Ministry of Social Affairs and Health, Finland

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Decree of the Ministry of Social Affairs and Health on the deliberate release of genetically modified organisms

Issued in Helsinki on 16 February 2005

1 Chapter – General provisions

Section 1

Scope of application

This Decree lays down provisions on the information and documents required in applications for the deliberate release of genetically modified organisms, the risk assessment report to be prepared regarding the deliberate release of genetically modified organisms, the monitoring plan for placing products on the market and the reporting of the results of the release of genetically modified organisms for any other purpose than for placing on the market.

Section 2

Definitions

For the purposes of this Decree:

1) *seed plant* means a plant that belongs to the taxonomic group Spermatophytae (Gymnospermae and Angiospermae);

2) *genetically modified seed plant* means a genetically modified organism that is a seed plant;

3) *direct effects* means such primary effects on the health of humans or animals or on the environment that are due to the genetically modified organism as such and that do not emerge as a consequence of a causal chain of events;

4) *indirect effects* on the health of humans or animals or on the environment means effects as a result of a causal chain of events on the environment that occur as a result of interaction with various mechanisms, e.g. with other organisms, transfer of genetic material or alterations in the use or handling;

5) *immediate effects* means effects on the health of humans or animals or on the environment that are observed during the release of the genetically modified organism; immediate effects can be direct or indirect;

6) *delayed effects* means such effects on the health of humans or animals or on the environment that are perhaps not observed during the release of the genetically modified organism but that emerge as a direct or indirect effect either at a later stage or after the completion of release.

Chapter 2 – Information and documents required in the applications for deliberate release of genetically modified organisms

Section 3

Deliberate release for any other purpose than for placing on the market

(1) Applications for the deliberate release of a genetically modified organism other than a seed plant for purposes other than for placing on the market shall specify the information provided for in Chapter 3 and the risk assessment according to Chapter 6.

(2) Applications for the deliberate release of a genetically modified seed plant for purposes other than for placing on the market shall specify the information provided for in Chapter 4 and the risk assessment according to Chapter 6.

(3) The applications referred to in paragraphs 1 and 2 shall be accompanied by a summary of the application in accordance with the Council Decision establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market, hereinafter Council Decision 2002/813/EC.

Section 4

Placing products on the market

(1) An application for the placing on the market of a genetically modified organism other than a seed plant as a product or contained in a product shall specify the information provided for in Chapter 3, the additional information provided for in Chapter 5, the risk assessment in accordance with Chapter 6 and the monitoring plan drawn up in accordance with Chapter 7.

(2) An application for the placing on the market of a genetically modified seed plant as a product or contained in a product shall specify the information provided for in Chapter 4, the additional information provided for in Chapter 5, the risk assessment in accordance with Chapter 6 and the monitoring plan drawn up in accordance with Chapter 7.

(3) The applications referred to in paragraphs 1 and 2 shall be accompanied by a summary of the application in accordance with the Council Decision establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms as or in products, hereinafter Council Decision 2002/812/EC, as well as by a separate document containing the information referred to in article 3 of the Commission Decision 2004/204/EC laying down detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for

in Directive 2001/18/EC of the European Parliament and of the Council, hereinafter Commission Decision 2004/204/EC.

Chapter 3 – Genetically modified organisms other than genetically modified seed plants

Section 5

Scope of application

This Chapter lays down provisions on the information required in applications for the deliberate release of genetically modified organisms other than seed plants.

Section 6

General content of the application

(1) As regards the information referred to in this Chapter only the particulars that are essential in the case concerned shall be furnished in the application. The details of the required information may vary case by case according to the nature and scale of the suggested deliberate release.

(2) When processing the application the Board for Gene Technology checks that the application contains the information that is essential in the case concerned and that the required information that has been furnished is detailed enough.

Section 7

General information

The application shall specify:

1) the name and address of the operator;

2) the name(s), qualifications and experience of the responsible scientist(s);

3) the title of the project regarding deliberate release;

4) a description of the methods used or a reference to the standardised or internationally recognised methods on which the information given by the operator is based; and

5) the names of the responsible research institutes on whose research the information given by the operator is based.

Section 8

Information relating to the genetically modified organism

(1) The application shall specify the following information and characteristics of the donor and recipient organism and, as necessary, of the parental organism:

1) scientific name;

2) taxonomy;

3) other names, such as usual name, name or code of the strain;

4) phenotypic and genetic markers;

5) degree of relatedness between donor and recipient organisms 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 genetic transfer is known to take place under natural circumstances;

10) verification of the genetic stability of the organisms and factors affecting it;

11) the following pathological, ecological and physiological traits of the organisms:

a) classification of hazard according to existing Community rules concerning the protection of the health of humans and animals and of 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) information describing pathogenicity and related to pathogenicity: infectivity, toxigenity, virulence, allergenicity, carrier of pathogen, possible vectors, and host range including non-target organisms; possible activation of latent viruses and proviruses and ability to colonise other organisms;

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

f) involvement in environmental processes such as primary production, nutrient turnover, decomposition of organic matter and respiration;

12) the following information describing the nature of indigenous vectors in the organism:

a) sequence;

b) frequency of mobilisation;

c) specificity;

d) presence of genes which confer resistance; and

13) prior genetic modifications.

(2) The application shall describe the following characteristics of the vector used for the genetic modification:

1) the nature and source of the vector;

2) sequence of transposons, vectors and other non-coding genetic segments used to construct the genetically modified organisms and to make the introduced vector and insert function in the genetically modified organism;

3) frequency of mobilisation of inserted vector and its genetic transfer capabilities and methods of determination; and

4) information on the degree to which the size of the vector is limited to the minimum amount of DNA required to perform the intended function.

(3) The application shall describe the following information relating to the characteristics of the genetically modified organism:

1) information relating to the genetic modification:

a) the method(s) of modification;

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

c) description of the insert and vector construction;

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

e) the methods and criteria used for selection; and

f) sequence, functional ability and location of the altered, inserted and deleted nucleic acid segments in question with particular reference to any known harmful sequence; and

2) the following information on the final genetically modified organism:

a) description of genetic traits 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 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; and

h) history of previous releases or uses of the genetically modified organism.

Section 9

Information relating to the health of humans, animals and plants

The application shall specify the following information on the genetically modified organism relating to the health of humans, animals and plants:

1) toxic or allergenic effects of the genetically modified organism and its metabolic products;

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

3) capacity for colonisations;

4) if the organism is pathogenic to humans who are immunocompetent, the following information relating the genetically modified organism shall be given:

a) diseases caused and mechanism of pathogenicity including invasiveness and virulence;

b) communicability;

c) infective dose;

d) host range and its possibility of alteration;

e) possibility of survival outside of human host;

f) presence of vectors or means of dissemination;

g) biological stability;

h) description of antibiotic-resistance patterns;

i) allergenicity;

j) availability of appropriate therapies; and

5) other possible hazards relating to the product intended to be released on the market.

Section 10

Information relating to the conditions of release and the receiving environment

(1) The application shall specify the following information on the deliberate release:

1) description of the proposed deliberate release including the purpose and the foreseen products to be placed on the market;

2) foreseen dates of the release and time planning of the experiment including frequency and duration of the release;

3) preparation of the site of release previous to the deliberate release;

4) size of the site;

5) methods to be used for the release;

6) quantities of the genetically modified organisms to be released;

7) measures aimed at the site of release including type and method of cultivation, mining, and irrigation;

8) worker protection methods taken during the deliberate release;

9) post-release treatment of the site;

10) techniques foreseen for elimination or inactivation of the genetically modified organisms at the end of the experiment; and

11) information on, and results of, previous deliberate releases of the genetically modified organism, especially at different scales and in different ecosystems.

(2) The application shall specify the following information on the environment, both on the site of release and in the wider environment:

1) geographical location and grid reference of the site(s) of release; in case of applications regarding the placing on the market of a product, the site of the 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 and drinking water reserves;

4) climatic characteristics of the region likely to be affected by the release;

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 by the deliberate release;

8) a comparison of the natural habitat of the recipient organism with the proposed sites of release; and

9) any known planned development or changes in land use on the site of release which could influence the environmental impact of the release.

Section 11

Information relating to the interactions between the genetically modified organism and the environment

(1) The application shall specify the following information relating to characteristics affecting the survival, multiplication and dissemination of the genetically modified organisms:

1) biological characteristics affecting survival, multiplication and dissemination;

2) known or predicted environmental conditions which may affect survival, multiplication and dissemination, such as wind, water, soil, temperature and pH; and

3) sensitivity to specific agents;

(2) The application shall specify the following information relating to the interactions of the genetically modified organism with the environment:

1) predicted habitat of the genetically modified organism;

2) studies of the behaviour and characteristics of the genetically modified organisms and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms and greenhouses; and

3) the following information relating to the genetic transfer capability of the genetically modified organism:

a) post-release transfer of genetic material from the genetically modified organism into organisms in affected ecosystems; and

b) post-release transfer of genetic material from indigenous organisms to the genetically modified organism;

4) likelihood of post-release selection leading to the expression of unexpected and undesirable traits in the genetically modified organism;

5) measures employed to ensure and to verify genetic stability and methods to verify genetic stability;

6) description of genetic traits which may prevent or minimise dispersal of genetic material;

7) routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact and burrowing;

8) description of ecosystems to which the genetically modified organism could be disseminated;

9) potential for excessive population increase in the environment;

10) competitive advantage of the genetically modified organism in relation to the unmodified recipient or parental organisms;

11) identification and description of the target organisms, where appropriate;

12) anticipated mechanism and result of interaction between the released genetically modified organism and the target organism, where appropriate;

13) identification and description of non-target organisms in case the deliberate release of the genetically modified organism may affect the organisms concerned harmfully, and the predicted mechanism of identified harmful interactions;

14) likelihood of post-release shifts in biological interactions or in host range;

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

e) known or predicted involvement in biogeochemical processes; and

17) other possible interactions with the environment.

