Council Decision of 3 October 2002 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 (2002/813/EC)

# COUNCIL DECISION

# of 3 October 2002

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

# (2002/813/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Directive 90/220/EEC<sup>(1)</sup>, and in particular Article 11(1) thereof,

Having regard to the proposal from the Commission,

Whereas:

- (1) Under Part B of Directive 2001/18/EC, prior notification must be given to the competent national authority of the planned release of a genetically modified organism (hereinafter referred to as GMO), or of a combination of such organisms, for purposes other than for placing on the market.
- (2) Within the framework established by the Directive 2001/18/EC for the exchange of information between the competent authorities and the Commission, the authority must then send a summary, in accordance with a specific format, of the notification to the Commission, which in turn must forward copies to the other Member States.
- (3) That format should reflect the need to enable the fullest possible exchange of relevant information, presented in a standardised and easily comprehensible manner, without prejudice to the fact that the information thus provided cannot serve as the basis for an environmental risk assessment.
- (4) The committee set up under Article 30(2) of Directive 2001/18/EC was consulted on 12 June 2002 and has not delivered an opinion on the Commission's proposal for a Decision,

HAS ADOPTED THIS DECISION:

## Article 1

For the purposes of summarising, for transmission to the Commission, notifications received pursuant to Article 6 of Directive 2001/18/EC, the competent authorities appointed by Member States under that Directive shall use the Summary Notification Information Format set out in the Annex to this Decision.

#### Article 2

This Decision is addressed to the Member States.

#### ANNEX

#### SUMMARY NOTIFICATION INFORMATION FORMAT FOR THE DELIBERATE RELEASE OF A GMO OR A COMBINATION OF GMOS FOR PURPOSES OTHER THAN FOR PLACING ON THE MARKET INTRODUCTION

The Summary Notification Information Format for deliberate releases of a GMO or of a combination of GMOs, has been established for the purposes and according to the procedures envisaged by Article 11 of Directive 2001/18/EC.

It is recognized that this Format is not designed to accommodate all the information required for carrying out an environmental risk assessment.

The space provided after each question is not indicative of the depth of the information required for the purposes of the Summary Notification Information Format.

The Summary Notification Information Format consists of a Part 1 and a Part 2.

Part 1 applies to products consisting of or containing genetically modified organisms other than higher plants and contains the following sections:

А	General Information
В	Information relating to the recipient or parental organisms from which
	the GMO is derived
С	Information relating to the genetic modification
D	Information on the organism(s) from which the insert is derived (donor)
Е	Information relating to the genetically modified organism
F	Information relating to the release
G	Interactions of the GMO with the environment and potential impact on
	the environment
Н	Information relating to monitoring
Ι	Information on post-release and waste treatment
J	Information on emergency response plans

In Part 1 the information entered should, however, adequately reflect (in a condensed form) the information submitted to the competent authority in accordance with Articles 6 and 7 of Directive 2001/18/EC under the conditions specified in the preface to Annex IIIA.

Part 2 applies to products consisting of or containing genetically modified higher plants. The term 'higher plants' means plants which belong to the taxonomic group *Gymnospermae* and *Angiospermae*. Part 1 contains the following sections:

- A General information
- B Information on the genetically modified plant
- C Information relating to the experimental release
- D Summary of the potential environmental impact of the release of the GMPts
- E Brief description of any measures taken for the management of risks F Summary of planned field trials designed to gain new data on the
  - Summary of planned field trials designed to gain new data on the environmental and human health impact of the release.

In Part 2 the information entered should, however, adequately reflect (in a condensed form) the information submitted to the competent authority in accordance with Articles 6 and 7 of Directive 2001/18/EC under the conditions specified in the preface to Annex IIIB.

## PART 1

# SUMMARY NOTIFICATION INFORMATION FORMAT FOR THE RELEASE OF GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS IN ACCORDANCE WITH ARTICLE 11 OF DIRECTIVE 2001/18/EC

#### A. General information

- 1. Details of notification
- (a) Member State of notification
- (b) Notification number
- (c) Date of acknowledgement of notification
- (d) Title of the project
- (e) Proposed period of release
- 2. Notifier

Name of institution or company

#### 3. GMO characterisation

(a) Indicate whether the GMO is a:	viroid	
	RNA virus	
	DNA virus	
	bacterium	
	fungus	
	animal	
	— mammals	
	— insect	
	— fish	
	<ul> <li>— other animal</li> </ul>	specify phylum, class
other, specify (kingdom, phylum and class)		
(b) Identity of the GMO (genus and species)		
(c) Genetic stability - according to Annex IIIa, II	, A(10)	

4. Is the same GMO release planned elsewhere in the Community (in conformity with Article 6(1)), by the same notifier?

Yes 🗆	No 🗆
If yes, insert the country code(s):	

#### 5. Has the same GMO been notified for release elsewhere in the Community by the same notifier?

Yes 🗆	No 🗆	
If yes:		
<ul> <li>Member State of notification</li> </ul>		
— Notification number		

#### 6. Has the same GMO been notified for release or placing on the market outside the Community by the same or other notifier?

