EXPLANATORY NOTES

Genetic Technology (Precision Breeding) Act 2023

Chapter 6

£6.90

GENETIC TECHNOLOGY (PRECISION BREEDING) ACT 2023

EXPLANATORY NOTES

What these notes do

These Explanatory Notes relate to the Genetic Technology (Precision Breeding) Act 2023 which received Royal Assent on 23 March 2023 (c. 6).

- These Explanatory Notes have been prepared by Department for Environment, Food and Rural Affairs in order to assist the reader of the Act and to help inform debate on it. They do not form part of the Act and have not been endorsed by Parliament.
- These Explanatory Notes explain what each part of the Act will mean in practice; provide background information on the development of policy; and provide additional information on how the Act will affect existing legislation in this area.
- These Explanatory Notes might best be read alongside the Act. They are not, and are not intended to be, a comprehensive description of the Act.

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Overview of the Act

1 This Act intends to reduce the regulatory burden and financial barriers in place for researchers and commercial breeders using precision breeding technologies.

2 This Act removes the plants and animals produced using modern biotechnologies, and the food and feed derived from them, from Genetically Modified Organisms (GMO) regulation if those organisms could have occurred naturally or been produced by traditional methods. It replaces GMO controls with proportionate and science-based measures.

3 The Act includes provisions to:

- Bring in two mandatory notification systems for precision bred organisms (PBOs), one for non-marketing purposes (research and development) and one for marketing purposes.
- Allow for new powers to introduce on-going obligations to report information relating to the health and welfare of precision bred vertebrate animals, and to prescribe the processes and powers the Secretary of State can use to take the necessary action in response to this post-marketing animal welfare information.
- Create a duty on the Secretary of State to create and maintain a new public register of notified information. The register is to be kept in electronic form and accessible on gov.uk.
- Grant powers to create a new regulatory framework for food and feed derived from PBOs, ensuring that appropriate regulation is in place before placing these products on the market. These powers include the power to make regulations that will outline the procedure for issuing a precision bred food and feed marketing authorisation, and the power to make regulations that will require the FSA to carry out risk assessments. Regulations will also set out the requirements within the resultant framework that must be satisfied before the Secretary of State can issue a food and feed marketing authorisation.
- Grant powers for the Food Standards Agency (FSA) to establish, publish and update a public register for PBOs authorised for food and feed use. An entry on this register would indicate that the Secretary of State has made a determination to authorise the PBO, and products derived from it to enter the market for food and feed uses based on the recommendation of the FSA.
- Grants powers to create an inspection and enforcement regime, including civil sanctions, in order to secure compliance with the obligations under the Act.

Policy background

4 The current GMO legislation, most of which derives from retained European Union (EU) law, is over 30 years old and has not kept pace with scientific developments and knowledge of the environmental impacts associated with precision breeding technologies. Current GMO legislation is also not reflective of the risk of organisms produced by modern biotechnology when the final product could have been produced by traditional breeding methods. Advice from the independent scientific committee - the Advisory Committee on Releases to the

Environment (ACRE) is that PBOs pose no greater risk than their traditionally bred or naturally arising counterparts[1].

5 This Act aligns with the scientific view of groups such as the EU Commission's Scientific Advice Mechanism, the European Academies' Scientific Advisory Council and the UK's Royal Society, as well as ACRE, who consider that it is the nature of the genetic change – and not the technique by which it was produced – that determines the risk posed by an organism and should therefore determine whether an organism should be regulated as a GMO[2].

6 Defra held a public consultation from 7 January to 17 March 2021, to gather views on the regulation of genetic technologies in England[3]. This focused on organisms, which are the product of precision breeding technologies such as gene editing that result in genetic changes similar to those found naturally in varieties of the same species, or in very similar species that could be combined by traditional breeding. The consultation received no new scientific evidence indicating that PBOs should be regulated as GMOs, and many responses expressed the view that GMOs are demonstrably different to the products of precision breeding.

7 In addition to public consultation, both Defra and the FSA undertook additional stakeholder engagement. This engagement included workshops, round table discussions, public polling, and consumer research. This engagement assisted both agencies by providing insight into academia, industry, and the public's perceptions, understanding the appetite for these modern technologies. The Government will continue to engage with stakeholders to seek views and to continue to develop policy in this area.

8 Defra and the FSA have also investigated international approaches to the regulation and food safety standards of Precision Bred and Novel Foods.

Legal background

9 The regulation of GMOs in the UK is mainly based on EU law passed in the 1990s and updated in the 2000s. These regulations were implemented in the UK through Part VI of the Environmental Protection Act 1990 (EPA) and subsequent secondary legislation and retained direct EU law.

10 Section 106 of the EPA (Part VI) and Regulation 5 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 ("the Deliberate Release Regulations 2002") use the EU definition of a GMO from Directive 2001/18/EC. The EPA introduces the additional concept of 'artificial modification' which more clearly establishes that it is the techniques used to develop an organism that determine its GM status; whether the genetic changes could have occurred naturally or by traditional methods has no bearing. The techniques of artificial modification are set out in regulation 5 of the Deliberate Release Regulations 2002. This list captures the techniques developed in the 1980s (and aligns with Annex 1A, part 1 of Directive 2001/18/EC). This regulation also lists natural processes and traditional breeding methods that are not regarded as being GM techniques (and aligns with Annex 1A, part 2 of Directive 2001/18/EC).

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[1] ACRE advice: the regulation of genetic technologies - GOV.UK (www.gov.uk)

[2] EC study on new genomic techniques (europa.eu)

[3] Genetic technologies regulation - GOV.UK (www.gov.uk)

11 The UK is a signatory of the Cartagena Protocol on Biosafety. The Cartagena Protocol on Biosafety is an international treaty governing the movements of GMOs from one country to another. This is implemented by retained EU Regulation 1946/2003, which establishes a system for notifying and providing information for the transboundary movements of GMOs. The Genetically Modified Organisms (Transboundary Movements) (England) Regulations 2004 provide for enforcement of this Regulation in England. The UK Government considers that the Cartagena Protocol does not apply to organisms produced using modern biotechnologies if those organisms could have occurred naturally or been produced by traditional methods.