Section 12

Information on monitoring, control, waste treatment and emergency response plans

(1) The application shall specify the following information on monitoring techniques:

1) methods for tracing the genetically modified organism and for monitoring its effects;

2) specificity, sensitivity and reliability of the monitoring techniques to identify the genetically modified organism and to distinguish it from the donor, recipient or, where appropriate, the parental organisms;

3) techniques for detecting transfer of the donated genetic material to other organisms; and

4) duration and frequency of the monitoring.

(2) The application shall specify the following information on the control of the deliberate release:

1) methods and procedures to avoid or minimize the spread of the genetically modified organism beyond the site of release or the designated area for use;

2) methods and procedures to protect the site of release from intrusion by unauthorized individuals; and

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

(3) The application shall specify the following information on waste treatment:

1) type of waste generated;

2) expected amount of waste; and

3) description of the treatment envisaged.

(3) The application shall specify the following information on the emergency response plans:

1) methods and procedures for controlling the genetically modified organisms in case of unexpected spread;

2) methods for decontamination of the areas affected, such as eradication of the genetically modified organisms;

3) methods for disposal or sanitation of plants, animals, soils or other material that were exposed to the genetically modified organisms during or after the spread;

4) methods for the isolation of the area exposed to the genetically modified organisms in connection with the spread; and

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

Chapter 4 – Genetically modified seed plants

Section 13

Scope of application

This Chapter lays down provisions on the information required in applications for the deliberate release of genetically modified seed plants.

Section 14

General content of the application

(1) As regards the information referred to in this Chapter only the particulars that are essential in the case concerned shall be furnished in the application. The details of the required information may vary from case to case according to the nature and scale of the proposed deliberate release.

(2) When processing the application the Board for Gene Technology checks that the application contains the information that is essential in the case concerned and that the required information that has been furnished is detailed enough.

Section 15

General information

The application shall specify:

1) the name and address of the operator;

2) the name(s), qualifications and experience of the responsible scientist(s);

3) the title of the project regarding deliberate release;

4) a description of the methods used or a reference to the standardised or internationally recognised methods on which the information furnished by the operator is based; and

5) the names of the responsible research institutes on whose research the information furnished by the operator is based.

Section 16

Information relating to the recipient or, where appropriate, the parental plant

(1) The application shall specify the following information relating to the full name of the recipient or parental plant:

1) family name;

2) genus;

3) species;

4) subspecies;

5) cultivar; and

6) usual name.

(2) The application shall specify the following information relating to the reproduction of the recipient or parental plant:

1) modes of reproduction;

2) potential factors affecting reproduction;

3) generation time; and

4) the sexual compatibility of the plant with other cultivated or wild plant species including the distribution in Europe of the compatible species;

(3) The application shall specify the following information relating to the survival of the recipient or parental plant:

1) ability to form structures for survival or dormancy; and

2) potential factors affecting survivability;

(4) The application shall specify the following information relating to the dissemination of the recipient or parental plant:

1) means and extent of dissemination, such as estimation of how viable pollen or seeds decline with distance; and

2) potential factors affecting dissemination;

(5) The application shall specify the following information relating to the recipient or parental plant:

1) the geographical distribution of the plant;

2) description of the natural habitat of the plant if it is question of a species which is not normally grown in the member states of the European Union, including information on natural predators, parasites, competitors and symbionts; and

3) any other potential interactions, relevant to the genetically modified seed plant, of the plant with organisms in the ecosystems where it is usually grown, including information on toxic effects on humans, animals and other organisms.

Section 17

Information relating to the genetic modification

The application shall specify the following information relating to the genetic modification of the genetically modified seed plant:

1) description of the methods used for the genetic modification;

2) the nature and source of the vector use; and

3) the size of each constituent fragment of the region to be inserted, the origin, name and intended function of the donor organism(s).

Section 18

Information relating to the genetically modified seed plant

The application shall specify the following information on the genetically modified seed plant:

1) description of the traits or characteristics which have been inserted or modified;

2) the following information on the sequences inserted or deleted:

a) the size and structure of the insert and methods used for its characterisation, including information on any part of the vector introduced into the seed plant or any carrier or foreign DNA remaining in the genetically modified seed plant;

b) in regard to deletions, the size and function of the deleted regions;

c) the copy number of the insert; and

d) the location of the insert in the plant cells, such as in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form, and the methods for its determination;

3) the following information on the expression of the insert:

a) information on the developmental expression of the insert during the lifecycle of the plant and methods used for its characterisation; and

b) the parts of the plants where the insert is expressed, such as roots, stem and pollen;

4) information on how the genetically modified seed plant differs from the parental or recipient plant in the following respects:

a) modes and the rate of reproduction;

b) dissemination; and

c) survivability;

5) the genetic stability of the insert and the phenotypic stability of the genetically modified seed plants;

6) any change to the ability of the genetically modified seed plant to transfer genetic material to other organisms;

7) information on any toxic, allergenic or other adverse effects on human health arising from the genetic modification;

8) information on the safety of the genetically modified seed plant to animal health, particularly regarding any toxic, allergenic or other adverse effects arising from the modification, where the genetically modified seed plant is intended to be used in animal feedstuffs;

9) interaction between the genetically modified seed plant with the target organisms, if applicable;

10) potential changes in the interactions of the genetically modified seed plant with non-target organisms resulting from the genetic modification;

11) potential interactions with the abiotic environment;

12) description of detection and identification techniques for the genetically modified seed plant; and

13) information about previous releases of the genetically modified seed plant, if applicable.

Section 19

Information relating to the site of release

The applications for deliberate release for purposes other than for placing on the market shall specify the following information on the site of release:

1) location and size of the release site;

2) description of the release site ecosystems, including climate, flora and fauna;

3) presence of sexually compatible wild relatives or cultivated plant species; and

4) proximity of the release site to officially recognised biotypes or protected areas which may be affected by the deliberate release.

Section 20

Information relating to the deliberate release

The applications for deliberate release for purposes other than for placing on the market shall specify the following information on the deliberate release:

1) purpose of the release;

2) the foreseen dates and duration of the release;

3) the method by which the genetically modified seed plant will be released;

4) preparing and managing the release site prior to, during and after the deliberate release, including cultivation practices and harvesting methods; and

5) approximate number of the genetically modified seed plant to be released or the number of plants per square metre.

Section 21

Information on control, monitoring, the post-release phase and waste treatment

The applications for deliberate release for purposes other than for placing on the market shall specify the following information on control, monitoring, the post-release phase and waste treatment:

1) the following information relating to the precautionary measures undertaken:

a) distances from other sexually compatible plant species, both wild relatives and crops; and

b) measures to minimise or prevent dispersal of any reproductive organ of the genetically modified seed plant, such as pollen, seeds or tuber;

2) description of the methods for post-release treatment of the site of release;

3) description of the post-release treatment of the genetically modified seed plant material including wastes;

4) description of monitoring plans and techniques;

5) description of emergency plans; and

6) methods and procedures to protect the site.

Chapter 5 – Additional information relating to placing products on the market

Section 22

Scope of application

This Chapter lays down provisions on the additional information required in applications for placing on the market of products falling within the scope of application of Chapters 3 and 4.

Section 23

General additional information required in all applications

In addition to the information required in Chapters 3 and 4 the application for placing on the market of a product shall specify the following information:

1) the proposed commercial name of the product and names of the genetically modified organisms in the product, and any specific identification, name or code used by the operator to identify the genetically modified organisms as or in the product; once the consent for placing the product on the market has been granted all new commercial names shall be notified to the Board for Gene Technology;

2) the name and full address of the person established in the European Community who is responsible for placing the product on the market, whether it be the manufacturer, importer or distributor;

3) the name and full address of the supplier(s) of control samples;

4) a description of how the product is intended to be used; in particular highlighting any differences in use or management of the genetically modified organisms as or in the product compared to similar non-modified organisms;

5) a description of the planned area of use of the product, including the geographical area(s) and types of environment where the product is intended to be used within the European Union and, where possible, an estimate of the scale of use in each area; and

6) intended categories of users of the product, such as industry, agriculture, skilled trades and consumer use by the public at large.

Section 24

Additional information relating to genetic modification required in all applications

(1) In addition to the information required under Chapters 3 and 4 the application for placing a product on the market shall specify, for the register referred to in Commission Decision 2004/204/EC, the information relating to genetic modification of the genetically modified organism that can be used for the detection and identification of particular products to facilitate post-marketing control and inspection. This information shall include at least the following:

1) details of nucleotide sequences or other information that is necessary to identify the product and its progeny, for example the methodology for detecting and identifying the product, including experimental data demonstrating the specificity of the methodology; and

2) information on supplying samples of the genetically modified organisms or their genetic material as or in the product to the Board for Gene Technology.

(2) The operator shall identify the information relating to the genetic modification of the product that the operator considers confidential and that cannot be placed in the publicly accessible information in the register referred to in Commission Decision 2004/204/EC.

Section 25

Additional information regarding labelling required in all applications

The application for placing on the market of a product shall specify, in addition to the information required under Chapter 3 or 4, the proposed labelling for the product in a label or in an accompanying document. This labelling shall include at least in summarised form:

1) the commercial name of the product;

2) a statement ”This product contains genetically specified organisms”;

3) the names of the genetically modified organisms as or in the product and the information referred to in section 23 (2);

4) a statement on how to obtain information about the publicly accessible information on the product concerned placed in the register referred to in Commission Decision 2004/204/EC.

Section 26

Additional information required where necessary

In addition to the information required in sections 23 – 25 the application for placing a product on the market shall specify, where necessary, the following:

1) measures to be undertaken in the event of damage or misuse;

2) specific instructions or recommendations for storage and handling;

3) specific instructions for carrying out monitoring, reporting to the operator and, where applicable, reporting to the Board for Gene Technology so that the Board will obtain comprehensive information about any possible adverse effects of the products; the instructions must be consistent with the provisions on the monitoring plan in Chapter 7;

4) planned restrictions in the approved use of the genetically modified organisms, such as where the product may be used and for what purposes;

5) the planned packaging;

6) estimated production in and imports to the territory of the European Union; and

7) planned additional labelling, which may include at least in summarised form the information referred to in sections 1 – 4 and 23 (4) and (5).