Yes 🗆	No 🗆
If yes: — Member State of notification — notification number	

#### 7. Summary of the potential environmental impact of the release of the GMOs

#### B. Information relating to the recipient or parental organisms from which the GMO is derived

1. Recipient or parental organism characterisation:

(a)	a) Indicate whether the recipient or parental organism is a:		
	viroid		
	RNA virus		
	DNA virus		
	bacterium		
	fungus		
	animal		
	— mammals		
	— insect		
	— fish		
	<ul> <li>— other animal</li> </ul>	□ (specify phylum, class)	
ot	her, specify		

<b>`</b>	NT
/	Name

(i)	order and/or higher taxon (for animals)
(ii)	genus
(iii)	species
(iv)	subspecies
(v)	strain
(vi)	pathovar (biotype, ecotype, race, etc.)
(vii)	) common name

▶<sup>(1)</sup> 3. Geographical distribution of the organism

(a)	Indigenous to, or otherwise established in, the country where the notification is made:		
	Yes 🗆	No 🗆	Not known
(b)	(b) Indigenous to, or otherwise established in, other EC countries		
	(i) Yes If yes. indicate the	type of ecosystem in which it is found:	
	Atlantic		
	Black Sea		
	Mediterranean		
	Boreal		
	Alpine		
	Continental		
	Macaronesian		
	Pannonian		
	Steppic		
	(ii) No		
	(iii) Not known		
(c)	(c) Is it frequently used in the country where the notification is made?		
	Yes 🗆	No 🗆	
(d)	Is it frequently kept in	n the country where the notification is made?	
	Yes 🗆	No 🗆	

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#### 4. Natural habitat of the organism

(a)	) If the organism is a microorganism		
	water		
	soil, free-living		
	soil in association with plant-root systems		
	in association with plant leaf/stem systems		
	in association with animals		
	other, specify		
(b)	b) If the organism is an animal: natural habitat or usual agroecosystem:		

#### 5(a) Detection techniques

#### 5(b) Identification techniques

6. Is the recipient organism classified under existing Community rules relating to the protection of human health and/or the environment?

Yes 🗆	No 🗆
If yes, specify	

 Is the recipient organism significantly pathogenic or harmful in any other way (including its extracellular products), either living or dead?

Yes 🗆	No 🗆	Not known □
If yes:		
(a) to which of the following organisms	: humans	
	animals 🛛	
	plants 🗆	
	other 🗆	
(b) give the relevant information specified under Annex III A, point II. (A)(11)(d) of Directive 2001/18/EC		

#### 8. Information concerning reproduction

(a) Generation time in natural ecosystems:		
(b) Generation time in the ecosystem where the	he release will take place:	
(c) Way of reproduction:	Sexual 🗆	Asexual 🗆
(d) Factors affecting reproduction:		

#### 9. Survivability

i) endospores	
ii) cysts	
iii) sclerotia	
iv) asexual spores (fungi)	
v) sexual spores (fungi)	
vi) eggs	
vii) pupae	
viii) larvae	
ix) other, specify	
elevant factors affecting survivability:	

#### 10(a) Ways of dissemination

#### 10(b) Factors affecting dissemination

 Previous genetic modifications of the recipient or parental organism already notified for release in the country where the notification is made (give notification numbers)

#### C. Information relating to the genetic modification

1. Type of the genetic modification

(i)	insertion of genetic material	
(ii)	deletion of genetic material	
(iii	base substitution	
(iv)	cell fusion	
(v)	other, specify	

#### 2. Intended outcome of the genetic modification

3(a) Has a vector been used in the process of modification?

Yes 🗆	No 🗆
If no, go straight to question 5.	

3(b) If yes, is the vector wholly or partially present in the modified organism?

Yes 🗆	No 🗆
If no, go straight to question 5.	

