

# Genetic Technology (Precision Breeding) Bill

Memorandum from the Department for the Environment, Food and Rural Affairs to the Delegated Powers and Regulatory Reform Committee

## CONTENTS

1. INTRODUCTION

2. PURPOSE AND EFFECT OF THE BILL

3. SUMMARY OF DELEGATED POWERS

4. ANALYSIS OF DELEGATED POWERS BY CLAUSE

ANNEX A - NON-LEGISLATIVE POWERS

ANNEX B – TABLE OF DELEGATED POWERS

## 1. Introduction

1. This memorandum has been prepared for the Delegated Powers and Regulatory Reform Committee by the Department for Environment, Food and Rural Affairs (“the Department”) to assist with its scrutiny of the Genetic Technology (Precision Breeding) Bill (“the Bill”).
2. The Bill contains 28 provisions which include delegated powers, which are set out in Annex B. The Department has considered the use of powers in the Bill as set out below and is satisfied that they are necessary and justified.
3. This memorandum refers to other powers in the Bill which do not confer powers to make delegated legislation, but which relate to administrative functions which may be of interest to the Committee. These are listed and summarised separately in Annex A.

## 2. Purpose and effect of the Bill

### 4. The purpose of the Bill is to:

- a. Remove plants and animals produced through precision breeding technologies from regulatory requirements applicable to GMOs (Genetically Modified Organisms).
- b. Introduce two replacement regulatory systems; one for precision bred organisms used for research purposes and the other for marketing purposes. The information collected will be published on a public register on GOV.UK.
- c. Establish a new science-based authorisation process for food and feed products developed using precision bred organisms.

### 5. The Bill applies substantively to England only.

### 6. The Bill is structured in 5 Parts.

### 3. Summary of delegated powers

7. Part 1 of the Bill deals with key definitions. The delegated power in clause 1 allows aspects of the definition of “modern biotechnology” to be amended by regulations where corresponding changes in other legislation have been made. As it can be used to amend primary legislation, it constitutes a Henry VIII power but is narrow in scope and can only be used in limited circumstances.
8. Part 2 of the Bill contains provision to regulate the release and marketing of precision bred organisms, together with a provision for risk assessments. Part 3 of the Bill contains provision to regulate food and feed produced from such organisms.
9. As these Parts involve regulatory activity, a significant proportion of the delegated powers in these Parts are powers to prescribe largely administrative matters and process in relation to applications and how they are dealt with by the relevant public bodies.
10. As with the delegated power in Part 1, the power in clause 10(2) concerns a Henry VIII power to amend definitions. Again, it is narrow in scope and can only be used in circumstances where corresponding definitions in other legislation have been amended.
11. The power in clause 26(1) is broader in nature, a general power to regulate food and feed produced from precision bred organisms.
12. Part 4 of the Bill concerns enforcement. Under clauses 31 to 38, matters of enforcement are dealt with under delegated powers. While these clauses set out elements of policy which are to be achieved through regulations, this will allow the enforcement provisions to be tailored to deal with the different regulatory requirements imposed under the Bill.
13. Part 5 of the Bill contains powers which are common to most Bills – powers to make consequential provision, to make commencement regulations and make transitional etc provision in connection with the Bill provisions coming into force. The power to make consequential provision is a Henry VIII power and its potential scope is wide (in terms of the primary legislation which may be amended by it), though it may only be exercised for narrow purposes.
14. As set out above, there are three Henry VIII powers in the Bill.

## 4. Analysis of delegated powers by clause

### **Part 1 – Precision Breeding: Definitions**

#### **Clause 1(8): Precision bred organism: power to make corresponding changes to definition of “modern biotechnology”**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Affirmative resolution procedure*

#### **Context and purpose**

15. The definition of “modern biotechnology” in clause 1(3) is used for the purposes of defining whether an organism is “precision bred” under clause 1(2).
16. The definition of “modern biotechnology” set out in the Bill cross refers to provisions in the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443) (“the Deliberate Release Regulations”).

#### **Justification for taking the power**

17. The Department considers that it is necessary and appropriate, if any amendments are made to the definition of “modern biotechnology” set out in the Deliberate Release Regulations, for it to be possible to make corresponding changes to the definition as it applies to this Bill. This will be important to ensure that the regime applicable to genetically modified organisms under the Environmental Protection Act 1990 aligns correctly with the provisions in this Bill regulating precision bred organisms.

#### **Justification for the procedure**

18. The Department considers that as regulations made under this power would amend primary legislation in a way that affects a key definition for the purposes of the Bill, they are likely to be of particular interest to Parliament and has therefore proposed that the regulations are subject to the affirmative procedure.

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

#### **Clause 4(2): Release of precision bred organism: notification requirements: prescribing the form of a release notice and any accompanying information requirements, and imposing minimum period between notice and release**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Negative resolution procedure*

#### Context and purpose

19. Under clause 3(1)(a), there is a prohibition on releasing a precision bred organism unless the person has satisfied the notification requirements in relation to the organism. (The other exceptions from the prohibition in clause 3(1), which concern progeny of precision bred organisms which may be released in England, also presuppose that the notification requirements have been complied with).
20. Clause 4 sets out the notification requirements. Clause 4(2) provides for the Secretary of State to prescribe in regulations the form of the notice which must be given, and other information which must be provided alongside the notice. Further, clause 4(2)(b) allows for the Secretary of State to require a minimum period to have elapsed between the notification requirements having been satisfied and the relevant organism being released, in the interests of transparency.

#### Justification for taking the power

21. The power allows the Secretary of State to deal with administrative matters relating to the notification requirement, which might warrant adjustment from time to time, through regulations. The Department considers this an appropriate approach.

#### Justification for the procedure

22. The Department proposes that as the power concerns administrative matters relating to the notification requirement, it is appropriate for this power to be subject to the negative resolution procedure.

#### **Clause 6(2): Application for precision bred confirmation: prescribing the form of a marketing notice and any accompanying information requirements**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Negative resolution procedure*

#### Context and purpose

23. Under clause 6(1), there is a prohibition on marketing a precision bred organism unless the organism is a marketable precision bred organism or is the qualifying progeny of such an organism.
24. Clause 6(2) defines “marketable precision bred organism”. In order to be such an organism, there must be a precision bred confirmation in respect of that organism in force.
25. Clause 7(1) provides for a person to apply for a precision bred confirmation in respect of an organism, by giving notice to the Secretary of State (defined as a “marketing notice”).
26. The power in clause 7(2) allows for the Secretary of State to prescribe the form of a marketing notice and any information which must accompany the notice.

