STATUTORY INSTRUMENTS

2025 No. 581

AGRICULTURE, ENGLAND
ENVIRONMENTAL PROTECTION, ENGLAND
FOOD, ENGLAND

The Genetic Technology (Precision Breeding) Regulations 2025

Made - - - - 13th May 2025

Coming into force in accordance with regulation 1(1)

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 4(1)(b), (3) and (4), 6(2), 9(1), (2) and (4), 16(1), (2) and (4), 17(1) and (3), 18(1) and (6), 20(1), (2) and (3), 21(3), 23(1), 26(1), (2), (3), (4), (6), (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(1) and (2), 38(1), (4), (5) and (7), 40(1), 42(1) and (2), 43(3) and (6) of the Genetic Technology (Precision Breeding) Act 2023 ("the Act")(**1**).

In relation to Parts 7, 8, 9 and 10 of, and Schedule 4 to, this instrument, there has been consultation as 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(**2**).

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) Regulations 2025 and come into force on the day which falls six months after the day on which they are made.

(2) Subject to paragraph (3), this Part, regulation 54 and Schedule 5 extend to England and Wales, Scotland and Northern Ireland.

(**1**) 2023 c. 6 ("the Act").
(**2**) EUR 2002/178 to which there are amendments not relevant to these Regulations.

(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;

"precision bred organism" means a precision bred plant(**3**);

"the precision breeding register" means the register established and maintained in accordance with section 18(1) of the Act.

Part 2

Release of Precision Bred Organism

Notification requirement for release of precision bred organism in England

3.—(1) This regulation applies for the purpose of section 4 of the Act (release of precision bred organism: notification requirements) in relation to the release(**4**) of a precision bred organism in England by a person.

(2) The release notice(**5**) must specify—

(a) the person who is proposing to release the precision bred organism from under their control;

(b) if the person in sub-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 description of other persons who may assist in the release.

(3) The person must give the release notice to the Secretary of State.

(4) The minimum period for the purpose of section 4(1)(b) of the Act is 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(**6**).

(5) The release notice must contain the information specified in Schedules 1 and 3.

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

(7) A release notice in relation to a precision bred organism ("the initial precision bred organism") may also serve as a release notice in relation to other precision bred organisms provided that those other precision bred organisms—

(a) belong to the same species as the initial precision bred organism;

(b) contain only the types of genetic changes as described in the release notice in accordance with paragraph 3 of Schedule 3.

(**3**) "Plant" is defined in section 2(1) of the Act and "precision bred" is defined in section 1 of the Act.
(**4**) "Release" is defined in section 3(3) of the Act.
(**5**) "Release notice" is defined in section 4(1)(a) of the Act.
(**6**) See regulation 53.

Transitional provisions for release

4.—(1) Where the circumstances in paragraph (2) apply, the procedure in paragraph (3) applies(**7**).

(2) The circumstances are—

(a) a person (in this regulation, "the regulation 9B notifier") has given the Secretary of State a notice of an intention to release a qualifying higher plant in England pursuant to regulation 9B of the Genetically Modified Organisms (Deliberate Release) Regulations 2002(**8**) 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 have not been released before the coming into force of these Regulations.

(3) The regulation 9B notifier may release the qualifying higher plants referred to in sub-paragraph (2)(b) which have not been released before the coming into force of these Regulations without having given the Secretary of State a release notice in accordance with the minimum period specified in regulation 3(4) provided that a release notice covering the qualifying higher plants is given to the Secretary of State before the end of the period of three months beginning with the day on which these Regulations come into force.

(4) A release notice given to the Secretary of State before the date these Regulations come into force may be treated by the Secretary of State as having been given on that date.

Part 3

Marketing of Precision Bred Organism

Application for precision bred confirmation - marketing notice

5.—(1) This regulation applies for the purposes of a marketing notice under section 6(1) of the Act (application for precision bred confirmation).

(2) A marketing notice under paragraph (1) must contain the information specified in Schedules 2 and 3.

(3) The marketing notice may be accompanied by any other information that the notifier(**9**) considers relevant.

(4) A marketing notice given in relation to a precision bred organism ("the initial precision bred organism") may serve as a marketing notice in relation to other precision bred organisms provided that those other precision bred organisms—

(a) belong to the same species as the initial precision bred organism;

(b) share the same altered characteristics as the initial precision bred organism, as described in the marketing notice in accordance with paragraph 5(e) of Schedule 2, where—

(i) the altered characteristics were caused in the same way by the genetic changes described in paragraph 5(e) of Schedule 2, and

(ii) the genetic changes in paragraph (i) result from the same techniques of modern biotechnology(**10**) described in paragraph 8(a) of Schedule 2;

(**7**) See also regulation 55.
(**8**) S.I. 2002/2443 amended by S.I. 2019/88, 2022/347; there are other amending instruments but none is relevant. "Qualifying higher plant" is defined in regulation 2 of those Regulations.
(**9**) "Notifier" is defined in section 6(1) of the Act.
(**10**) "Modern biotechnology" is defined in section 1(3) of the Act.

(c) have been analysed in accordance with the analysis and procedures described in relation to the initial precision bred organism under paragraph 9 of Schedule 2.

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

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 gives the notifier an information notice requesting 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 until the day of receipt by the advisory committee of the further information requested.

(2) If the information requested in the information notice is not provided within 90 days of the date of the information notice, the marketing notice is to be treated as withdrawn.

Revocation of precision bred confirmation

7.—(1) The Secretary of State may revoke a precision bred confirmation(**11**) relating to an organism 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 a precision bred confirmation.

(2) Where credible evidence of the matters described in paragraph (1)(a) to (c) is made available to the Secretary of State otherwise than by or on behalf of the notifier, the Secretary of State must give notice to the notifier that such information has been made available to the Secretary of State.

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

(a) the evidence made available to the Secretary of State;

(b) the date by which the notifier must respond to the notice with any representations.

(4) Where the Secretary of State proposes to revoke a precision bred confirmation, having considered any representations made by the notifier under paragraph (3)(b), the Secretary of State must, except in urgent cases—

(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 persons affected by the proposal;

(b) invite persons affected by the proposal to make written representations to the Secretary of State about the proposal within such time period as the Secretary of State considers appropriate.

(5) Where the Secretary of State proposes to revoke a precision bred confirmation following receipt of credible evidence of the matters described in paragraph (1), the Secretary of State—

(a) in the case of paragraph (1)(a), may request a report from the advisory committee with advice on whether the precision bred confirmation should be revoked;

(**11**) "Precision bred confirmation" is defined in section 8(1)(a)(i) of the Act.

(b) in the case of paragraph (1)(b) or (c), must request a report from the advisory committee with advice on whether the precision bred confirmation should be revoked;

(c) must, when requesting a report under sub-paragraphs (a) or (b), provide to the advisory committee the evidence of the matters described in paragraph (1)(a) to (c) made available to the Secretary of State and any representations made by the notifier under paragraph (3)(b).

(6) After receipt of the advisory committee's report, or in any event where a report has not been requested in accordance with paragraph (5)(a), the Secretary of State must—

(a) if satisfied that the organism is not precision bred—

(i) decide to revoke the precision bred confirmation, and

(ii) give a notice of the kind described in paragraph (7) to the notifier;

(b) if satisfied that the organism is precision bred, give notice to the notifier of that fact.

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

(a) notice that the precision bred confirmation is to be revoked;

(b) the date on which the revocation will take effect, subject to any review or appeal;

(c) the reason for the revocation;

(d) circumstances in which the revocation notice may be reviewed and appealed;

(e) the procedure for any review or appeal;

(f) the steps to be taken by the notifier following receipt of the revocation notice;

(g) a statement that in view of the revocation—

(i) the organism is not considered by the Secretary of State to be a precision bred organism;

(ii) the organism may be subject to legislation which regulates genetically modified organisms;

(iii) subject to any review or appeal, any food and feed marketing authorisation in relation to the organism is also to be treated as revoked.

(8) Following the revocation of a precision bred confirmation, the Secretary of State must provide the notifier and other persons affected by the revocation with information as to the appropriate steps to be taken by the notifier and other persons affected by the revocation following the revocation of the precision bred confirmation.

(9) The Secretary of State must update the precision breeding register with details of the revocation in accordance with regulations 10(5)(b) and (c) and 11(4).

(10) Revocation of a precision bred confirmation under this regulation has the effect that any food and feed marketing authorisation issued under regulation 30 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 (regulation of food and feed produced from precision bred organisms) must also be treated as revoked and the Secretary of State must accordingly—

(a) notify the Food Standards Agency(**12**) that the precision bred confirmation has been revoked, and

(b) supply a copy of the revocation notice issued under paragraph (6)(a)(ii) to the Food Standards Agency to enable the food and feed register(**13**) to be updated with notice of the revocation.