4. If the answer to 3(b) is yes, supply the following information

(a)	Type of vector		
	plasmid		
	bacteriophage		
	Virus		
	cosmid		
	transposable element		
	other, specify		

(b)	Identity of the vector		
(c)	Host range of the vector		
(d)	Presence in the vector of seque	ences giving a selecta	ble or identifiable phenotype
	Yes 🗆	No 🗆	
	antibiotic resistance		
	Other, specify Indication of which antibiotic	resistance gene is in:	erted
(e)	Constituent fragments of the v	/ector	
(f)	Method for introducing the ve	ctor into the recipie	t organism
	<ul> <li>(i) transformation</li> <li>(ii) electroporation</li> <li>(iii) macroinjection</li> <li>(iv) microinjection</li> <li>(v) infection</li> <li>(vi) other, specify</li> </ul>		

5. If the answer to question B.3(a) and (b) is no, what was the method used in the process of modification?

(i) transformation	
(ii) mikroinjection	
(iii) microencapsulation	
(iv) macroinjection	
(v) other, specify	

#### 6. Composition of the insert

(a) Composition of the insert

(b) Source of each constituent part of the insert

(c) Intended function of each constituent part of the insert in the GMO

(d)	(d) Location of the insert in the host organism				
	— on a free plasmid				
	<ul> <li>integrated in the chromosome</li> </ul>				
	— other, specify				
(e)	Does the insert contain parts whose produ	ict or function are not known?			
	Yes 🗆	No 🗆			
	If yes, specify				

#### D. Information on the organism(s) from which the insert is derived

1. Indicate whether it is a:

viroid	
RNA virus	
DNA virus	
bacterium	
fungus	
animal	
— mammals	
- insect	
— fish	
<ul> <li>— other animal</li> </ul>	□ (please specify phylum, class)
other, specify	

#### 2. Complete name

(i)	order and/or higher taxon (for animals)
(ii)	family name (for plants)
(iii)	genus
(iv)	species
(v)	subspecies
(vi)	strain
(vii)	cultivar/breeding line

(viii) pathovar				
x) common name				

3. Is the organism significantly pathogenic or harmful in any other way (including its extracellular products), either living or dead?

Yes 🗆	No 🗆	Not known 🛛
If yes, specify the following		
(a) to which of the following organisms	? Humans	
	animals	
	plants	
	other	
(b) are the donated sequences involved in any way to the pathogenic or harmful properties of the organism?		
Yes 🗆	No 🗆	Not known
If yes, give the relevant information	under Annex III A, point II(A)(11)(d):	

4. Is the donor organism classified under existing Community rules relating to the protection of human health and the environment, such as Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work?

Yes 🗆	No 🗆
If yes, specify	

5. Do the donor and recipient organism exchange genetic material naturally?

Yes 🗆	No 🗆	Not known 🛛
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#### E. Information relating to the genetically modified organism

1. Genetic traits and phenotypic characteristics of the recipient or parental organism which have been changed as a result of the genetic modification

(a) is the GMO different f	from the recipient as far as survivability is concerned	?
Yes 🗆	No 🗆	Not known 🗆
Specify		
(b) is the GMO in any way	y different from the recipient as far as mode and/or r	ate of reproduction is concerned?
Yes 🗆	No 🗆	Unknown 🗆
Specify		

(c) is the GMO in any way different from the recipient as far as dissemination is concerned?			
Yes 🗆	No 🗆	Not known 🛛	
Specify			
(d) is the GMO in an	ny way different from the recipient as far as pathogenicity is conco	erned?	
(d) is the GMO in an Yes □	ny way different from the recipient as far as <i>pathogenicity</i> is conco No □	erned? Not known □	
	, , , , , , , , , , , , , , , , , , , ,		

#### 2. Genetic stability of the genetically modified organism

3. Is the GMO significantly pathogenic or harmful in any way (including its extracellular products), either living or dead?

Yes 🗆	No 🗆		Unknown 🗆
(a) to which of the following organisms?	humans animals plants other		
(b) give the relevant information specified unc	ler Annex III A, point II(A)(I	1)(d) and II(C)(2)(i)	

#### 4. Description of identification and detection methods

(a) Techniques used to detect the GMO in the environment
(b) Techniques used to identify the GMO

### F. Information relating to the release

1. Purpose of the release (including any significant potential environmental benefits that may be expected)

Is the site of the release different from the natural habitat or from the ecosystem in which the recipient or parental organism is regularly used, kept or found?