12 Retained EU GM Food and Feed Regulations (1829/2003/EC) govern the use of GM human food and animal feed. This covers food and feed products containing living GMOs as well as non-living products derived from them. Persons intending to market GMOs can seek authorisation to cultivate GM crops under these regulations in addition to seeking approval to use them as food and feed. Alternatively, they can seek authorisation for cultivation under the GMO Deliberate Release legislation and separately, seek authorisation for their use in food and/or feed. If the organism is not intended for use in food or feed, it can be authorised for marketing under the GMO Deliberate Release legislation. The GM food and feed regulations refer to the definition of a GMO in the EU Directive 2001/18/EC.

Territorial extent and application

13 Section 47 sets out the territorial extent of the provisions of the Act. The extent of an Act is the legal jurisdiction of which it forms part of the law; application refers to where it has practical effect.

14 The regulation of precision bred organisms is a devolved matter and the provisions of this Act generally extend to England and Wales only and apply in relation to England only. Section 41 amends the Environmental Protection Act 1990 which extends to England and Wales and Scotland, so that section and the definitions in Part 1 of the Act to which those amendments refer likewise extend to England and Wales and Scotland. The general provisions in sections 42 to 48 extend to England and Wales and Scotland and Northern Ireland.

15 As a result of the changes proposed in the Act, it will be possible to market precision bred plants and animals in England without the need for consent under Part 6 of the Environmental Protection Act 1990. The mutual recognition principle in the United Kingdom Internal Market (UKIM) Act 2020 will apply to precision bred plants and animals, and food and feed derived from them, which are produced in or imported into England, meaning that it would be possible to place them legally on the market in Scotland and Wales if they can be marketed lawfully in England as a result of this Act and the delegated legislation to be made under it. Precision bred organisms, and food derived from them, moved to Northern Ireland from Great Britain will need to comply with the arrangements agreed under the Windsor Framework.

16 See the table in Annex A for a summary of the position regarding territorial extent and application in the United Kingdom.

Commentary on provisions of Act

Part 1: Precision Breeding: Definitions

1: Precision bred organism

18 This section provides the definition of "precision bred organism" and related terms for the purposes of this Act.

19 Subsection (1) defines "precision bred organism" as a precision bred plant, or a precision bred animal.

20 Subsection (2) of this section establishes the conditions under which an organism is considered to be precision bred for the purposes of the Act. It dictates that the genome of such organisms must have been altered using modern biotechnology, that these alterations must be stable and that all features of its genome that have been made using modern biotechnology could also have arisen by traditional processes, whether or not in conjunction with selection techniques, alone. It also dictates that an organism cannot be precision bred if it contains any genetic features which have been made by artificial modification techniques, other than modern biotechnology.

21 Subsection (3) outlines the definition of modern biotechnology for the purposes of this Act. This aligns with the techniques listed in regulation 5(1)(a) or (b) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443). Regulation 5(1)(a) of those Regulations lists techniques which are considered to constitute artificial alteration of an organism for the purposes of Part VI of the Environmental Protection Act 1990, while regulation 5(1)(b) lists techniques which are not considered to constitute artificial alteration of an organism for that purpose.

22 Subsection (4) further outlines the definition of a stable genomic feature laid out in subsection (2). It dictates that the genomic feature must be capable of being passed on to subsequent generations whether by sexual or asexual means.

23 Subsection (5) outlines matters to be disregarded when conducting the test of whether an organism made using modern biotechnology could also have arisen via traditional processes. These are: the number of times a genomic feature repeats in the genome (copy number), the set of chemical modifications to the genome and its associated proteins (epigenetic status), and the position of a genomic feature within the genome (location).

24 Subsection (6) outlines a list of traditional processes for plants and animals, in relation to this Part. The lists cover the range of genomic alterations that could occur through traditional processes.

25 Subsection (7) defines "artificial modification technique", for subsection (2), as any technique by which genes or other genetic material can be artificially modified within Part 6 of the Environmental Protection Act 1990.

26 Subsection (8) allows the definition of "modern biotechnology" to be amended to mirror changes that may occur in regulation 5 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443), or if the powers in subsection (4B) or (4C) of section 106 of the Environmental Protection Act 1990 are exercised to prescribe techniques that are (or are not, as the case may be), considered to constitute artificial modification for the purposes of that Act.

27 Subsection (9) specifies that regulations made under this section are subject to the draft affirmative procedure.

28 Subsection (10) makes it possible for organisms to which subsection (11) applies to qualify for "precision bred" status regardless of the exclusion outlined in subsection (2)(d), provided they meet all other criteria set out in subsection (2).

29 Subsection (11) outlines which artificially modified organisms should have the potential to gain "precision bred" status. These are organisms which are not considered to be genetically modified in Part 6 of the Environmental Protection Act 1990. Specifically, organisms with genetic features produced through techniques mentioned in regulation 5 paragraph (3) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443), and organisms mentioned in regulations under subsection (4C) of section 106 of the Environmental Protection Act 1990.

2: Meaning of "plant" and "animal"

30 This section defines "plant" and "animal" for the purposes of this Act.

31 Subsection (1) of this section describes the scope of what is considered a plant for the purposes of this Act. It defines plants as residing within the group Archaeplastida, or Phaeophyceae.

32 Subsection (2) describes the scope of what is considered an animal, for the purposes of this Act. It defines animals as residing in the group Metazoa but excludes humans at any developmental stage as well as human admixed embryos.

33 Subsection (3) outlines what is and is not considered an 'organism' in relation to subsections (1) and (2). This includes an embryo and all subsequent developmental stages, a seed or vegetative propagule (in plants) but excludes a gamete, as defined in subsection (4).

34 Subsection (4) outlines the definition of a "gamete", for the purposes of this Act. This includes a mature germ cell (i.e., egg, sperm (animals) or pollen (plants)) capable of initiating fertilisation but excludes an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo.

35 Subsection (5) describes the extent of what is considered an "embryo", "human" and "human admixed embryo" for the purposes of this section.