(**12**) The Food Standards Agency is established by section 1 of the Food Standards Act 1999 (c. 28) (see also section 28(2)(a) of the Act).

(**13**) "Food and feed register" is defined in section 27(1) of the Act.

(11) The obligations in paragraph (10)(a) and (b) arise when the revocation of the precision bred confirmation is final such that there are no further steps that may be taken under regulation 8 (review) and regulation 9 (appeal).

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) (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 a commercial interest in marketing a precision bred organism in a notice issued under regulation 7(6)(a) may require the Secretary of State to review the decision to issue the notice on the grounds in paragraph (4).

(3) A request for a review under paragraphs (1) or (2) must be made to the Secretary of State before the end of the period of 28 days beginning with the day on which the notice referred to in paragraph (1) is sent by the Secretary of State(**14**).

(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.

(5) As part of the review, the Secretary of State may have due regard to any relevant information or evidence.

(6) Where information or evidence relevant to the genetic changes to the precision bred organism concerned is provided to the Secretary of State, the Secretary of State must—

(a) request a report from the advisory committee on the information or evidence;

(b) provide to the advisory committee the information and evidence to which the Secretary of State has regard under paragraph (5).

(7) The advisory committee must provide a report following a request made under paragraph (6) without undue delay.

(8) After having considered any report provided pursuant to the request under paragraph (6)(a), the Secretary of State must complete the review and—

(a) decide whether to confirm, vary or withdraw the notice;

(b) give notice to the notifier, and any person with a commercial interest who has requested a review under paragraph (2), setting out—

(i) the Secretary of State's decision, and

(ii) the reasons for that decision;

(c) inform the notifier, and any person with a commercial interest who has requested a review under paragraph (2), of the right to appeal to the First-tier Tribunal.

(9) The Secretary of State may suspend the operation of a revocation notice to which the review relates pending the outcome of the review.

(**14**) See also regulation 53.

Appeal to the First-tier Tribunal

9.—(1) A notifier, or any person with a commercial interest in a notice, who requested a review of a notice under regulation 8(1) or (2), and who is not satisfied with the outcome of the review under that regulation may appeal to the First-tier Tribunal on the grounds in paragraph (3).

(2) An appeal to the First-tier Tribunal under paragraph (1) must be made before the end of the period of 28 days beginning with the day on which the notice described in regulation 8(8)(b) was sent by the Secretary of State.

(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.

(4) 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.

(5) 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) to (4) 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 their control;

(b) a description of any 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 Schedules 1 and 3;

(d) a summary of any enforcement notices issued under regulation 44 relating to the release notice.

(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 Schedules 2 and 3;

(c) a description of the intended use of the precision bred organism covered by the marketing notice;

(d) details of intended genetic changes made to the precision bred organism resulting from the application of modern biotechnology;

(e) details of any unintended genetic changes made to the precision bred organism resulting from the application of modern biotechnology;

(f) a description of how the genetic changes in sub-paragraph (d) were introduced into the precision bred organism;

(g) a description of the analysis and procedures used to confirm the precision bred organism only contains genetic sequences that could arise by traditional processes(**15**);

(h) if the marketing notice covers more than one precision bred organism, information about those other precision bred organisms in accordance with paragraph 10 of Schedule 2;

(i) any report the Secretary of State has received from the advisory committee under section 7(2) of the Act (report by the advisory committee) as to whether the organism to which the marketing notice relates is precision bred;

(j) any information provided to the advisory committee in accordance with an information notice given by the committee;

(k) information relating to a withdrawal of a marketing notice;

(l) a summary of any enforcement notices issued under regulation 44 relating to the marketing notice.

(5) The Secretary of State must add the following information about a precision bred confirmation to the precision breeding register—

(a) a copy of the precision bred confirmation and a reference to the marketing notice in respect of which it was issued;

(b) where the precision bred confirmation is revoked, confirmation of that revocation and the contents of the notice by which the confirmation was revoked;

(c) advice received from the advisory committee as to whether a precision bred confirmation should be revoked;

(d) any enforcement notices issued relating to the precision bred confirmation.

(6) The Secretary of State must add the following information to the precision breeding register—

(a) notices refusing a precision bred confirmation under section 8(1)(b) of the Act (issue of precision bred confirmation);

(b) information relating to any review which is pending under regulation 8 or any appeal which is pending under regulation 9.

Keeping of the precision breeding register

11.—(1) The information prescribed in regulation 10(3) must be added to the precision breeding register before the end of the period of 20 days beginning with the day the release notice is received by the Secretary of State.

(2) The information prescribed in regulation 10(4)(a) to (j), (5)(a) and (6)(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 (issue of precision bred confirmation).

(**15**) "Traditional processes" is defined in section 1(6) of the Act.

(3) The information prescribed in regulation 10(4)(k) 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(4)(l) and (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.

(6) The information prescribed in regulation 10(6)(b) must be added to the precision breeding register—

(a) in the case of a review, as soon as reasonably practicable after the request for a review is received by the Secretary of State;

(b) in the case of an appeal, as soon as reasonably practicable after the Secretary of State is notified of the appeal.

Part 5

Environmental risk assessment

Environmental risk assessment for precision bred organism in contained use

12.—(1) A person must not import a precision bred organism where its destination is in England, or acquire(**16**) a precision bred organism which is in England, for the purposes of contained use unless, before importing or acquiring the organism, the person has carried out an environmental risk assessment(**17**) by reference to the nature of the organism and the manner in which the person intends to keep it after the importation or acquisition.

(2) Paragraph (1) does not apply to a person proposing to do an act mentioned in that paragraph for the purposes of—

(a) the release of a precision bred organism under section 3 of the Act (restrictions on release of precision bred organism in England);

(b) the marketing of a precision bred organism under section 5 of the Act (restrictions on marketing of precision bred organism in England).

(3) A person who carries out an environmental risk assessment under paragraph (1) must keep a record of the assessment for 10 years.

(4) In this regulation, "contained use" means an activity in which precision bred organisms are cultured, stored, transported, destroyed, disposed of or used in any other way and for which physical, chemical or biological barriers, or any combination of such barriers, are used to limit their contact with, and to provide a high level of protection for, humans and the environment.

(**16**) "Acquire" is defined in section 17(5)(a) of the Act.
(**17**) "Environmental risk assessment" is defined in section 17(2) of the Act.

Part 6

Monitoring and inspection of release and marketing

Inspectors

13. An inspector(**18**) has the following functions—

(a) monitoring compliance with Part 2 obligations(**19**);

(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, 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 confirmation, under Part 2 of the Act.

Powers of entry

15.—(1) An inspector may enter any premises other than a private dwelling for the purpose of carrying out an inspection (as to which, see regulation 16).

(2) An inspection must be carried out at a reasonable hour, as agreed between the inspector and the owner, occupier or person otherwise in control of the premises.

(3) Where no such agreement can be reached, the inspection may be carried out at what is considered to be a reasonable hour in the opinion of the inspector, provided that the inspector has notified the owner, occupier or person otherwise in control of the premises at least 48 hours before the time at which the inspection is to take place.

(4) Where the conditions in paragraph (5) are met, an inspector may enter a premises at any reasonable hour without agreement with, or providing notice to, the owner, occupier or person otherwise in control of the premises.

(5) The conditions are—

(a) the inspector has a reasonable suspicion that—

(i) there is a failure to comply with a Part 2 obligation in connection with the premises;

(ii) an offence has been committed in connection with a Part 2 obligation;

(b) one or more of the conditions in paragraph (9) is met.

(6) An inspector may enter a private dwelling for the purpose of carrying out an inspection—

(a) with the consent of the owner, occupier or person otherwise in control of the premises, or

(b) without the consent of the owner, occupier or person otherwise in control of the premises under a warrant issued under paragraph (7).

(7) A justice of the peace may issue a signed warrant authorising an inspector to enter any private dwelling—

(a) at what is considered, in the opinion of the justice of the peace, to be any reasonable hour,

(**18**) "Inspector", in respect of Part 2 of the Act, means an inspector appointed by the Secretary of State under section 19(1) of the Act.

(**19**) "Part 2 obligation" is defined in section 21(1) of the Act. See also regulation 14.

(b) where the justice of the peace is satisfied that there is a reasonable basis for a suspicion of the kind described in paragraph (5)(a), and

(c) where one or more of the conditions in paragraph (9) is met.

(8) Where paragraph (7)(c) is met by the condition in paragraph (9)(a) being met, the justice of the peace must be satisfied that—

(a) notice of an intention to apply for a warrant has been served on the owner, occupier or other person in control of the premises, or

(b) no such notice has been served because serving a notice would interfere with the purpose of entry or effectiveness of inspection.