Yes 🗆	No 🗆
If yes, specify	

#### 3. Information concerning the release and the surrounding area

(a) Geographical location (administrative region and where appropriate grid reference):

(b) Size of the site (m<sup>2</sup>):

(i) actual release site (m2):

(ii) wider release area (m2):

(c) Proximity to internationally recognised biotopes or protected areas (including drinking water reservoirs), which could be affected:

(d) Flora and fauna including crops, livestock and migratory species which may potentially interact with the GMO

#### 4. Method and amount of release

(a) Quantities of GMOs to be released:

(b) Duration of the operation:

c) Methods and procedures to avoid and/or minimise the spread of the GMOs beyond the site of the release

5. Short description of average environmental conditions (weather, temperature, etc.)

 Relevant data regarding previous releases carried out with the same GMO, if any, specially related to the potential environmental and human health impacts from the release

# G. Interactions of the GMO with the environment and potential impact on the environment, if significantly different from the recipient or parent organism

#### Name of target organisms (if applicable)

(i)	order and/or higher taxon (for animals)
(ii)	family name (for plants)
(iii)	genus
(iv)	species
(v)	subspecies
6.7	
(V1)	strain
(1111)	cultivar/breeding line
(VII)	cuntvar/breeding line
(viii	) pathovar
(*11	, barrow
(ix)	common name
(134)	

2. Anticipated mechanism and result of interaction between the released GMOs and the target organism (if applicable)

3. Any other potentially significant interactions with other organisms in the environment

4. Is post-release selection such as increased competitiveness, increased invasiveness for the GMO likely to occur?

Yes 🗆	No 🗆	Not known 🛛
Give details		

5. Types of ecosystems to which the GMO could be disseminated from the site of release and in which it could become established

 Complete name of non-target organisms which (taking into account the nature of the receiving environment) may be unintentionally significantly harmed by the release of the GMO

(i)	order and/or higher taxon (for animals)
(ii)	family name (for plants)
(iii)	genus
(iv)	species
(v)	subspecies
(vi)	strain
(vii)	cultivar/breeding line
(viii)	pathovar
(ix)	common name

7. Likelihood of genetic exchange in vivo

(a) from the GMO to other organisms in the release ecosystem:

(b) from other organisms to the GMO:

(c) likely consequences of gene transfer:

 Give references to relevant results (if available) from studies of the behaviour and characteristics of the GMO and its ecological impact carried out in simulated natural environments (e.g. microcosms, etc.):

 Possible environmentally significant interactions with biogeochemical processes (if different from the recipient or parental organism)

#### H. Information relating to monitoring

1. Methods for monitoring the GMOs

2. Methods for monitoring ecosystem effects

3. Methods for detecting transfer of the donated genetic material from the GMO to other organisms

4. Size of the monitoring area (m<sup>2</sup>)

5. Duration of the monitoring

6. Frequency of the monitoring

#### I. Information on post-release and wate treatment

1. Post-release treatment of the site

2. Post-release treatment of the GMOs

3(a) Type and amount of waste generated

#### 3(b) Treatment of waste

#### J. Information on emergency response plans

1. Methods and procedures for controlling the dissemination of the GMO(s) in case of unexpected spread

#### 2. Methods for removal of the GMO(s) of the areas potentially affected

3. Methods for disposal or sanitation of plants, animals, soils, etc. that could be exposed during or after the spread

4. Plans for protecting human health and the environment in the event of an undesirable effect

### PART 2

# SUMMARY NOTIFICATION INFORMATION FORMAT FOR THE RELEASE OF GENETICALLY MODIFIED HIGHER PLANTS

(ANGIOSPERMAE AND GYMNOSPERMAE)

#### A. General information

1. Details of notification

(a) Notification number

(b) Date of acknowledgement of notification

(c) Title of the project

(e) Proposed period of release

2. Notifier

(a) Name of institute or company

3. Is the same GMPt release planned elsewhere, inside or outside the Community [in conformity with Article 6(1)] by the same notifier?

Yes 🗆	No 🗆
If yes, insert the country code(s):	

4. Has the same GMPt been notified for release elsewhere, inside or outside the Community, by the same notifier?

Yes 🗆	No 🗆
If yes, notification number:	

#### B. Information of the genetically modified plant

1. Identity of the recipient or parental plant

(a) Family name	
(b) Genus	
(c) Species	
(d) Subspecies (if applicable)	
(e) Cultivar/breeding line (if applicable)	
(f) Common name	

 Description of the traits and characteristics which have been introduced or modified, including marker genes and previous modifications

#### 3. Type of the genetic modification

(a) Insertion of genetic material
(b) Deletion of genetic material
(c) Base substitution
(d) Cell fusion
(e) Other, specify

4. In the case of insertion of genetic material, give the source and intended function of each constituent fragment of the region to be inserted