Part 2: Precision Bred Organisms, Release, Marketing, and Risk Assessments

Release

3: Restrictions on release of precision bred organisms in England

36 This section sets out the conditions under which a person who has a precision bred organism under their control may release that organism into the environment in England.

37 Subsection (1) outlines that a person who has a precision bred organism under their control must not release a precision bred organism in England unless the notification requirements set out in section 4 have been satisfied in relation to the release, the person is specified in the notification and the release is carried out in accordance with the notice; or the organism is either a marketable precision bred organism (as defined in section 5(2) is the qualifying progeny of a marketable precision bred organism). "Qualifying progeny" is defined in section 24.

38 Subsection (2) describes the circumstances in which a precision bred organism can be considered under a person's control.

39 Subsection (3) describes the circumstances in which a precision bred organism is considered to be released.

4: Release of precision bred organism: notification requirements

40 This section sets out the notification requirements for the release of a precision bred organism in England.

41 Subsection (1) sets out the legal requirements for a notification of release of a precision bred organism. The notification requirements are satisfied in relation to the release if a person gives the Secretary of State a notice of the intention to release an organism (with any required information) and if the person has paid the fees required by regulations made under section 40, and any minimum period required by regulations has elapsed between satisfying the requirements and releasing the organism.

42 Subsection (2) requires the notice to specify persons in relation to the release.

43 Subsection (3) sets out a power to make regulations to make provisions for the details of the release notification form, such as the form and content of the release notice, and any other required information.

44 Subsection (4) provides that these regulations may prescribe who can be specified in relation to a notice.

45 Subsection (5) provides that the meaning of "release" is as in section 3(3).

46 Subsection (6) specifies that regulations under subsection (1)(b) are subject to the negative procedure.

47 Subsection (7) specifies that regulations under subsection (3) are subject to the affirmative procedure.

Marketing

5: Restrictions on marketing of precision bred organisms in England

48 This section sets out the notification requirements for the marketing of a precision bred organism in England.

49 Subsection (1) contains restrictions on the marketing of precision bred organisms in England: a person must not market a precision bred organism in England unless the organism is a marketable precision bred organism or is the qualifying progeny of a marketable precision bred organism.

50 Subsection (2) defines a "marketable precision bred organism" as one which will have to have received a precision bred confirmation (under section 8(1)(a)), and, for a relevant animal, have an animal marketing authorisation.

51 Subsection (3) explains what it means to market precision bred organisms in England, for the purposes of this Act.

52 Subsection (4) sets out where relevant definitions can be found in the Act.

53 Subsection (5) explains what is meant by a confirmation or authorisation being "in force".

Precision bred confirmation

6: Application for precision bred confirmation

54 This section describes the application process for a precision bred confirmation.

55 Subsection (1) establishes that a person may apply for confirmation, from the Secretary of State, that an organism is a precision bred organism by giving a notice (a "marketing notice") to the Secretary of State.

56 Subsection (2) provides for regulations that may be used to establish the form and content of the marketing notice and the required information that must accompany it.

57 Subsection (3) requires the Secretary of State to refer the marketing notice and any required information that accompanied it to the advisory committee as soon as practical after receiving this information and after receiving any fee that is required under section 36.

58 Subsection (4) specifies that regulations made under this section are subject to the affirmative procedure.

7: Report by advisory committee

59 This section sets out the requirements for the report of the advisory committee.

60 Subsection (1) establishes this section applies where a marketing notice has been referred to the advisory committee by the Secretary of State.

61 Subsection (2) establishes a period of 90 days as the timeframe in which the advisory committee must provide a report to the Secretary of State. This report must outline whether the advisory committee considers the organism to be precision bred and its reasons for that conclusion.

62 Subsection (3) provides that the committee may request further information from the notifier under an 'information notice' request, if they deem it necessary in order to assess and report if an organism is precision bred.

63 Subsection (4) provides that the committee report must contain any information provided by the notifier as a result of an information notice.

64 Subsection (5) provides for the committee report to be subject to regulations made under section 23 regarding time limits.

8: Issue of precision bred confirmation

65 Subsection (1) of this section provides for the Secretary of State, upon receipt of the advisory committee report, to issue the notifier with a precision bred confirmation and provide the notifier notice of it if the Secretary of State is satisfied the organism is precision bred. If not satisfied the organism is precision bred, the Secretary of State must give notice to the notifier of that fact, stating the reasons for such notice as required by subsection (2).

9: Revocation of precision bred confirmation

66 This section provides for the revocation of a precision bred confirmation.

67 Subsection (1) enables regulations to provide to the Secretary of State a power to revoke a precision bred confirmation if no longer satisfied that the organism is precision bred.

68 Subsection (2) provides that the Secretary of State must, in those such regulations, outline the procedures which must be followed in order to revoke a precision bred confirmation. Regulations must include provisions for publication of such revocation, allowing the persons affected by the revocation to make representation about it, the consequences of such revocation, and the details of information which will be published on the PB Public Register.

69 Subsection (3) provides that if a precision bred confirmation is revoked, any marketing authorisations issued under regulations under Part 3 (Food and feed produced from precision bred organisms) in reliance on the organism being a marketable precision bred organism, and

for relevant animals a precision bred animal marketing authorisation relating to the animal cease to have effect.

70 Subsection (4) enables regulations under this section to confer a function on the advisory committee, for instance to provide the Secretary of State with advice relating to the revocation of a precision bred confirmation.

71 Subsection (5) specifies that regulations made under this section are subject to the negative procedure.

Relevant animals: precision bred animal marketing authorisation

10: "Relevant animal"

72 This section defines what a "relevant animal" is.

73 Subsection (1) explains that a "relevant animal" for the purposes of this Act is a vertebrate.

74 Subsection (2) provides that regulations may be made in order to extend the definition of a "relevant animal" if the definition in the Animal Welfare Act 2006 is extended to include invertebrates of any description.

75 Subsection (3) explains that the meanings of "vertebrate" and "invertebrate" are set out in the Animal Welfare Act 2006, as follows: "vertebrate" means any animal of the Sub-phylum Vertebrata of the Phylum Chordata and "invertebrate" means any animal not of that Sub-phylum.

