

## SCHEDULE 3

### PART I

#### MATTERS TO BE TAKEN INTO ACCOUNT IN CARRYING OUT AN ASSESSMENT FOR THE PURPOSES OF REGULATION 6

1. The following matters shall 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 micro-organism,
  - (ii) the inserted genetic material (originating from the donor organism),
  - (iii) the vector,
  - (iv) the donor micro-organism (where that donor micro-organism is used during the activity involving genetic modification), and
  - (v) the resulting genetically modified micro-organism;
- (b) the characteristics of the activity;
- (c) the severity of the potentially harmful effects; and
- (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) disease to animals or plants;
- (c) adverse effects resulting from the inability to treat disease or offer an effective prophylaxis;
- (d) adverse effects resulting from establishment or dissemination of the genetically modified micro-organisms in the environment;
- (e) adverse effects resulting from the natural transfer of genetic material to or from other organisms;
- (f) adverse effects resulting from the likely interaction of the genetically modified micro-organism with other organisms at the premises where the activity involving genetic modification is to be conducted.