#### Justification for taking the power

27. The power allows the Secretary of State to deal with administrative matters relating to the marketing notice, which might warrant adjustment from time to time, through regulations. The Department considers this an appropriate approach.

#### Justification for the procedure

28. The Department proposes that as the power concerns administrative matters relating to the marketing notice, it is appropriate for this power to be subject to the negative resolution procedure.

#### **Clause 9(1): Revocation of precision bred confirmation: conferring power to revoke precision bred confirmation and procedure to be followed**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Negative resolution procedure*

#### Context and purpose

29. Under clause 5(1), there is a prohibition on marketing a precision bred organism unless the organism is a marketable precision bred organism or is the qualifying progeny of such an organism.
30. Clauses 6 to 8 govern the process through which a precision bred confirmation can be applied for, considered and issued.
31. The precision bred confirmation issued under clause 8 records the fact that the Secretary of State is satisfied that the organism is precision bred for the purposes of this Bill, based on the information available to the Secretary of State.
32. If, having issued the precision bred confirmation, the Secretary of State is no longer satisfied that the organism is precision bred – for example, as a result of additional relevant information being available to the Secretary of State – it is considered appropriate that the Secretary of State should have power to revoke the precision bred confirmation that was issued.

### Justification for taking the power

33. The Department considers it appropriate that, where the Secretary of State is no longer satisfied that the organism is precision bred, the precision bred confirmation should be revoked so as to prevent releases or marketing of that organism.
34. The Department considers that while the purpose to be served by the Secretary of State having a power to revoke a precision bred confirmation is clear, it is appropriate for there to be a process governing how such revocation should take place, and there will be consequential matters to deal with following a revocation (including the need for appropriate adjustments in the precision bred organisms register provided for under clause 18). Such matters might warrant adjustment from time to time and are therefore better dealt with through regulations.

### Justification for the procedure

35. The Department proposes that as the power concerns the Secretary of State having appropriate ability to revoke a precision bred confirmation where no longer satisfied that it is appropriate, in addition to procedural and administrative matters relating to such a revocation, it is appropriate for this power to be subject to the negative resolution procedure.

### **Clause 10(2): “Relevant animal”: extend definition to cover invertebrates**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Affirmative resolution procedure*

### Context and purpose

36. Clause 10(1) defines “relevant animal”, principally for the purposes of clause 11 and associated provisions which govern precision bred animal marketing authorisations.
37. Under clause 5, a person must not market a precision bred organism which is a relevant animal unless there is in force both a precision bred confirmation and a precision bred animal marketing authorisation in respect of that animal (see clause 5(2)(b) as regards the definition of “marketable precision bred organism” in relation to relevant animals).
38. The definition of “relevant animal” in clause 10(1) covers all animals which are vertebrates. Clause 10(3) provides that “vertebrates” for these purposes has the meaning given under section 1(5) of the Animal Welfare Act 2006.
39. Clause 10(2) provides that if the definition of “animal” in the Animal Welfare Act 2006 is extended under section 1(3) of that Act to include invertebrates of any description, the Secretary of State has power to amend the definition of “relevant animal” in this Bill so as to include such additional invertebrates of that description.

### Justification for taking the power



40. The policy intention is for the procedures for safeguarding the health and welfare of animals in this Bill to apply to the same animals as are covered by the Animal Welfare Act 2006. However, this intention is complicated by the fact that the power in section 1(3) of that Act allows for the definition to be extended for some purposes and not others. If that were to happen, there would not be a single definition under the 2006 Act which could be referred to for the purposes of this Bill.

41. In order to ensure that the definition of “relevant animal” is sufficiently clear and certain, while substantively aligning with the definition(s) in the 2006 Act, the Department considers that it is necessary and appropriate, if any amendments are made to the definition of “animal” in the Animal Welfare Act 2006 using the power to extend the definition in section 1(3) of that Act, for it to be possible to make corresponding changes to the definition as it applies to this Bill.

#### Justification for the procedure

42. The Department considers that as regulations made under this power would amend primary legislation in a way that affects a key definition for the purposes of the Bill, they are likely to be of particular interest to Parliament and has therefore proposed that the regulations are subject to the affirmative procedure.

#### **Clause 11(5): Application for precision bred animal marketing authorisation: prescribing the form for applications and accompanying information requirements**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Negative resolution procedure*

#### Context and purpose

43. Clause 10(1) defines “relevant animal”, principally for the purposes of clause 11 and associated provisions which govern precision bred animal marketing authorisations.

44. Under clause 5, a person must not market a precision bred organism which is a relevant animal unless there is in force both a precision bred confirmation and a precision bred animal marketing authorisation in respect of that animal (see clause 5(2)(b) as regards the definition of “marketable precision bred organism” in relation to relevant animals).

45. Clause 6(1) provides for a person to apply for a precision bred confirmation in respect of an organism, by giving notice to the Secretary of State (defined as a “marketing notice”).

46. Clause 11 provides for a person who gives a marketing notice in relation to a relevant animal to apply for a precision bred animal marketing authorisation in relation to that relevant animal also.

47. Clause 11(3) provides that an application must include an animal welfare declaration, under which the notifier declares that they do not expect the health or welfare of the relevant animal (or its progeny) to be adversely affected by any trait resulting from precision breeding.

48. Clause 11(4) provides that an application must include an assessment of the risks to the health or welfare of the relevant animal (or its progeny) which could be reasonably expected to result from any trait resulting from precision breeding, together with an explanation of the steps taken by the notifier to identify such risks.

49. Without prejudice to the substance of those requirements in clause 11(3) and (4), clause 11(5) provides the Secretary of State with power to make regulations to prescribe the form and content of an application for a precision bred animal marketing authorisation and any further information which must accompany the application.

#### Justification for taking the power

50. The power allows the Secretary of State to deal with administrative matters relating to the application for a precision bred animal marketing authorisation, which might warrant adjustment from time to time, through regulations. The Department considers this an appropriate approach.