(9) The conditions are—

(a) entry to the premises has been refused by the owner, occupier or other person in control of the premises or the Secretary of State has reasonable grounds to suspect that entry is likely to be refused;

(b) entry is required urgently;

(c) the premises are unoccupied or the occupier is temporarily absent.

(10) An inspector must produce, if required, a duly authenticated document confirming the inspector's authority.

(11) The owner, occupier or person otherwise in control of the premises may refuse an inspector entry if the inspector fails to produce, when required, a duly authenticated document confirming the inspector's authority.

Powers of inspection

16.—(1) An inspector may after entering premises under regulation 15—

(a) inspect the premises or any part thereof;

(b) search the premises or any part thereof;

(c) take photographs while on or in the premises;

(d) take copies of documents on or in the premises;

(e) take samples of any material, substance, item or object while on or in the premises;

(f) require any person to provide information connected with the reason for the inspection.

(2) Information obtained under paragraph (1) 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(**20**).

Powers of entry and inspection - supplementary provisions

17.—(1) An inspector may be accompanied by such other persons as the inspector considers necessary in carrying out their functions under this Part.

(2) An inspector who, under regulation 15, enters any premises which are unoccupied or from which the occupier is temporarily absent must leave the premises as effectively secured as they were before entry.

(3) The owner or occupier of the premises or such other person in control of the premises, or the employee or agent of the owner, occupier or person in control of the premises must provide such assistance as the inspector may reasonably require.

(**20**) 1990 c. 43; part 6 was amended by S.I. 2002/2443; there are other amending instruments but none is relevant.

Part 7

Food and feed produced from precision bred organisms

Interpretation of this Part

18. In this Part—

"applicant" means a person who applies for a food and feed marketing authorisation(**21**) under regulation 20 or 22;

"authorisation-holder" means a person who has been issued a food and feed marketing authorisation under this Part;

"Food Standards Advisory Committee" means the Advisory Committee on Novel Foods and Processes or any advisory committee appointed under section 5(3) of the Food Standards Act 1999(**22**);

"representative" means a person, nominated by the applicant, who may be contacted in relation to the application for the food and feed marketing authorisation concerned.

Marketing of food and feed produced from precision bred organisms - requirement for authorisation

19.—(1) No person may place on the market(**23**) in England food or feed produced from a precision bred organism unless—

(a) a food and feed marketing authorisation in respect of the precision bred organism used to produce the food or feed has been issued by the Secretary of State under this Part,

(b) any conditions or limitations to which the food and feed marketing authorisation is subject are met, and

(c) the food and feed marketing authorisation has not been revoked.

(2) A precision bred organism under paragraph (1) must be—

(a) a marketable precision bred organism(**24**), or

(b) the qualifying progeny(**25**) of a marketable precision bred organism.

(3) A food and feed marketing authorisation in respect of a precision bred organism includes the authorisation of the qualifying progeny of that organism provided that any features of the qualifying progeny resulting from the application of modern biotechnology are inherited from—

(a) that precision bred organism, or

(b) another precision bred organism in respect of which a food and feed marketing authorisation is in force.

(4) Qualifying progeny are subject to all of the conditions and limitations of every food and feed marketing authorisation by virtue of which they are authorised under paragraph (3)(a) and, where it applies, paragraph (3)(b).

Application for a food and feed marketing authorisation

20.—(1) A person may apply for a food and feed marketing authorisation under this regulation if—

(**21**) "Food and feed marketing authorisation" is defined in section 30(1) of the Act.
(**22**) 1999 c. 28 to which there are amendments not relevant to these Regulations.
(**23**) Section 30(3) of the Act makes provision about the meaning of food or feed being placed on the market.
(**24**) "Marketable precision bred organism" is defined in section 5(2) of the Act.
(**25**) "Qualifying progeny" is defined in section 24 of the Act.

(a) the precision bred organism is an organism in respect of which a precision bred confirmation is in force(**26**);

(b) the person is able to demonstrate that the relevant precision bred organism belongs to a species that has a history of safe food use in accordance with paragraph (2);

(c) the person is able to demonstrate that the application of modern biotechnology to the precision bred organism does not introduce genetic changes that are expected to—

(i) significantly alter the nutritional quality of the organism as it is being consumed as food or feed at the date of the application in a way that is likely to be disadvantageous to the consumer;

(ii) significantly elevate the toxicity of any food or feed produced from the precision bred organism;

(iii) alter the allergenicity of any food or feed produced from the precision bred organism;

(iv) introduce any additional features that may affect the safety of any food or feed produced from the precision bred organism.

(2) In paragraph (1)(b), "history of safe food use" means that the safety of the species in question as food has been confirmed with compositional data and from experience of continued food use in the customary diet of a significant number of people in the United Kingdom or the European Union beginning before 15th May 1997.

(3) A person may apply to the Food Standards Agency for a food and feed marketing authorisation under this regulation by making an application containing the information specified in paragraph 1 of Schedule 4.

(4) The information provided pursuant to paragraph (3) must be sufficiently detailed to allow the Food Standards Agency to assess the application having regard to the nature and scale of the application.

(5) The application may be accompanied by any other information that the applicant considers relevant.

(6) If an applicant is not established in Great Britain, the applicant must appoint a representative who is established in Great Britain in the application.

(7) Upon receipt of an application under paragraph (1), the Food Standards Agency must, as soon as reasonably practicable—

(a) acknowledge receipt of the application;

(b) verify whether the application contains the information specified in paragraph 1 of Schedule 4 (as read with paragraph (4) of this regulation).

(8) If, notwithstanding any further information provided pursuant to regulation 24, the application does not contain the information specified in paragraph 1 of Schedule 4, the Food Standards Agency must advise the applicant that the application is invalid.

Requirement to report verified applications for a food and feed marketing authorisation under regulation 20 to the Secretary of State

21. If an application under regulation 20 contains the information specified in paragraph 1 of Schedule 4, the Food Standards Agency must report that to the Secretary of State together with any other matters that the Food Standards Agency considers relevant to the issuing of a food and feed marketing authorisation.

(**26**) "In force" in respect of a precision bred confirmation is defined in section 5(5) of the Act.

Application for a food and feed marketing authorisation - where a Food Standards Agency assessment is required

22.—(1) A person may apply for a food and feed marketing authorisation under this regulation if—

(a) the precision bred organism is an organism in respect of which a precision bred confirmation is in force;

(b) the person reasonably concludes that—

(i) the precision bred organism does not belong to a species that has a history of safe food use as defined in regulation 20(2);

(ii) the application of modern biotechnology to the precision bred organism may introduce genetic changes such that any of paragraphs (i) to (iv) of regulation 20(1)(c) apply or might apply to the precision bred organism.

(2) A person may apply to the Food Standards Agency for a food and feed marketing authorisation under this regulation by making an application containing the information specified in Schedule 4.

(3) The information provided pursuant to paragraph (2) must be sufficiently detailed to allow the Food Standards Agency to assess the application having regard to the nature and scale of the application.

(4) If an applicant is not established in Great Britain, the applicant must appoint a representative who is established in Great Britain in the application.

(5) The application may be accompanied by—

(a) any previous application made under this Part by any other person provided that the agreement in writing of that other person is obtained;

(b) any other information that the applicant considers relevant.

Verification of information in application made under regulation 22

23.—(1) Upon receipt of an application under regulation 22, the Food Standards Agency must—

(a) acknowledge receipt of the application;

(b) verify whether the application contains the information specified in Schedule 4 (as read with regulation 22(3)).

(2) If, notwithstanding any further information provided pursuant to regulation 24, the application does not contain the information specified in Schedule 4, the Food Standards Agency must advise the applicant that the application is invalid.

(3) If the application contains the information specified in Schedule 4, the Food Standards Agency must determine the requirements of the assessment of the safety of the precision bred organism for use in food and feed to be carried out under regulation 26, which may include a risk assessment.

Request for further information

24.—(1) The Food Standards Agency may request that the applicant provides further information, including evidence, in support of their application, if required, as part of the verification under regulation 20(7)(b) or regulation 23(1)(b).

(2) Where the Food Standards Agency has requested further information under paragraph (1), the applicant must provide that information within the time period specified by the Food Standards Agency in the request.

(3) If the further information requested under paragraph (2) is not provided within the time period specified by the Food Standards Agency, the application is to be treated as withdrawn and the Food Standards Agency must advise the applicant accordingly.

Publication of verified applications

25. The Food Standards Agency must publish summaries of applications which have been verified under regulation 20(7)(b) or regulation 23(1)(b)(**27**).

Assessment by the Food Standards Agency

26.—(1) Where the Food Standards Agency determines under regulation 23(3) that the information provided in accordance with regulation 22(2) is sufficient to demonstrate the safety of the precision bred organism for use in food and feed without further assessment, the Food Standards Agency must report their conclusions on the application to the Secretary of State together with an assessment of any other legitimate factors the Food Standards Agency considers relevant to the issuing of a food and feed marketing authorisation.