76 Subsection (4) specifies that regulations made under this section are subject to the draft affirmative procedure.

11: Application for precision bred animal marketing authorisation

77 This section sets out the application process for a precision bred animal marketing authorisation.

78 Subsection (1) explains that this section applies where the Secretary of State has received a marketing notice relating to an animal.

79 Subsection (2) explains that the person who gave a marketing notice in respect of an animal who wishes to obtain a precision bred animal marketing authorisation for that animal can apply to the Secretary of State.

80 Subsection (3) sets out that when making an application for a precision bred animal marketing authorisation the applicant must include an animal welfare declaration.

81 Subsection (4) lists the information requirements and fees which must accompany an application for a precision bred animal marketing authorisation.

82 Subsection (5) allows for the form and content of an application for a precision bred animal marketing authorisation and related documentation to be set out in regulations and allows for regulations to require additional information to be provided with the application.

83 Subsection (6) explains that the Secretary of State must refer an application for a precision bred animal marketing authorisation and any related information to the welfare advisory body.

84 Subsection (7) sets out that when the Secretary of State must refer the application to the welfare advisory body and allows the Secretary of State to decide to wait until a confirmation of precision breeding is issued in relation to the relevant animal.

85 Subsection (8) explains that the duty to refer the application to the welfare advisory committee does not apply if the Secretary of State decides not to issue a precision breeding confirmation in relation to the relevant animal.

86 Subsection (9) allows for regulations to set out when a person other than the notifier can apply for a precision bred marketing authorisation for a precision-bred animal.

87 Subsection (10) specifies that regulations made under subsection (5) are subject to the affirmative procedure.

88 Subsection (11) specifies that regulations made under subsection (9) are subject to the negative procedure.

12: Report by welfare advisory body

89 This section refers to the report by the welfare advisory body.

90 Subsection (1) explains that this section applies where the Secretary of State refers a precision bred animal marketing authorisation to the welfare advisory body.

91 Subsection (2)(a) to (c) outlines what must be included in the report from the welfare advisory body to the Secretary of State and that the report must be provided within a set timeframe.

92 Subsection (3) explains that the timeframe for the reporting period will be set out in regulations, and that it will begin on the day the application is referred to the welfare advisory body.

93 Subsection (4) enables the welfare advisory body to request further information from a person submitting an application under an 'information notice' before the end of the reporting period set out in subsection (3).

94 Subsection (5) sets out that the advisory body's report to the Secretary of State must be accompanied by any information that the body was provided with after issuing an information notice.

95 Subsection (6) confirms that subsections (2) and (3) are subject to regulations under section 23 on Advisory bodies and time limits.

96 Subsection (7) specifies that regulations made under this section are subject to the negative procedure.

13: Issue of precision bred animal marketing authorisation

97 This section sets out the process for issuing a precision bred marketing authorisation.

98 Subsection (1) (a) to (c) explains what the Secretary of State must do when he receives a report from the welfare advisory body. It sets out that he must decide if a precision bred animal marketing authorisation can be issued and notify the applicant of his decision, including any reasons for not issuing the authorisation.

99 Subsection (2) (a) to (b) sets out that the Secretary of State must consider whether the notifier's declaration explains the traits produced by precision breeding in the animal and identifies any risks to the health or welfare of the animal or its qualifying progeny (as defined in section 24) associated with those traits. This subsection explains that if he is satisfied with how these elements have been considered, the Secretary of State may issue a precision bred animal marketing authorisation.

Protection of relevant animals following issue of marketing authorisation

14: Precision bred animal marketing authorisations: reporting obligations

100 This section provides for reporting obligations concerning precision bred marketing authorisations.

101 Subsection (1) (a) to (b) and (2) set out that draft affirmative regulations may make provisions to require the notifier, or any other person specified, to report information to the Secretary of State about the welfare of the relevant animal and its qualifying progeny (as defined in section 24). This subsection also provides that when the relevant animal is supplied to another person, the notifier may be required to take steps to collect that health and welfare information, or enable it to be collected, from the other person.

102 Subsection (3) provides for the periods during which reporting obligations would apply.

103 Subsection (4) specifies that regulations made under this section are subject to the draft affirmative procedure.

15: Suspension and revocation of precision bred animal marketing authorisation

104 This section provides for the suspension and revocation of a precision bred marketing authorisation.

105 Subsection (1) (a) to (c) sets out that regulations made under this section can enable the Secretary of State to suspend or revoke a precision bred animal marketing authorisation, either because of new information about animal health or welfare, or because of a failure by any person to comply with a legal requirement to report information about a relevant animal's health and welfare.

106 Subsection (2) (a) to (c) explains that Regulations made under this section must set out the procedure to be followed if the Secretary of State plans to suspend or revoke a precision bred animal marketing authorisation – including who should be notified and who can appeal, what the effect of the suspension or revocation is and what changes should be made to the register of precision bred organisms.

107 Subsection (3) confirms that regulations under this section can also confer a function to the welfare advisory body as part of the process if needed.

108 Subsection (4) confirms that nothing in this section affects the power to make provision in relation to a failure to comply with regulations under section 14.

109 Subsection (5) specifies that regulations made under this section are subject to the negative procedure.

Reviews and appeals relating to Part 2

16: Reviews and appeals relating to Part 2

110 This section provides for reviews and appeals relating to Part 2.

111 Subsection (1) requires the Secretary of State to make regulations for reviews and appeals against decisions made under this part.

112 Subsection (2) provides that regulations must secure that the appellant has the rights to require the Secretary of State to review, and then to appeal to the First-tier Tribunal against the decisions made under Part 2 of this Act and provides for the grounds on which that review or appeal can be made. These are that the decision was based on an error of fact, was wrong in law, unreasonable or on any other grounds prescribed by regulations.

113 Subsection (3) describes the decisions an appellant is able to request a review or appeal against: a decision not to issue or to revoke a precision bred confirmation; or a decision not to issue, to revoke or to suspend a precision bred animal marketing authorisation.