#### Justification for the procedure

51. The Department proposes that as the power concerns administrative matters relating to the application for a precision bred animal marketing authorisation, it is appropriate for this power to be subject to the negative resolution procedure.

#### **Clause 11(9): Application for precision bred animal marketing authorisation: prescribing circumstances in which an application for a health and welfare marketing authorisation may be made by someone other than the person who gave the marketing notice.**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Negative resolution procedure*

#### Context and purpose

52. Clause 10(1) defines “relevant animal”, principally for the purposes of clause 11 and associated provisions which govern precision bred animal marketing authorisations.

53. Under clause 5, a person must not market a precision bred organism which is a relevant animal unless there is in force both a precision bred confirmation and a precision bred animal marketing authorisation in respect of that animal (see clause 5(2)(b) as regards the definition of “marketable precision bred organism” in relation to relevant animals).

54. Clause 6(1) provides for a person to apply for a precision bred confirmation in respect of an organism, by giving notice to the Secretary of State (defined as a “marketing notice”).

55. Clause 11 provides for a person who gives a marketing notice in relation to a relevant animal to apply for a precision bred animal marketing authorisation in relation to that relevant animal also.

56. Clause 11(9) provides the Secretary of State with power to prescribe by regulations the circumstances in which an application for a precision bred animal marketing authorisation in relation to a relevant animal may be made by a person other than the notifier.

57. Clause 11(9) provides that where a person other than the notifier makes the application for a precision bred animal marketing authorisation in relation to a relevant animal pursuant to

such regulations, references to the notifier in relation to the marketing authorisation and an application for it are to be read as references to that other person instead.

#### Justification for taking the power

58. The Department considers that the ability for another person than the person who gave a marketing notice to apply for a precision bred animal marketing authorisation may provide useful flexibility to the regime but anticipates that it may not be appropriate in all circumstances, and it is possible that the circumstances may warrant adjustment from time to time. Accordingly, the Department considers it appropriate to deal with the matter through regulations.

#### Justification for the procedure

59. The Department considers that as this is a narrow power relating to a point of detail in relation to the application process for a precision bred animal marketing authorisation, the negative resolution procedure is appropriate.

#### **Clause 12(3): Report by welfare advisory body: specifying the reporting period within which the welfare advisory body must provide its report (and may require additional information from the notifier)**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Negative resolution procedure*

#### Context and purpose

60. Under clause 11(6), after receiving an application for a precision bred animal marketing authorisation, the Secretary of State must refer the application to the welfare advisory body for their advice by sending them the relevant documents and information.

61. Clause 12 provides for the welfare advisory body to provide their advice to the Secretary of State by way of a report before the end of the reporting period.

62. Clause 12(3) provides the Secretary of State with power to prescribe by regulations the length of the reporting period, which period begins with the day on which the application is referred to the welfare advisory body.

63. The reporting period prescribed by such regulations is relevant to the consideration of the power in clause 23(1) to provide for a reporting period not to run, and for applications to be treated as withdrawn, where information notices are outstanding, discussed below.

#### Justification for taking the power

64. The Department considers that the decision as to the period within which the welfare advisory body must provide its advice to the Secretary of State is an administrative one, and one which may warrant adjustment from time to time, and the Department accordingly considers it appropriate to deal with the matter through regulations.

#### Justification for the procedure

65. The Department considers that as this is a narrow point of administrative detail in relation to the application for a precision bred animal marketing authorisation, the negative resolution procedure is appropriate.

#### **Clause 14: Precision bred animal marketing authorisations: reporting obligations: requiring the notifier and other persons to provide prescribed information about a precision bred animal and its progeny**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Affirmative resolution procedure*

#### Context and purpose

66. Clause 10(1) defines “relevant animal”, principally for the purposes of clause 11 and associated provisions which govern precision bred animal marketing authorisations.

67. Under clause 5, a person must not market a precision bred organism which is a relevant animal unless there is in force both a precision bred confirmation and a precision bred animal marketing authorisation in respect of that animal (see clause 5(2)(b) as regards the definition of “marketable precision bred organism” in relation to relevant animals).

68. Clause 6(1) provides for a person to apply for a precision bred confirmation in respect of an organism, by giving notice to the Secretary of State (defined as a “marketing notice”).

69. Clause 11 provides for a person who gives a marketing notice in relation to a relevant animal to apply for a precision bred animal marketing authorisation in relation to that relevant animal also.

70. Clause 11(9) provides power for the Secretary of State to prescribe circumstances in which a person other than the person who gave the marketing notice in relation to the relevant animal may apply for a precision bred animal marketing authorisation in respect of that relevant animal. In those circumstances, the other person will be treated as “the notifier” instead for the purposes of relevant provisions in the Bill.

71. Clause 14 provides power for the Secretary of State to impose requirements on the notifier (or on another person as set out in the Regulations). There are two types of requirement which may be imposed.

72. The first is a requirement to provide the Secretary of State with prescribed information about the health or welfare of the relevant animal (or its progeny).

73. The second arises in circumstances where the notifier (or other prescribed person) provides the relevant animal or its progeny to another person. The second requirement is a requirement that the notifier (or other prescribed person) take prescribed steps to collect

information falling within the first requirement, or enable/facilitate the collection of such information, from the person to whom the relevant animal (or its progeny) has been provided.

74. Clause 15 contains provisions which are relevant to circumstances where the obligations imposed under clause 14 have not been complied with.

#### Justification for taking the power

75. The Department considers that this power to impose reporting requirements provides a valuable mechanism for securing assurance in relation to relevant animals covered by a precision bred animal marketing authorisation once they begin to be marketed.
76. The Department considers that it is appropriate for these obligations to be imposed by regulations, as this will allow the requirements to be set out in appropriate detail in respect of different circumstances and will allow the requirements to be adjusted from time to time.

#### Justification for the procedure

77. The Department anticipates that the subject matter and detail of regulations made under this power will be of great interest to Parliament and accordingly proposes the affirmative procedure.

