SCHEDULE 1

PRINCIPLES FOR ENVIRONMENTAL RISK ASSESSMENT

PART C

METHODOLOGY

CHAPTER C.1

GENERAL AND SPECIFIC CONSIDERATION FOR THE ENVIRONMENTAL RISK ASSESSMENT

Step 1: Intended and unintended changes

4.—(1) As part of the identification and evaluation of the potential adverse effects referred to in Part A of this schedule, the environmental risk assessment must identify the intended and unintended changes resulting from the genetic modification and must evaluate their potential to cause adverse effects on human health and on the environment.

(2) Intended changes resulting from the genetic modification are changes that are designed to occur and which fulfil the original objectives of the genetic modification.

(3) Unintended changes resulting from the genetic modification are consistent changes which go beyond the intended change(s) resulting from the genetic modification.

(4) Intended and unintended changes can have either direct or indirect, and either immediate or delayed effects on human health and on the environment.

Step 2: Long-term adverse effects and cumulative long-term adverse effects in the environmental risk assessment of applications to which Part 3 of these Regulations applies

5.—(1) Long-term effects of a genetically modified organism are effects resulting either from a delayed response by organisms or their progeny to long-term or chronic exposure to a genetically modified organism or from an extensive use of a genetically modified organism in time and space.

(2) The identification and evaluation of the potential long-term adverse effects of a genetically modified organism on human health and on the environment must take into account the following—

(a) the long-term interactions of the genetically modified organism and the receiving environment,

(b) the characteristics of the genetically modified organism which become important on a long- term basis, and

(c) data obtained from repeated deliberate releases or placings on the market of the genetically modified organism over a long period.

(3) The identification and evaluation of the potential cumulative long-term adverse effects referred to in the introduction of this schedule must also take into account the genetically modified organisms deliberately released or placed on the market in the past.

Step 3: Quality of the data

6.—(1) In order to carry out an environmental risk assessment for an application to which Part 3 of these Regulations applies, the applicant must collate already available data from scientific literature or from other sources, including monitoring reports, and must generate the necessary data

by performing, where possible, appropriate studies. Where applicable, the applicant must justify in the environmental risk assessment why generating data by studies is not possible.

(2) The environmental risk assessment for applications to which Part 2 of these Regulations applies must be based at least on already available data from scientific literature or from other sources and may be supplemented by additional data generated by the applicant.

(3) Where data generated outside the United Kingdom is provided in the environmental risk assessment, its relevance to receiving environment(s) in the United Kingdom must be justified.

(4) Data provided in the environmental risk assessment for applications to which Part 3 of these Regulations applies, must comply with the following requirements—

(a) where toxicological studies carried out to assess risk to human or animal health are provided in the environmental risk assessment, the applicant must provide evidence to demonstrate that they were conducted in facilities which comply with—

(i) if carried out in **[**F2Great Britain**]**, **[**F3assimilated**]** law relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances,

(ii) if carried out in a member State of the EU **[**F4or in Northern Ireland**]**, EU law relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances, or

(iii) if carried out elsewhere, the 'OECD Principles on Good Laboratory Practice',

(b) where studies other than toxicological studies are provided in the environmental risk assessment, they must—

(i) comply with the principles of Good Laboratory Practice laid down in **[**F5assimilated**]** law, where relevant, or

(ii) be conducted by organisations accredited under the relevant ISO standard, or

(iii) in the absence of a relevant ISO standard, be conducted in accordance with internationally recognised standards,

(c) information on the results obtained from the studies referred to in sub-paragraphs (a) and (b) and on the study protocols used must be reliable and comprehensive and must include the raw data in an electronic format suitable for carrying out statistical or other analysis,

(d) the applicant must specify, where possible, the size of effect that each study performed intends to detect and justify it,

(e) the selection of sites for field studies must be based on relevant receiving environments in view of the potential exposure and impact that would be observed where the genetically modified organism may be released. The selection must be justified in the environmental risk assessment, and

(f) the non-genetically modified comparator must be appropriate for the relevant receiving environment(s) and must have a genetic background comparable to the genetically modified organism. The choice of the comparator must be justified in the environmental risk assessment.

