ANNEX III A

INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS

I.GENERAL INFORMATION

A. Name and address of the notifier (company or institute)

B. Name, qualifications and experience of the responsible scientist(s)

C. Title of the project

II. INFORMATION RELATING TO THE GMO

A. Characteristics of (a) the donor, (b) the recipient or (c) (where appropriate) parental organism(s):

1. scientific name,

2. taxonomy,

3. other names (usual name, strain name, etc.),

4. phenotypic and genetic markers,

5. degree of relatedness between donor and recipient or between parental organisms,

6. description of identification and detection techniques,

7. sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques,

8. description of the geographic distribution and of the natural habitat of the organism including information on natural predators, preys, parasites and competitors, symbionts and hosts,

9. organisms with which transfer of genetic material is known to occur under natural conditions,

10. verification of the genetic stability of the organisms and factors affecting it,

11. pathological, ecological and physiological traits:

    (a) classification of hazard according to existing Community rules concerning the protection of human health and/or the environment;

    (b) generation time in natural ecosystems, sexual and asexual reproductive cycle;

    (c) information on survival, including seasonability and the ability to form survival structures;

    (d) pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (proviruses). Ability to colonise other organisms;

    (e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;

(f) involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.

12. Nature of indigenous vectors:

(a) sequence;

(b) frequency of mobilisation;

(c) specificity;

(d) presence of genes which confer resistance.

13. History of previous genetic modifications.

B. Characteristics of the vector

1. nature and source of the vector,

2. sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function in the GMO,

3. frequency of mobilisation of inserted vector and/or genetic transfer capabilities and methods of determination,

4. information on the degree to which the vector is limited to the DNA required to perform the intended function.

C. Characteristics of the modified organism

1. Information relating to the genetic modification:

(a) methods used for the modification;

(b) methods used to construct and introduce the insert(s) into the recipient or to delete a sequence;

(c) description of the insert and/or vector construction;

(d) purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;

(e) methods and criteria used for selection;

(f) sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence.

2. Information on the final GMO:

(a) description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;

(b) structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism;

(c) stability of the organism in terms of genetic traits;

(d) rate and level of expression of the new genetic material. Method and sensitivity of measurement;

(e) activity of the expressed protein(s);

(f) description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;

(g) sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;

(h) history of previous releases or uses of the GMO;

(i) considerations for human health and animal health, as well as plant health:

(i) toxic or allergenic effects of the GMOs and/or their metabolic products;

(ii) comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

(iii) capacity for colonisation;

(iv) if the organism is pathogenic to humans who are immunocompetent:

— diseases caused and mechanism of pathogenicity including invasiveness and virulence,
— communicability,
— infective dose,
— host range, possibility of alteration,
— possibility of survival outside of human host,
— presence of vectors or means of dissemination,
— biological stability,
— antibiotic resistance patterns,
— allergenicity,
— availability of appropriate therapies;

(v) other product hazards.

III. INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING ENVIRONMENT

A. Information on the release

1. description of the proposed deliberate release, including the purpose(s) and foreseen products,

2. foreseen dates of the release and time planning of the experiment including frequency and duration of releases,

3. preparation of the site previous to the release,

4. size of the site,

5. method(s) to be used for the release,

6. quantities of GMOs to be released,

7. disturbance on the site (type and method of cultivation, mining, irrigation, or other activities),

8. worker protection measures taken during the release,

9. post-release treatment of the site,

10. techniques foreseen for elimination or inactivation of the GMOs at the end of the experiment,

11. information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems.

B. Information on the environment (both on the site and in the wider environment):

1. geographical location and grid reference of the site(s) (in case of notifications under part C the site(s) of release will be the foreseen areas of use of the product),

2. physical or biological proximity to humans and other significant biota,

3. proximity to significant biotopes, protected areas, or drinking water supplies,

4. climatic characteristics of the region(s) likely to be affected,

5. geographical, geological and pedological characteristics,

6. flora and fauna, including crops, livestock and migratory species,

7. description of target and non-target ecosystems likely to be affected,

8. a comparison of the natural habitat of the recipient organism with the proposed site(s) of release,

9. any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

IV. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOs AND THE ENVIRONMENT

A. Characteristics affecting survival, multiplication and dissemination

1. biological features which affect survival, multiplication and dispersal,

2. known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, etc.),

3. sensitivity to specific agents.

B. Interactions with the environment

1. predicted habitat of the GMOs,

2. studies of the behaviour and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses,

3. genetic transfer capability

(a) postrelease transfer of genetic material from GMOs into organisms in affected ecosystems;

(b) postrelease transfer of genetic material from indigenous organisms to the GMOs,

4. likelihood of postrelease selection leading to the expression of unexpected and/or undesirable traits in the modified organism,

5. measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimise dispersal of genetic material. Methods to verify genetic stability,

6. routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.,

7. description of ecosystems to which the GMOs could be disseminated,

8. potential for excessive population increase in the environment,

9. competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s),

10. identification and description of the target organisms if applicable,

11. anticipated mechanism and result of interaction between the released GMOs and the target organism(s) if applicable,

12. identification and description of non-target organisms which may be adversely affected by the release of the GMO, and the anticipated mechanisms of any identified adverse interaction,

13. likelihood of postrelease shifts in biological interactions or in host range,

14. known or predicted interactions with non-target organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens,

15. known or predicted involvement in biogeochemical processes,

16. other potential interactions with the environment.

V. INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

A. Monitoring techniques

1. methods for tracing the GMOs, and for monitoring their effects,

2. specificity (to identify the GMOs, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques,

3. techniques for detecting transfer of the donated genetic material to other organisms,

4. duration and frequency of the monitoring.

B. Control of the release

1. methods and procedures to avoid and/or minimise the spread of the GMOs beyond the site of release or the designated area for use,

2. methods and procedures to protect the site from intrusion by unauthorised individuals,

3. methods and procedures to prevent other organisms from entering the site.

C. Waste treatment

1. type of waste generated,

2. expected amount of waste,

3. description of treatment envisaged.

D. Emergency response plans

1. methods and procedures for controlling the GMOs in case of unexpected spread,

2. methods for decontamination of the areas affected, for example eradication of the GMOs,

3. methods for disposal or sanitation of plants, animals, soils, etc., that were exposed during or after the spread,

4. methods for the isolation of the area affected by the spread,

5. plans for protecting human health and the environment in case of the occurrence of an undesirable effect.