#### **Clause 15(1): Suspension and revocation of precision bred animal marketing authorisation: prescribing circumstances in which the Secretary of State may suspend or revoke a precision bred animal marketing authorisation**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Negative resolution procedure*

#### Context and purpose

78. Clause 10(1) defines “relevant animal”, principally for the purposes of clause 11 and associated provisions which govern precision bred animal marketing authorisations.
79. Under clause 5, a person must not market a precision bred organism which is a relevant animal unless there is in force both a precision bred confirmation and a precision bred animal marketing authorisation in respect of that animal (see clause 5(2)(b) as regards the definition of “marketable precision bred organism” in relation to relevant animals).
80. Clause 6(1) provides for a person to apply for a precision bred confirmation in respect of an organism, by giving notice to the Secretary of State (defined as a “marketing notice”).
81. Clause 11 provides for a person who gives a marketing notice in relation to a relevant animal to apply for a precision bred animal marketing authorisation in relation to that relevant animal also.
82. Clause 15 provides for the Secretary of State to make regulations which allow the Secretary of State to suspend or revoke a precision bred animal marketing authorisation.
83. Such regulations may include provision allowing the Secretary of State to suspend a precision bred animal marketing authorisation where there has been a breach of the reporting

obligations imposed under clause 14, or where the Secretary of State receives information relating to the health or welfare of the relevant animal (or its progeny).

84. Such regulations may also include provision allowing the Secretary of State to revoke a precision bred animal marketing authorisation where there has been a breach of the reporting obligations imposed under clause 14, or where the Secretary of State considers that the health or welfare of the relevant animal (or its progeny) is likely to be adversely affected by traits resulting from precision breeding.
85. Such regulations must make provision for the procedure applicable to suspensions and revocations, including an opportunity for affected persons to make representations. They must also deal with the consequences arising where a precision bred animal marketing authorisation has been suspended or revoked, including the provision to be made in the register in respect of it, without prejudice to the possibility that enforcement notices may be issued under clause 32 in respect of any relevant breach which has taken place for the purposes of this Bill. As part of such provision, the Secretary of State may prescribe functions to be conferred on the welfare advisory body.

#### Justification for taking the power

86. The Department considers that the ability to suspend and revoke precision bred animal marketing authorisations provides valuable assurance in relation to the health and welfare of relevant animals which are marketed. In particular, it reinforces the enforcement provisions under this Bill so as to help ensure that the reporting obligations imposed by clause 14 are complied with.
87. The Department considers that it is appropriate for these provisions to be imposed by regulations, as this will allow the requirements to be set out in appropriate detail in respect of different circumstances and will allow the requirements to be adjusted from time to time.

#### Justification for the procedure

88. The Department anticipates that the subject matter and detail of regulations made under this power will be of great interest to Parliament and accordingly proposes the affirmative procedure.

#### **Clause 16(1): Reviews and appeals relating to Part 2: prescribing process**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Negative resolution procedure*

#### Context and purpose

89. Part 2 to the Bill contains a number of provisions under which the Secretary of State takes important decisions, including those listed in clause 16(3): to refuse applications for a

precision bred confirmation or a precision bred animal marketing authorisation, or to revoke (or suspend, as regards the latter) any which have been issued.

90. Clause 16(1) provides that the Secretary of State must make provision by regulations in respect of reviews and appeals concerning such decisions. Clause 16(2) contains various elements of policy which such regulations must reflect.

#### Justification for taking the power

91. The Department considers that it is appropriate for the detail of the review and appeal processes to be dealt with by regulations, as this will allow relevant matters to be set out in appropriate detail in respect of different circumstances and will allow the requirements to be adjusted from time to time.

#### Justification for the procedure

92. The Department proposes that as the key substantive requirements of the review and appeal processes are set out in clause 16(2), it is appropriate for the regulations to be subject to the negative procedure.

### **Clause 17(1): Restrictions on the importation and acquisition of precision bred organisms in England: power to impose environmental risk assessment duty**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Negative resolution procedure*

#### Context and purpose

93. Clause 17(1) allows for the Secretary of State to make regulations requiring a person to carry out an environmental risk assessment before importing a precision bred organism where its destination is in England or acquiring a precision bred organism which is in England.

94. This allows the Secretary of State to make equivalent provision for such environmental risk assessments as is currently provided for under section 108(1)(a) of the Environmental Protection Act 1990 in respect of the import or acquisition of genetically modified organisms which are precision bred organisms under this Bill. The existing requirement to carry out such environmental risk assessments in those circumstances will be removed when the amendment to the 1990 Act in clause 42, which is consequential on the wider policy set out in this Bill, comes into force.

95. The Secretary of State proposes to retain the substantive obligations to carry out environmental risk assessments in respect of import and acquisition only so as to maintain the existing arrangements in respect of contained use for genetically modified organisms and precision bred organisms. In other respects, the Secretary of State does not propose to retain those obligations under the 1990 Act, as part of the wider policy in respect of precision bred organisms set out in this Bill.

#### Justification for taking the power

96. The Department considers that it is appropriate to set out the relevant obligations in regulations. The corresponding provision in the 1990 Act allowed for the detail in relation to risk assessments to be set out in regulations, together with exemption provisions.

#### Justification for the procedure

97. The Department proposes that as the regulations will primarily be concerned with matters of detail concerning the nature of the risk assessment to be carried out, it is appropriate for this power to be subject to the negative procedure.

#### **Clause 18(6): Precision breeding register: provisions as to keeping of register**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Negative resolution procedure*

#### Context and purpose

98. Clause 18(1) imposes a duty on the Secretary of State to establish and maintain a register containing information in relation to various matters arising under the Bill.

99. Clause 18(5) requires that the register be accessible to the public free of charge and by electronic means.

100. Clause 18(2) to (4) contains provision as regards information which must not be included on the register for reasons of commercial confidentiality, and information which cannot be excluded from the register for reasons of commercial confidentiality.

101. Without prejudice to these requirements, clause 18(6) allows the Secretary of State to make regulations in respect of the keeping of the register, which includes prescribing information and additional matters for the purposes of clause 18(1).

#### Justification for taking the power

102. The Department considers that it is appropriate for the detail of the keeping of the register to be dealt with by regulations, as this will allow relevant matters to be set out in appropriate detail in respect of different circumstances and will allow the requirements to be adjusted from time to time.

