SCHEDULE 4

PART I

MATTERS TO BE TAKEN INTO ACCOUNT IN CARRYING OUT AN ASSESSMENT FOR THE PURPOSES OF REGULATION 7

1. The following matters shall be taken into account in carrying out an assessment for the purposes of regulation 7—

(a) the identification of 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, and

(v) the resulting genetically modified organism;

(b) the characteristics of the activity involving genetic modification;

(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) 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.