c) are not met.
- (2) If an applicant is uncertain whether the criteria in regulation 20(1)(c) are met, the person must make an application under this regulation.
- (3) An applicant may apply for a Tier 2 marketing authorisation by giving the Food Standards Agency a marketing authorisation application containing the information required in Schedule 4 to these Regulations.
- (4) The information required under paragraph (3) must be given to the extent and the level of detail that such information is appropriate to the nature and scale of the application.
- (5) The notice may contain —
- (a) any other information that the person making the application considers relevant;
 - (b) any information from any previous application by some other person under this Part provided that the agreement in writing of those other persons is obtained.

Assessment by the Food Standards Agency

- 22.—**(1) Upon receipt of an application under regulation 21, The Food Standards Agency must—
- (a) acknowledge receipt of the application;
 - (b) allocate a unique reference number to the application;
 - (c) verify that the requirements of regulation 21(3) are met;
- (2) Where the requirements of regulation 21(3) are not met, the Food Standards Agency must advise the applicant that the application is invalid.
- (3) The Food Standards Agency may request the applicant provide additional information, including evidence, in support of their application, if required.
- (4) Where the Food Standards Agency has requested additional information under paragraph (3), the applicant must provide that information within any time period specified by the Food Standards Agency.
- (5) If the additional information requested under paragraph (3) is not supplied within the time period in paragraph (4), the application will be treated as withdrawn.
- (6) Having completed the steps in paragraph (1), including any request for additional information under paragraph (3), the Food Standards Agency must carry out a risk assessment of the application having particular regard to those criteria set out in regulation 20(1)(c) that are not met.
- (7) When considering a marketing authorisation application, the Food Standards Agency may require the applicant to provide additional information, including evidence, in support of their application.
- (8) Where the Food Standards Agency has requested additional information under paragraph (7), the applicant must provide that information within any time period specified by the Food Standards Agency.

(9) If the additional information requested under paragraph (7) is not supplied within the time period in paragraph (8), the application will be treated as withdrawn.

(10) The Food Standards Agency may consult or request advice or information in relation to the marketing authorisation application from a Food Standards Advisory Committee.

(11) The Food Standards Agency may consult or request advice or information from such other persons with the relevant expertise as necessary to enable them to conduct a risk assessment under paragraph (6).

(12) The Food Standards Agency must forward to any committee, other advisory body or person that it consults or requests advice or information from under paragraphs (10) or (11) the following information—

- (a) the marketing authorisation application;
- (b) any risk assessment carried out in relation to the application;
- (c) any other relevant information.

(13) Any advice or information provided under paragraphs (10) or (11) must be provided without undue delay.

(14) Subject to regulation 26, any advice or information provided under paragraphs (10) or (11) must be published.

(15) Any obligations imposed on any committee, other advisory body or persons under paragraphs (10) or (11) are not Part 3 obligations^(a).

(16) The Food Standards Agency must provide the Secretary of State with a report advising the Secretary of State on the following matters—

- (a) the outcome of the Food Standard Agency's risk assessment including any recommendations to the Secretary of State arising from it;
- (b) whether the requirements under regulation 19(3) are satisfied;
- (c) a risk management assessment of other legitimate factors relevant to the application under consideration;
- (d) whether the marketing authorisation should be subject to—
 - (i) any conditions,
 - (ii) any limitations,including any recommendations to the Secretary of State regarding those conditions or limitations;
- (e) any other relevant matters.

Food and feed marketing authorisations

23.—(1) Upon receipt of a report from the Food Standards Agency under regulations 20 or 22, the Secretary of State must decide—

- (a) whether to grant a marketing authorisation;
- (b) any conditions that must attach to the marketing authorisation;
- (c) any limitations that must attach to the marketing authorisation.

(2) The Secretary of State must advise the Food Standards Agency of the decisions under paragraph (1) as soon as reasonably practicable following receipt of the report from the Food Standards Agency.

^(a) see section 29(3)(b) of the Act.

(3) If not satisfied that a marketing authorisation should be granted, the Secretary of State must give reasons for the decision.

(4) The Food Standards Agency must advise the applicant of the Secretary of State's decisions under paragraph (1) as soon as reasonably practicable following receipt of the decision.

(5) The notification under paragraph (4) must include the following information—

- (a) the decision;
- (b) any conditions that attach to the marketing authorisation;
- (c) any limitations that attach to the marketing authorisation.