#### Justification for the procedure

103. The Department proposes that as the key substantive requirements in respect of the register are set out elsewhere in clause 18, it is appropriate for the regulations to be subject to the negative procedure.

#### **Clause 20(1): Monitoring and inspection of Part 2 obligations: power to make provision for monitoring compliance and investigating suspected non-compliance**

*Power conferred on: Secretary of State*



*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Affirmative resolution procedure*

#### Context and purpose

104. Clause 21(1) defines “Part 2 obligations” under the Bill concerning enforcement.
105. Clause 20(1) provides the Secretary of State with power to make regulations for monitoring compliance with Part 2 obligations and investigating suspected failures to comply. Clause 20(2) sets out substantive matters which such regulations may cover, including the appointment of inspectors and the conferral of functions upon them.
106. Clause 20(3) contains constraints upon the regulation making power in clause 20(1), both as regards what it may not contain (criminal offences, powers of entry into a private dwelling without a warrant, the use of force in respect of a power of entry) and what regulations must include (prohibition on wider use or disclosure).

#### Justification for taking the power

107. The Department considers that it is appropriate for the detail of enforcement provisions in respect of Part 2 obligations to be set out through regulations, given that clause 20(2) and (3) set out the key elements of policy in respect of the matter.

#### Justification for the procedure

108. The Department considers that while clause 20(2) and (3) set out the key elements of policy, nevertheless enforcement powers are a subject matter of great interest to Parliament, and it accordingly proposes the affirmative procedure.

### **Clause 22(3): Advisory bodies: designation of welfare advisory body**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Negative resolution procedure; but affirmative if the regulations include consequential provision that amends or repeals an Act*

#### Context and purpose

109. Under clause 11(6), after receiving an application for a precision bred animal marketing authorisation, the Secretary of State must refer the application to the welfare advisory body for their advice by sending them the relevant documents and information.
110. Clause 12 provides for the welfare advisory body to provide their advice to the Secretary of State by way of a report before the end of the reporting period.
111. The provision of advice under clause 12 is the principal function for the welfare advisory body, though there are other functions (for example, under clause 22(5) and, potentially, pursuant to regulations made under clause 15(3) in relation to the suspension or revocation of a precision bred animal marketing authorisation).

112. Clause 22(3) provides for the Secretary of State to be able to designate by regulations the body which is to act as the welfare advisory body. Clause 22(4) contains detail as to the nature of the entities which may be designated as such.

#### Justification for taking the power

113. The Department intends to bring the provisions of the Bill concerning precision bred animals into force after precision bred plants and once the regulatory system to safeguard animal welfare is established. As such, the Department considers it unnecessary to identify the welfare advisory body on the face of the Bill and prefers to take power to do so by regulations at a later, more appropriate time.

#### Justification for the procedure

114. The Department considers that while the identity of the welfare advisory body will be of interest to Parliament, the appointment itself is a straightforward administrative matter and accordingly proposes the negative procedure.

#### **Clause 23(1): Advisory bodies: time limits etc: power to provide for a reporting period not to run, and for applications to be treated as withdrawn, where information notices are outstanding**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Negative resolution procedure*

#### Context and purpose

115. This power relates to functions of the advisory committee and of the welfare advisory body under the Bill.

116. Under clause 6(3), after receiving an application for a precision bred confirmation in respect of an organism by way of a marketing notice under clause 6(1), the Secretary of State must refer the matter to the advisory committee for their advice by sending them the relevant documents and information.

117. Clause 7(2) provides for the advisory committee to provide their advice to the Secretary of State by way of a report before the end of the 90-day reporting period. However, clause 7(3) allows the advisory committee to issue an information notice requesting additional information from the notifier.

118. Under clause 11(6), after receiving an application for a precision bred animal marketing authorisation, the Secretary of State must refer the application to the welfare advisory body for their advice by sending them the relevant documents and information.

119. Clause 12 provides for the welfare advisory body to provide their advice to the Secretary of State by way of a report before the end of the reporting period (as prescribed by regulations made under clause 12(3)). However, clause 12(4) allows the welfare advisory body to issue an information notice requesting additional information from the notifier.

120. Clause 23(1) allows the Secretary of State to make provision causing the reporting period not to run (in other words, for the deadline to provide advice to be extended) where an information notice has been issued and the requested information has not been provided, and for the relevant application to be treated as withdrawn if requested information is not provided within a prescribed period.

#### Justification for taking the power

121. The Department considers that, while it is important that the advisory committee and welfare advisory body provide timely advice to the Secretary of State to allow decisions under this Bill to be made promptly, it would be inappropriate to impose time constraints in circumstances where relevant information has not been provided. Further, the Department considers that the efficient operation of the application process would not be well served by having live applications which remain pending indefinitely because the applicant has not provided information as requested. As such, the Department considers that time limits of this nature are appropriate.

122. The Department considers that it is appropriate for the detail of how the time limits operate to be dealt with by regulations, as this will allow relevant matters to be set out in appropriate detail in respect of different circumstances and will allow the requirements to be adjusted from time to time.

#### Justification for the procedure

123. The Department proposes that as the key policy objectives to be achieved through the time limits are set out in clause 23(1), it is appropriate for the regulations to be subject to the negative procedure.

### **Clause 25: Precision bred animal marketing authorisation: adverse effects: power to prescribe what constitutes adverse effects**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Affirmative resolution procedure*

#### Context and purpose

124. Under clause 11, an applicant for a precision bred animal marketing authorisation must submit with the application an animal welfare declaration, under which the notifier declares that they do not expect the health or welfare of the relevant animal (or its progeny) to be adversely affected by any trait resulting from precision breeding, informed by the risk assessment which must also be submitted under clause 11(4).

125. Under clause 15(1), regulations may be made allowing the Secretary of State to revoke a precision bred animal marketing authorisation where the Secretary of State considers that the health or welfare of the relevant animal (or its progeny) is likely to be adversely affected by any trait resulting from precision breeding.

126. Clause 25 allows the Secretary of State to prescribe circumstances in which the health or welfare of a relevant animal (or its progeny) is, or is not, considered to be adversely affected by any trait resulting from precision breeding.

