ANNEX III

Principles to be followed for the assessment referred to in Article 4(2)

This Annex describes in general terms the elements to be considered and the procedure to be followed to perform the assessment referred to in Article 4(2). Technical guidance notes[(1)] may be developed in accordance with the regulatory procedure referred to in Article 20(3) in order to facilitate the implementation and explanation of this Annex, in particular as regards Section B.

A. **Elements of assessment**

1. The following should be considered as potentially harmful effects:

— disease to humans, including allergenic or toxic effects,

— disease to animals or plants,

— deleterious effects due to the impossibility of treating a disease or providing an effective prophylaxis,

— deleterious effects due to establishment or dissemination in the environment,

— deleterious effects due to the natural transfer of inserted genetic material to other organisms.

2. The assessment referred to in Article 4(2) should be based on the following:

(a) the identification of any potentially harmful effects, in particular those associated with:

(i) the recipient micro-organism;

(ii) the genetic material inserted (originating from the donor organism);

(iii) the vector;

(iv) the donor micro-organism (as long as the donor micro-organism is used during the operation);

(v) the resulting GMM;

(b) the characteristics of the activity;

(c) the severity of the potentially harmful effects;

(d) the likelihood of the potentially harmful effects being realised.

B. **Procedure**

3. The first stage in the assessment process should be to identify the harmful properties of the recipient and, where appropriate, the donor micro-organism, and any harmful properties associated with the vector or inserted material, including any alteration in the recipient's existing properties.

4. In general, only GMMs which show the following characteristics would be considered appropriate for inclusion in class 1 as defined in Article 4(3):

(i) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants[(2)];

(ii) the nature of the vector and the insert is such that they do not endow the GMM with a phenotype likely to cause disease to humans, animals or plants[(2)], or likely to have deleterious effects on the environment;

(iii) the GMM is unlikely to cause disease to humans, animals or plants[(2)] and is unlikely to have deleterious effects on the environment.

5. In order to obtain the necessary information to implement this process the user may firstly take into account relevant Community legislation (in particular Directive 2000/54/EC). International or national classification schemes (e.g. World Health Organisation, National Institutes of Health) and their revisions due to new scientific knowledge and technical progress may also be considered.

These schemes concern natural micro-organisms and as such are usually based on the ability of micro-organisms to cause disease to humans, animals or plants and on the severity and transmissibility of the disease likely to be caused. Directive 2000/54/EC classifies micro-organisms, as biological agents, into four classes of risk on the basis of potential effects on a healthy human adult. These classes of risk can be used as guidance for the purposes of categorisation of the contained use activities in the four classes of risk referred to in Article 4(3). The user may also take into consideration classification schemes referring to plant and animal pathogens (which are usually established on a national basis). The abovementioned classification schemes give only a provisional indication of the risk class of the activity and the corresponding set of containment and control measures.

6. The hazard identification process carried out in accordance with points 3 to 5 should lead to the identification of the level of risk associated with the GMM.

7. Selection of the containment and other protective measures should then be made on the basis of the level of risk associated with the GMMs together with consideration of:

(i) the characteristics of the environment likely to be exposed (e.g. whether in the environment likely to be exposed to the GMMs there are known biota which can be adversely affected by the micro-organisms used in the contained use activity);

(ii) the characteristics of the activity (e.g. its scale and/or nature);

(iii) any non-standard operations (e.g. the inoculation of animals with GMMs; use of equipment likely to generate aerosols).

Consideration of items (i) to (iii) for the particular activity may increase, reduce or leave unaltered the level of risk associated with the GMM as identified under point 6.

8. The analysis carried out as described above will finally lead to the assignment of the activity to one of the classes described in Article 4(3).

9. The final classification of the contained use should be confirmed by reviewing the completed assessment referred to in Article 4(2).

(**1**) See Commission Decision 2000/608/EC of 27 September 2000 concerning the guidance notes for risk assessment outlined in Annex III to Directive 90/219/EEC on the contained use of genetically modified micro-organisms (OJ L 258, 12.10.2000, p. 43).

(**2**) This would only apply to animals and plants in the environment likely to be exposed.