(6) The Secretary of State must not give a marketing authorisation in the following circumstances—

- (a) if the required information has not been provided by the applicant;
- (b) if the requirements in regulation 19(3) are not satisfied;
- (c) if there are other legitimate factors which do not support a decision to authorise;
- (d) If an application has been made under regulation 20 and the Secretary of State considers that the process in regulation 21 is the appropriate process for the marketing authorisation notice.

(7) If the Secretary of State refuses a marketing authorisation, a summary of the recommendation provided to the Secretary of State by the Food Standards Agency must be published by the Food Standard Agency on its website.

(8) The Food Standards Agency must enter the decision made under this regulation and other required information to the Food and Feed Register in accordance with regulation 27.

(9) Upon application by the applicant or authorisation-holder, the Secretary of State may decide to add, cancel or vary conditions or limitations to a marketing authorisation at any time.

Duties on authorisation-holders

24.—(1) After a marketing authorisation has been issued in accordance with regulation 23, the authorisation holder must comply with any conditions or limitations which have been included in the marketing authorisation.

(2) The authorisation-holder and other persons authorised by the marketing authorisation to place the food and feed that is the subject of the marketing authorisation on the market must ensure that precision bred organisms are not marketed in a way that is not in accordance with the marketing authorisation.

(3) If the authorisation-holder proposes to amend the terms of the marketing authorisation, the authorisation holder must apply to the Secretary of State in accordance with regulation 21(3).

(4) An authorisation-holder must advise the Food Standards Agency immediately if they become aware of changes in circumstances that affect the marketing authorisation.

Revocation or variation of a food and feed marketing authorisation

25.—(1) The Secretary of State may consider the revocation or variation of a marketing authorisation in the following circumstances—

- (a) if the Food Standards Agency or the Secretary of State becomes aware of any new scientific or technical information which might influence the evaluation of the safety of use or quality of the precision bred organism for use as food or feed;

- (b) if the Food Standards Agency or the Secretary of State become aware of any other information which might influence the evaluation of the safety of use or quality of the precision bred organism for use as food or feed.
 - (c) an authorisation-holder of their own accord is not satisfied that the product covered by the marketing authorisation meets the conditions or limitations of the marketing authorisation or the authorisation is no longer required;
- (2) When information is made available to either the Food Standards Agency or the Secretary of State in accordance with paragraph (1)(a) or (b), the authorisation-holder may be given the opportunity to respond to the information made available under paragraph (1)(a) or (b) within a reasonable time period.
- (3) When information is made available under paragraph (1), the Food Standards Agency may on its own initiative or at the request of the Secretary of State prepare a report for the Secretary of State assessing whether the precision bred organism for use in food or feed continues to meet the requirements of the marketing authorisation.
- (4) Upon receipt of a report under paragraph (3), the Secretary of State may take any appropriate measures, which may include the variation or revocation of the marketing authorisation or revoking, adding to or varying any limitations or conditions attaching to the marketing authorisation.
- (5) A decision to revoke a marketing authorisation under paragraph (4) may include transitional arrangements to allow for the removal of products from the market or other good reason.
- (6) The Food Standards Agency must update the Food and Feed Register in accordance with regulation 27.

Confidentiality

- 26.—**(1) An applicant may request confidential treatment of certain commercial information submitted under this Part where disclosure of such information may harm their competitive position
- (2) For the purposes of paragraph (1) applicants must indicate which parts of the information provided they wish to be treated as commercially confidential in accordance with paragraph 1(5) of Schedule 4 to these Regulations.
- (3) Upon receipt of a request under paragraph (2), the Food Standards Agency must determine which information is to be treated as commercially confidential and notify the applicant of its decision.
- (4) Paragraph (3) ceases to apply if the Food Standards Agency determines that the information is no longer commercially confidential (whether or not on request by a person).
- (5) The following information must not be considered commercially confidential—
- (a) the information set out in regulation 27(1);
 - (b) information relevant to the effects of the precision bred organism for use in food and feed on human or animal health.
- (6) The Food Standards Agency must take the necessary measures to ensure appropriate confidentiality of the information received by them under this Part except for information which must be made public if circumstances so require in order to protect human or animal health.
- (7) If an applicant withdraws or has withdrawn an application, the Food Standards Agency must respect the confidentiality of commercial information, including research and development information, as well as any information in respect of which a claim of confidentiality is disputed.
- (8) The application of paragraphs (1) to (7) does not affect the exchange of information between the Food Standards Agency and the Secretary of State.