#### Justification for taking the power

127. The Department considers that it is important to ensure that technical issues such as any thresholds or exceptions which may be needed for the assessment of adverse effect on animal welfare can be fully considered and set out in suitable levels of detail for precision bred animals through regulations. This will be important to ensure that these new administrative procedures for authorising precision bred animals will work as intended.

#### Justification for the procedure

**128.** The Department anticipates that the subject matter and detail of regulations made under this power will be of great interest to Parliament and accordingly proposes the affirmative procedure.

### **Part 3 – Food and feed produced from precision bred organisms**

#### **Clause 26(1): Regulation of food and feed produced from precision bred organisms: general power to regulate**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Affirmative resolution procedure*

#### Context and purpose

129. Part 3 provides for the regulation of food and feed produced from precision bred organisms.

130. Clause 26(1) provides a broad power for the Secretary of State to make regulations for this purpose, while the rest of the clause illustrates the matters to be dealt with through such regulations, including prohibitions on placing such food or feed on the market in England without authorisation (clause 26(2)(a) and (7)), requirements for traceability (clause 26(2)(b)), requirements to be satisfied before a food and feed marketing authorisation can be issued (clause 26(3)) and procedural matters (clause 26(4) and (5)).

131. Clause 26(6) provides that such regulations may confer functions on the Food Standards Agency.

#### Justification for taking the power

132. The Department considers that delegated powers are appropriate because of the need for FSA to consult on implementation and impacts of new food and feed legislation. The powers will be used to develop the new administrative requirements and processes, in addition to developing and outlining specific scientific and technical requirements that will need to be made available to applicants under the new regulatory regime.

#### Justification for the procedure

133. The Department considers that while the existing food and feed legislation provide a reliable indication of how the power will in practice be exercised, nevertheless the power is broad and covers a subject matter of great interest to Parliament, and it accordingly proposes the affirmative procedure.

#### **Clause 27(1): Food and feed marketing authorisations: register: power to establish and maintain register**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Affirmative resolution procedure*

#### Context and purpose

134. Clause 26 provides a broad power to regulate food and feed produced by precision bred organisms through regulations.

135. Clause 27 allows the Secretary of State to make provision by regulations to require the Food Standards Agency to establish and maintain a register in relation to food and feed marketing authorisations issued under clause 26.

#### Justification for taking the power

136. The Department considers that as the regulatory provisions to which the food and feed marketing authorisations register will relate are to be set out in regulations made under clause 26, it follows that it is necessary for the provisions concerning the register must also be set out in regulations.

#### Justification for the procedure

137. The Department considers that as the content of the food and feed marketing authorisations register is not set out on the face of the Bill in the same way as clause 18 sets out the content for the register which the Secretary of State must establish and maintain under that clause, it is likely that Parliament may have a greater interest in the regulations made under this power, and accordingly proposes the affirmative procedure.

**Clause 28(1): Monitoring and inspection of Part 3 obligations: power to make provision for monitoring compliance and investigating suspected non-compliance**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Affirmative resolution procedure*

Context and purpose

138. Clause 29(1) defines “Part 3 obligation” concerning enforcement.

139. Clause 28(1) provides the Secretary of State with power to make regulations for monitoring compliance with Part 3 obligations and investigating suspected failures to comply. Clause 28(2) sets out substantive matters which such regulations may cover, including the appointment of inspectors and the conferral of functions upon them.

140. Clause 28(3) contains constraints upon the regulation making power in clause 28(1) as regards what it may not contain (criminal offences, powers of entry into a private dwelling without a warrant).

Justification for taking the power

141. The Department considers that it is appropriate for the detail of enforcement provisions in respect of Part 3 obligations to be set out through regulations, given that clause 28(2) and (3) set out the key elements of policy.

142. Further, as the regulatory provisions to which these circumstances will relate are to arise under regulations made under clause 26, it follows that it is necessary for the circumstances themselves must also be set out in regulations.

Justification for the procedure

143. The Department considers that while clause 28(2) and (3) set out the key elements of policy, nevertheless enforcement powers are a subject matter of great interest to Parliament, and it accordingly proposes the affirmative procedure.

**Part 4 – Enforcement**

**Clause 31(4): Meaning of “relevant breach” etc: power to make equivalent provision to sections 20-22 of the Food Safety Act 1990 as regards breaches of requirements**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Affirmative resolution procedure*

### Context and purpose

144. Clause 31(1) defines “obligations” under the Bill for the purposes of Part 4 concerning enforcement.
145. Clause 31(3) provides that a “relevant breach” is a breach of an obligation by the person in question.
146. Clause 31(4) allows for the Secretary of State to prescribe circumstances in which a breach does or does not constitute a “relevant breach” so as to give rise to enforcement action (such as enforcement notices issued under clause 32). It provides that the circumstances which may be prescribed must correspond to the circumstances which are set out in sections 20 to 22 of the Food Safety Act 1990.

### Justification for taking the power

147. The Department considers that, as a matter of substance, it is likely to be appropriate to treat circumstances corresponding to those set out in sections 20 to 22 of the Food Safety Act 1990 in an equivalent manner under this Bill.
148. The Department considers that as the regulatory provisions to which these circumstances will relate are to arise under regulations made under clause 26, it follows that it is necessary for the circumstances themselves must also be set out in regulations.

### Justification for the procedure

149. The Department considers that while the existing food and feed regulatory regime (including sections 20 to 22 of the Food Safety Act 1990) provides a reliable indication of how the power will in practice be exercised, nevertheless the subject matter is of great interest to Parliament, and it accordingly proposes the affirmative procedure.

### **Clause 32(1): Enforcement: power to issue enforcement notices**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Affirmative resolution procedure*

### Context and purpose

150. Clause 31(1) defines “obligation” under the Bill concerning enforcement.
151. Clause 31(3) defines “relevant breach” by reference to a failure of a person to comply with such an obligation
152. Clause 32(1) provides the Secretary of State with power to make regulations for monitoring compliance with obligations, and investigating suspected failures to comply, including the issue of enforcement notices (defined so as to comprise compliance notices, stop notices and monetary penalty notices). Clauses 33, 34 and 35 respectively contain additional detail as to the purpose to be secured by each such notice.

153. Clause 36 contains further detail which must be included in regulations made under clause 32(1) in respect of all three types of enforcement notice, covering matters of transparency as to the basis on which the notice has been issued, the availability of reviews or appeals against the notice issued, and the consequences of failing to comply with the notice.

