

## SCHEDULE 4

Regulations 16(2), 16(5) and 28

### INFORMATION TO BE INCLUDED IN APPLICATIONS FOR CONSENT TO MARKET GENETICALLY MODIFIED ORGANISMS

#### PART I

##### GENERAL INFORMATION

1. The proposed commercial name of the product and names of the genetically modified organisms in the product, and any specific identification, name or code used by the applicant to identify the genetically modified organism.

2. The name and address in the Community of the person who is responsible for the placing on the market, whether it be the manufacturer, importer or distributor.

3. The name and address of the supplier of control samples.

4. A description of how the product and the genetically modified organism as or in the product are intended to be used, highlighting any differences in use or management of the genetically modified organism compared to similar non-genetically modified products.

5. A description of the geographical area and types of environment where the product is intended to be used within the Community, including, where possible, an estimate of the scale of use in each area.

6. A description of the intended categories of users of the product, such as industry, agriculture, skilled trades or consumer use by the public at large.

7. Information on the genetic modification for the purposes of placing on one or several registers modifications in organisms, which can be used for the detection and identification of particular genetically modified organism products to facilitate post marketing control and inspection. This information should include where appropriate the lodging of samples of the genetically modified organism or its genetic material with the Scottish Ministers, and details of nucleotide sequences or other type of information which is necessary to identify the genetically modified organism product and its progeny, for example the methodology for detecting and identifying the genetically modified organism product, including experimental data demonstrating the specificity of the methodology. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register should be identified.

8. Information regarding proposed labelling, which must include, in a label or an accompanying document, at least in summarised form, a commercial name of the product, a statement that “This product contains genetically modified organisms”, the name of the genetically modified organism and the name and address of the person established in the Community who is responsible for the placing on the market, and how to access the information in the publicly accessible part of the register.

#### PART II

##### ADDITIONAL RELEVANT INFORMATION

9. The measures to be taken in the event of the escape of the organisms in the product or misuse of the product.

10. Specific instructions or recommendations for storage and handling of the product.

**Status:** This is the original version (as it was originally made).

**11.** Specific instructions for carrying out monitoring and reporting to the applicant and, if required, the Scottish Ministers, which are consistent with Part C of Annex VII of the Deliberate Release Directive, so that the Scottish Ministers can be effectively informed of any adverse effect.

**12.** The proposed restrictions in the approved use of the genetically modified organism, such as where the product may be used and for what purposes.

**13.** The proposed packaging.

**14.** The estimated production in and/or imports to the Community.

**15.** Any proposed additional labelling, which may include, at least in summarised form, the information referred to in paragraphs 4 and 5 of Part I of this Schedule, or paragraphs 9 to 12 of this Part.