PART 8

The Food and Feed Register

Food and feed marketing authorisations register

27.—(1) The Food Standards Agency must establish and maintain a marketing authorisations register (the “Food and Feed Register”) containing the following information —

- (a) the name of the precision bred organism authorised for use in food and feed;
- (b) the unique reference number (URN) for the authorised precision bred organism;
- (c) the name and address of the authorisation-holder;
- (d) the date of the marketing authorisation;
- (e) the purpose of the genetic change to the precision bred organism;
- (f) any conditions or limitations attached to the marketing authorisation;
- (g) a summary of the risk assessment carried out under regulation 22(4);
- (h) a link to the relevant entry on the Precision Breeding Register confirming the status of the precision bred organism.
- (i) any revocations attached to the marketing authorisation;
- (j) any withdrawn marketing authorisations.

(2) The information required in paragraph 1(a) to (h) must be added to the Food and Feed register as soon as reasonably practicable after the marketing authorisation has been issued.

(3) The information requested under paragraph 1(i) must be added to the Food and Feed register as soon as reasonably practicable after the revocation has been issued.

(4) The information requested under paragraph 1(j) must be added to the Food and Feed register as soon as reasonably practicable after the marketing authorisation is withdrawn.

(5) The Food Standards Agency must ensure that the register is accessible to the public free of charge by electronic means.

PART 9

Monitoring and Inspection of Food and Feed Marketing Authorisations

Enforcement authorities

28. The following are designated enforcement authorities for the purposes of 28(1) of the Act—

- (a) Food Standards Agency^(a);
- (b) “Food authorities” which has the same meaning as set out in section 5(1) and (3) of the Food Safety Act 1990^(b) except that it does not include the appropriate Treasurer referred to in section 5(1)(c) of that Act (which deals with the Inner Temple and Middle Temple);
- (c) “Feed authorities” which means an authority identified in section 67(1) of the Agriculture Act 1970^(c) as having the duty to enforce Part IV of that Act within its area or district

(a) See section 1 of the Food Standards Act 1999 c. 28.

(b) 1990 c. 16.

(c) 1970 c. 40.

as the case may be and unless the context otherwise requires any reference to Part IV in that section must be construed as a reference to Part 3 of the Act.

Inspectors

29.—(1) In this Part, “inspector” means an inspector appointed by an enforcement authority designated under regulation 28.

(2) An inspector under paragraph (1), has the following functions—

- (a) monitoring compliance with Part 3 obligations;
- (b) investigating suspected failures to comply with Part 3 obligations.

(3) An inspector appointed under this Part is not liable in any civil or criminal proceedings for anything done in the purported exercise of the inspector’s functions under this Part or Part 10 if the court is satisfied that the act was done in good faith and that there were reasonable grounds for doing it.

(4) Relief from liability of an inspector under paragraph (3) does not affect any liability of any other person in respect of the inspector’s act.

Part 3 obligation

30. In these Regulations, references to a failure to comply with a Part 3 obligation 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 revoke or vary a marketing authorisation or to vary, revoke or impose conditions or limitations under Part 3 of the Act.

Inspection

31.—(1) For the purposes of carrying out their functions, inspectors may—

- (a) on producing, if so required, some duly authenticated document confirming the inspector’s authority;
- (b) at any reasonable hour;
- (c) enter any land or premises, other than a private dwelling.

(2) Inspectors must inform the owner or occupier or person who has control of the land or premises of the purpose of the proposed inspection and, where possible, agree a suitable date and time for that inspection.

(3) Where it is not possible to agree a suitable date and time, the inspector must notify the owner or occupier or person who has control of the land or premises of the purpose of the inspection and the date and time at least 48 hours in advance of that inspection.

Powers of entry

32.—(1) An inspector may, at any reasonable hour, enter any land or premises, other than a private dwelling, without notice, if—

- (a) there is a reasonable suspicion of—
 - (i) a failure to comply with a Part 3 obligation,
 - (ii) an offence having been committed under any other legislation insofar as it is relevant to a Part 3 obligation;