(2) The Food Standards Agency may take into account any further information provided under regulation 24 or any other information available to the Food Standards Agency through other means when preparing a report under paragraph (1).

(3) If paragraph (1) does not apply, the Food Standards Agency must carry out an assessment of the safety of the precision bred organism for use in food and feed, having particular regard to the matters referred to in regulation 22(1)(b).

(4) The Food Standards Agency may request that the applicant provides further information, including evidence, as part of the assessment under paragraph (3).

(5) Where the Food Standards Agency has requested further information under paragraph (4), the applicant must provide that information within the time period specified by the Food Standards Agency in the request.

(6) If the further information requested under paragraph (5) is not supplied within the time period specified by the Food Standards Agency the application is to be treated as withdrawn and the Food Standards Agency must advise the applicant accordingly.

Advice or information from the Food Standards Advisory Committee etc.

27.—(1) The Food Standards Agency may consult or request advice or information in relation to the application from the Food Standards Advisory Committee or such other persons with the relevant expertise as necessary to enable the Food Standards Agency to conduct an assessment.

(2) The Food Standards Agency must forward a summary of the application and any other relevant information to any committee or other person that it consults or requests advice or information from under paragraph (1).

(3) Any advice or information provided under paragraph (1) must be provided without undue delay.

(4) The Food Standards Agency must publish any advice or information provided under paragraph (1) unless that advice or information is treated as commercially confidential by the applicant and the Food Standards Agency under regulation 34(**28**).

(5) Any obligations imposed on any committee or other persons under this regulation are not Part 3 obligations(**29**).

(**27**) See also regulation 35.
(**28**) See also regulation 35.
(**29**) "Part 3 obligation" is defined in section 29(1) of the Act (see also section 29(3)(b) of the Act).

Requirement to report on safety assessment etc. to the Secretary of State

28. Where regulation 26(3) applies, 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 assessment of the safety of the precision bred organism for use in food and feed conducted by the Food Standards Agency including any recommendations to the Secretary of State arising from it;

(b) whether the criteria in sub-paragraphs (a) to (d) of regulation 30(3) are met;

(c) an assessment of any other legitimate factors which may be relevant to the application under consideration;

(d) whether the food and feed 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.

Withdrawal of application for a food and feed marketing authorisation

29. An applicant may withdraw an application at any time by giving notice to the Food Standards Agency.

Determination on authorisation by the Secretary of State

30.—(1) Upon receipt of a report from the Food Standards Agency under regulation 21 or 28 the Secretary of State must decide whether to issue a food and feed marketing authorisation.

(2) If the Secretary of State decides to issue a food and feed marketing authorisation, the Secretary of State must decide—

(a) any conditions to which the authorisation must be subject;

(b) any limitations to which the authorisation must be subject.

(3) The Secretary of State may issue a food and feed marketing authorisation if it appears to the Secretary of State that—

(a) any food or feed produced from the organism to which the food and feed marketing authorisation would apply would not have adverse effects on animal or human health;

(b) the way in which any such food or feed would be placed on the market would not mislead consumers;

(c) the production of any such food or feed in place of other food or feed that it might reasonably be expected to replace would 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 would not be nutritionally disadvantageous to humans or animals.

(4) When considering whether the requirements in paragraph (3) are met, the Secretary of State must—

(a) have regard to any report which has been provided by the Food Standards Agency under regulation 21 or 28;

(b) not apply any test in connection with these requirements which would not otherwise be applicable in relation to any food or feed produced from organisms which are not produced from the application of modern biotechnology.

(5) The Secretary of State must not issue a food and feed marketing authorisation if—

(a) the Secretary of State concludes from the assessment of the safety of the precision bred organism or having considered any other legitimate factors that a food and feed marketing authorisation cannot be issued;

(b) an application has been made under regulation 20 and the Secretary of State cannot reasonably conclude that the requirements of regulation 20(1) have been met.

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

(7) If the Secretary of State decides not to issue a food and feed marketing authorisation, the Secretary of State must give reasons for the decision to the Food Standards Agency.

Communication of the Secretary of State's decision to the applicant

31.—(1) The Food Standards Agency must notify the applicant of the Secretary of State's decisions under regulation 30(1) and (2) (where applicable) as soon as reasonably practicable following receipt of the decisions.

(2) The notification must include the following information—

(a) whether a food and feed marketing authorisation has been issued by the Secretary of State;

(b) the date the decision was made;

(c) if a food and feed marketing authorisation has been issued—

(i) any conditions to which it is subject,

(ii) any limitations to which it is subject;

(d) if a food and feed marketing authorisation has not been issued, the reasons for the decision.

Duties on authorisation-holders and other persons placing authorised food and feed on the market

32.—(1) The authorisation-holder and other persons placing on the market food or feed produced from a precision bred organism in respect of which a food and feed marketing authorisation is in force must comply with any conditions or limitations to which the food and feed marketing authorisation is subject.

(2) In this regulation, and regulation 33, a food and feed marketing authorisation is "in force" if it has been issued and not revoked.

(3) An authorisation-holder or other persons placing on the market, or proposing to place on the market, food or feed produced from a precision bred organism in respect of which a food and feed marketing authorisation is in force must advise the Food Standards Agency immediately if they—

(a) become aware of any change in circumstances that may affect the safe use of the precision bred organism in food or feed;

(b) are proposing to apply a production process to the precision bred organism or the food produced from it which would, but for the application of Article 2(2)(aa) of Regulation (EC) 2015/2283 of the European Parliament and of the Council on novel foods, etc.(**30**), result in a new food being produced that falls within the definition set out in Article 3(2)(a) of that Regulation.

(**30**) EUR 2015/2283 amended by S.I. 2019/702; there are other amendments but none is relevant. Schedule 5 to this instrument inserts article 2(2)(aa).

(4) Where an authorisation-holder or other person placing on the market, or proposing to place on the market, food or feed produced from a precision bred organism in respect of which a food and feed marketing authorisation is in force is uncertain whether paragraph (3) applies they must consult the Food Standards Agency for advice.

Revocation or variation of a food and feed marketing authorisation

33.—(1) The Secretary of State may revoke or vary a food and feed marketing authorisation in the following circumstances—

(a) if the Food Standards Agency or the Secretary of State becomes aware of—

(i) any new scientific or technical information which might influence the assessment of the safety of the precision bred organism for use in food and feed;

(ii) any other information which might affect the assessment of the safety of the precision bred organism for use in food and feed;

(iii) any information suggesting that a precision bred organism in respect of which a food and feed marketing authorisation is in force, or food produced from that precision bred organism, has been subject to a subsequent production process which would, but for the application of Article 2(2)(aa) of Regulation (EC) 2015/2283 of the European Parliament and of the Council on novel foods, etc., result in a new food being produced that falls within the definition set out in Article 3(2)(a) of that Regulation;

(b) if an authorisation-holder notifies the Food Standards Agency that—

(i) the authorisation-holder is no longer satisfied that the conditions or limitations to which the food and feed marketing authorisation is subject are sufficient to ensure the safety of the food or feed produced from the precision bred organism in respect of which the food and feed marketing authorisation is in force;

(ii) the authorisation-holder is satisfied that any of the conditions or limitations to which the food and feed marketing authorisation is subject is no longer required.

(2) If the authorisation-holder is proposing a variation to the food and feed marketing authorisation, the authorisation-holder must make an application to the Food Standards Agency setting out the proposed variation and the reasons for the request.

(3) If a variation to the food and feed marketing authorisation is proposed because of an administrative or other change that does not affect the safe use of the precision bred organism in food and feed, the authorisation-holder must apply to the Food Standards Agency setting out the variation proposed and the reasons for it so that the food and feed register can be updated in accordance with regulation 35(6).

(4) The authorisation-holder must be given the opportunity to respond to the information referred to in paragraph (1)(a) within a reasonable time period unless the urgency of the matter does not allow it.

(5) Where the Secretary of State becomes aware of information under paragraph (1), the Secretary of State must request a report from the Food Standards Agency assessing whether the food and feed marketing authorisation continues to be sufficient to ensure the safety of the precision bred organism for use in food and feed.

(6) Where the Food Standards Agency becomes aware of information under paragraph (1) or where the Secretary of State requests a report under paragraph (5), the Food Standards Agency must prepare a report for the Secretary of State assessing whether the food and feed marketing authorisation continues to be sufficient to ensure the safety of the precision bred organism for use in food and feed.

(7) If the Food Standards Agency concludes that variations to the food and feed marketing authorisation would be appropriate, the Food Standards Agency must include a recommendation in the report that the food and feed marketing authorisation should be varied.