Chapter 6 – Risk assessment

General provisions

Section 27

General principles of risk assessment

The following general principles shall be observed in the risk assessment referred to in section 8 of the Gene Technology Act (377/1995) in accordance with the principle of advance preparedness:

1) such modified characteristics and use of the genetically modified organism that may have adverse effects shall be compared to the characteristics of the organism from which the genetically modified organism concerned was developed and to its use in comparable situations;

2) the risk assessment shall be carried out in a scientifically sound and transparent manner based on available scientific and technical data so that the information, methods and tests that are used are clearly described;

3) the risk assessment must be carried out on a case by case basis; the required information and its details may vary depending on the type of the genetically modified organism, its intended use and the potential receiving environment, taking into account e.g. the genetically modified organisms already in the environment concerned;

4) the risk assessment shall include an analysis of the potential cumulative long-term effects on the health of humans and animals and on the environment related to the deliberate release of the

genetically modified organism; these effects may affect e.g. flora and fauna, soil fertility, soil degradation of organic material, the feed/food chain, biological diversity, and resistance problems in relation to antibiotics; and

5) if new information on the genetically modified organism and its effects on the health of humans and animals and on the environment becomes available, it may be necessary to carry out a new risk assessment in order to determine whether the risk has changed and whether it is necessary to change risk management correspondingly.

Section 28

Antibiotic resistance marker genes

(1) The risk assessment shall take into account in particular the genetically modified organisms that have genes that cause resistance to antibiotics used in the treatment of humans and animals. The purpose is to identify and gradually abandon such antibiotic resistance marker genes that may have adverse effects on the health of humans and animals and on the environment.

(2) The gradual abandonment shall be carried out:

1) by 31 December 2004 at the latest in regard to the products for which the consent for placing on the market has been granted in accordance with Chapter 6 of the Gene Technology Act; and

2) by 31 December 2008 at the latest in regard to the genetically modified organisms for which the consent for placing on the market has been granted in accordance with Chapter 5 of the Gene Technology Act.

Section 29

Information relating to characteristics and release of the genetically modified organism

(1) The risk assessment shall take into account on a case by case basis the relevant technical and scientific details regarding the characteristics and deliberate release of the following genetically modified organisms:

1) the characteristics of the recipient or parental organism(s);

2) the genetic modification in inclusion or deletion of genetic material;

3) essential information on the vector and donor;

4) characteristics of the genetically modified organisms;

5) intended deliberate release or use and its scale;

6) potential receiving environments; and

7) interactions between these.

(2) Information from releases of similar organisms and organisms with similar traits and their interaction with similar environments can assist the risk assessment.

Section 30

Instructions

The instructions for risk assessment based on the Commission Decision establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC are found in Annex 1.

The stages of risk assessment

Section 31

Identification of potential adverse effects

(1) Any characteristics relating to the genetically modified organism concerned that may result in adverse effects on the health of humans or animals or on the environment must be identified by comparing the characteristics of the genetically modified organism with those of the non-modified organisms under corresponding conditions of the release or use. No potential adverse effect may be discounted on the basis that it is unlikely to occur.

(2) Potential adverse effects of the genetically modified organism will vary from case to case, and may include:

1) disease to humans, including allergenic or toxic effects;

2) disease to animals or plants including toxic, and where appropriate, allergenic effects;

3) effects on the dynamics of populations of species in the receiving environment and their genetic diversity;

4) altered susceptibility to pathogens facilitating the dissemination of infectious diseases or creating new reservoirs or vectors;

5) compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine; and

6) effects on biogeochemistry, particularly carbon and nitrogen recycling through changes in soil decomposition of organic material;

(3) Potential adverse effects of the genetically modified organism may occur directly or indirectly through mechanisms, which may include:

1) the spread of the genetically modified organism into the environment;

2) the transfer of the inserted genetic material to other organisms, or to the same organism whether genetically modified or not;

3) phenotypic and genetic instability of the genetically modified organism;

4) interactions with other organisms; and

5) changes in management, including agricultural practices.

Section 32

Evaluation of the potential consequences of adverse effects

The magnitude of each consequence of the genetically modified organism that potentially occurs shall be estimated taking into account the intended environment and manner of the release of the genetically modified organism. The evaluation shall be made assuming that the adverse effect will occur. The magnitude of the consequences shall be expressed as follows:

1) high consequences;

2) moderate consequences;

3) low consequences; or

4) negligible consequences.

Section 33

Evaluation of the likelihood of the occurrence of potential adverse effects

The likelihood of the occurrence of each potential adverse effect of the genetically modified organism shall be evaluated taking into account the characteristics of the environment into which the genetically modified organism is intended to be released and the manner of the release. The likelihood of the occurrence shall be expressed as follows:

1) high;

2) moderate;

3) low; or

4) negligible.

Section 34

Estimation of the risks posed by potential adverse effects

The risk posed by the potential adverse effect of each identified genetically modified organism to the health of humans and animals and on the environment shall be estimated on the basis of the state

of the art by combining the likelihood of the adverse effect occurring and the magnitude of the consequences, if it occurs.

Section 35

Definition of the needed risk management strategy

The risks related to the deliberate release of the genetically modified organisms that require risk management shall be estimated on the basis of the information referred to in sections 32 – 34, and the methods that are most suitable for risk management shall be determined case by case.

Section 36

Determination of the overall risk

The overall risk of the genetically modified organism shall be estimated taking into account the magnitude of the potential adverse effects and the likelihood of their occurrence, including the risk management methods determined case by case.

Conclusions on the health and environmental impacts of the genetically modified organisms

Section 37

Genetically modified organisms other than genetically modified seed plants

The conclusions that are made on the basis of the risk assessment regarding the potential health and environmental effects of a genetically modified organism other than a seed plant shall specify the following information:

1) likelihood of the genetically modified organism to become persistent and invasive in natural habitats under the conditions of the proposed release;

2) any selective advantage or disadvantage conferred by the genetically modified organism and the likelihood of this becoming realised under the conditions of the proposed release;

3) potential for gene transfer to other species under conditions of the proposed release and any selective advantage or disadvantage conferred to those species;

4) potential immediate or delayed environmental impact of the direct and indirect interactions between the genetically modified organism and the target organism, if applicable;

5) potential immediate and delayed environmental impact of the direct and indirect interactions between the genetically modified organism with non-target organisms, including impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens;

6) possible immediate or delayed effects on human health resulting from potential direct or indirect interactions of the genetically modified organism and persons working with, coming into contact with or in the vicinity of the release of the genetically modified organism;

7) possible immediate or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the genetically modified organism and any product derived from it, if it is intended to be used as animal feed;

8) possible immediate or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the genetically modified organism and target or non-target organisms in the vicinity of the release; and

9) possible immediate or delayed, direct and indirect environmental impacts of the specific techniques used for the management of the genetically modified organism where these are different from those used for non-modified organisms.

Section 38

Genetically modified seed plants

The conclusions that are made on the basis of the risk assessment regarding the potential health and environmental effects of a genetically modified seed plant shall specify the following information:

1) likelihood of the genetically modified seed plant becoming more persistent than the recipient or parental plant in agricultural habitats or more invasive in natural habitats;

2) any selective advantage or disadvantage of the seed plant;

3) potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the genetically modified seed plant and any selective advantage or disadvantage conferred to those plant species;

4) potential immediate or delayed environmental impact resulting from direct and indirect interactions between the genetically modified seed plant and target organisms, such as predators, parasitoids, and pathogens;

5) possible immediate or delayed environmental impact resulting from direct and indirect interactions of the genetically modified seed plant with non-target organisms, also taking into account organisms which interact with target organisms, including impact on population levels of competitors, herbivores, parasites and pathogens and, where applicable, with symbionts;

6) possible immediate or delayed effects on human health resulting from potential direct or indirect interactions of the genetically modified organism and persons working with, coming into contact with or in the vicinity of the deliberate release of the genetically modified seed plant;

7) possible immediate or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the genetically modified seed plant and any product derived from it, if it is intended to be used as animal feed;

8) possible immediate or delayed effects on biogeochemical processes resulting from potential direct or indirect interactions of the genetically modified seed plant and target and non-target organisms in the vicinity of the release of the genetically modified seed plants; and

9) possible immediate or delayed, direct and indirect environmental impacts of the specific techniques used for the cultivation, management and harvesting of the genetically modified seed plant where these are different from those used for non-modified seed plants.

Chapter 7 – Monitoring plan regarding the placing on the market of products

Section 39

General principles for drawing up the monitoring plan

When drawing up the monitoring plan referred to in section 11 (2) of the Gene Technology Act the following general principles shall apply:

1) the monitoring plan shall be detailed and it has to be drawn up on a case by case basis taking into account the risk assessment carried out prior to the placing of the product on the market, including the characteristics or the product, its intended use, scale of the use and the environmental conditions of the intended site of release;

2) the monitoring plan shall be based on the state of the art and practices;

3) the monitoring plan shall be drawn up so that it facilitates the observation, in a systematic manner, of the release of a genetically modified organism as or in the product in the receiving environment and the interpretation of these observations with respect to safety to the health of humans and animals and protection of the environment;

4) the monitoring plan shall include a case-specific monitoring for the purpose of ensuring that the conclusions and assumptions of the risk assessment regarding the occurrence and consequences of adverse effects are valid (*case-specific monitoring*), as applicable, and always a general surveillance for the purpose of identifying the adverse effects that are not anticipated in the risk assessment (*general surveillance*);

5) when drawing up the monitoring plan it is possible to make use of the information obtained in connection with monitoring a release of the genetically modified organism concerned for purposes other than for placing on the market; and

6) the monitoring plan and the methods used for monitoring shall be reviewed at suitable intervals and, as necessary, be updated and adapted.

Section 40

General principles for observing the monitoring plan

In observing the monitoring plan the following general principles shall apply:

1) the monitoring according to the monitoring plan is started once the Board for Gene Technology has granted the consent referred to in section 21 of the Gene Technology Act for placing the product on the market;

2) the information collected in accordance with the monitoring plan shall be interpreted in the light of other existing environmental conditions; in case changes in the environment are observed, further assessment shall be carried out, if appropriate, to establish if the changes are due to the product placed on the market or some other reason; and

3) case-specific monitoring shall be carried out for a sufficient time period to detect immediate and direct as well as, where appropriate, delayed or indirect effects which have been identified in the environmental risk assessment.