154. Clause 37 provides that regulations made under clause 32(1) must allow for reviews and appeals against notices issued and sets out detailed requirements which such regulations must contain.

#### Justification for taking the power

155. The Department considers that clauses 31 to 37 set out much of the policy under this Bill in relation to enforcement notices, but that it is appropriate for the detail of enforcement notices to be dealt with by regulations, as this will allow relevant matters to be set out in appropriate detail in respect of different circumstances (particularly those where the relevant obligations are ones which will themselves be set out in regulations, for the reasons given in relation to relevant powers above), and will allow the requirements to be adjusted from time to time.

#### Justification for the procedure

156. The Department considers that while clauses 31 to 37 provide a reliable indication of how the power in clause 32(1) will in practice be exercised, nevertheless the power is broad and covers a subject matter of great interest to Parliament, and it accordingly proposes the affirmative procedure.

#### **Clause 38(1): Costs: Power to impose costs incurred in relation to enforcement notices**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Affirmative resolution procedure*

#### Context and purpose

157. Clause 31(1) defines “obligation” under the Bill concerning enforcement.

158. Clause 31(3) defines “relevant breach” by reference to a failure of a person to comply with such an obligation

159. Clause 32(1) provides the Secretary of State with power to make regulations for monitoring compliance with obligations, and investigating suspected failures to comply, including the issue of enforcement notices (defined so as to comprise compliance notices, stop notices and monetary penalty notices).

160. Clause 38(1) provides the Secretary of State with power to make provision by regulations to require a person to pay costs incurred by the Secretary of State in relation to the issue of an enforcement notice. Clause 38(4) and (6) set out substantive matters which the regulations



must secure, in relation to issues such as transparency, reviews, appeals, interest and debt recovery.

161. Clause 38(4)(c) provides that where a person shows that costs have been unnecessarily incurred, the regulations must provide that the person is not liable to pay such costs.

#### Justification for taking the power

162. The Department considers that clause 38 sets out much of the policy under this Bill in relation to the recovery of costs associated with enforcement notices, but that it is appropriate for the detail to be dealt with by regulations, as this will allow relevant matters to be set out in appropriate detail in respect of different circumstances (particularly given that detailed provisions on enforcement notices will themselves be set out in regulations, for the reasons given in relation to clause 32 above), and will allow the requirements to be adjusted from time to time.

#### Justification for the procedure

163. The Department considers that while clause 34 sets out much of the policy which will govern how the power in clause 32(1) will in practice be exercised, nevertheless the subject matter of costs recovery is of great interest to Parliament, and it accordingly proposes the affirmative procedure.

### **Part 5 – General**

#### **Clause 39(1): Fees: Power to impose fees in respect of functions under the Bill**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Negative resolution procedure*

#### Context and purpose

164. Under this Bill, there are various provisions under which public bodies are to exercise functions, often in the context of applications (see, for example, clause 8(1) as regards the issue of a precision bred confirmation).

165. In order to support the wider Government objective of recovering the costs it incurs in the delivery of services, the Department considers it desirable that the Secretary of State should be able to prescribe a fee to be payable in respect of any function conferred by or under this Bill. Clause 39(1) provides the Secretary of State with power to prescribe fees by regulations to that effect, subject to clause 39(3) which provides that the Secretary of State must have regard to the desirability of balancing the income received from fees in relation to the function in question, and the costs incurred in exercising related functions, taking one year with the next.

#### Justification for taking the power

166. The Department considers that it is appropriate for fees to be set out in regulations, allowing them to be set out in suitable levels of detail and adjusted from time to time.

#### Justification for the procedure

167. The Department considers that the detail relating to fees imposed for the purposes of cost recovery in relation to the exercise of functions is appropriate for the negative procedure.

#### **Clause 40: Notices and documents: Prescribing procedural matters in respect of delivery of notices**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Negative resolution procedure*

#### Context and purpose

168. Under this Bill, there are various provisions under which a notice or other document is to be issued or received (see, for example, clause 6(1) as regards a marketing notice given by a notifier applying for a precision bred confirmation).

169. While it is a point of detail, the time and manner in which a document is given or received under this Bill may have some significance. For example, under clause 7(2), the advisory committee is under a duty to provide a report to the Secretary of State within 90 days after a marketing notice has been referred to it under clause 6(3).

#### Justification for taking the power

170. The Department considers that it is appropriate for administrative details concerning the delivery of notices and documents to be set out in regulations, allowing them to be set out in suitable levels of detail and adjusted from time to time.

#### Justification for the procedure

171. The Department considers that the detail relating to the delivery of notices and documents is appropriate for the negative procedure.

#### **Clause 42(1): Power to make consequential provision**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: Affirmative resolution procedure where modifying primary legislation, otherwise negative resolution procedure*

#### Context and purpose

172. The policy set out in this Bill will need to be reflected in other legislation, which is not amended by it, particularly secondary legislation. For example, there are references to genetically modified organisms which, following the policy set out in this Bill, should be treated as references to precision bred organisms in future.

173. Accordingly, clause 42(1) provides the Secretary of State with power to make supplementary, incidental or consequential provision by regulations in connection with any provision of or made under this Bill.

174. Clause 42(2) provides that this includes power to modify primary legislation, retained direct EU legislation or subordinate legislation (across the whole of the United Kingdom).

175. This power may only be exercised to make provision, which is merely supplementary, incidental to or consequential in connection with a provision of, or made under, the Bill, to make that provision work effectively. It cannot be used to make stand-alone substantive legislative changes. The Department's view is that this power is needed to ensure that the provisions made by the Bill and regulations made under it fit effectively within the legal framework that exists at the time when those provisions are brought into force or those regulations are made (as the case may be).

#### Justification for taking the power

176. The Department considers that it is not an efficient use of Parliamentary time for all such matters to be dealt with on the face of a Bill, and a power to make supplementary, incidental or consequential provision by regulations is common.

177. While the power is broad in terms of the legislation which might be amended by it, it is a narrow power insofar as it can only be exercised for limited purposes which flow from the policy set out in or under the Bill.