(8) In preparing its report, the Food Standards Agency may—

(a) request further information or evidence from the authorisation-holder or any person placing, or proposing to place on the market, food or feed produced from the precision bred organism in respect of which the food and feed marketing authorisation is in force;

(b) consult or request advice or information from the Food Standards Advisory Committee or such other persons with the relevant expertise as necessary to enable the Food Standards Agency to prepare the report under paragraph (6).

(9) The authorisation-holder must provide any information requested by the Food Standards Agency under paragraph (8)(a) within the time period specified by the Food Standards Agency in the request.

(10) If the authorisation-holder fails to provide the information within the time period specified by the Food Standards Agency, the Food Standards Agency must prepare its report based on information that is available to the Food Standards Agency.

(11) Any advice or information provided under paragraph (8)(b) must be provided without undue delay.

(12) The Food Standards Agency must publish any advice or information provided under paragraph (8)(b) unless that advice or information is treated as commercially confidential by the applicant and the Food Standards Agency under regulation 34.

(13) Any obligations imposed on any committee or other persons under paragraph (8)(b) are not Part 3 obligations.

(14) Having considered the report provided by the Food Standards Agency under paragraph (6), the Secretary of State must decide what, if any, measures are appropriate to take in respect of the food and feed marketing authorisation, which may include the variation or revocation of the food and feed marketing authorisation or cancelling, adding to or varying any limitation or condition to which the food and feed marketing authorisation is subject.

(15) The measures decided under paragraph (14) may include transitional arrangements.

(16) The Food Standards Agency must report the Secretary of State's decision under paragraph (14) to the authorisation-holder as soon as reasonably practicable.

Confidentiality

34.—(1) Where an applicant has included a statement in the application for a food and feed marketing authorisation in accordance with paragraph 1(6) of Schedule 4, indicating that certain information should be treated as commercially confidential, the Food Standards Agency must decide which of the information identified it proposes to treat as commercially confidential and notify the applicant of its decision.

(2) After being informed of the Food Standards Agency's decision, the applicant may withdraw their application before the end of the period of 21 days beginning with the day on which notice of the decision was sent by the Food Standards Agency, during which period the confidentiality of the information provided must be observed by the Food Standards Agency.

(3) The Food Standards Agency may decide that information provided under regulations 32 and 33 is commercially confidential except where paragraph (5) applies.

(4) Information may be treated as commercially confidential if disclosure of such information would, or would be likely to, prejudice the commercial interests of any person or is a trade secret.

(5) The following information must not be considered commercially confidential—

(a) the information set out in regulation 35 (the food and feed marketing authorisations register);

(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 that the Food Standards Agency has decided is to be treated as commercially confidential 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 any commercial information—

(a) which the applicant has indicated should be treated as confidential;

(b) in respect of which a claim for confidentiality is disputed.

(8) Paragraphs (1) to (7) do not prevent the exchange of information treated as commercially confidential between the Food Standards Agency and the Secretary of State.

Part 8

The food and feed register

Food and feed marketing authorisations register

35.—(1) The Food Standards Agency must establish and maintain a public register (the "food and feed register") containing the following particulars in relation to each food and feed marketing authorisation—

(a) the name of each precision bred organism authorised under regulation 30;

(b) a unique reference number for the authorised precision bred organism;

(c) the name and address of the authorisation-holder;

(d) the date of issue of the food and feed marketing authorisation;

(e) the purpose of the intended genetic change to the precision bred organism referred to in paragraph 5(e) of Schedule 2;

(f) any conditions or limitations to which the food and feed marketing authorisation is subject;

(g) a summary of any assessment of the safety of the precision bred organism carried out under regulation 26;

(h) a link to the relevant entry on the precision breeding register made under regulation 10(4) confirming the precision bred status of the precision bred organism;

(i) any revocation of all or part of the food and feed marketing authorisation;

(j) any withdrawal by the authorisation-holder of the food and feed marketing authorisation.

(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 required 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 required 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 may make changes to entries in the food and feed register where the Food Standards Agency is aware of verifiable information that suggests information in the register is incorrect or misleading.

(6) If an authorisation-holder notifies the Food Standards Agency of an administrative or other change proposed to the food and feed marketing authorisation under regulation 33(3), the Food Standards Agency must consider whether the variation must be reflected on the food and feed register and update the register accordingly.

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

Part 9

Monitoring and inspection of Part 3 obligations

Part 3 obligation

36. References in these Regulations and in the Act 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 a food and feed marketing authorisation or to vary, revoke or impose conditions or limitations under Part 3 of the Act.

Enforcement authorities

37.—(1) The following bodies are designated as enforcement authorities(**31**)—

(a) the Food Standards Agency;

(b) food authorities;

(c) feed authorities.

(2) In this regulation—

(a) "food authorities" has the same meaning as set out in section 5(1) and (3) of the Food Safety Act 1990(**32**) 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);

(b) "feed authorities" means an authority identified in section 67(1) of the Agriculture Act 1970(**33**) as having the duty to enforce Part 4 of that Act within its area or district as the case may be.

(3) Enforcement authorities may appoint inspectors to carry out functions under these Regulations.

(**31**) "Enforcement authorities" are defined in section 28(1) of the Act.
(**32**) Section 5 was amended by paragraph 16(1) of Schedule 9 to the Local Government (Wales) Act 1994 (c. 19), paragraph 163(2) of Schedule 13 to the Local Government etc (Scotland) Act 1994 (c. 39), paragraphs 7, 8, and 9 of Schedule 5 to the Food Standards Act 1999 (c. 28) and Part 1 of Schedule 3 to the Public Health etc. (Scotland) Act 2008 (asp 5).
(**33**) 1970 c. 40. Section 67(1) was amended by Schedule 30 to the Local Government Act 1972 (c. 70), paragraph 15(3) of Schedule 8 to the Local Government Act 1985 (c. 51), paragraph 38(5) of Schedule 16 and Schedule 18 to the Local Government (Wales) Act 1994 (c. 19) and S.S.I. 2020/467.

Inspectors

38.—(1) In relation to Part 3 obligations, “inspector” means an inspector appointed by an enforcement authority.

(2) An inspector 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.

(3) Relief from liability of an inspector under paragraph (2) does not affect any liability of any other person in respect of the inspector’s act.

Powers of entry

39.—(1) An inspector may enter any premises other than a private dwelling for the purpose of carrying out an inspection (as to which see regulation 40).

(2) An inspection must be carried out at a reasonable hour, as agreed between the inspector and the owner, occupier or person otherwise in control of the premises.

(3) Where no such agreement can be reached, the inspection may be carried out at what is considered to be a reasonable hour in the opinion of the inspector, provided that the inspector has notified the owner, occupier or person otherwise in control of the premises at least 48 hours before the time at which the inspection is to take place.

(4) Where the conditions in paragraph (5) are met, an inspector may enter a premises at any reasonable hour without agreement with, or providing notice to, the owner, occupier, or person otherwise in control of the premises.

(5) The conditions are—

(a) the inspector has a reasonable suspicion that—

(i) there is a failure to comply with a Part 3 obligation in connection with the premises;

(ii) an offence has been committed in connection with a Part 3 obligation;

(b) one of the conditions in paragraph (9) is met.

(6) An inspector may enter a private dwelling for the purpose of carrying out an inspection—

(a) with the consent of the owner, occupier or person otherwise in control of the premises, or

(b) without the consent of the owner, occupier or person otherwise in control of the premises under a warrant issued under paragraph (7).

(7) A justice of the peace may issue a signed warrant authorising an inspector to enter any private dwelling—

(a) at what is considered, in the opinion of the justice of the peace, to be a reasonable hour,

(b) where the justice of the peace is satisfied that there is a reasonable basis for the suspicion of the kind described in paragraph (5)(a), and

(c) where one or more of the conditions in paragraph (9) is met.

(8) Where paragraph (7)(c) is met by the condition in paragraph (9)(a) being met, the justice of the peace must be satisfied that—

(a) notice of an intention to apply for a warrant has been served on the owner, occupier or other person in control of the premises, or

(b) no such notice has been served because serving notice would interfere with the purpose of entry or effectiveness of inspection.

(9) The conditions are—

(a) entry to the premises has been refused by the owner, occupier or other person in control of the premises or the Secretary of State has reasonable grounds to suspect that entry is likely to be refused;

(b) entry is required urgently;

(c) the premises are unoccupied or the occupier is temporarily absent.

(10) An inspector must produce, if required, a duly authenticated document confirming the inspector's authority.

(11) The owner, occupier or person otherwise in control of the premises may refuse an inspector entry if the inspector fails to produce, when required, a duly authenticated document confirming the inspector's authority.