- (b) the inspector produces, if so required, a duly authenticated document confirming the inspector's authority; and
 - (c) one of the conditions in paragraph (4) is met.
- (2) An inspector may, at any reasonable hour, enter any private dwelling without notice if a warrant has been obtained in accordance with paragraph (3).
- (3) A justice of the peace may, by signed warrant, permit an inspector to enter any private dwelling, if necessary by reasonable force, if the justice on sworn information in writing is satisfied that—
- (a) there is a reasonable basis for the suspicion under paragraph (1)(a);
 - (b) one or more of the conditions in paragraph (4) is met; and
 - (c) if only the condition in paragraph (4)(a) is met—
 - (i) notice of intention to apply for a warrant has been served on the owner or occupier or other person with control of the property, or
 - (ii) such notice has not been served because serving such a notice would interfere with the purpose or effectiveness of the entry.
- (4) The conditions are that—
- (a) entry to the land or premises has been refused or the Secretary of State has reasonable grounds to suspect that entry is likely to be refused;
 - (b) entry is required urgently;
 - (c) the land or premises are unoccupied or the occupier is temporarily absent.
- (5) A warrant signed in accordance with paragraph (3) is valid for one month from the date of the signature.
- (6) An inspector who enters any land or premises which are unoccupied or from which the occupier is temporarily absent must leave them as effectively secured as they were before entry.

Powers of inspection

- 33.—**(1) An inspector who carries out an inspection of land or premises in accordance with regulations 31 or 32, may—
- (a) inspect and search premises;
 - (b) undertake examination, search and seizure of property;
 - (c) take copies of documents;
 - (d) take photographs and samples;
 - (e) impose requirements;
 - (f) require the provision of information.
- (2) Inspectors may be accompanied by such other persons as the inspector considers necessary in carrying out their functions under this Part.
- (3) the owner or occupier of the land or premises or such other person with control of the premises, or the employee or agent of that person must give the inspector such assistance as the authorised person may reasonably request.

PART 10

Enforcement of relevant breaches

Relevant breaches

34.—(1) This Part applies in relation to the enforcement of relevant breaches^(a) under Part 4 of the Act.

(2) For the purposes of the Act and these Regulations, the following matters are treated as relevant breaches—

- (a) obstructing an inspector;
- (b) providing false information to an inspector;
- (c) impersonating an inspector.

(3) Where a person has failed to comply with a Part 3 obligation due to an act or default of some other person, that other person may be treated as having failed to comply with the Part 3 obligation.

(4) Enforcement action may be taken against the other person referred to in paragraph (2) whether or not action is taken against the first-mentioned person.

(5) A failure to comply with a Part 3 obligation is not to be regarded as a relevant breach where the person can prove that—

- (a) they took all reasonable precautions and exercised all due diligence to avoid the failure to comply with the Part 3 obligation by themselves or by a person under their control;
- (b) In paragraph (a), a person who neither—
 - (i) prepared the food or feed in respect of which the relevant breach is alleged to have occurred, or
 - (ii) imported it into Great Britain,

must be taken to have established the defence in paragraph (a) if they satisfy the requirements in sub-paragraphs (c) or (d);

- (c) a person satisfies the requirements of this sub-paragraph if they prove—
 - (i) that the failure to comply with the Part 3 obligation was due to an act or default of another person who was not under their control, or to reliance on information supplied by such a person,
 - (ii) that they carried out all such checks of the food or feed in question as were reasonable in all the circumstances, or that it was reasonable in all the circumstances for them to rely on checks carried out by the person who supplied the food or feed to him;
 - (iii) that they did not know and had no reason to suspect at the time of the alleged failure to comply with the Part 3 obligation that the act or omission would amount to a failure to comply with the Part 3 obligation;
- (d) a person satisfies the requirements of this sub-paragraph if they prove—
 - (i) that the failure to comply with the Part 3 obligation was due to an act or default of another person who was not under their control, or to reliance on information supplied by such a person,

^(a) “relevant breach” has the meaning in section 31 of the Act.

- (ii) that the sale or intended sale of which the alleged failure to comply with a Part 3 obligation was not a sale or intended sale under their name or mark, and
- (iii) that they did not know, and could not reasonably have been expected to know, at the time of the alleged failure to comply with the Part 3 obligation that their act or omission would amount to a failure to comply with the Part 3 obligation under the relevant provision.

(6) A failure to comply with a Part 3 obligation is not to be regarded as a relevant breach where the person can prove that—

- (a) they are a person whose business it is to publish or arrange for the publication of advertisements; and
- (b) that they received the advertisement in the ordinary course of business and did not know and had no reason to suspect that its publication would amount to a failure to comply with a Part 3 obligation.

Enforcement notices

35.—(1) An inspector may issue either of the following enforcement notices in relation to a relevant breach—

- (a) compliance notice;
 - (b) stop notice.
- (2) A monetary penalty notice in relation to a relevant breach may be issued by—
- (a) the Secretary of State;
 - (b) an inspector.

