COMMISSION DIRECTIVE 94/15/EC

of 15 April 1994

adapting to technical progress for the first time Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms [1], and in particular Article 20 thereof,

Whereas Annex II to Directive 90/220/EEC contains the information required to be provided in a notification for a deliberate release of genetically modified organisms (GMOs);

Whereas the information requirements for notifications for a deliberate release of GMOs, as set out in Annex II, are very broad in order to apply to all types of GMOs; whereas some of the information is only applicable or appropriate for specific types of organisms;

Whereas, on the basis of the experience gained with the releases of genetically modified higher plants, it is appropriate to adapt Annex II to technical progress by making provision for a sub-Annex specific to higher plants;

Whereas it is therefore appropriate that Annex II should be divided in two sub-Annexes: Annex II A outlining the information required in the notifications concerning releases of GMOs other than higher plants, and Annex II B outlining the information required in the notifications concerning releases of genetically modified higher plants;

Whereas the measures provided for in this Directive are in accordance with the opinion of the committee provided for in Article 21 of Directive 90/220/EEC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex II to Directive 90/220/EEC is replaced by the Annex hereto.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 June 1994. They shall immediately inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities.*

Done at Brussels, 15 April 1994.

For the Commission

Yannis PALEOKRASSAS

Member of the Commission

[1] OJ No L 117, 8. 5. 1990, p. 15.

ANNEX

'ANNEX II

INFORMATION REQUIRED IN THE NOTIFICATION

The notification for a deliberate release referred to in Article 5 and of the placing on the market referred to in Article 11 is to include, as appropriate, the information set out below in the sub-Annexes.

Not all points included will apply to every case. It is to be expected that individual notifications will address only the particular subset of considerations which is appropriate to individual situations.

The level of detail required in response to each subset of considerations is also likely to vary according to the nature and scale of the proposed release.

Annex II A applies to releases of all types of genetically modified organisms other than higher plants. Annex II B applies to releases of genetically modified higher plants.

The term "higher plants" means plants which belong to the taxonomic groups *Gymnospermae* and *Angiospermae.*

ANNEX II 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. potential for genetic transfer and exchange with other organisms;
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 e.g.: seeds, spores or sclerotia;
    (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 colonize 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 mobilization;
    (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 mobilization 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) 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) health considerations :

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

(ii) product hazards ;

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

(iv) capacity for colonization ;

(v) 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.

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 ;