Section 41

Content of the monitoring plan

(1) The monitoring plan shall include the following components:

1) the monitoring strategy;

2) monitoring methods; and

3) analyses, reports and revisions.

(2) The component of the monitoring plan regarding the monitoring strategy shall:

1) specify how the results of the risk assessment will be verified taking into account the use of the product in question and the receiving environment;

2) give an account of the approach chosen to observe in a systematic manner the potential adverse effects that will arise as a result of the placing on the market of the products in regard to both the general surveillance and case-specific monitoring; in this connection attention shall also be paid to monitoring the potential cumulative long-term effects referred to in section 27 (4);

3) determine the basic level of the receiving environment to identify the changes that will possibly be detected in the monitoring;

4) give a proposal for the time of application of the monitoring plan and the intervals for its revision:

5) identify, in regard to each step in the monitoring plan, who will carry out the tasks the monitoring plan requires and who is responsible for the observance of the monitoring plan and for informing the operator and the Gene Technology Board of any adverse effects on the health of humans or animals or on the environment that are possibly observed;

6) describe the existing established monitoring methods related to organisms other than genetically modified organisms that are possibly made use of in the monitoring; such monitoring systems can be e.g. the established species and plant protection monitoring systems; and

7) give consideration to mechanisms for identifying and confirming any observed adverse effects on the health of humans or animals or on the environment to enable the operator or the Board for Gene Technology, as appropriate, to undertake measures to protect the health of humans and animals and the environment.

(3) The component of the monitoring plan regarding the monitoring methods shall:

1) determine and give reasons for the variables or environmental factors that the monitoring is aimed at;

2) inform where the monitoring regarding the placing on the market of the product is carried out as well as the size of the area;

3) inform the frequency of carrying out of the intended inspections,

4) specify the samples and the methods of sampling and analysis by which the determined variables are intended to be monitored;

5) describe how and how often the monitoring material will be collected and who will do it; and

6) inform the deadlines for the reports on monitoring results and the frequency of reporting.

(4) The component of the monitoring plan regarding the analyses, reports and revisions shall:

1) inform how often the monitoring material will be evaluated, reviewed and dealt with in the general analysis;

2) evaluate the monitoring material on the basis of the statistical material;

3) report how the monitoring material will be made available to the operator and the Board for Gene Technology; and

4) specify how the operator will publish or report the information collected through the monitoring.

Section 42

Instructions

The instructions for the monitoring plan based on the Commission Decision establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC are found in Annex 2.

Chapter 8 – Reporting of results of the deliberate release of genetically modified organisms for purposes other than for placing on the market

Section 43

Reporting of results of the deliberate release of genetically modified seed plants for purposes other than for placing on the market

(1) The operator shall submit to the Board for Gene Technology a final report of each application for the deliberate release of a genetically modified seed plant for purposes other than for placing on

the market, as well as a final report and interim reports for the post-release monitoring, as appropriate.

(2) The final report shall be submitted after the last harvesting of the genetically modified seed plant. The Board for Gene Technology determines the timetable for any interim reports of the monitoring in its consent decision regarding the application. The final report on the post-release monitoring shall be submitted after the post-release monitoring has been completed.

(3) The operator shall submit the final and interim reports on the deliberate release of genetically modified seed plants for purposes other than for placing on the market to the Board for Gene Technology using the format referred to in Commission Decision (2003/701/EC) establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council a format for presenting the results of the deliberate release into the environment of genetically modified higher plants for purposes other than placing on the market.

Section 44

Additional information during the deliberate release of genetically modified seeds plants for purposes other than for placing on the market

The Board for Gene Technology may request additional information from the operator prior to the end of the deliberate release of genetically modified seed plants for purposes other than for placing on the market.

Section 45

Entry into force

This Decree enters into force on 1 March 2005.

ANNEXES

Annex I

INSTRUCTIONS FOR RISK ASSESSMENT

The text in italics is taken directly from the Decree.

General

Risk assessment is carried out regarding the deliberate release of genetically modified organisms for any other purposes than for placing on the market and regarding the placing on the market of products. The risk assessment regarding the deliberate release for any other purposes than for placing on the market may often differ from the risk assessment regarding the placing on the market of products due to, for example, the differences related to the information, the duration of the operation and the site.

General principles of risk assessment (section 27)

The following general principles shall be observed in the risk assessment in accordance with the precautionary principle:

1) such modified characteristics and use of the genetically modified organism that may have adverse effects shall be compared to the characteristics of the organism from which the genetically modified organism concerned was developed and to its use in comparable situations;

A baseline of the receiving environment, including its organisms and their interactions and their known variations, should be determined before any harmful characteristics of the genetically modified organism can be identified. The baseline would serve as a point of reference against which future changes can be compared. For example, in the case of vegetatively propagated crops, comparative analysis should include the parental species used to generate the transgenic lines. In the case of crops that reproduce sexually, comparators would include appropriate isogenic lines. If crops are developed using back-crossing, it would be important that in such cases substantial equivalence testing would use the most appropriate controls and would not simply rely on comparisons with original parental material.

If the existing data are not sufficient, a baseline has to be defined on other references to allow a comparison. The baseline will depend to a considerable extent on the receiving environment, including biotic and abiotic factors (for example, natural preserved habitats, agricultural farmland or contaminated land) or a combination of different environments.

2) the risk assessment shall be carried out in a scientifically sound and transparent manner based on available scientific and technical data so that the information, methods and tests that are used are clearly described;

Evaluation of potential adverse effects should be based on scientific and technical data and on common methodology for the identification, gathering and interpretation of the relevant data. Data, measurements and tests should be clearly described. In addition, the use of scientifically sound modelling procedures could provide missing data useful for the risk assessment.

The risk assessment would have to take into account uncertainty at various levels. Scientific uncertainty results usually from five characteristics of the scientific method: the variable chosen, the measurements made, the samples taken, the models used and the causal relationships employed. Scientific uncertainty may also arise from a controversy on existing data or lack of some relevant data. Uncertainty may relate to qualitative or quantitative elements of the analysis. The level of knowledge or data for a baseline is reflected by the level of uncertainty, which has to be provided by the operator (assessment of uncertainty, including lack of data, knowledge gaps, standard deviation, complexity, etc.) in comparison with the scientific uncertainties in current practice.

The risk assessment may not always result in definitive answers to all the questions considered because of lack of data. For potential long-term effects, in particular, the availability of data may be very low. In these cases in particular appropriate risk management (safeguards) would have to be considered in accordance with the precautionary principle in order to prevent adverse effects on human health and the environment.

The risk assessment should include the results of adequate research into the potential risks involved in the deliberate release or placing on the market of genetically modified organisms, along with any clearly documented comparable experience.

In the risk assessment, use of the step-by-step approach (i.e. all the steps beginning with experiments in the contained use system through deliberate release up to placing on the market) can be useful. Data from each step should be collected as early as possible during the procedure. Simulated environmental conditions in a contained space could give results of relevance to deliberate release (for example, the behaviour of microorganisms can be simulated in microcosms, or the behaviour of plants can be simulated in greenhouses to a certain extent).

If it is question of placing on the market of a product, relevant and available data from deliberate releases for any other purposes than for placing on the market should be provided from the types of environment where the genetically modified organism as or in a product will be used.

3) the risk assessment must be carried out on a case by case basis; the required information and its details may vary depending on the type of the genetically modified organism, its intended use and the potential receiving environment, taking into account e.g. the genetically modified organisms already in the environment concerned;

In accordance with section 7 (1) (3) of the Decree, the risk assessment shall use the case-by-case principle because of the broad range of individual characteristics of different organisms (genetically modified organism by genetically modified organism) and different environments (site by site and region by region).

There may be a huge variety in the environmental effects of genetically modified microorganisms (because of their small size and their often unknown interactions), plants (for example, seed plants used for food and feed, or trees because of their potential longevity), and animals (for example, insects because of their small size and their high potential for overcoming barriers; or saltwater fish because of their high distribution potential). These differences should be taken into account in the risk assessment based on the case-by-case evaluation.

In accordance with the case-by-case principle, the broad range of environmental characteristics (site-specific or regional-specific) should be taken into account. To support a case-by-case assessment, it may be useful to classify regional data by habitat area, reflecting aspects of the receiving environment relevant to genetically modified organisms (for example, botanical data on the occurrence of wild relatives of genetically modified plants in different agricultural or natural habitats of Europe).

In accordance with the case-by-case principle the operator should also take into account potentially harmful interactions of the genetically modified organism with any relevant genetically modified organisms that may have been deliberately released or placed on the market in the past, including repeated releases of the same genetically modified organism, such as the use of plant protection products. Repeated releases, as compared to occasional releases, might in time cause a high background level of the genetically modified organism to become permanent in the environment.

4) the risk assessment shall include an analysis of the potential cumulative long-term effects on the health of humans and animals and on the environment related to the deliberate release of the genetically modified organism; these effects may affect e.g. flora and fauna, soil fertility, soil degradation of organic material, the feed/food chain, biological diversity, and resistance problems in relation to antibiotics;

In considering the potential cumulative long-term effects pursuant to section 27(1)(4) of the Decree, the risk assessment should take into account issues such as:
a) the long-term interactions of the genetically modified organism and the receiving environment,
b) the characteristics of a genetically modified organism which become important on a long-term basis,
c) repeated deliberate releases over a long period,
d) the genetically modified organisms deliberately released in the past.

Further information may be required on long-term effects in particular (for instance, multiple herbicide resistances) and there must be adequate research, partly within the framework of the monitoring plans, which can provide important data for assessing cumulative long-term effects.

5) if new information on the genetically modified organism and its effects on the health of humans and animals and on the environment becomes available, it may be necessary to carry out a new risk

assessment in order to determine whether the risk has changed and whether it is necessary to change risk management correspondingly.

In the case of new information, irrespective of whether immediate measures need to be taken, there may have to be a new risk assessment, in accordance with section 27(1) (5) of the Decree, to assess the need to change the terms of authorisation for the genetically modified organism's deliberate release, or to adjust risk management measures. New information affecting the re-evaluation of the risk assessment can arise from research or from monitoring plans, or from relevant experience elsewhere.