114 Subsection (4) provides that additional provisions concerning appeals may be made by regulations, including the powers of the First-tier Tribunal on an appeal.

115 Subsection (5) specifies that regulations made under this section are subject to the negative procedure.

Risk assessments

17: Restrictions on importation and acquisition of precision bred organisms in England

116 This section provides for restrictions on importation and acquisition of precision bred plants and animals in contained use conditions.

117 Subsection (1) provides that regulations may be made requiring a person to carry out an environmental risk assessment for precision bred organisms that are imported to a place in England or that are acquired in England. The Government intends that this should have limited application in that it envisages it only applying to precision bred animals and plants before they are released into the environment or marketed (after which point, they are subject to the regulatory provisions on release and marketing in this Act). It provides for existing requirements placed on Genetically Modified Organisms and Precision Bred plants and animals in contained use conditions (such as laboratories) to be maintained. In the majority of cases, a mixture of Genetically Modified and Precision Bred organisms will be present in laboratories and other contained use facilities and this subsection will provide for the current regulations on environmental risk assessment to continue to apply. These are proportionate and science based.

118 Subsection (2) establishes the meaning of an environmental risk assessment for the purposes of any regulations that are made under subsection (1).

119 Subsection (3) establishes the provisions that may be made in regulations for environmental risk assessments, including keeping them under review and keeping records for provision to the Secretary of State.

120 Subsection (4) makes provision requiring persons carrying out environmental risk assessments to obtain advice from prescribed persons.

121 Subsection (5) defines the terms ‘acquire’ and ‘damage to the environment’.

122 Subsection (6) specifies that regulations made under this section are subject to the negative procedure.

Register

18: Precision breeding register

123 This section refers to the Precision Breeding Register. Subsection (1) requires the Secretary of State must establish and maintain a register and prescribes the information the register must contain.

124 Subsection (2) provides for the Secretary of State not to include information in the register if they determine that such information is commercially confidential, subject to subsection (4).

125 Subsection (3) explains the circumstances of the requirements in subsection (2) cease to apply when the Secretary of State determines that the information is no longer commercially confidential.

126 Subsection (4) provides that neither the name of any person giving the notices and required information mentioned in subsection (1)(a) nor the general description of any precision bred organism are considered to be commercially confidential.

127 Subsection (5) provides for the Secretary of State to ensure the register is accessible to the public, free of charge, in electronic form.

128 Subsection (6) enables the Secretary of State to make regulations for the keeping of the register.

129 Subsection (7) specifies that regulations made under subsection (1) are subject to the affirmative procedure.

130 Subsection (8) specifies that regulations made under subsection (6) are subject to the negative procedure.

Monitoring and inspection

19: Inspectors

131 This section refers to monitoring and inspection powers.

132 Subsection (1) provides for the Secretary of State to appoint inspectors for the purposes of Part 2 of this Act.

133 Subsection (2) provides for the inspectors appointed under this section to not be liable in any civil or criminal proceedings for anything done in the purported exercise of their functions if the court deems in was done in good faith and there were reasonable grounds for doing it.

134 Subsection (3) does not cover any liability of any other person in respect to the inspector's act.

135 Subsection (4) defines what an "inspector" is for the purposes of Part 2 of this Act.

20: Monitoring and inspection of Part 2 obligations

136 This section provides for monitoring and inspections in respect of Part 2 obligations.

137 Subsection (1) enables the Secretary of State to make regulations for monitoring compliance with the obligations under this Part and investigate compliance failures.

138 Subsection (2) provides for the Secretary of State to make regulations regarding the appointment of inspectors and their functions and provides for a non-exhaustive list of what these regulations might cover.

139 Subsection (3) establishes that regulations made under this section may not create criminal offences, confer power of entry into private dwellings except under a warrant or authorise the use of force on power of entry. Regulations must also prohibit inspectors from wider use or disclosure of information obtained under them.

140 Subsection (4) specifies that regulations made under this section are subject to the draft affirmative procedure.

21: Meaning of "Part 2 obligation"

141 This section describes the meaning of an obligation under Part 2 in relation to release, marketing and risk assessments of PBOs.

142 Subsection (1) defines a "Part 2 obligation" as an obligation imposed under Part 2 (except for those circumstances described in subsection (2)), or a requirement arising from a stop notice or compliance notice issued in connection with Part 2.

143 Subsection (2) establishes that a Part 2 obligation is not one imposed by an information notice or any obligation of the Secretary of State, an advisory body, or an inspector.

144 Subsection (3) allows regulations to provide that a failure to comply with a Part 2 obligation can also relate to the provision of misleading or false information in relation to a Part 2 obligation or an authorisation.

145 Subsection (4) defines "requirement" to include "prohibition".

146 Subsection (5) specifies that regulations made under section (3) are subject to the draft affirmative procedure.

Release and marketing: general provisions

22: Advisory bodies

147 This section sets out the advisory bodies for Part 2 of this Act.

148 Subsection (1) establishes the advisory committee referenced in this Part is the same committee established under section 124(1) of the Environmental Protection Act 1990.

149 Subsection (2) places a duty on the advisory committee to give advice on applications, reports and the issuing and revocation of precision breeding confirmation as required by the Secretary of State.

150 Subsection (3) defines "welfare advisory body" for the purposes of this Part as the body so designated by regulations.

151 Subsection (4) allows the welfare advisory body to be a committee appointed by the Secretary of State for the purposes of this Part, or a body which was established previously by or under any other Act or which exercises functions of a public nature.

152 Subsection (5) places a duty on the welfare advisory body to provide advice to the Secretary of State on any matter relevant to the Secretary of State's functions under sections 11 to 15.

153 Subsection (6) establishes that subsections (7) and (8) apply to the welfare advisory committee if it is appointed by the Secretary of State under subsection 4(a).

154 Subsection (7) enables members of the committee to hold and vacate office in accordance with the terms of their appointment.

155 Subsection (8) enables the Secretary of State to pay members of the committee remuneration and allowances, as decided by the Secretary of State.