Powers of inspection

40. An inspector may after entering premises under regulation 39—

(a) inspect the premises or any part thereof;

(b) search the premises or any part thereof;

(c) examine, search and seize property on or in the premises;

(d) take copies of documents while on or in the premises;

(e) take photographs while on or in the premises;

(f) take samples of any material, substance, item or object on or in the premises;

(g) impose requirements connected with the reason for the inspection;

(h) require any person to provide information connected with the reason for the inspection.

Powers of entry and inspection - supplementary provisions

41.—(1) An inspector may be accompanied by such other persons as the inspector considers necessary in carrying out their functions under this Part.

(2) An inspector who, under regulation 39, enters any premises which are unoccupied or from which the occupier is temporarily absent must leave the premises as effectively secured as they were before entry.

(3) The owner or occupier of the premises or such other person in control of the premises, or the employee or agent of the owner or occupier or person in control of the premises, must provide such assistance as the inspector may reasonably require.

Part 10

Enforcement of relevant breaches

Relevant breaches

42.—(1) For the purposes of the Act and these Regulations, the following matters are treated as relevant breaches(**34**)—

(a) obstructing an inspector(**35**);

(b) providing false information to an inspector;

(**34**) "Relevant breach" is defined in section 31(1) of the Act.
(**35**) "Inspector" is defined in section 19(1) as regards Part 2 of the Act, and in section 30(1) as regards Part 3 of the Act.

(c) impersonating an inspector.

(2) 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.

(3) Enforcement notices(**36**) may be issued against the other person referred to in paragraph (2) whether or not an enforcement notice is issued against the first-mentioned person.

Defences to relevant breaches

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

(2) In paragraph (1), a person who neither—

(a) prepared the food or feed in respect of which the relevant breach is alleged to have occurred, nor

(b) imported it into Great Britain,

is to be taken to have established the defence in paragraph (1) if they satisfy the requirements in paragraphs (3) or (4).

(3) A person satisfies the requirements of this paragraph if they can prove—

(a) 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 due to reliance on information supplied by such a person,

(b) 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 them, and

(c) 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.

(4) A person satisfies the requirements of this paragraph if they can prove—

(a) 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 due to reliance on information supplied by such a person,

(b) that the sale or intended sale giving rise to the alleged failure to comply with a Part 3 obligation was not a sale or intended sale under their name or mark, and

(c) 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 the act or omission would amount to a failure to comply with the Part 3 obligation.

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

(a) that 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.

(**36**) "Enforcement notice" is defined in section 32(3) of the Act.

Enforcement notices

44.—(1) An inspector may issue either of the following enforcement notices in accordance with this Part to a person in relation to a relevant breach—

(a) a compliance notice(**37**);

(b) a stop notice(**38**).

(2) A monetary penalty notice(**39**) may be issued to a person in relation to a relevant breach by—

(a) as regards a Part 2 obligation, the Secretary of State;

(b) as regards a Part 3 obligation, an inspector.

Content of enforcement notices

45.—(1) An enforcement notice issued under regulation 44 must state—

(a) the grounds for issuing the notice, which must include—

(i) the relevant obligation(**40**) to which the relevant breach relates, and

(ii) the matters which constitute the failure to comply with that obligation in the opinion of the person issuing the notice;

(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

46.—(1) A compliance notice issued under regulation 44(1)(a) 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 within which the specified steps must be taken must be not less than 14 days beginning with the day on which the notice is issued.

Stop notices

47.—(1) A stop notice issued under regulation 44(1)(b) 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) Any steps specified in a stop notice issued to a person must be steps that the inspector issuing the stop notice considers will ensure that the specified activity will be carried on in a way that does not involve the person committing a relevant breach.

(3) 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.

(**37**) "Compliance notice" is defined in section 33(1) of the Act.
(**38**) "Stop notice" is defined in section 34(1) of the Act.
(**39**) "Monetary penalty notice" is defined in section 35(1) of the Act.
(**40**) "Relevant obligation" is defined in section 31(2)(b) of the Act.

Monetary penalty notices

48.—(1) The Secretary of State or an inspector, as the case may be, may issue a monetary penalty notice under regulation 44(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, as the case may be.

(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, including liability for interest under paragraph (4).

(4) Interest is payable on the amount of any monetary penalty for each day beginning with the day after the last day for payment specified in the notice to the day on which the sum specified in the monetary penalty notice is paid.

(5) For the purposes of paragraph (4), the rate of interest applicable on any day is one percentage point above the Bank of England base rate.

(6) In this regulation, and regulation 51, "Bank of England base rate" means—

(a) except where sub-paragraph (b) applies, the rate announced from time to time by the Monetary Policy Committee(**41**) 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

(b) 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.

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

Review of enforcement notices

49.—(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 before the end of the period of 28 days beginning with the day on which the notice is issued.

(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) in the case of a compliance notice or a stop notice, 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—

(**41**) The Monetary Policy Committee is established under section 13 of the Bank of England Act 1998 (c. 11).

(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, and

(ii) the reasons for that decision;

(c) where relevant, 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

50.—(1) If the person who requested a review under regulation 49(1) is not satisfied with the outcome of the review, that person may appeal the decision to issue the notice to the First-tier Tribunal.

(2) An appeal must be made before the end of the period of 28 days beginning with the day on which the notice under regulation 49(5) is issued.

(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) in the case of a compliance notice or stop notice, 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—

(a) uphold the enforcement notice;

(b) vary the enforcement notice;

(c) revoke the enforcement notice;

(d) take such steps as the Secretary of State, or an inspector, as the case may be, 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.

(5) The operation of any compliance notice or monetary penalty notice to which the appeal relates is suspended pending the outcome of the appeal.

Costs

51.—(1) An appropriate authority(**42**) 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) "Costs" include—

(a) investigation costs;

(b) administration costs;

(**42**) "Appropriate authority" is defined in section 38(2) of the Act.

(c) costs of obtaining expert advice (including legal advice).

(3) Interest is payable on the amount of any costs notice for each day from the end of the period for payment beginning with the day specified in the notice to the day on which the sum specified in the costs notice is paid.

(4) For the purposes of paragraph (3), the rate of interest applicable on any day is one percentage point above the Bank of England base rate(**43**).

(5) 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).

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

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

Review of, and appeal against, costs notices

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

(a) require the Secretary of State to review a relevant decision(**44**), and

(b) if not satisfied with the outcome of the review, appeal against the relevant decision in accordance with paragraph (5).

(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;

(d) that the decision was unreasonable for any other reason.

(3) A review under paragraph (1)(a) must be requested in writing within 28 days beginning with the day the costs notice is issued.

(4) On review of a costs notice, the Secretary of State must—

(a) decide whether to uphold, vary or revoke the costs notice;

(b) give notice to the person who requested the review, within a reasonable period, setting out—

(i) the Secretary of State's decision, and

(ii) the reasons for that decision;

(c) where relevant, inform the person of the right to appeal to the First-tier Tribunal.

(5) An appeal under paragraph (1)(b) must be made to the First-tier Tribunal before the end of the period of 28 days beginning with the day on which the review decision is made pursuant to paragraph (1)(a).

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

(**43**) See regulation 48(6).
(**44**) "Relevant decision" is defined in section 38(6) of the Act.

Part 11

General

Notices

53. In these Regulations, a notice or other document—

(a) is to be given or issued in writing which includes by electronic means;

(b) is, if 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, to be treated as being received.

Consequential amendments

54. Schedule 5 has effect.

Revocation

55.—(1) The Genetically Modified Organisms (Deliberate Release) Regulations 2002(**45**) are amended as follows—

(a) in regulation 2, omit the definition of "qualifying higher plant";

(b) in regulation 9, for the heading substitute "Exempt Activities";

(c) omit regulations 9A, 9B and Schedule 3A;

(d) in regulation 34, omit paragraph (1A);

(e) in regulation 35, omit paragraph (A1).

(2) The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022(**46**) are revoked(**47**).

Daniel Zeichner
Minister of State
Department for Environment, Food and Rural Affairs

13th May 2025

(**45**) S.I. 2002/2443 amended by S.I. 2019/88, 2022/347; there are other amending instruments but none is relevant.
(**46**) S.I. 2022/347.
(**47**) See also regulation 4.

Schedules

Schedule 1 — Regulation 3(5)

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 in accordance with regulation 3(2)(a).

2. Where the person whose details are provided in paragraph 1 is a legal person, the name, position, address, telephone number and email address of a natural person who is an employee or agent of that organisation who may be contacted in relation to the release notice in accordance with regulation 3(2)(b).

3. A description of any persons assisting in the release of precision bred organisms in accordance with regulation 3(2)(c) which may include, but is not limited to, whether research institutes or farmers have been contracted to assist in field trials in connection with the release.

4. A general description of the precision bred organism in accordance with Schedule 3.

5. Confirmation that the person named in paragraph 1—

(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(2) of the Act (precision bred organism).