Therefore, a risk assessment should not be viewed as static. It should be regularly reviewed and updated or perhaps changed to take account of relevant new data. Any reviews should consider the effectiveness, efficiency and accuracy of the risk assessment and risk management, taking account of data from research, other deliberate releases and monitoring data. This would also depend on the level of uncertainty determined by the risk assessment. Following any such reviews, the risk assessment and management should be adapted or upgraded as appropriate.

Risk assessment and monitoring are closely linked. The risk assessment provides the basis for the monitoring plans, which focus on the potential adverse effects on human health and the environment. The requirements for the monitoring plans for the deliberate release of genetically modified organisms for any other purposes than for placing on the market and for the placing on the market of products are different. Monitoring results may confirm the risk assessment or may lead to re-evaluation of the risk assessment.

Information relating to characteristics and release of the genetically modified organism (section 29)

The information on recipient, donor, vector, genetic modification and the genetically modified organism, on the basis of information required in chapters 3 and 4 of the Decree, is independent of the environment in which the genetically modified organism is to be deliberately released, and the conditions under which it will be deliberately released. This information is the basis for identifying any potential harmful characteristics of the genetically modified organism. Knowledge and experience gained in releases of the same or similar genetically modified organisms may provide important information on the potential hazards of the release in question.

Information on intended deliberate release, receiving environment and interaction between these, as required in chapters 3 and 4 of the Decree, relates to the particular environment into which the genetically modified organism will be released, and the conditions, including the scale of the release. This information will determine the extent of any potentially harmful characteristics of the genetically modified organism.

The stages of risk assessment (sections 31-36)

Risk assessment consists of the following six steps:

Step 1: Identification of potential adverse effects (section 31)
Step 2: Evaluation of the potential consequences of adverse effects (section 32)
Step 3: Evaluation of the likelihood of the occurrence of potential adverse effects (section 33)
Step 4: Estimation of the risks posed by potential adverse effects (section 34)
Step 5: Definition of the needed risk management strategy (section 35)
Step 6: Determination of the overall risk (section 36)

Identification of potential adverse effects (section 31)

In step 1 of the risk assessment the characteristics of the genetically modified organisms that may cause adverse effects should be identified. Most of the identifiable harmful characteristics which may cause adverse effects will be related to the genes of interest, deliberately introduced into the

genetically modified organism and the corresponding proteins being expressed from these genes. Additional adverse effects, for example, pleiotropic effects, might have been generated as a result of the method used to create the transgenes, and of the location of the construction in the genome of the genetically modified organism where the transgenes were inserted. Where more than one transgene is transferred into a recipient or where a transgene is transferred into a genetically modified organism, the potential interaction of the different transgenes has to be taken into account considering potentially epigenetic or regulatory effects.

If a harmful characteristic is present in the genetically modified organism, it is always present and it can be regarded as an inherent property. Harmful characteristics can give rise, with a given likelihood, to negative consequences and these consequences in turn can have different orders of magnitude (step 2 of the risk assessment). Finally, the individual harmful characteristics have to be summarised for the genetically modified organism.

At this stage of the risk assessment, however, it is only necessary to consider the harmful characteristics introduced as a result of genetic modification that could cause adverse effects. This step of the risk assessment provides the scientific basis for the following steps. Even at this stage, it is critical to identify, for each potential harmful characteristic, the specific level of scientific uncertainty so that it can be taken into account at a later stage.

Potential adverse effects of the genetically modified organism may occur directly or indirectly through mechanisms, which may include:

1) the spread of the genetically modified organism into the environment;

Distribution pathways show the potential pathways of distribution of the genetically modified organism or of the potential harmful characteristic into and within the environment (for example, human toxicity: inhalation of toxic microorganisms or toxic proteins).

The potential of a genetically modified organism to spread into the environment will depend, for example, on:

a) its biological fitness (genetically modified organisms designed for better performance in the environment of interest by the expression of traits leading to increased competitiveness in natural environments, or qualitative and quantitative change in composition of ingredients, or genetically modified organisms with resistance to natural selection pressure like disease, or abiotic stress like heat, cold, salt, or production of anti-microbial substances in microorganisms);
b) the conditions of the deliberate release (particularly the area of release and the scale, that is to say, the number of genetically modified organisms released);
c) the likelihood of a deliberate release, or unintentional releases into the environment, for example, concerning genetically modified organisms for processing;
d) pathways of dispersal of viable material (for example, seeds, spores and so on) by wind, water, animals, etc.; and
e) particular environmental considerations (site-specific or regional-specific): to allow a site-by-site or a region-by-region assessment it may be useful to classify data by habitat area, reflecting aspects of the receiving environment relevant to the genetically modified organism (for example, botanical data on the occurrence of crossable wild relatives of genetically modified plants in different agricultural or natural habitats of Europe).

It is also important to assess the length of time an individual genetically modified organism or a specific number of genetically modified organisms of a certain species is generally likely to survive, and the readiness with which it can be disseminated and become established in a variety of habitats. Consideration will need to be given to reproductive, survival and dormant forms, including, for example:

— for plants: the viability of pollen, seeds and vegetative structures; and
— for microorganisms: the viability of spores as survival forms, or the potential of the microorganisms to enter the viable but not cultivable state.

The overall spread potential may vary considerably, depending on the species, the genetic modification and the receiving environment (for example plant cultivation in the desert or fish cultivation in the sea).

2) the transfer of the inserted genetic material to other organisms, whether genetically modified or not;

A harmful characteristic could result in adverse effects through gene transfer within the same species or to other species (vertical and horizontal gene transfer). The speed and extent of gene transfer to other species (usually sexually compatible in the case of higher organisms) may depend, for example, on:

a) the reproductive properties of the genetically modified organism itself, including the modified sequences;
b) the conditions of release, and particular environmental considerations such as climate (for example, wind);
c) differences in reproduction biology;
d) agricultural practices;
e) the availability of potential crossing partners;
f) transport and pollinating vectors (for example, insects or birds, animals in general); and
g) the availability of hosts for parasites.

The occurrence of specific adverse effects through gene transfer may be linked to the number of genetically modified organisms released. Large fields of transgenic plants may have a completely different potential for gene transfer from small fields, even on a proportional basis. Moreover, qualitative and quantitative information about the existence of potential crossing partners or recipients (for plants within relevant distances) is very important.

For higher plants and animals, further distinctions should be made regarding possible gene transfer to the same, closely related, distantly related and unrelated species.

In the case of microorganisms, horizontal gene transfer plays a more important role. Certain genetic material can be easy transferred between more closely related organisms, for example, via plasmids or phages. The potential rapid growth rate of microorganisms can enable gene transfer at relatively high levels compared to higher organisms.

Transfer of transgenes may lead to a mixed population of genetically modified organisms or to different gene-plant combinations after a time, which can then give rise to complex patterns of especially long-term adverse effects. These will become more complex as more transgenic material is transferred into a population (for example, gene stacking).

In some cases, the method of genetic modification may change the potential for gene transfer, such as in the case of non-integrating plasmids or viral vectors. The method of genetic modification may also decrease the potential for gene transfer, for example, chloroplast transformation.

Gene transfer may result in persistence of the introduced genetic material in natural populations. If a genetically modified organism has the potential for gene transfer, this does not necessarily mean intrinsic risk, or a change in the capacity to survive, to become established or cause adverse effects. This will depend on the genetic material inserted, the species and the receiving environment, including the potential recipients.

3) phenotypic and genetic instability of the genetically modified organism;

In applying section 31(3) (3) of the Decree, the extent to which genetic instability might lead to phenotypic instability and result in a hazard should be considered. Instability of the genetic modification may in certain cases result in reversion into the wild type phenotype. Other cases should be considered, for example:

a) if in a transgenic plant line that contains more than one transgene, the subsequent segregation process results in these transgenes being divided up in the progeny, there could be plants with less transgenes but new phenotypes;
b) if attenuated mutants may, due to instability (because of the construction of the particular mutation) revert to virulence;
c) if duplication of transgenes leads to gene silencing;
d) if copy numbers are very high;
e) if re-insertion of transposable elements results in new phenotypes, due to inactivation of the transgene by the insertion of mobile genetic elements;
f) if the level of transgene expression is important (for example, a very low expression of a toxic substance), the genetic instability of the regulatory elements may result in a higher transgene expression.

Phenotypic instability could result from interaction with the environment during cultivation, so the effects of environmental and agronomic factors on expression of transgenes should be considered in the risk assessment.

If transgene expression is limited to a certain compartment in the genetically modified organism (such as a certain plant tissue), instability of regulation could result in expression of the transgene in the entire organism. In this context regulatory signals (such as promoters) play an important role and should be considered.

Also the expression of the transgene at a certain time in the life cycle of the organism or under specific environmental conditions should be considered.

Specific infertility transgenes may have been introduced into the genetically modified organism to make it infertile (for example, to prevent transfer and spread of certain transgenes). Instability of the infertility transgenes could result in reactivation of the fertility of the plant allowing the spread of the transgenes, which could have adverse affects.

The stability of the different transgene(s) not only in the primary genetically modified organism but also in its progeny is of importance for long-term effects in particular.

4) interactions with other organisms;

In applying section 31(3)(4) of the Decree, possible interactions with other organisms, including other genetically modified organisms, have to be carefully assessed, taking into account the complexity of multitrophic interactions. Directly hazardous interactions which could cause adverse effects might include:

a) exposure to humans (such as farmers, consumers);
b) exposure to animals;
c) competition for natural resources like soil, area, water, light;
d) displacement of natural populations of other organisms;
e) delivery of toxic substances; and
f) different growth patterns.

In general, if biological fitness is enhanced by the genetic modification, the genetically modified organism may invade new environments and replace existing species. Often the occurrence of specific adverse effects is proportionally linked to scale of release.

5) changes in management, including agricultural practices.

