

## SCHEDULE 4

Regulation 6

### PART 1

#### Matters to be taken into account in carrying out an assessment for the purposes of regulation 6

1. The following matters must be taken into account in carrying out an assessment for the purposes of regulation 6—

- (a) any potentially harmful effects, in particular those associated with—
    - (i) the recipient organism;
    - (ii) the inserted genetic material (originating from the donor organism);
    - (iii) the vector;
    - (iv) the donor organism;
    - (v) the resulting genetically modified organism;
  - (b) the characteristics of the contained use;
  - (c) the severity of the potentially harmful effects;
  - (d) the likelihood of the potentially harmful effects being realised.
2. In paragraph 1, “potentially harmful effects” includes—
- (a) disease to humans including allergenic or toxic effects;
  - (b) acting as a human disease vector or reservoir;
  - (c) adverse effects to humans arising from change in behaviour or in physical nature;
  - (d) adverse effects arising from the inability to treat human disease or offer effective prophylaxis.

### PART 2

#### Steps to be included when carrying out an assessment for the purposes of regulation 6

3. An assessment carried out for the purposes of regulation 6 must include—
- (a) identification of any harmful properties of the recipient and, where appropriate, the donor organism;
  - (b) identification of any harmful properties associated with the vector or inserted material, including any alteration in the existing properties of the recipient;
  - (c) identification of the provisional level of risk associated with the genetically modified organisms;
  - (d) selection of containment and other protective measures on the basis of—
    - (i) the provisional level of risk; and
    - (ii) the characteristics of the contained use;
  - (e) adjustment of the level of risk in the light of the matters referred to in sub-paragraph (d);
  - (f) review and reconsideration of the containment and other protective measures in the light of the steps required by sub-paragraphs (a) to (e).