Schedule 2 — Regulation 5(2)

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

1. Name, organisation name, address, telephone number and email address of the person with overall responsibility for marketing the precision bred organism.

2. Where the person whose details are provided in paragraph 1 is a legal person, the name, position, address, telephone number and email address of a natural person who is an employee or agent of that organisation who may be contacted in relation to the marketing notice.

3. A general description of the precision bred organism in accordance with Schedule 3.

4. A description of the intended use of the precision bred organism.

5. Information about intended genetic changes made to the precision bred organism resulting from the application of modern biotechnology including—

(a) the details of genetic changes made;

(b) the location of genetic changes;

(c) the stability of genetic changes;

(d) when a genetic change involves the insertion of any genetic material, a description of all the genetic elements inserted and the organism from which they originated;

(e) the purpose of the genetic changes described in sub-paragraphs (a) to (d), including how they alter the characteristics of the precision bred organism.

6. Information about any unintended genetic changes made to the precision bred organism resulting from the application of modern biotechnology, if present, including—

(a) the details of genetic changes made;

(b) the location of genetic changes;

(c) the stability of genetic changes.

7. Information about—

(a) the analysis and procedures used to check for unintended genetic changes;

(b) the processes used to remove unintended genetic changes, where this was undertaken.

8. A description of how intended genetic changes described in paragraph 5 were introduced into the precision bred organism, including—

(a) which techniques of modern biotechnology were used;

(b) information about any transgenic intermediates used.

9. A description of the analysis and procedures used to confirm the precision bred organism contains only genetic sequences that could arise by traditional processes.

10. Where a marketing notice serves as a marketing notice in relation to other precision bred organisms under regulation 5(4), information about those other organisms, including—

(a) the total number of precision bred organisms being notified;

(b) confirmation that all the other precision bred organisms meet the criteria set out in regulation 5(4);

(c) descriptions of any variation in intended genetic changes introduced to the other precision bred organisms, as set out in paragraph 5;

(d) descriptions of any variation in unintended genetic changes introduced to the other precision bred organisms, as set out in paragraph 6.

Schedule 3 — Regulation 3(5) and 5(2)

General description information

Details of the precision bred organism

1. The genus and species.

2. The intended alterations to characteristics of the organism.

3. The types of genetic changes introduced to cause the alterations described in paragraph 2.

4. The techniques of modern biotechnology used to make the genetic changes described in paragraph 3.

Schedule 4 Regulations 20(3) and 22(2)

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

1.—(1) The name, organisation name, address, telephone number and email address of the applicant.

(2) If the applicant is not established in Great Britain, the name, organisation name, address, telephone number and email address of a person established in Great Britain who is the representative of the applicant.

(3) Complete, unredacted copies of the following—

(a) the marketing notice applicable to the precision bred organism which is the subject of the application;

(b) the required information provided under Schedule 2 in the marketing notice;

(c) the precision bred confirmation issued by the Secretary of State under section 8 of the Act;

(d) where the precision bred confirmation covers the confirmation of more than one precision bred organism, a list of the precision bred organisms to which the application relates and the corresponding genetic changes to each precision bred organism.

(4) With respect to the information provided under paragraphs 5 and 6 of Schedule 2 in the marketing notice, a description of how the genetic change introduced to the precision bred organism to which the application relates affects the edible part of the organism, including information on—

(a) how the genetic change may affect the use of the organism in food and feed;

(b) which parts of the organism are destined for use in food and feed;

(c) a description of the intended use of the precision bred organism in food and feed.

(5) Statements to demonstrate how the applicant has reached the conclusions in relation to the precision bred organism for each of the criteria set out in paragraphs (1)(b) and (c) of regulation 20 including accompanying descriptive text setting out the applicant's key considerations and justification in respect of each criterion.

(6) If the applicant is making a request under regulation 34 that information be considered commercially confidential—

(a) a statement setting out the information which the applicant wishes to be treated as commercially confidential;

(b) an explanation as to why disclosure of such information would, or would be likely to, prejudice the commercial interests of any person, or is a trade secret.

2. Additionally, in relation to an application under regulation 22, where the applicant reasonably concludes that one or more of the criteria in paragraph (1)(b) and (c) of regulation 20 does not, or may not, apply to the precision bred organism—

(a) statements to explain why those criteria do not, or may not apply to the precision bred organism;

(b) complete, unredacted copies of the supporting evidence used by the applicant to make the explanatory statements in sub-paragraph (a) in relation to the precision bred organism which evidence may include, but is not limited to, test results, scientific analyses, data studies, surveys or scientific records.

Schedule 5 Regulation 54

Consequential Amendments to legislation relating to precision bred organism

Part 1

Amendment of assimilated direct legislation

Amendment to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed

1.—(1) Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed(**48**) is amended as follows.

(2) In Article 2, in point 5, after the second reference to "Directive 2001/18 EC", insert "and, in relation to England, excluding precision bred plants".

(3) At the end of Article 2, insert—

"(25) 'precision bred plant' has the same meaning as in section 1, as read with section 2(1), of the Genetic Technology (Precision Breeding) Act 2023.".

Amendment to Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, etc.

2.—(1) Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, etc.(**49**) is amended as follows.

(2) After Article 2(2), insert—

"(3) In relation to England, this Regulation does not apply to—

(a) products consisting of, or containing, precision bred plants placed on the market in accordance with Part 2 of the Genetic Technology (Precision Breeding) Act 2023 and regulations made under it;

(b) food and feed produced from precision bred plants placed on the market in accordance with Part 3 of the Genetic Technology (Precision Breeding) Act 2023 and regulations made under it.".

(3) In Article 3—

(a) in point 1, after the second reference to "Directive 2001/18/EC", insert "and, in relation to England, excluding precision bred plants";

(b) after point 15, insert—

"(16) 'Precision bred plant' has the same meaning as in section 1, as read with section 2(1), of the Genetic Technology (Precision Breeding) Act 2023.".

(**48**) EUR 2003/1829 amended by S.I. 2019/705, 2020/1504 and 2023/959; there are other amendments but none is relevant. [the numbering of this amendment takes into account regulation 14 of the draft Food and Feed (Regulated Products) (Amendment etc) Regulations due to come into force before these Regulations].

(**49**) EUR 2003/1830 amended by S.I. 2019/90 and 2020/1421; there are other amendments but none is relevant.

Amendment to Regulation (EC) No 1946/2003 of the European Parliament and of the Council on transboundary movements of genetically modified organisms

3.—(1) Regulation (EC) No 1946/2003 of the European Parliament and of the Council on transboundary movements of genetically modified organisms(**50**) is amended as follows.

(2) After Article 2(2), insert—

"(3) In relation to England, precision bred plants are excluded from the scope of this Regulation.".

(3) At the end of Article 3, insert—

"(25) 'precision bred plant' has the same meaning as in section 1, as read with section 2(1), of the Genetic Technology (Precision Breeding) Act 2023.".

Amendment to Regulation (EC) 1332/2008 of the European Parliament and of the Council on food enzymes, etc.

4.—(1) Regulation (EC) 1332/2008 of the European Parliament and of the Council on food enzymes, etc.(**51**) is amended as follows.

(2) In the heading to Article 8, at the end, insert "or, in relation to England, the Genetic Technology (Precision Breeding) Act 2023".

(3) After Article 8(2), insert—

"(3) In relation to England, a food enzyme falling within the scope of the Genetic Technology (Precision Breeding) Act 2023 may be authorised in accordance with this Regulation only when it is covered by a food and feed marketing authorisation under Part 3 of that Act.

(4) In relation to England, when a food enzyme that is already authorised is produced from a different source falling within the scope of the Genetic Technology (Precision Breeding) Act 2023, it will not require a new authorisation under this Regulation, as long as the new source is covered by a food and feed marketing authorisation under Part 3 of that Act and the food enzyme complies with the specifications established under this Regulation.".

Amendment to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives

5.—(1) Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives(**52**) is amended as follows.

(2) In the heading of Article 13, at the end, insert "or, in relation to England, the Genetic Technology (Precision Breeding) Act 2023".

(3) After Article 13(2), insert—

"(3) In relation to England, a food additive falling within the scope of the Genetic Technology (Precision Breeding) Act 2023 may be authorised in accordance with this Regulation only when it is covered by a food and feed marketing authorisation under Part 3 of that Act.

(4) In relation to England, when a food additive that is already authorised is produced from a different source falling within the scope of the Genetic Technology (Precision Breeding) Act 2023, it will not require a new authorisation under this Regulation, as long as

(**50**) EUR 2003/1946 amended by S.I. 2019/90; there are other amending instruments but none is relevant.
(**51**) EUR 2008/1332 amended by S.I. 2019/860; there are other amending instruments but none is relevant.
(**52**) EUR 2008/1333 amended by S.I. 2019/860; there are other amending instruments but none is relevant.

the new source is covered by a food and feed marketing authorisation under Part 3 of that Act and the food additive complies with the specifications established under this Regulation.”.