In applying section 31(3)(5) of the Decree, the relevance of changes in management procedures as an unavoidable consequence of the deliberate release of the genetically modified organism has to be assessed on the basis of existing procedures. Changes in farm management could, for example, relate to:

a) sowing, planting, growing, harvesting or transporting crops (for example, planting in small or large fields), timing;
b) crop rotation (for example, cultivating the same plant species every year or every fourth year);
c) disease and pest control (for example, type and dose of insecticide for plants, or antibiotics for animals, or alternative measures);
d) resistance management (for example, type and dose of herbicide for herbicide-tolerant plants, or change in use of biological control via Bt-proteins, or impact of viruses);
e) isolation in land agricultural and aquatic agricultural systems (for example, isolation distances in plant cultivation or quality of isolation in fish farms);
f) agricultural practices (farming genetically modified organisms and non transgenic farming, including organic farming),
g) management in non-agricultural systems (for example, isolation distances of natural habitats from genetically modified organism planting areas).

Evaluation of the potential consequences of adverse effects (section 32)

In step 2 of the risk assessment the potential consequences of adverse effects should be evaluated. Apart from the likelihood that the potential harmful characteristics will occur, evaluating the magnitude of the consequences is an important part of risk assessment. The magnitude is the extent to which the consequences of any potential harmful characteristics of the genetically modified organisms to be deliberately released will be realised.

The magnitude is to be seen in relation to the baseline and likely to be influenced by:

a) genetic construction;
b) each adverse effect identified;
c) the number of genetically modified organisms released (scale);
d) the environment into which the genetically modified organisms are to be released;
e) the conditions of the release, including control measures; and
f) combinations of the above.

For each adverse effect identified, the consequences for other organisms, populations, species or ecosystems exposed to the genetically modified organism have to be evaluated. This requires detailed knowledge of the environment into which the genetically modified organism is to be released (site, region) and the method of release. Consequences will range from negligible or insignificant and self-limiting to high or significant, either having an immediate and serious adverse effect or possibly leading to long-term, permanent adverse effects. In some cases, it is not possible to identify an adverse effect in a particular environment. In such cases, the risk associated with that particular adverse effect could be assessed as negligible or insignificant.

The following are suggested as illustrative and qualitative examples in a very broad sense. They are not intended to be definitive or exclusive, but to give an indication of the considerations that might be taken into account when weighing up the consequences:

High level consequences might be significant changes in the numbers of one or more species of other organisms, including endangered and beneficial species in the short or long term. Such changes might include a reduction in or complete eradication of a species leading to a negative effect on the functioning of the ecosystem and/or other connected ecosystems. Such changes would

probably not be readily reversible and any recovery of the ecosystem that did take place would probably be slow.

Moderate consequences might be significant changes in population densities of other organisms, but not a change which could result in the total eradication of a species or any significant effect on endangered or beneficial species. Transient and substantial changes in populations might be included if likely to be reversible. There could be long-term effects, provided there are no serious negative effects on the functioning of the ecosystem.

Low level consequences might be non-significant changes in population densities of other organisms, which do not result in the total eradication of any population or species of other organisms and have no negative effects on functioning of the ecosystem. The only organisms that might be affected would be non-endangered, non-beneficial species in the short or long term.

Negligible consequences would mean that no significant changes had been caused in any of the populations in the environment or in any ecosystems.

The above examples reflect the potential adverse effects of genetically modified organisms on populations, although in some cases, it may be more appropriate to consider the likely effects on individual organisms. One single harmful characteristic could have more than one adverse effect, and in fact the magnitudes of the individual adverse effects could be different. The adverse effects of one single harmful characteristic on human health, and agricultural and natural habitats could vary.

The potential consequences could be summarised in such a way as to cover all the ecological entities which could be affected (such as species, populations, trophic levels, ecosystems) including safeguard measures and the level of uncertainty.

Evaluation of the likelihood of the occurrence of potential adverse effects (section 33)

In step 3 of the risk assessment the likelihood of the occurrence of potential adverse effects should be evaluated. This step is to estimate how likely it is that adverse effects will actually occur. In some cases both the likelihood and the frequency should be addressed. As in step 2, besides the harmful characteristic itself, the number of genetically modified organisms, the receiving environment and the conditions of the release are important for defining the likelihood. Climatic, geographical, soil and demographic conditions, and the types of flora and fauna in the potential receiving environment are some of the important considerations.

For capability of survival, therefore, it is appropriate to assess the proportion of genetically modified organisms that are likely to survive, outside the intended risk management measures proposed for the deliberate release. Where gene transfer is likely, the probable number of such events or the extent to which transfer will occur should be considered. If the genetically modified organism has pathogenic or toxic characteristics, the proportion of target organisms in the environment likely to be affected should be assessed.

Moreover, the likelihood of the occurrence of an effect will depend on the specific risk management measures that may prevent that risk from occurring (for example, pollen dispersal is impossible due to the destruction of the inflorescences).

For each adverse effect identified, the relative likelihood of the consequence can probably not be assessed quantitatively, but it can be expressed in terms of high, moderate, low or negligible, in accordance with section 33 of the Decree.

The above examples reflect the potential adverse effect of the genetically modified organism on populations, although in some cases, it may be more appropriate to consider the likely effects on individual organisms. One single harmful characteristic could have more than one adverse effect, so

the likelihood of individual adverse effects could also be different. The adverse effects of one single harmful characteristic on human health, agricultural and natural habitats could vary.

Likelihood could be summarised in a way which covers all the ecological entities which could be affected (such as species, populations, trophic levels, ecosystems) including measures for limiting the potential effects as well as the level of uncertainty.

Estimation of the risks posed by potential adverse effects (section 34)

In step 4 of the risk assessment the risks posed by potential adverse effects should be estimated. In this step of the risk assessment, on the basis of the conclusions reached in steps 2 and 3, an estimate of the risk of adverse effects should be made for each harmful characteristic identified in step 1. Quantitative evaluation is unlikely to be possible in this context. The evaluation for each harmful characteristic should consider:

a) the magnitude of the consequences;
b) the likelihood of the occurrence of the adverse effect; and
c) if a harmful characteristic has more than one adverse effect, the magnitude and likelihood of occurrence of each individual adverse effect.

Each genetically modified organism has to be considered on a case-by-case basis. Any general attempt to quantify what has been described before has to be made very carefully. For example, in one case the high magnitude of the consequences of an adverse effect may be combined with a negligible likelihood of it occurring, resulting in the whole range from high risk down to negligible risk. The result will depend on the circumstances of the case and the weighting of certain factors by the operator, all of which should be set out clearly and justified in the recorded risk assessment.

The overall uncertainty for each identified risk has to be described, possibly including documentation relating to:

a) assumptions and extrapolations made at various levels in the risk assessment;
b) different scientific assessments and viewpoints;
c) uncertainties;
d) the known limits of mitigation measures; and
e) conclusions that can be derived from the data.

Although the risk assessment should be based on quantifiable outcomes, it is likely that many of the results of the risk assessment will have to be qualitative. But it is necessary, wherever possible, to have risk assessment results which are comparable, for example, with results concerning non-modified organisms.

Definition of the needed risk management strategy (section 35)

In step 5 of the risk assessment the needed risk management strategy should be defined. Before applying risk management, consideration should be given, with a view to prevention, to modifying the release, preferably until the risk is negligible. For example, genetic elements, which may cause adverse effects or are undefined, should be avoided in the gene construction process. If this is not possible, these genetic elements should preferably be removed from the genetically modified organism at a later stage, prior to its deliberate release. The definition of the needed risk management strategy should be taken into account in steps 1 to 4 of the risk assessment. Risk management should cover the identified risks and the uncertainties. Safeguard measures should be proportionate to the level of risk and to the level of uncertainty. When relevant data becomes available at a later stage, risk management should be adapted in line with that new data.

To reduce the risk by management, the measures should clearly achieve that end. For example, if there is a risk of a gene toxic to insects inserted into a crop plant being transferred to related plant

species, suitable safeguard measures might include spatial or temporal isolation from those related species or perhaps changing the release site to an area where there is no risk.

Risk management strategy can include measures at every relevant stage of the handling and use of genetically modified organisms. They can also include a wide range of measures, including various means to isolate reproduction, physical or biological barriers, and cleaning machines or containers in contact with genetically modified organisms, and so on. Detailed risk management procedures will depend on:

a) the use of the genetically modified organism (type and scale of deliberate release or placing on the market);
b) the type of genetically modified organism (for example, genetically modified microorganisms, annual seed plant, long-life seed plant or animal, genetically modified organism with single or multiple modification, and the use of one or many genetically modified organisms;
c) the general type of habitat (for example, biogeochemical status, climate, availability of inter- and interspecific crossing partners, centres of origin, connection of different habitats);
d) the type of agricultural habitat (for example, agriculture, forestry, aquatic culture, rural areas, size of sites, number of different genetically modified organisms); and
e) the type of natural habitat (for example, status of preserved areas).

In the risk management strategy there should be a clear statement of the implications of risk management, the necessary adjustments to experiments or to conditions for placing on the market of the product, and also how much these measures are likely to reduce the risk.

Determination of the overall risk (section 36)

In step 6 of the risk assessment, on the basis of step 4 and, if appropriate, step 5, a final evaluation should be made of the overall risk, including the magnitude and likelihood of the occurrence of the adverse effects of the genetically modified organism, based on the combination of the risks from each individual adverse effect, including cumulative effects from other genetically modified organisms. This final evaluation should be expressed in the form of a summary of the overall risks from deliberate release, including the overall uncertainties.

Annex II

The text in italics is taken directly from the Decree.

General principles for drawing up the monitoring plan (section 39)

When considering the case-specific monitoring referred to in section 39 (1)(4) of the Decree, focus should be, when included in the monitoring plan, on potential effects arising from the placing on the market of a product that have been highlighted as a result of the conclusions and assumptions of the risk assessment. However, whilst it is possible to predict that certain effects may occur, on the basis of risk assessment and available scientific information, it is considerably more difficult to plan for potential effects or variables that cannot be foreseen or predicted. It may, however, be possible through appropriate planning of monitoring to optimise the chances for early detection of such effects. The monitoring plan should therefore incorporate general surveillance for unanticipated or unforeseen adverse effects.

