SCHEDULE 3 Regulations 2(3), 3(4) and 5

PART 1

Matters to be taken into account in carrying out an assessment for the purposes of regulation 5

1. The following matters must be taken into account in carrying out an assessment for the purposes of regulation 5—

(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 contained use);

(v) the resulting genetically modified micro-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;

(e) the disposal of waste and effluents.

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 contained use is to be conducted.

PART 2

Steps to be included when carrying out an assessment for the purposes of regulation 5

3. An assessment carried out for the purposes of regulation 5 must include—

(a) identification of any harmful properties of the recipient and, where appropriate, the donor micro-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) recognition that, in general, only contained use which shows the following characteristics is appropriate for inclusion in class 1 as described in Schedule 1—

(i) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants;

(ii) the nature of the vector and the insert is such that they do not endow the genetically modified micro-organism with a phenotype likely to cause disease to humans, animals or plants, or likely to cause deleterious effects on the environment; and

(iii) the genetically modified micro-organism is unlikely to cause disease to humans, animals or plants and is unlikely to have deleterious effects on the environment;

(d) consideration of relevant EU legislation, including Directive (EC) No 2000/54 of the European Parliament and the Council on the protection of workers from risks related to exposure to biological agents at work(**1**), other classification schemes referring to plant and animal pathogens, and other international and national classification schemes for genetically modified micro-organisms;

(e) identification of the provisional level of risk associated with the genetically modified micro-organism;

(f) consideration of—

(i) the characteristics of the environment likely to be exposed;

(ii) the characteristics of the contained use involving micro-organisms;

(iii) any contained use of micro-organisms which cannot be controlled adequately by standard laboratory procedures, and which presents risks which require controls for each individual case;

(g) adjustment of the provisional level of risk in the light of the matters referred to in sub-paragraph (f);

(h) selection of the appropriate containment measures from those specified in the applicable table in Schedule 8 on the basis of the provisional level of risk as adjusted in accordance with sub-paragraph (g);

(i) assignment of the contained use to the appropriate containment level, in accordance with paragraph 4;

(j) classification of the contained use in the class of the same number as that of the appropriate containment level;

(k) review and reconsideration of that classification in the light of the completed risk assessment.

4. To assign a contained use to the appropriate containment level for the purposes of paragraph 3(i), the person carrying out the risk assessment must—

(a) first identify for each selected containment measure the column in the applicable table in Schedule 8 having the lowest number in which that selected containment measure is shown as being required, regardless of whether or not such requirement is subject to any qualification;

(b) then select the highest number of all the columns identified in accordance with sub-paragraph (a); and

(c) then assign the contained use to the containment level of that highest number.

5. In paragraph 4, "selected containment measure" means an appropriate containment measure selected in accordance with paragraph 3(h).

(**1**) OJ No L 262, 17.10.2000, p21.