Content of enforcement notices

36.—(1) An enforcement notice issued under regulation 35 must state—

- (a) the grounds for issuing the notice, which must include—
 - (i) the relevant obligation to which the relevant breach relates, and
 - (ii) the matters which, in the opinion of the inspector or Secretary of State issuing the notice, constitute the failure to comply with that obligation.
 - (b) the person's rights to require a review of or appeal against the notice;
 - (c) the consequences of a failure to comply with the notice.
- (2) A notice issued under this Part may be revoked or varied—
- (a) by the Secretary of State, in the case of a monetary penalty notice issued by the Secretary of State;
 - (b) by an inspector in any other case.

Compliance notices

37.—(1) A compliance notice issued under regulation 35(1) 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.

(2) The steps specified in the compliance notice must be steps that the inspector considers will ensure that the relevant breach does not continue or recur.

(3) The period specified in the compliance notice must be not less than 14 days beginning with the date on which the notice is received.

Stop notices

38.—(1) A stop notice issued under regulation 35(1) may be issued 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.

(2) The inspector issuing the stop notice must consider that the steps specified in the stop notice are steps that will ensure the specified activity will be carried on in a way that does not involve the person committing a relevant breach.

(3) Where the Secretary of State considers it necessary or expedient to enforce the stop notice, the Secretary of State may apply to the court for an injunction.

(4) An application for an injunction under paragraph (3) may be made without notice.

Monetary penalty notices

39.—(1) The Secretary of State or an inspector may issue a monetary penalty notice under regulation 35(2) only where satisfied that the person to whom it is issued has committed a relevant breach.

(2) The amount of any monetary penalty must be determined by the Secretary of State or an inspector.

(3) The monetary penalty notice must state—

- (a) how payment may be made;
- (b) the period within which payment must be made;
- (c) the consequences of late payment or failure to pay.

(4) Where interest is payable on late payment of a monetary penalty, the notice must state the interest to be paid as follows—

- (a) Interest is payable on the amount of any monetary penalty for each day from the end of the period for payment specified in the notice to the date on which the sum specified in the monetary penalty notice is paid.
- (b) For the purposes of paragraph (a), the rate of interest applicable on any day is one percentage point above the Bank of England base rate.
- (c) In paragraph (b) “Bank of England base rate” means—
 - (i) except where sub-paragraph (ii) applies, the rate announced from time to time by the Monetary Policy Committee of the Bank of England as the official dealing rate, being the date at which the Bank is willing to enter into transactions for providing short term liquidity in the money markets, or
 - (ii) if an order under section 19 of the Bank of England Act 1998^(a) (reserve powers) is in force, any equivalent rate determined by the Treasury under that section.

(5) Amounts payable under this regulation, including the monetary penalty, and any interest or other penalty for late payment are recoverable as a civil debt.

Review of enforcement notices

40.—(1) A person to whom an enforcement notice is issued under this Part may require the Secretary of State to review the decision to issue the notice.

(2) A request for a review under paragraph (1) must be made within 28 days of the date of receipt of the notice.

(a) 1998 c. 11.

- (3) The grounds for a review under paragraph (1) are—
- (a) that the decision was based on an error of fact;
 - (b) that the decision was wrong in law;
 - (c) that any steps specified in the notice were unreasonable;
 - (d) 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;
 - (e) in the case of a monetary penalty notice, that the amount of the penalty was unreasonable;
 - (f) that the decision was unreasonable for any other reason.
- (4) The Secretary of State may give due regard to any additional information or evidence provided by the person making the request under paragraph (1).
- (5) On review of an enforcement notice, the Secretary of State must—
- (a) decide whether to uphold, vary or revoke the notice;
 - (b) give notice to the person who requested the review, within a reasonable period, setting out—
 - (i) the Secretary of State's decision,
 - (ii) the reasons for that decision,
 - (c) inform the person of the right to appeal to the First-tier tribunal.
- (6) The Secretary of State may suspend the operation of any compliance notice or monetary penalty notice to which the review relates pending the outcome of the review.

Appeal against enforcement notices

41.—(1) If not satisfied with the outcome of a review under regulation 40, a person may appeal the decision to issue the notice to the First-tier Tribunal.

(2) An appeal must be made within 28 days of the date of receipt of the Secretary of State's notice issued under regulation 40(5).