156 Subsection (9) specifies that regulations made under section (3) are subject to the affirmative procedure.

23: Advisory bodies: time limits etc

157 This section sets out additional provisions for the advisory bodies.

158 Subsection (1) allows for Secretary of State to make regulations for the notification to be treated as paused while information requested by an information notice has not been provided and withdrawn if the requested information is not provided to the advisory body's satisfaction within a prescribed period.

159 Subsections (2) and (3) define "information notice", "relevant application", and "reporting period" for these purposes.

160 Subsection (4) specifies that regulations made under this section are subject to the negative procedure.

24: "Qualifying progeny"

161 This section establishes the meaning of a "qualifying progeny" of a marketable precision bred organism.

25: Precision bred animal marketing authorisation: adverse effects

162 Subsection (1) enables the Secretary of State to specify in regulations subject to the affirmative procedure when the health or welfare of a precision bred animal or its qualifying progeny is, or is not, considered to be adversely affected by a trait which results from precision breeding. This would allow the Secretary of State to establish thresholds for assessing risk or exceptions which may need to be considered as part of the decision to issue, suspend, or revoke a precision bred animal marketing authorisation.

163 Subsection (2) specifies that regulations made under this section are subject to the draft affirmative procedure.

Part 3: Food and Feed Produced from Precision Bred Organisms

26: Regulation of food and feed produced from precision bred organisms

164 This section sets out powers for the regulation of food and feed derived from precision bred organisms.

165 Subsection (1) will grant a general power to introduce a regulatory framework governing the placing on the market of food and feed from precision bred organisms.

166 Subsection (2) provides for regulations made under the general power in subsection (1) to make provision for the matters set out in (a) and (b).

167 Subsection (3) provides that regulations which prohibit any person from placing food or feed from PBOs on the market except in accordance with a marketing authorisation issued by the Secretary of State may include the criteria that must be met in order for the Secretary of State to grant such an authorisation.

168 Subsection (4) and (5) provide powers for establishing an application procedure to be followed for food and feed marketing authorisations and provision that such authorisations be issued subject to conditions and limitations and to be varied or cancelled.

169 Subsection (6) grants powers to make regulations that confer functions on the Food Standards Agency.

170 Subsection (7) allows regulations to provide that an obligation on any other person than the Food Standards Agency, is not a Part 3 obligation referenced in section 29.

171 Subsection (8) outlines that, where regulations are made under subsection (2) (a) to authorise a precision bred organism for food and feed use, such regulations may prescribe which person(s) is authorised to market the precision bred organism for food and feed use and any other limitations on the authorisation that are necessary.

172 Subsection (9) prescribes that any regulations made under this section are subject to the draft affirmative procedure.

27: Food and feed marketing authorisations: register

173 This section sets out the requirements of a register for precision bred products and the associated marketing authorisation of such products and how the limitations of these authorisations can be varied or cancelled.

174 Subsection (1) grants a power to make regulations requiring the Food Standards Agency to establish a register of precision bred products that have been granted marketing authorisation for uses in food and feed and setting out the information required to be included in such a register

175 Subsection (2) sets out the information relating to food and feed marketing authorisations that regulations may state are to be included in the register.

176 Subsection (3) states that the prescribed particulars to be included in the register may include information of any precision bred confirmation or precision bred animal marketing authorisation issued by the Secretary of State in relation to a food or feed marketing authorisation.

177 Subsection (4) prescribes that any regulations made under this section are subject to the draft affirmative procedure.

28: Monitoring and inspection of Part 3 obligations

178 This section makes provisions for monitoring and inspection obligations of Part 3.

179 Subsection (1) grants powers to make regulations for designating bodies within subsection (2) as enforcement authorities with various functions.

180 Subsection (2) identifies bodies which may be designated as enforcement authorities.

181 Subsection (3) grants powers to make regulations for enforcement authorities in connection with monitoring compliance with relevant obligations and investigating suspected breaches, including the conferral on inspectors of powers of entry, inspection, examination and search and seizure. Subsection (3) also provides for regulations to apply (with or without modifications) any provision made under the Food Safety Act 1990 (to include the appointment of public analysts under section 27) and section 67 of the Agriculture Act 1970.

182 Subsection (4) prevents regulations made under section 28 from being able to establish criminal offences and or conferring powers of entry into private dwellings without the need for a warrant.

183 Subsection (5) prescribes that any regulations made under this section are subject to the draft affirmative procedure.

29: Meaning of "Part 3 obligation"

184 This section describes the meaning of obligation under Part 3.

185 Subsection (1) provides a definition of a "Part 3 obligation".

186 Subsection (2) clarifies that an obligation to comply with the conditions of a food and feed marketing authorisation is included within the scope of a "Part 3 obligation" in addition to any requirement imposed by an inspector in exercise of functions conferred upon them.

187 Subsection (3) specifies the obligations which fall outside of scope of the definition of a "Part 3 obligation".

188 Subsection (4) allows regulations to provide that a failure to comply with a Part 3 obligation can also relate to the provision of misleading or false information in relation to a Part 3 obligation or an authorisation"

189 Subsection (5) provides that "requirement" includes "prohibition" for these purposes.

190 Subsection (6) prescribes that any regulations made under this section are subject to the draft affirmative procedure.

30: Interpretation of Part 3

191 This section sets out definitions and clarifications used in association with Part 3.

192 Subsection (1) provides definitions of terms that are used in Part 3 of the Act. These terms are frequently used across food legislation, both in retained EU law and domestic food law. Definitions of key terms including 'food' and 'feed' are aligned with the definitions in retained Regulation (EC) 178/2002, which is the main piece of retained direct principal EU legislation governing the regulation of food in England.

193 Subsection (2) outlines that products in Part 3 are defined as being produced from precision bred organisms if they contain or consist of the whole or parts of a precision bred organism.

194 Subsection (3) outlines that 'placing on the market' means the holding of food or feed for the purpose of sale- including offering for sale or any other form of transfer whether free of charge or not- and the sale, distribution, and other forms of transfer themselves, in line with Article 3(8) of retained Regulation (EC) 178/2002. The term "placing on the market" is defined broadly in retained EU food law to extend to the holding of the food and feed for the purpose of the sale.