Textual Amendments

F2 Words in sch. 1 para. 6(4)(a)(i) substituted (2.2.2023) by The Agriculture (Retained EU Law and Data) (Scotland) Act 2020 (Consequential Modifications) and Agricultural Products, Aquatic Animal Health and Genetically Modified Organisms (EU Exit) (Amendment) Regulations 2022 (S.S.I. 2022/361), regs. 1, **14(2)(i)**

F3 Word in sch. 1 para. 6(4)(a)(i) substituted (1.1.2024) by The Retained EU Law (Revocation and Reform) Act 2023 (Consequential Amendments) (Scotland) Regulations 2023 (S.S.I. 2023/374), reg. 1(1), **sch. 2 para. 2(4)**

F4 Words in sch. 1 para. 6(4)(a)(ii) inserted (2.2.2023) by The Agriculture (Retained EU Law and Data) (Scotland) Act 2020 (Consequential Modifications) and Agricultural Products, Aquatic Animal Health and Genetically Modified Organisms (EU Exit) (Amendment) Regulations 2022 (S.S.I. 2022/361), regs. 1, **14(2)(ii)**

F5 Word in sch. 1 para. 6(4)(b)(i) substituted (1.1.2024) by The Retained EU Law (Revocation and Reform) Act 2023 (Consequential Amendments) (Scotland) Regulations 2023 (S.S.I. 2023/374), reg. 1(1), **sch. 2 para. 2(5)**

Step 4: Stacked transformation events in applications to which Part 3 of these Regulations applies

7. The following must apply to the environmental risk assessment of a genetically modified organism containing stacked transformation events in applications to which Part 3 of these Regulations applies—

(a) the applicant must provide an environmental risk assessment for each single transformation event in the genetically modified organism or refer to already submitted applications (or equivalent notifications) for those single transformation events,

(b) the applicant must provide an assessment of the following aspects—

(i) the stability of the transformation events,

(ii) the expression of the transformation events, and

(iii) the potential additive, synergistic or antagonistic effects resulting from the combination of the transformation events, and

(c) where the progeny of the genetically modified organism can contain various sub-combinations of the stacked transformation events, the applicant must provide a scientific rationale justifying that there is no need to provide experimental data for the concerned sub-combinations, independently of their origin, or, in the absence of such scientific rationale, must provide the relevant experimental data.

CHAPTER C.2

CHARACTERISTICS OF THE GENETICALLY MODIFIED ORGANISM AND OF THE RELEASES

8.—(1) The environmental risk assessment must take into account the relevant technical and scientific details regarding characteristics of—

(a) the recipient or parental organism(s),

(b) the genetic modification(s), be it insertion or deletion of genetic material, and relevant information on the vector and the donor,

(c) the genetically modified organism,

(d) the intended release or use including its scale,

(e) the potential receiving environment(s) into which the genetically modified organism will be released and into which the transgene may spread, and

(f) the interaction(s) between these characteristics.

(2) Relevant information from previous releases of the same or similar genetically modified organisms and organisms with similar traits and their biotic and abiotic interaction with similar

receiving environments, including information resulting from the monitoring of such organisms, must be considered in the environmental risk assessment, subject to regulations 11(2) and 16(3).

CHAPTER C.3

STEPS IN THE ENVIRONMENTAL RISK ASSESSMENT

9. The environmental risk assessment must be conducted for each relevant area of risk referred to in Chapters D.1 and D.2 of Part D of this schedule in accordance with the following six steps.

Step 1: Problem formulation including hazard identification

10.—(1) The problem formulation must—

(a) identify any changes in the characteristics of the organism, linked to the genetic modification, by comparing the characteristics of the genetically modified organism with those of the chosen non-genetically modified comparator under corresponding conditions of release or use,

(b) identify potential adverse effects on human health or the environment which are linked to the changes that have been identified under sub-paragraph (1)(a),

(c) identify relevant assessment end-points,

(d) identify and describe the exposure pathways or other mechanisms through which adverse effects may occur,

(e) formulate testable hypotheses, and define relevant measurement end-points, to allow, where possible, a quantitative evaluation of the potential adverse effect(s), and

(f) consider possible uncertainties, including knowledge gaps and methodological limitations.