- (3) The grounds for an appeal under paragraph (1) are —
- (a) that the decision was based on an error of fact;
 - (b) that the decision was wrong in law;
 - (c) that any steps specified in the notice were unreasonable;
 - (d) 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;
 - (e) in the case of a monetary penalty notice, that the amount of the penalty was unreasonable;
 - (f) that the decision was unreasonable for any other reason.
- (4) The First-tier Tribunal may give due regard to any additional information or evidence provided by the person making the appeal under paragraph (1).
- (5) The First-tier Tribunal may—
- (a) uphold the enforcement notice;
 - (b) vary the enforcement notice;
 - (c) revoke the enforcement notice;
 - (d) take such steps as the Secretary of State could take in relation to the notice;
 - (e) remit the decision whether to confirm the notice, or any matter relating to that decision, to the Secretary of State.

(6) The First-tier Tribunal may suspend the operation of any compliance notice or monetary penalty notice to which the appeal relates pending the outcome of the appeal.

Costs

42.—(1) An appropriate authority^(a) may issue a costs notice requiring a person to pay the costs incurred by the authority in relation to an enforcement notice up to the time of its issue.

(2) A costs notice must specify the amount required to be paid which may include—

- (a) investigation costs;
- (b) administration costs;
- (c) costs of obtaining expert advice (including legal advice).

(3) Where interest is payable on late payment of a costs notice, the notice must state the interest to be paid as follows—

- (a) Interest is payable on the amount of any costs notice for each day from the end of the period for payment specified in the notice to the date on which the sum specified in the costs notice is paid.
- (b) For the purposes of paragraph (a), the rate of interest applicable on any day is one percentage point above the Bank of England base rate.
- (c) In paragraph (b) “Bank of England base rate” means—
 - (i) except where sub-paragraph (ii) applies, the rate announced from time to time by the Monetary Policy Committee of the Bank of England as the official dealing rate, being the date at which the Bank is willing to enter into transactions for providing short term liquidity in the money markets, or
 - (ii) if an order under section 19 of the Bank of England Act 1998 (reserve powers) is in force, any equivalent rate determined by the Treasury under that section.

(4) A person to whom a costs notice is issued may require the person issuing it to provide a detailed breakdown of the amount in paragraph (2).

(5) A person to whom a costs notice is issued is not liable to pay any costs which that person shows have been unnecessarily incurred.

(6) Amounts payable by virtue of this regulation, including the costs and any interest or other penalty for late payment are recoverable as a civil debt.

Review and appeal of costs notices

43.—(1) A person to whom a costs notice has been issued may—

- (a) require the Secretary of State to review the relevant decision^(b); and
- (b) if not satisfied with the outcome of the review, appeal against the relevant decision in accordance with paragraph (4).

(2) The grounds on which a review may be required or an appeal brought are—

- (a) 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;
- (b) that the decision was based on an error of fact;
- (c) that the decision was wrong in law; and
- (d) that the decision was unreasonable for any other reason.

^(a) “appropriate authority” has the meaning in section 38(2) of the Act.

^(b) “Relevant decision” has the meaning in section 38(6) of the Act.

(3) A review under paragraph (1)(a) must be requested in writing within 28 days of the date of the costs notice.

(4) An appeal under paragraph (1)(b) must be brought to the First-tier Tribunal within 28 days of the date of the review decision made under paragraph (1)(a).

(5) The operation of any costs notice is suspended where an appeal is brought under this regulation pending the outcome of the appeal.

PART 11

General

Notices

44. In these Regulations, a notice or other document is—

- (a) to be given or issued in writing which includes by electronic means;
- (b) to be treated as being received when the sender receives a dated confirmation of receipt from the intended recipient either through an automated email response if received by email or by otherwise sending an email acknowledgement of receipt to the sender.

Consequential Amendments

45. Schedule 5 sets out consequential amendments to legislation in respect of England to the extent specified in that Schedule.

Name
Parliamentary Under Secretary of State
Department for Environment, Food and Rural Affairs

SCHEDULES

SCHEDULE 1

Regulation 3(3)

Information that must be provided to the Secretary of State in a release notice

1. Name, address, telephone number and email address of the person who is proposing to release the precision bred organism from under their control.
2. Where the person whose details are provided in paragraph (1) is an organisation, the name, position, address, telephone number and email address of an employee or agent of that organisation who may be contacted in relation to the release notice.
3. A description of other persons who may assist in the release of the precision bred organism.
4. A general description of the precision bred organism in accordance with Schedule 3.
5. Confirmation that the person responsible for the release—
 - (a) will put in place appropriate measures, as necessary, to prevent material from the precision bred organism being marketed until such time as a precision bred confirmation is issued in respect of the organism; and
 - (b) has assessed that all organisms covered by the release notice meet the criteria for a precision bred organism set out in section 1 of the Act.