Part 4: Enforcement

Enforcement of relevant breaches: general provisions

31: Meaning of "relevant breach" etc

195 This section sets out provisions regarding a "relevant breach".

196 Subsection (1) contains a definition of what a "relevant breach" means for the purposes of this Act.

197 Subsection (2) provides that in Part 4, an "inspector" means an appointed inspector under section 19 or under regulations under section 28.

198 Subsection (3) grants powers to create regulations that may outline certain circumstances where a failure to comply with a Part 3 obligation will not be deemed to constitute a relevant breach. Such circumstances may include where the breach was due to the fault of another person or where a person can demonstrate that they took all reasonable precautions and exercised due diligence to avoid the breach in question. Subsection (a) also provides a power for regulations to enable the transfer of liability to another person in circumstances where the commission of the relevant breach was due to the fault of that other person.

199 Subsection (4) confirms that regulations relating to this subsection are subject to the draft affirmative procedure.

32: Enforcement

200 This section sets out provisions regarding enforcement.

201 Subsection (1) enables the Secretary of State to make provisions in regulations with respect to the issuing of compliance notices, stop notices and monetary penalty notices.

202 Subsection (2) grants powers to make regulations to ensure that requirements included in the stop notice can be legally enforced in the courts by way of application for an injunction by the Secretary of State.

203 Subsection (3) describes what "enforcement notice" means.

204 Subsection (4) confirms that regulations relating to this subsection are subject to the draft affirmative procedure.

Enforcement notices

33: Compliance notices

205 This section sets out provisions regarding compliance notices.

206 Subsection (1) describes what a "compliance notice" means.

207 Subsection (2) provides for the conditions for the issue of a compliance notice under regulations.

208 Subsection (3) signposts the sections where further provisions about compliance notices are made.

209 Subsection (4) clarifies that for a step to have been "specified" it must have been specified as such in the compliance notice.

34: Stop notices

210 This section sets out provisions regarding stop notices. Subsection (1) describes what a "stop notice" means.

211 Subsection (2) provides for conditions for the issue of a stop notice under regulations.

212 Subsection (3) signposts the sections where further provisions about stop notices are made.

213 Subsection (4) clarifies that for a step to have been "specified" it must have been specified as such in the stop notice.

35: Monetary penalty notices

214 This section sets out provisions regarding monetary penalty notices. Subsection (1) describes what a "monetary penalty notice" is for the purposes of this Act.

215 Subsection (2) defines the "appropriate authority" for the purposes of the monetary penalty notice.

216 Subsection (3) provides for the Secretary of State to make provisions for a monetary penalty to be imposed as a sanction to a relevant offence by the Secretary of State or an inspector only when satisfied that the person has committed a relevant breach.

217 Subsection (4) provides for the Secretary of State to make provisions for the manner in which the payments are made, the period within the payment must be made and the consequences of late payment.

218 Subsection (5) provides for the Secretary of State to make provisions for the payment of interest on late payment and for how any amounts payable are to be recoverable.

36: Content of enforcement notices: further provision

219 This section sets out further provisions on enforcement notices. Subsections (1) and (2) set out the requirements and the information which must be included in an enforcement notice when served by the Secretary of State on a person.

220 Subsection (3) states regulations made to enable the issuance of enforcement notices may provide for the conferral of powers on an inspector or the Secretary of State (as appropriate) to amend or revoke such notices.

37: Enforcement notices: reviews and appeals

221 This section sets out provisions on reviews and appeals of enforcement notices. Subsection (1) provides that regulations must secure that the person served an enforcement notice has the right to review and appeal against that notice being served and provides for the grounds on which that appeal can be made, make an appeal to the First-tier tribunal, and provides for further regulations to be made in relation to the notice pending the outcome of the appeal.

222 Subsection (2) provides that regulations may make provision conferring on the Secretary of State and the First-tier Tribunal functions for the purposes of them carrying out their roles on a review of a decision to issue an enforcement notice and on an appeal of the outcome of that review respectively.

Costs

38: Costs

223 This section sets out provisions regarding costs. Subsection (1) grants powers to create regulations that may allow the appropriate authority, by a "cost notice", to recover costs incurred by them in relation to the issuance of an enforcement notice

224 Subsection (2) established what "appropriate authority" means.

225 Subsection (3) contains a non-exhaustive definition of "costs" for the purposes of subsection (1).

226 Subsection (4) requires that any regulations made under subsection (1) must ensure that notices specify the amount payable, and satisfy requirements for issuing the costs notice, in accordance with points (a) to (e).

227 Subsection (5) states regulations must include provisions granting a right of appeal for the person(s) to whom a costs notice has been served and the suspension of the operation of a costs notice pending the outcome of any appeal which has been brought.

228 Subsection (6) provides the definition for a "relevant decision".

229 Subsection (7) states regulations made under this section may also include provisions related to the collections of costs prescribed by cost notices and interest on late payment.

230 Subsection (8) confirms that regulations relating to this subsection will be subject to the draft affirmative procedure.

Part 5: General

39: Fees

231 This section sets out provisions regarding fees.

232 Subsection (1) is a power to enable regulations to be made which make provision for a fee to be made payable, in respect of the exercise of certain functions, to the appropriate authority as defined in subsection (2).

233 Subsection (3) sets out the information relating to the payment of fees that must be included within regulations made under powers granted in this section.

234 Subsection (4) relates to the desirability of, as far as possible, setting fees that are equal to the cost of providing the function.

235 Subsection (5) confirms that regulations relating to this subsection will subject to the draft affirmative procedure.

40: Notices and documents

236 This section provides for the Secretary of State to make regulations in respect of how a notice or other document is issued or confirmed as being received under this part.

237 Subsection (2) confirms that regulations brought forward under this section will be subject to the negative procedure.

41: Consequential amendment of the Environmental Protection Act 1990

238 This section makes consequential amendments to the Environmental Protection Act 1990.

239 Subsection (2) inserts a new section (106A) into the Environmental Protection Act 1990 in order to exclude precision bred organisms from Part VI of the Act as it applies in relation to England and describes the circumstances where this subsection applies.