Pursuant to section 39(6) of the Decree, the monitoring plan should not be viewed as static, but it should be reviewed at appropriate intervals and updated or adapted as necessary on the basis of the results obtained during monitoring. Reviews of the monitoring plans should examine the effectiveness and efficiency of data measurements and collection, including sampling and analysis. The review should also evaluate whether the monitoring measures are effective in addressing the evaluations and any questions arising from the risk assessments. For example, if specific models are used for predictive purposes, a validation based on the data collected and subsequent appraisal should be conducted. Similarly, new developments and progress in sampling and analytic techniques should also be taken into account where appropriate.

General principles for observing the monitoring plan (section 40)

Pursuant to section 40(2) of the Decree, one of the general principles for observing the monitoring plan is that the interpretation of the data collected via monitoring should take account of existing environmental conditions, and where unexpected changes in the environment are observed, further assessment may need to be carried out to establish whether they have arisen as a consequence of the placing on the market of the product or as a result of other factors. When considering the data collected via monitoring, the existing environmental conditions and activities should therefore be taken account of to determine an appropriate baseline. General surveillance and environmental monitoring programmes in general may assist in this context.

Content of the monitoring plan (section 41)

(1) The monitoring plan shall include the following components:
1) the monitoring strategy;
2) monitoring methods; and
3) analyses, reports and revisions.

The monitoring strategy referred to in section 40(1)(1) importantly requires identification of the potential effects that may arise from the placing on the market of the product, the degree to which they need to be monitored and appropriate approaches and time-scales over which to monitor.

In the first instance, the likelihood of potential direct, indirect, immediate or delayed adverse effects arising from the GMO as or in a product should be considered in line with its intended use and the receiving environment.

For example, when considering a crop modified for resistance against a specific insect, direct effects may include death and changes in the population of both target and non-target insects that arise as a result of the toxin produced by the GMO as or in a product. In this case indirect effects may include effects where, for example, a reduction in the population of target insects impacts on populations of other organisms that normally feed on these insects.

Indirect effects may involve interactions between a number of organisms and the environment making it more difficult to predict any potential effect. Observations of indirect effects are also likely to be delayed. These factors must, however, be considered as part of the strategy.

The build-up of resistance by insects to the Bt-toxin through continued exposure is an example of a delayed effect.

Immediate and delayed effects may themselves be either direct or indirect but imply a time-scale for change. Direct effects are more likely to appear in the immediate or short term at a level that can be detected. Indirect effects may take a longer time period to manifest but nevertheless may need to be taken into account.

(2) The component of the monitoring plan regarding the monitoring strategy shall:

1) specify how the results of the risk assessment will be verified taking into account the use of the product in question and the receiving environment;

This should take account of the conclusions and assumptions from the risk assessment, based on scientific evaluation and the recommendations of expert committees. In addition, issues arising from the risk assessment that are subject to a degree of uncertainty, for example possible effects that may appear only where releases are of a large scale, are also required as part of the monitoring strategy.

2) give an account of the approach chosen to observe in a systematic manner the potential adverse effects that will arise as a result of the placing on the market of the products in regard to both the general surveillance and case-specific monitoring; in this connection attention shall also be paid to monitoring the potential cumulative long-term effects referred to in section 27 (4);

The approach should provide the means to detect potential adverse effects at an early stage of manifestation. Early detection of any adverse effects attributable to a GMO will allow for more rapid reassessment and implementation of measures to reduce any consequences to the environment.

The design of monitoring plans for GMOs as or in products to be placed on the market should be built using a step-by-step approach taking account of existing data and monitoring methodology. A step-by-step approach will in many cases also need to take account of the scale of release. The first step may be founded on evidence from experimental trials with subsequent steps based on large-scale field trials and ultimately to surveys on commercial plots. Experience and information gained through the monitoring of deliberate releases of GMOs as or in a product for any other purposes than for placing on the market is, therefore, likely to be useful in designing the post marketing monitoring regime required for the placing on the market of GMOs.

Both case-specific monitoring and general surveillance could make use of established routine surveillance practices.

Case-specific monitoring in the monitoring strategy

Case-specific monitoring serves to confirm that scientifically sound assumptions, in the risk assessment, regarding potential adverse effects arising from a GMO and its use are correct.

The approach should:

a) focus on all the potential effects on human and animal health and the environment identified in the risk assessment, taking into account, among other things, different locations, soil types, climatic conditions, and
b) define a specified time period in which to obtain results.

The first step in developing a monitoring plan for case-specific monitoring is to determine the case-specific objectives of the monitoring strategy. This includes determining which assumptions regarding the occurrence and impact of potential adverse effects of the GMO or its use were made in the risk assessment. Where the conclusions of the risk assessment identify an absence of risk or negligible risk, however, then case-specific monitoring may not be required.

Potential adverse effects that are identified in the risk assessment should only be included in the monitoring plan on the basis that monitoring could contribute to the confirmation or rejection of the assumptions associated with these effects.

If the intended use of a GMO includes cultivation, then consideration may have to be given to the monitoring of potential risks arising from pollen transfer, dissemination and persistence of these GMOs. The degree to which these phenomena are likely to occur will also be dependent on the scale of this use and the receiving environment including the proximity to and scale of production of sexually compatible conventional crop species and wild relatives.

Potential environmental risks arising from GMOs approved only for import and processing will likely often be assessed as extremely limited given that they will not be intentionally introduced into the environment and that they are unlikely to disseminate.

Potential effects on human or animal health or the environment arising from the deliberate release of a GMO will firstly depend on the inherent nature of a GMO and its specific genetic modification. For example, potential effects arising from transfer of pollen from genetically modified crops to non GM-crops or related wild-type plants will in the first instance be largely dependent on whether the genetically modified crop is out-crossing or self-pollinating. The presence of wild relatives may also need to be considered in this context.

However, for example, the potential development of insect resistance to the Bt-toxin will only be linked to GMOs modified to express this specific toxin. Similarly, it would only be relevant to monitor the potential transfer of antibiotic resistance genes and the possible consequences with respect to GMOs that include antibiotic marker genes as part of the modification.

After identification of the objectives on the basis of potential adverse effects, the next step should be to identify the parameters that need to be measured in order to achieve these objectives. Parameters as well as the methods used to measure and evaluate them must be valid and fit-for-purpose.

General surveillance in the monitoring strategy

General surveillance is largely based on routine observation and should be used to identify the occurrence of unforeseen adverse effects of the GMO or its use for human or animal health and the environment that were not predicted in the risk assessment. This is likely to involve observation of phenotypic characteristics but more detailed analyses are not precluded.

In contrast to case-specific monitoring, general surveillance should:

a) Seek to identify and record any indirect, delayed and/or cumulative adverse effects that have not been anticipated in the risk assessment;
b) Be carried out over a longer time period and possibly a wider area.

The type of general surveillance, including locations, areas and any parameters to be measured, will largely depend on the type of unanticipated adverse effect being surveyed. For example, any unanticipated adverse effects on a cultivated ecosystem, such as changes in bio-diversity, cumulative environmental impacts from multiple releases and interactions, may require a different approach to the general surveillance of other effects arising from gene transfer.

General surveillance could, where compatible, make use of established routine surveillance practices such as monitoring of agricultural crops, plant protection, veterinary and medical products as well as ecological monitoring, environmental observation and nature conservation programmes. The monitoring plan may also provide details as to how relevant information collected through established routine surveillance practices conducted by third parties will be retrieved by, or made available to, the operator.

If established routine surveillance practice is used in the general surveillance, this practice should be described as well as the changes in the practice needed to fulfil a relevant general surveillance.

3) determine the baseline of the receiving environment to identify the changes that will possibly be detected in the monitoring;

Determination of the baseline status of the receiving environment is a pre-requisite for the identification and evaluation of changes observed via monitoring. The baseline serves as a point of reference against which any changes arising from the placing on the market of a GMO can be compared. This baseline should, therefore, be determined prior to attempting to detect and monitor any such changes. Parallel monitoring of 'GMO-areas' and comparable 'non-GMO reference areas' may provide an alternative, and this may be important where environments are highly dynamic.

Therefore, reliable information about the status of the receiving environment, on the basis of adequate environmental observation systems, may be required prior to implementation of monitoring programmes and environmental policy actions. Environment observation programmes are designed to take proven or suspected and plausible ecosystem relationships into account and may assist in the determination of the:

a) status of the environment and changes therein;
b) causes of such changes; and
c) expected development of the environment.

Examples of indicators of the status of the receiving environment may include animals, plants and micro-organisms from different organism groups and ecosystems. Relevant indicators may be considered on the basis of the characteristics of the GMO in question and the parameters to be monitored. Sexual compatibility of other organisms with the GMO may also be relevant in this context. For a particular indicator species, a number of possible measurement parameters or fitness variables will exist, including the likes of numbers, growth rate, bio-mass, reproductive effort, population rate of increase/decrease and genetic diversity.

It may also be necessary to consider baselines in relation to changes in management practice resulting from the use of GMOs. This could include, for example, changes in pesticide usage with respect to the cultivation of crop species modified for tolerance to herbicides and resistance to insects. It may also be appropriate when considering the monitoring plan for herbicide-tolerant genetically modified crops, to consider herbicide use for conventional crops as part of an appropriate baseline.

4) give a proposal for the time of application of the monitoring plan and the intervals for its revision;

In the proposal for the time of application of the monitoring plan it should be considered that monitoring should be carried out over a time period of sufficient length to detect not only immediate potential effects, where appropriate, but also delayed effects which have been identified in the environmental risk assessment. Consideration should also be given to the interplay between the estimated level of risk and the duration of the release. A prolonged period of release may increase the risk of cumulative effects. The non-appearance of immediate effects over a prolonged period, on the other hand, may allow monitoring to focus on delayed and indirect effects. It should

also be considered whether it is necessary to extend the monitoring plan beyond the period of the consent. This may be the case, for example, where the persistence of GMOs in the environment has the potential to be significant.

The proposed time-period of the monitoring plan should be indicated, including an outline of the likely frequency of visits/inspections and any intervals for review of the monitoring plan. This should take account of the likely appearance of any potential effects as highlighted in the risk assessment. For example, consideration should be given to any potential adverse effect resulting from the dissemination, reproduction and persistence/survival of a GMO in the environment following its placing on the market. This may be a matter of days or months for genetically modified microorganisms released in bio-remediation programmes, but could extend to a number of years where certain crop species are concerned. The likelihood of dissemination and persistence of the modified sequences themselves should also be considered in terms of crosses with sexually compatible species.