Amendment to Regulation (EC) No 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods, etc.

6.—(1) Regulation (EC) No 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods, etc. (**53**) is amended as follows.

(2) In the heading of Article 12, at the end, insert “or, in relation to England, the Genetic Technology (Precision Breeding) Act 2023”.

(3) After Article 12(2), insert—

“(3) In relation to England, a flavouring or source material falling within the scope of the Genetic Technology (Precision Breeding) Act 2023 may be authorised in accordance with this Regulation only when it is covered by a food and feed marketing authorisation under Part 3 of that Act.

(4) In relation to England, when a flavouring that is already authorised is produced from a different source falling within the scope of the Genetic Technology (Precision Breeding) Act 2023, it will not require a new authorisation under this Regulation, as long as the new source is covered by a food and feed marketing authorisation under that Act and the flavouring complies with the specifications established under this Regulation.”.

Amendment to Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed, etc.

7.—(1) Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed, etc.(**54**) is amended as follows.

(2) In Article 2(2)—

(a) in point (g), omit “and”;

(b) after point (h), insert—

“(i) in relation to England, the Genetic Technology (Precision Breeding) Act 2023 and regulations made under it.”.

Amendment to Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, etc.

8.—(1) Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, etc. (**55**) is amended as follows.

(2) In Article 3—

(a) at the end of paragraph 16, insert “but, in relation to England, does not include precision bred plants”;

(b) after paragraph 34, insert—

“(35) ‘precision bred plant’ has the same meaning as in section 1, as read with section 2(1), of the Genetic Technology (Precision Breeding) Act 2023.”.

(**53**) EUR 2008/1334 amended by S.I. 2019/860; there are other amending instruments but none is relevant.
(**54**) EUR 2009/767 amended by S.I. 2019/654; there are other amending instruments but none is relevant.
(**55**) EUR 2009/1107 amended by S.I. 2019/556; there are other amending instruments but none is relevant.

Amendment to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals (recast)

9.—(1) Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals (recast)(**56**) is amended as follows.

(2) After Article 2(2)(g), insert—

"(ga) in relation to England, precision bred plants.";

(3) After Article 3(26), insert—

"(27) 'precision bred plant' has the same meaning as in section 1, as read with section 2(1), of the Genetic Technology (Precision Breeding) Act 2023.".

Amendment to Commission Regulation (EU) No 68/2013 on the Catalogue of feed materials

10.—(1) Commission Regulation (EU) No 68/2013 on the Catalogue of feed materials(**57**) is amended as follows.

(2) In the Annex—

(a) in Part A, in point (2), at the end of the first sentence, insert "and, in relation to England, to the Genetic Technology (Precision Breeding) Act 2023 for feed materials that are or are produced from precision bred plants or result from a fermentation process involving precision bred plants. In this Annex, "precision bred plants" has the same meaning as in section 1, as read with section 2(1), of the Genetic Technology (Precision Breeding) Act 2023";

(b) in Part C, in chapter 12, after the first sentence, insert "In relation to England, feed materials listed in this chapter that are or are produced from precision bred plants, or result from a fermentation process involving precision bred plants, must be compliant with the Genetic Technology (Precision Breeding) Act 2023.".

Amendment to Regulation (EU) No 1143/2014 of the European Parliament and of the Council on the prevention and management of the introduction and spread of invasive alien species

11.—(1) Regulation (EU) No 1143/2014 of the European Parliament and of the Council on the prevention and management of the introduction and spread of invasive alien species(**58**) is amended as follows.

(2) After Article 2(2)(b), insert—

"(ba) in relation to England, precision bred plants within the meaning of section 1, as read with section 2(1), of the Genetic Technology (Precision Breeding) Act 2023;".

Amendment to Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, etc

12.—(1) Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, etc.(**59**) is amended as follows.

(2) After Article 2(2)(a), insert—

(**56**) EUR 2012/649 amended by S.I. 2019/720; there are other amending instruments but none is relevant.
(**57**) EUR 2013/68 amended by S.I. 2019/654; there are other amending instruments but none is relevant.
(**58**) EUR 2014/1143 to which there are amendments not relevant to these Regulations.
(**59**) EUR 2015/2283 to which there are amendments not relevant to these Regulations.

“(aa) within England, food produced from precision bred plants within the meaning of section 1, as read with section 2(1), and section 30(2), of the Genetic Technology (Precision Breeding) Act 2023;”.

Part 2

Amendment of subordinate legislation that applies in Great Britain

Amendment to the Genetically Modified Organisms (Contained Use) Regulations 2014

13.—(1) The Genetically Modified Organisms (Contained Use) Regulations 2014(**60**) are amended as follows.

(2) After regulation 3(2)(c), insert—

“(d) in relation to England, a precision bred plant is released or marketed in cases or circumstances in which the notification or authorisation of the Secretary of State is required under the following provisions of the Genetic Technology (Precision Breeding) Act 2023—

(i) section 4 (release of precision bred organism),

(ii) section 5 (marketing of precision bred organism),

(iii) section 26 (regulation of food or feed produced from precision bred organisms).”.

(3) After regulation 3(6), insert—

“(7) In paragraph (2)(d), “precision bred plants” means precision bred plants as defined in section 1, as read with section 2(1), of the Genetic Technology (Precision Breeding) Act 2023.”.

Part 3

Amendment of subordinate legislation that applies in England

Amendment to the Environmental Damage (Prevention and Remediation) (England) Regulations 2015

14.—(1) The Environmental Damage (Prevention and Remediation) (England) Regulations 2015(**61**) are amended as follows.

(2) At the end of paragraph 9(2) of Schedule 2, insert “excluding precision bred plants within the meaning of section 1, as read with section 2(1), of the Genetic Technology (Precision Breeding) Act 2023.”.

(**60**) S.I. 2014/1663 to which there are amendments not relevant to these Regulations.
(**61**) S.I. 2015/810, to which there are amendments not relevant to these Regulations.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made under powers in the Genetic Technology (Precision Breeding) Act 2023 (c. 6) ("the Act") in connection with the coming into force of provisions of the Act in respect of precision bred plants. The Act provides for the regulation of precision bred organisms released or marketed in England.

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

Regulation 4 makes transitional provision relating to regulation 3 concerning the release of qualifying higher plants already notified under the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443) (as to which, see also regulation 55).

Regulations 5 and 6 and Schedules 2 and 3 provide for the content of marketing notices and the process and procedure for making an application to the Secretary of State for precision bred confirmation in respect of a precision bred plant.

Regulation 7 sets out the process for revoking a precision bred confirmation.

Regulations 8 and 9 provide for the review and appeal of a decision not to issue a precision bred confirmation or a decision to revoke a precision bred confirmation.

Regulations 10 and 11 provide for the precision breeding register.

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

Part 6 provides for the monitoring and inspection of precision bred organisms.

Regulations 18 to 25 and Schedule 4 set out the processes for applying for marketing authorisations for food and feed produced from precision bred plants and the required information for inclusion in an application made under regulation 20 or 22. An application under regulation 22 requires additional information to enable a safety assessment to be carried out by the Food Standards Agency.

Regulations 26 to 29 provide for the assessment of applications for food and feed marketing authorisations by the Food Standards Agency, including obtaining expert advice and the provision of reports to the Secretary of State.

Regulations 30 and 31 set out the requirements for the consideration of marketing authorisation applications, and the issuing of marketing authorisations, by the Secretary of State.

Regulations 32 and 33 record the duties on the authorisation-holders of marketing authorisations and other persons proposing to place authorised food and feed on the market and sets out the circumstances and process for varying and revoking food and fees marketing authorisations.

Regulation 34 provides a process for the management of commercially confidential information under Part 7. Regulation 35 provides for a food and feed register.

Part 9 provides for the monitoring and inspection of food and feed marketing authorisations.

Part 10 provides for enforcement by way of civil enforcement notices including monetary penalty notices and for reviews and appeals against such notices.

Regulations 53 and 54 and Schedule 5 make general provision in relation to notices and consequential amendments. Regulation 55 revokes the Genetically Modified Organisms) (Deliberate Release) (Amendment) (England) Regulations 2022 (S.I. 2022/347) and removes the amendments made by those Regulations to the Genetically Modified Organisms (Deliberate Release) Regulations 2002.

A full impact assessment has not been produced for this instrument as no, or no significant impact on the private, voluntary or public sector is foreseen. A de minimis assessment of the effect that this instrument will have on the cost of business has been prepared and is available from the Department for Environment, Food and Rural Affairs, 2 Marsham Street, London, SW1P 4DF.