SCHEDULE 2

Regulation 5(2)

Information that must be provided to the Secretary of State in a marketing notice

1. The name, organisation name, address, email address and telephone number of—
 - (a) the notifier;
 - (b) the person with overall responsibility for marketing the precision bred organism;
 - (c) any representative of the person in sub-paragraph (a).
2. General description of the precision bred organism in accordance with Schedule 3.
3. A description of the intended use of the precision bred organism.
4. Information about the changes made to the precision bred organism including—
 - (a) any alterations to characteristics resulting from the application of modern biotechnology;
 - (b) information about the genetic changes made to achieve characteristics described in paragraph (a), including—
 - (i) the specific genetic changes made,
 - (ii) their location,
 - (iii) their genetic stability,
 - (iv) when the genetic change involves the insertion of any genetic material, a description of all the genetic elements inserted and the organisms from which they originated;

5. a description of how the genetic changes were introduced into the precision bred organisms, including—
- (a) which techniques of modern biotechnology were used,
 - (b) if used, information about any transgenic intermediates.
6. A description of the procedures and analysis undertaken to—
- (a) confirm the precision bred organisms only contain genetic sequences that could arise by traditional processes;
 - (b) minimise the potential for unintended genetic changes to be present in the precision bred organisms;
 - (c) identify any unintended genetic changes which are attributable to the use of modern biotechnology, including—
 - (i) descriptions of unintended genetic changes set out as prescribed in paragraph 4(b),
 - (ii) the approach used to remove unintended genetic changes, where this was undertaken.
7. If the marketing notice covers more than one precision bred organism—
- (a) the number of precision bred organisms must be stated;
 - (b) confirmation must be provided that all precision bred organisms—
 - (i) have the same characteristics described in paragraph 4(a),
 - (ii) were developed in the same way as described in paragraph 5,
 - (iii) have been analysed in accordance with paragraph 6(a);
 - (c) variation in the intended genetic changes introduced to different precision bred organisms, which are relevant to information provided under paragraph 4(b), must be provided;
 - (d) variation in any unintended genetic changes introduced to different precision bred organisms which are relevant to information provided under paragraph 6(c) must be provided.

SCHEDULE 3

Regulations 3(5), 10(3)

General description information

1. The full name of the organism, including—
- (a) genus;
 - (b) species.
2. Details of the precision bred organism, including—
- (a) the intended alterations to characteristics of the organism;
 - (b) the type or types of genetic changes introduced to confer the alterations described in paragraph (a);
 - (c) the techniques of modern biotechnology used to make the genetic changes described in paragraph (b).

SCHEDULE 4

Regulations 20(3),21(3)

Information to be provided to the Food Standards Agency in a food and feed marketing authorisation application

- 1.—(1) The name, organisation name, address, email address and telephone number of—
 - (a) the applicant; and
 - (b) any representative of the person in sub-paragraph (a).
 - (2) Completed, unredacted copies of the following—
 - (a) the relevant marketing notice provided to the Secretary of State under regulation 5 of these Regulations;
 - (b) the documents supplied to the Secretary of State with the marketing notice under sub-paragraph (a);
 - (c) the relevant precision bred confirmation issued by the Secretary of State;
 - (d) where the precision bred confirmation covers the confirmation of more than one precision bred organism in accordance with regulation 19(4) of these Regulations, a list of the individual precision bred organisms and genetic change in each precision bred organism must be provided, .
 - (3) Additional mandatory information as follows—
 - (a) the identity of the precision bred organism which the food or feed is produced from—
 - (i) full name of the precision bred organism,
 - (ii) genus,
 - (iii) species;
 - (b) With respect to the information provided under paragraph 4 of Schedule 2 to these Regulations in the marketing notice given under Part 2 of the Act, a description of how the genetic change introduced to the precision bred organism affects the edible part of the organism, including information on—
 - (i) how the genetic change may affect the use of the organism in food and feed,
 - (ii) the identification of the parts destined for use in food and feed,
 - (iii) a description of the intended use of the precision bred organism for food and feed.
 - (4) Statements to demonstrate how the precision bred organism meets each of the criteria in regulation 20(1)(c) including accompanying descriptive text setting out the applicant's key considerations and justification in respect of each criterion.
 - (5) Having regard to regulations 26 and 27, if the applicant is making a request that information be considered commercially confidential, a statement setting out the information which the applicant wishes to be considered commercially confidential because disclosure may harm their competitive position, including the necessary details to substantiate the request. Verifiable justification must be given in such cases.
2. Additionally, in relation to a Tier 2 application, where the precision bred organism does not, or may not, meet one or more of the criteria in regulation 20(1)(c)—
- (a) a statement to explain why the criteria are not, or may not be, met; and
 - (b) complete, unredacted copies of the source material used in the assessment of the precision bred organism for each criterion that has not been met, which may include but is not limited to test results, scientific analyses, data, studies, surveys or scientific records.