(2) For the purposes of sub-paragraph (1)(b)—

(a) potential adverse effects must not be discounted on the basis that they are unlikely to occur,

(b) potential adverse effects will vary from case to case, and may include—

(i) effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations leading to a potential decline in biodiversity,

(ii) altered susceptibility to pathogens facilitating the dissemination of infectious diseases or creating new reservoirs or vectors,

(iii) compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine,

(iv) effects on biogeochemistry (biogeochemical cycles), including carbon and nitrogen recycling through changes in soil decomposition of organic material,

(v) disease affecting humans, including allergenic or toxic reactions, and

(vi) disease affecting animals and plants, including toxic, and, in the case of animals, allergenic reactions, where appropriate, and

(c) where potential long-term adverse effects of a genetically modified organism are identified, they must be assessed in the form of desk based studies using, where possible, one or more of the following—

(i) evidence from previous experiences,

(ii) available data sets or literature, or

(iii) mathematical modelling.

(3) For the purposes of sub-paragraph (1)(c), the potential adverse effects that could impact the identified assessment end-points must be considered in the next steps of the risk assessment.

(4) For the purposes of sub-paragraph (1)(d), adverse effects may occur directly or indirectly through exposure pathways or other mechanisms which may include—

(a) the spread of the genetically modified organism(s) in the environment,

(b) the transfer of the inserted genetic material to the same organism or other organisms, whether genetically modified or not,

(c) phenotypic and genetic instability,

(d) interactions with other organisms, and

(e) changes in management, including, where applicable, in agricultural practices.

Step 2: Hazard characterisation

11.—(1) The magnitude of each potential adverse effect must be evaluated. This evaluation must assume that such an adverse effect will occur. The environmental risk assessment must consider that the magnitude is likely to be influenced by the receiving environment(s) into which the genetically modified organism is intended to be released and by the scale and conditions of the release.

(2) Where possible, the evaluation must be expressed in quantitative terms.

(3) Where the evaluation is expressed in qualitative terms, a categorical description ('high', 'moderate', 'low' or 'negligible') must be used and an explanation of the scale of effect represented by each category must be provided.

Step 3: Exposure characterisation

12.—(1) The likelihood or probability of each identified potential adverse effect occurring must be evaluated to provide, where possible, a quantitative assessment of the exposure as a relative measure of probability, or otherwise a qualitative assessment of the exposure. The characteristics of the receiving environment(s) and the scope of the application must be taken into consideration.

(2) Where the evaluation is expressed in qualitative terms, a categorical description ('high', 'moderate', 'low' or 'negligible') of the exposure must be used and an explanation of the scale of effect represented by each category must be provided.

Step 4: Risk characterisation

13.—(1) The risk must be characterised by combining, for each potential adverse effect, the magnitude with the likelihood of that adverse effect occurring to provide a quantitative or semi quantitative estimation of the risk.

(2) Where a quantitative or semi quantitative estimation is not possible, a qualitative estimation of the risk must be provided. In that case, a categorical description ('high', 'moderate', 'low' or 'negligible') of the risk must be used and an explanation of the scale of effect represented by each category must be provided.

(3) Where relevant, the uncertainty for each identified risk must be described and, where possible, expressed in quantitative terms.

Step 5: Risk management strategies

14.—(1) Where risks are identified that require, on the basis of their characterisation, measures to manage them, a risk management strategy must be proposed for each risk.

(2) The risk management strategies must be described in terms of reducing the hazard or the exposure, or both, and must be proportionate to the intended reduction of the risk, the scale and conditions of the release and the levels of uncertainty identified in the environmental risk assessment

(3) The consequent reduction in overall risk must be quantified where possible.

Step 6: Overall risk evaluation and conclusions

15.—(1) A qualitative and, where possible, quantitative evaluation of the overall risk of the genetically modified organism must be made taking into account the results of the risk characterisation, the proposed risk management strategies and the associated levels of uncertainty.

(2) The overall risk evaluation must include, where applicable, the risk management strategies proposed for each identified risk.

(3) The overall risk evaluation and conclusions must also propose specific requirements for the monitoring plan of the genetically modified organism and, where appropriate, the monitoring of the efficacy of the proposed risk management measures.

(4) For applications to which Part 3 of these Regulations applies, the overall risk evaluation must also include an explanation of the assumptions made during the environmental risk assessment and of the nature and magnitude of uncertainties associated with the risks, and a justification of the risk management measures proposed.**]**

Changes to legislation:
There are currently no known outstanding effects for the The Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002, PART C.