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Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

PART A

GENERAL PROVISIONS

Article 1 Objective
Article 2 Definitions
Article 3 Exemptions
Article 4 General obligations

PART B

DELIBERATE RELASE OF GMOs FOR ANY OTHER PURPOSE THAN FOR PLACING ON THE MARKET

Article 5 (1) Articles 6 to 11 shall not apply to medicinal...
Article 6 Standard authorisation procedure
Article 7 Differentiated procedures
Article 8 Handling of modifications and new information
Article 9 Consultation of and information to the public
Article 10 Reporting by notifiers on releases
Article 11 Exchange of information between competent authorities and the Commission

PART C

PLACING ON THE MARKET OF GMOs AS OR IN PRODUCTS

Article 12 Sectoral legislation
Article 12a Transitional measures for adventitious or technically unavoidable presence of genetically modified organisms having benefited from a favourable risk evaluation
Article 13 Notification procedure
Article 14 Assessment report
Article 15 Standard procedure
Article 16 Criteria and information for specified GMOs
Article 17 Renewal of consent
Article 18 Community procedure in case of objections
Article 19 Consent
Article 20 Monitoring and handling of new information
Article 21 Labelling
Article 22 Free circulation
Article 23 Safeguard clause
Article 24 Information to the public

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PART D

FINAL PROVISIONS

Article 25	Confidentiality
Article 26	Labelling of GMOs referred to in Article 2(4), second subparagraph
Article 26a	Measures to avoid the unintended presence of GMOs
Article 26b	Cultivation
Article 26c	Transitional measures
Article 27	Adaptation of annexes to technical progress
Article 28	Consultation of Scientific Committee(s)
Article 29	Consultation of Committee(s) on Ethics
Article 29a	Exercise of the delegation
Article 30	Committee procedure
Article 31	Exchange of information and reporting
Article 32	Implementation of the Cartagena Protocol on biosafety
Article 33	Penalties
Article 34	Transposition
Article 35	Pending notifications
Article 36	Repeal
Article 37	This Directive shall enter into force on the day of...
Article 38	This Directive is addressed to the Member States.

ANNEX I A

TECHNIQUES REFERRED TO IN ARTICLE 2(2)

PART 1

PART 2

ANNEX I B

TECHNIQUES REFERRED TO IN ARTICLE 3

Techniques/methods of genetic modification yielding organisms to be excluded from...
mutagenesis, cell fusion (including protoplast fusion) of plant cells of...

ANNEX II

PRINCIPLES FOR THE ENVIRONMENTAL RISK ASSESSMENT

This Annex describes in general terms the objective to be...
With a view to contributing to a common understanding of...
‘direct effects’ refers to primary effects on human health or...

A general principle for environmental risk assessment is also that...

A. Objective

B. General Principles

C. Methodology
- C.1. General and specific considerations for the e.r.a.
  1. Intended and unintended changes
  2. Long-term adverse effects and cumulative long-term adverse effects in the...
  3. Quality of the data
  4. Stacked transformation events in Part C notifications
- C.2. Characteristics of the GMO and of the releases
- C.3. Steps in the e.r.a.
  1. Problem formulation including hazard identification
  2. Hazard characterisation
  3. Exposure characterisation
  4. Risk characterisation
  5. Risk management strategies
  6. Overall risk evaluation and conclusions

D. Conclusions on the specific areas of risk of the e.r.a....
- D.1. In the case of GMOs other than higher plants
- D.2. In the case of genetically modified higher plants (GMHP)

ANNEX III

INFORMATION REQUIRED IN THE NOTIFICATION

Notifications referred to in Parts B and C of this...
The provision of a given subset of information listed in...
The appropriate level of detail for each subset of information...
For each required subset of information, the following shall be...
the summaries and results of the studies referred to in...
Future developments in genetic modification may necessitate adapting this Annex...

ANNEX III A

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

I. GENERAL INFORMATION

II. INFORMATION RELATING TO THE GMO
- A. Characteristics of (a) the donor, (b) the recipient or (c)...
- B. Characteristics of the vector
- C. Characteristics of the modified organism

III. INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING...
- A. Information on the release
- B. Information on the environment (both on the site and in...

IV. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOs AND THE...
- A. Characteristics affecting survival, multiplication and dissemination
- B. Interactions with the environment

V. INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS...
- A. Monitoring techniques
- B. Control of the release
- C. Waste treatment
- D. Emergency response plans

ANNEX III B

INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED HIGHER PLANTS (GMHPs) (GYMNOSPERMAE AND ANGIOSPERMAE)

I. INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6 AND...
- A. General information
  1. Name and address of the notifier (company or institute)
  2. Name, qualifications and experience of the responsible scientist(s)
  3. Title of the project
  4. Information relating to the release
  5. Information relating to the site of release
- B. Scientific information
  1. Information relating to the recipient plant or, where appropriate, to...
  2. Molecular characterisation
  3. Information on specific areas of risk
  4. Information on control, monitoring, post-release and waste treatment plans
  5. Description of detection and identification techniques for the GMHP.
  6. Information about previous releases of the GMHP, if applicable.

II. INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLE 13
- A. General information
  1. Name and address of the notifier (company or institute).
  2. Name, qualifications and experience of the responsible scientist(s).
  3. Designation and specification of the GMHP.
  4. Scope of the notification.
- B. Scientific information
  1. Information relating to the recipient plant or, where appropriate, to...
  2. Molecular characterisation
  3. Comparative analysis of agronomic and phenotypic characteristics and of composition...

4. Specific information for each area of risk
5. Description of detection and identification techniques for the GMHP.
6. Information about previous releases of the GMHP, if applicable.

ANNEX IV

ADDITIONAL INFORMATION

This Annex describes in general terms the additional information to...
The following information shall be provided in the notification for...

ANNEX V

CRITERIA FOR THE APPLICATION OF DIFFERENTIATED PROCEDURES (ARTICLE 7)

The criteria referred to in Article 7(1) are set out...
The taxonomic status and the biology (for example mode of...

ANNEX VI

GUIDELINES FOR THE ASSESSMENT REPORTS

The assessment report provided for by Articles 13, 17, 19...
Identification of the characteristics of the recipient organism which are...

ANNEX VII

MONITORING PLAN

This Annex describes in general terms the objective to be...

A. Objective

B. General principles

C. Design of the monitoring plan

ANNEX VIII

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(**1**) OJ C 139, 4.5.1998, p. 1.

(**2**) OJ C 407, 28.12.1998, p. 1.

(**3**) Opinion of the European Parliament of 11 February 1999 (OJ C 150, 28.5.1999, p. 363), Council Common Position of 9 December 1999 (OJ C 64, 6.3.2000, p. 1) and Decision of the European Parliament of 12 April 2000 (OJ C 40, 7.2.2001, p. 123). Decision of the European Parliament of 14 February 2001 and Decision of the Council of 15 February 2001.

(**4**) OJ L 117, 8.5.1990, p. 15. Directive as last amended by Commission Directive 97/35/EC (OJ L 169, 27.6.1997, p. 72).

(**5**) OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 1999/80/EC (OJ L 210, 10.8.1999, p. 13).

(**6**) OJ L 214, 24.8.1993, p. 1. Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).

(**7**) OJ L 237, 28.8.1997, p. 18.

(**8**) OJ L 184, 17.7.1999, p. 23.