SCHEDULE 5

Regulation 45

Consequential Amendments

1. [Placeholder for consequential amendments]

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision for systems to regulate the release for research purposes, and marketing of, precision bred plants. They also provide for risk assessments for precision bred plants imported or acquired for contained use and provide for an authorisation process for food and feed produced from precision bred plants.

Regulation 3 and Schedule 1 set out the notification requirements for the release of precision bred plants and the content of release notices.

Regulation 4 provides for the transitional arrangements in relation to regulation 3 in respect of qualifying higher plants notified under the Genetically Modified Organism (Deliberate Release) (Amendment)(England Regulations 2022 which must be re-notified under these Regulations within 3 months of these Regulations coming into force.

Regulation 5 and Schedule 2 provide for the content of marketing notices and the process and procedure for application to the Secretary of State for precision bred confirmation of a precision bred plant. Schedule 3 provides for the content of the general description of a precision bred plant.

Regulation 6 extends the reporting period in relation to the provision of further information to the advisory committee advising on a precision bred confirmation and provides for a marketing notice to be treated as withdrawn if further information is not provided within 60 days.

Regulation 7 sets out the circumstances and process for revocation of a precision bred confirmation.

Regulations 8 and 9 provide for the review and appeal of a decision to issue a precision bred confirmation and a decision to revoke a precision bred confirmation.

Regulation 10 sets out the information to be included in the Precision Breeding Register and regulation 11 provides for the keeping of the Register.

Regulation 12 sets out the risk assessment requirements for precision bred plants imported and acquired for contained use.

Part 6 provides for the monitoring and inspection of the release and marketing of precision bred organisms including the functions of inspectors and powers of inspections and entry.

Regulations 18 to 21 and Schedule 4 set out the process for applying for marketing authorisations for food and feed produced from precision bred plants and the required information for inclusion in a food and feed marketing authorisation notice. Regulation 19 includes the assignment of functions to the Food Standards Authority in relation to food and feed marketing authorisations.

Regulation 22 provides for the risk assessment of applications for food and feed marketing authorisations by the Food Standards Authority, including obtaining expert advice and the provision of reports to the Secretary of State.

Regulation 23 sets out the requirements for the consideration of marketing authorisation applications, and the issuing of marketing authorisations, by the Secretary of State.

Regulation 24 records the duties on the authorisation-holders of marketing authorisations.

Regulation 25 sets out the circumstances and process for the variation and revocation of food and feed marketing authorisations.

Regulation 26 provides a process for the management of commercially confidential information. Regulation 27 sets out the information to be included in the Food and Feed Register and provides for the keeping of the Register.

Part 9 provides for the monitoring and inspection of food and feed marketing authorisations including setting out the designated enforcement authorities, the appointment and functions of inspectors and powers of inspection and entry.

Part 10 provides for the enforcement of these Regulations by way of civil sanctions in respect of relevant breaches in regulation 34 (including the issue of various notices). Regulations 35 and 36 provide for enforcement notices and the content of enforcement notices including authority to withdraw or amend any notice. Regulations 37 and 38 provide for compliance notices and stop notices while Regulation 39 enables the Secretary of State and inspectors to issue monetary penalty notices. Regulation 40 provides for the review of an enforcement notice by the Secretary of State while regulation 41 provides a right of appeal to the First-tier Tribunal. All notices, except stop notices may be suspended pending the determination of an appeal. The First-tier Tribunal may on appeal withdraw, confirm or vary any requirement of a notice or remit the decision to the Secretary of State. Regulation 42 provides for the recovery of costs associated with enforcement while regulation 43 sets out the provisions for the review and appeal of costs notices.

Regulation 44 makes general provision in relation to notices and regulation 45 and Schedule 5 set out the consequential amendments.

An impact assessment []