#### Justification for the procedure

178. The Department considers that where regulations made under this power modify primary legislation, they are likely to be of particular interest to Parliament and has therefore proposed that such regulations are subject to the affirmative procedure. The Department considers that where regulations made under the power do not modify primary legislation, the negative procedure is appropriate.

**Clause 48(3) and (4): Short title and commencement: power to make commencement regulations bringing provisions of the Bill into force**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: No procedure*

#### Context and purpose

179. Except to the extent that it provides that the Bill comes into force on Royal Assent (as regards provisions which do not have substantive operative force), clause 48 provides that the Secretary of State may bring the provisions of the Bill into force by way of commencement regulations.

#### Justification for taking the power

180. The Department considers it standard to provide that Bill provisions should come into force by way of commencement regulations. This is particularly appropriate in this case where the policy intention is that provisions concerning precision bred plants should be brought into force substantially earlier than provisions concerning precision bred animals.

#### Justification for the procedure

181. The Department considers it standard for a power to make commencement regulations to be subject to no Parliamentary procedure.

#### **Clause 48(7): Short title and commencement: power to make transitional etc provision in connection with coming into force**

*Power conferred on: Secretary of State*

*Power exercised by: Regulations made by statutory instrument*

*Parliamentary procedure: No procedure*

#### Context and purpose

182. Clause 48(7) allows the Secretary of State to make regulations containing transitional, transitory or saving provision in connection with the coming into force of any provision of this Bill.

183. Such a power is intended to allow for a smooth transition where substantive changes to the law are being made.

#### Justification for taking the power

184. The Department considers it standard for the Secretary of State to have power to make transitional, transitory or saving provision by regulations in connection with the coming into force of provisions under a Bill.

Justification for the procedure

185. The Department considers it standard for the power to make such regulations to be subject to no Parliamentary procedure.

## Annex A: Non-legislative powers

The table below lists powers which are considered not to be legislative with an explanation of why this is thought to be the case.

Clause	Power
46(2)	<b>Crown application: A power to certify that it appears to the Secretary of State appropriate in the interests of national security that powers of entry conferred under this Act should not be exercisable in relation to Crown premises specified in the certificate</b>

**Clause 46(2): Crown application: A power to certify that it appears to the Secretary of State appropriate in the interests of national security that powers of entry conferred under this Act should not be exercisable in relation to Crown premises specified in the certificate**

*Power conferred on: Secretary of State*

*Power exercised by: Certificate issued by Secretary of State*

*Parliamentary procedure: None*

### Context and purpose

186. Clause 46(1) provides that the Bill binds the Crown generally.

187. However, clause 46(2) proceeds on the basis that where the Secretary of State considers it appropriate in the interests of national security that powers of entry under the Bill should not be exercisable in relation to specified Crown premises, those powers of entry will not be exercisable in respect of such premises specified in a certificate issued by the Secretary of State.

### Justification for taking the power

188. The Secretary of State is in a good position from which to balance the potentially competing interests between the effective application of the policy in this Bill and the national security interests which may relate to some, but not all, Crown premises.

### Justification for the procedure

189. The Department considers the power for the Secretary of State to issue certificates is restricted to a narrow purpose clearly set out on the face of the Bill and does not consider that Parliamentary scrutiny is warranted in relation to it.

Annex B: Table of legislative powers

Clause	Power conferred	Parliamentary Procedure
Part 1 – Precision Breeding: Definitions		
1(8)	Power to make corresponding changes to definition of “modern biotechnology”	Affirmative
Part 2 – Precision Bred Organisms: Release, Marketing and Risk Assessments		
4(2)	Power to prescribe the form of a release notice and any accompanying information requirements, and imposing minimum period between notice and release	Negative
6(2)	Power to prescribe the form of a marketing notice and any accompanying information requirements	Negative
9(1)	Power to confer power to revoke precision bred confirmation and procedure to be followed	Negative
10(2)	Power to extend definition of “relevant animal” to cover invertebrates	Affirmative
11(5)	Power to prescribe the form for applications for precision bred animal marketing authorisations and accompanying information requirements	Negative
11(9)	Power to prescribe circumstances in which an application for a health and welfare marketing authorisation may be made by someone other than the person who gave the marketing notice	Negative
12(3)	Power to specify the reporting period within which the welfare advisory body must provide its report (and may require additional information from the notifier)	Negative
14	Power to require the notifier and other persons to provide prescribed information about	Affirmative

	a precision bred animal and its progeny	
15(1)	Power to prescribe circumstances in which the Secretary of State may suspend or revoke a precision bred animal marketing authorisation	Negative
16(1)	Power to prescribe process for reviews and appeals under Part 2	Negative
17(1)	Power to impose environmental risk assessment duty	Negative
18(6)	Power to regulate keeping of register	Negative
20(1)	Power to make provision for monitoring compliance and investigating suspected non-compliance (Part 2 obligations)	Affirmative
22(3)	Power to designate welfare advisory body	Negative (Affirmative if consequential provision involves amending or repealing primary legislation)
23(1)	Power to provide for a reporting period not to run, and for applications to be treated as withdrawn, where information notices are outstanding	Negative
25	Power to prescribe what constitutes "adverse effects"	Affirmative
<b>Part 3 – Food and Feed produced from Precision Bred Organisms</b>		
26(1)	Power to regulate food and feed produced from precision bred organisms	Affirmative
27(1)	Power to establish and maintain register in relation to food and feed marketing authorisations	Affirmative
28(1)	Power to make provision for monitoring compliance and investigating suspected non-compliance (Part 3 obligations)	Affirmative
<b>Part 4 – Enforcement</b>		
31(4)	Power to make equivalent provision to sections 20-22 of the Food Safety Act 1990 as regards breaches of requirements	Affirmative
32(1)	Power to issue enforcement	Affirmative



	notices	
38(1)	Power to impose costs incurred in relation to enforcement notices	Affirmative
Part 5 – General		
39(1)	Power to impose fees in respect of functions under the Bill	Negative
40	Power to prescribe procedural matters in respect of delivery of notices	Negative
42(1)	Power to make consequential provision	Affirmative where modifying primary legislation, otherwise negative
48(3) and (4)	Power to make commencement regulations	No procedure
48(7)	Power to make transitional etc provision in connection with coming into force	No procedure