The planning of inspections will largely be dependent on the type of effect to be monitored. For example, effects arising from pollen transfer will only be visible following flowering although it would be pertinent to visit the site prior to flowering to establish the extent to which sexually compatible species are present in the vicinity. Similarly, monitoring for the appearance of volunteers in subsequent growing seasons will be linked to the time of seed shed and persistence and germination of the subsequent seed bank.

Prior visits may also be necessary, as appropriate, prior to the onset of monitoring in order to establish relevant baselines.

Monitoring plans and their time-periods should not be considered as fixed, but reviewed and amended in light of results obtained during the monitoring programme.

5) identify, in regard to each step in the monitoring plan, who will carry out the tasks the monitoring plan requires and who is responsible for the observance of the monitoring plan and for informing the operator and the Board for Gene Technology of any adverse effects on the health of humans or animals or on the environment that are possibly observed;

In accordance with section 41(2)(5) of the Decree, the operator should clearly assign responsibilities for each step of the monitoring plan in the monitoring plan. This would apply to both case-specific monitoring and also general surveillance as part of the monitoring plan. Whilst the operator retains responsibility for ensuring that monitoring is carried out, this does not preclude that third parties such as consultants and users could be involved in the monitoring by carrying out various tasks the monitoring plan requires. In case of general surveillance this could include the Commission, the Member States and/or the Board for Gene Technology. Where third parties are employed or contracted to conduct monitoring studies, the structure of their involvement should be detailed. The operator is responsible for the compilation of the monitoring data and results and has to ensure the transmission of this information to the Commission and the Board for Gene Technology according to the monitoring plan, particularly with respect to the identification of any adverse effects.

It is not precluded that the Member States of the European Communities carry out additional monitoring in the form of case-specific monitoring or general surveillance. The aim of such surveillance is to enable the risk manager to take appropriate measures without delay should any undesirable and unidentified effects arise in the framework of prior risk assessment. This should not, however, be considered a substitute for the monitoring plan, which remains under the responsibility of the operator for implementation (although, with the consent of relevant parties, may form part of it).

6) describe the existing established monitoring methods related to organisms other than genetically modified organisms that are possibly made use of in the monitoring;

It may be possible to extend existing monitoring systems to address potential adverse effects arising from the placing on the market of GMOs. These systems may include observation programmes in the field of agriculture, food surveys, nature conservation, long-term ecological monitoring systems, environment observation programmes and veterinary surveys.

For example, seed production systems that follow OECD certification rules and therefore include routine inspections of fields and surrounding areas could be adapted to on-field monitoring for specified parameters.

Monitoring and surveillance of conventional commercial crops is already carried out, as a matter of course in Member States, with regard to calculation of fertiliser application as well as pest, disease and weed control. This type of monitoring and surveillance is conducted on a regular basis throughout the growing season by consultants selling the relevant agronomic products and the growers themselves. It may, therefore, be possible to attach a similar service to sales of genetically modified seed, where representatives of the company, or contracted consultants, may provide at least some form of general surveillance. Instructions concerning surveillance, monitoring and reporting could be distributed to growers purchasing genetically modified seed stocks, and contractual agreements could be formulated as a condition of sale or use.

Growers or agronomic consultants could conduct surveys of major unforeseen changes or effects such as dissemination and establishment of volunteer plants in adjacent areas if clear instructions are provided. Under these circumstances, it is foreseen that monitoring and surveillance for adverse effects could be incorporated into routine practices for determining agronomic inputs for pest and weed control.

The component of the monitoring plan regarding the monitoring methods shall:

1) determine and give reasons for the variables or environmental factors that the monitoring is aimed at;

Firstly, it will be necessary to identify the relevant parameters/elements to be monitored with appropriate justification for their selection. This will largely be dependent upon the conclusions of the risk assessment. Decisions as to the parameters or elements to be monitored must be taken on a case-by-case basis in line with the modified characteristics of the GMO in question. This would include the likes of monitoring of intended effects on target organisms arising from the modification, an example of which would be monitoring of corn borer populations with respect to the cultivation of Bt-maize varieties.

However, non-specific elements may also need to be considered as part of the monitoring plan, and examples of such elements are presented as follows although others are not precluded:

a) Effects on non-target organisms arising from the modification, including development of resistance in wild relatives or pest organisms, change in the host range or in the dispersal of pest organisms and viruses, development of new viruses;
b) Dispersal, establishment and persistence into non-target environments or eco-systems;
c) Out-crossing/breeding (e.g. occurrence, means and rates of out-crossing/breeding), with sexually compatible wild relatives in natural populations;
d) Unintended changes in the basic behaviour of the organism, for example, changes in reproduction, number of progeny, growth behaviour and survival ability of the seeds;
e) Changes in bio-diversity (e.g. in number or composition of species).

2) inform where the monitoring regarding the placing on the market of the product is carried out as well as the size of the area;

The monitoring plan should include details as to where the monitoring will be carried out and over what area and the size of the area. This may be at the level of individual Member States, geographical regions, individual sites, plots or any other area(s) deemed appropriate.

The areas and/or samples to be monitored with respect to possible effects arising from the placing on the market of the GMO as or in a product should be identified, including those for the purpose of reference or control. Any reference or control areas and/or samples must be sufficiently representative in terms of different environments and conditions of use for meaningful conclusions to be drawn. Moreover, any sampling methodology should be scientifically and statistically sound. On this basis, such data can provide important information on the variation of indicators, which will increase the power of the effect detection.

When considering the areas to be monitored with regard to, for example, a genetically modified crop species, its characteristics (both inherent and modified) as well as its reproduction and dissemination and the types of ecosystems that may be affected could be considered in determining the areas selected for monitoring. Relevant areas to monitor should include selected agricultural fields where the crop is commercially grown as well as surrounding habitats.

It may also be necessary to extend monitoring/surveillance to adjacent or neighbouring cultivated and non-cultivated areas, post-harvest surveillance areas for volunteer plants and protected areas. Certain types of habitats, such as disturbed areas and species-rich plant communities, are more prone to invasion than others. Disturbed areas with low vegetation and high abundance of herbs and grasses are particularly suitable for the purpose of monitoring. Firstly, they are widely distributed and often found close to more intensively cultivated agricultural areas. Secondly, these areas are often typical of roadsides, ditches and edges of fields where accidental loss and dispersal of seeds is most likely to occur in the first instance.

Monitoring for the possibility of transfer of genetic material to sexually compatible organic and conventional crops may also be considered. This will require evaluation of the extent to which such crops are grown in adjacent or neighbouring areas.

3) inform the frequency of carrying out of the intended inspections;

The monitoring plan should indicate the timing and number of intended inspection visits to a site, which may be represented in the form of a timetable. In this respect, consideration should importantly be given to the time when potential adverse effects are most likely to appear as well as the area(s) to be monitored.

4) specify the samples and the methods of sampling and analysis by which the determined variables are intended to be monitored;

The methodology to subsequently monitor these parameters/elements should also be clearly identified and outlined, including techniques for sampling and analysis. Standard methodology, as provided for by the likes of European CEN Standards and OECD-methods for monitoring organisms in the environment, should be followed where appropriate, and reference to the source of the methodology provided. Methods used for monitoring should be scientifically sound and valid under the experimental conditions in which they are to be applied; therefore, consideration should be given to the characteristics of the methods, such as selectivity, specificity, reproducibility, any limitations, detection limits, and the availability of appropriate controls.

The monitoring plan should also indicate how the methodology is expected to be updated, if appropriate, according to the selected monitoring approach/strategy.

Statistical analysis could also be employed when designing the appropriate sampling and testing methodology, in order to determine optimal sample sizes and minimum monitoring periods for the required statistical level of effect detection.

5) describe how and how often the monitoring material will be collected and who will do it;

This may be of particular importance where third parties are employed or contracted to collect data. Operators may need to provide the third parties carrying out the work with standard mechanisms, formats and protocols for data collection and recording in order to ensure consistency. For example, standardised recording sheets or direct logging or registration of data on standardised 'spread-sheets' via portable computers could be provided. The operator may also need to detail how the data will be collated, importantly how information is to be retrieved from third parties, such as consultants or users.

(4) The component of the monitoring plan regarding the analyses, reports and revisions shall:

1) inform how often the monitoring material will be evaluated, reviewed and dealt with in the general analysis;
2) evaluate the monitoring material on the basis of the statistical material;

Evaluation of data should, where appropriate, include statistical analysis with appropriate standard error values to enable subsequent decisions to be taken on a sound basis. These will include decisions as to whether evaluations highlighted in the risk assessment are correct. In this respect, correct baselines and/or controls relating to the status of the receiving environment are also paramount for accurate evaluations. Use of statistical analysis should also provide information as to whether the type of methodology, including sampling and testing, is appropriate.

The evaluation of results from monitoring may reveal whether other parameters should be monitored under the programme. Appropriate responses to any preliminary findings may also need to be examined, in particular, where potential negative impacts on vulnerable habitats and organism groups are suggested.

The interpretation of the data collected by monitoring may need to be considered in the light of other existing environmental conditions and activities. Where changes in the environment are observed, further assessment may be required to establish whether they are a consequence of the GMO or its use, or whether such changes may be the result of environmental factors other than the placing of the GMO as or in a product on the market. It may be necessary to re-evaluate the baselines used for comparison in this respect.

The monitoring plan should be structured in such a way, that the results of both the case-specific monitoring and general surveillance as well as additional research could clearly be used in the decision-making process for renewal of approval for products.

3) report how the monitoring material will be made available to the operator and the Board for Gene Technology;

For example, the monitoring plan should indicate how relevant information collected through any established or routine surveillance practices will be made available to the operator and the Board for Gene Technology.

4) specify how the operator will publish or report the information collected through the monitoring.

This could for example be achieved via:

a) information sheets to users and other stakeholders;
b) workshops to present and exchange information with stakeholders;
c) archived in-company documents;
d) inclusion of the information on company web-sites; and
e) publication of information in trade and scientific publications.