SCHEDULE 1

PRINCIPLES FOR ENVIRONMENTAL RISK ASSESSMENT

PART C

METHODOLOGY

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, CHAPTER C.3.