240 Subsection (3) inserts into section 124(1) of the Environmental Protection Act 1990, which establishes an advisory committee, a cross-reference to the additional functions of that committee provided for under this Act.

42: Powers to make Consequential Provision

241 This section sets out further powers for consequential provisions in connection with any provision of or made under this Act. Subsection (1) gives powers to make supplementary, incidental and consequential provisions by regulations, which could be used to modify primary legislation, retained direct EU legislation or subordinate legislation. (See sections 43 and 44 for additional details).

242 Subsection (3) provides that regulations made under these powers will be subject to the draft affirmative procedure if they contain provision modifying primary legislation.

243 Subsection (4) provides that other regulations made under these powers will be subject to the negative procedure.

43: Regulations

244 Subsection (1) states this section relates to all regulations made under this Act, apart from the commencement regulations

245 Subsections (2) to (3) provide that regulations made under this Act are to be made by statutory instrument and may make transitional, transitory or saving provisions; and that different provision may be made for different purposes or areas.

246 Subsection (4) provides for regulations made under the draft affirmative procedure to be laid before and approved by a resolution of each House of Parliament before they are made.

247 Subsection (5) provides what is meant by "the negative resolution procedure" in relation to regulations made under this Act.

248 Subsection (6) provides that regulations made under the negative procedure may be made subject to the draft affirmative procedure.

44: Interpretation

249 This provision defines various terms used for the purposes of this Act.

45: Financial provisions

250 This section provides that any expenditure incurred under or by virtue of this Act by the Secretary of State or by the Food Standards Agency, and any sums payable out of money so provided under any other Act are to be paid out of money provided by Parliament.

46: Crown application

251 Subsection (1) provides for the Act to apply to the Crown.

252 Subsection (2) provides the Secretary of State with power to certify on grounds of national security that powers of entry may not be exercised in respect of certain Crown premises.

253 Subsection (3) defines "Crown premises" for the purpose of this Act.

254 Subsection (4) provides an exemption to powers of entry in relation to His Majesty's private estates and subsection (5) notes that his private estates are defined in the Crown Private Estates Act 1862.

47: Extent and application to sea areas

255 Section 47 establishes the extent and territorial applications of various Parts of this Act.

48: Short title and Commencement

256 Subsection (1) provides that the title for this Act will be "Genetic Technology (Precision Breeding) Act 2023".

257 Subsection (2) to (5) provide that Parts 1 and 5 (except sections 39-41) come into force on Royal Assent, as do regulation making powers under the Act. In other respects, the Act comes into force as appointed by commencement regulations.

258 Subsections (6) to (8) enable the Secretary of State, by regulations, to make provisions in connection with the coming into force of the provisions of the Act and provide for such regulations to be made by statutory instrument. Commencement regulations under this section are not subject to Parliamentary procedure.

Commencement

259 Part 1 comes into force on the day on which this Act is passed.

260 Parts 2 to 4 and sections 39 and 40 come into force— (a) so far as necessary to enable the exercise of any power to make regulations, on the day on which this Act is passed; (b) for remaining purposes, on such day as regulations may appoint.

261 Section 41 comes into force on such day as regulations may appoint. The rest of Part 5 comes into force on the day on which this Act is passed. Regulations under this section may appoint different days for different purposes. Regulations may make transitional, transitory, or saving provision in connection with the coming into force of any provision of this Act. Regulations under this section are to be made by statutory instrument.

Related documents

262 The following documents are relevant to the Act and can be read at the stated locations:

- Government Response to "*The Regulation of Genetic Technologies*" consultation
- ACRE advice: the regulation of genetic technologies - GOV.UK (www.gov.uk)
- EUR-Lex - 62016CJ0528 - EN - EUR-Lex (europa.eu)

Annex A - Territorial extent and application

263 Section 47 sets out the territorial extent of the provisions of the Act. The extent of an Act is the legal jurisdiction of which it forms part of the law; application refers to where it has practical effect.

264 The regulation of precision bred organisms is a devolved matter and most of the provisions of this Act extend to England and Wales only and apply in relation to England only. Section 41 amends legislation which extends to England and Wales and Scotland, so that section and the definitions in Part 1 of the Act to which those amendments refer likewise extend to England and Wales and Scotland. The general provisions in sections 42 to 48 extend to England and Wales and Scotland and Northern Ireland.

Provision	Extends to E & W and applies to England?	Extends to E & W and applies to Wales?	Extends and applies to Scotland?	Extends and applies to Northern Ireland?	Would corresponding provision be within the competence of the National Assembly for Wales?	Would corresponding provision be within the competence of the Scottish Parliament?	Would corresponding provision be within the competence of the Northern Ireland Assembly?	Legislative Consent Motion needed?
Part 1 and section 41	Yes	Yes	Yes	No	Yes	Yes	Yes	No
Section 42-48	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
All other sections	Yes	No	No	No	Yes	Yes	Yes	No

Annex B - Hansard References

265 The following table sets out the dates and Hansard references for each stage of the Act's passage through Parliament.

Stage	Date	Hansard Reference
House of Commons		
First Reading	25 May 2022	Vol. 715 Col. 317
Second Reading	15 June 2022	Vol. 716 Col. 374
Programme Motion	15 June 2022	Vol 716. Col. 401
Money Resolution	15 June 2022	Vol 716. Col. 401
Public Bill Committee	28 June 2022 30 June 2022	Official Report
Report and Third Reading	31 October 2022	Vol. 721 Col. 668
House of Lords		
First Reading	1 November 2022	Vol. 825 Col. 126
Second Reading	21 November 2022	Vol. 825 Col. 1196
Committee of the whole House	12 December 2022	Vol. 826 Col. 463
	14 December 2022	Vol. 826 Col. 666
	14 December 2022	Vol. 826 Col. 707
Report	25 January 2023	Vol. 827 Col. 218
Third Reading	01 February 2023	Vol. 827 Col. 684
Royal Assent	24 March 2023	Vol. 828 Col. 1957

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