5. In the case of deletion or other modification of genetic material, give information on the function of the deleted or modified sequences

6. Brief description of the method used for the genetic modification

 If the recipient or parental plant is a forest tree species, describe ways and extent of dissemination and specific factors affecting dissemination

#### C. Information relating to the experimental release

 Purpose of the release (including any relevant information available at this stage) such as agronomic purposes, test of hybridisation, changed survivability or dissemination, test of effects on target or non-target organisms

2. Geographical location of the release site

Size of the site (m<sup>2</sup>)

4. Relevant data regarding previous releases carried out with the same GM-plant, if any, specifically related to the potential environmental and human health impacts from the release

#### D. Summary of the potential environmental impact of the release of the GMPTS in accordance with Annex II, D2 to Directive 2001/18/EC

Note especially if the introduced traits could directly or indirectly confer an increased selective advantage in natural environments; also explain any significant expected environmental benefits

E. Brief description of any measures taken by the notifier for the control of risks including isolation designed to limit dispersal, for example for monitoring and post-harvest monitoring proposals

F. Summary of planned field trials designed to gain new data on the environmental and human health impact of the release (where appropriate)

(**1**) OJ L 106, 17.4.2001, p. 1.

#### **Changes to legislation:**

There are outstanding changes not yet made to Council Decision of 3 October 2002 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 (2002/813/EC). Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

View outstanding changes

#### Changes and effects yet to be applied to :

- Decision revoked by 2023 c. 28 Sch. 1 Pt. 2
- Annex words omitted by S.I. 2019/90 reg. 9(5)(a)
- Annex Pt. 1 heading words omitted by S.I. 2019/90 reg. 9(6)(a)
- Annex words substituted by S.I. 2019/90 reg. 9(5)(b)
- Art. 1 substituted by S.I. 2019/90 reg. 9(2)
- Art. 2 omitted by S.I. 2019/90 reg. 9(3)

# Changes and effects yet to be applied to the whole legislation item and associated provisions

provisions	
_	Annex Pt. 1 s. Apara. 1(a) omitted by S.I. 2019/90 reg. 9(6)(b)(i)
_	Annex Pt. 1 s. Bpara. 6 word omitted by S.I. 2019/90 reg. 9(6)(c)(ii)
_	Annex Pt. 1 s. Dpara. 4 heading word omitted by S.I. 2019/90 reg. 9(6)(d)(i)
_	Annex Pt. 1 s. Epara. 3(b) words inserted by S.I. 2019/90 reg. 9(6)(e)
_	Annex Pt. 2 s. Apara. 3 words inserted by S.I. 2019/90 reg. 9(7)(a)(i)(bb)
_	Annex Pt. 1 s. Apara. 4 heading words substituted by S.I. 2019/90 reg. 9(6)(b)(ii)(aa)
_	Annex Pt. 1 s. Apara. 4 words substituted by S.I. 2019/90 reg. 9(6)(b)(ii)(bb)
_	Annex Pt. 1 s. Apara. 5 heading words substituted by S.I. 2019/90 reg. 9(6)(b)
	(iii)(aa)
_	Annex Pt. 1 s. Apara. 5 words substituted by S.I. 2019/90 reg. 9(6)(b)(iii)(bb)
_	Annex Pt. 1 s. Apara. 6 heading words substituted by S.I. 2019/90 reg. 9(6)(b)
	(iv)(aa)
_	Annex Pt. 1 s. Apara. 6 words substituted by S.I. 2019/90 reg. 9(6)(b)(iv)(bb)
_	Annex Pt. 1 s. Bpara. 3(a) words substituted by S.I. 2019/90 reg. 9(6)(c)(i)(aa)

- Annex Pt. 1 s. Bpara. 3(b) words substituted by S.I. 2019/90 reg. 9(6)(c)(i)(bb)
- Annex Pt. 1 s. Bpara. 3(c)(d) words substituted by S.I. 2019/90 reg. 9(6)(c)(i)(cc)
- Annex Pt. 1 s. Dpara. 4 words substituted by S.I. 2019/90 reg. 9(6)(d)(ii)
- Annex Pt. 2 s. Apara. 3 heading words substituted by S.I. 2019/90 reg. 9(7)(a)(i)(aa)
- Annex Pt. 2 s. Apara. 4 heading words substituted by S.I. 2019/90 reg. 9(7)(a)(ii)(aa)
- Annex Pt. 2 s. Apara. 4 words substituted by S.I. 2019/90 reg. 9(7)(a)(ii)(bb)
- Annex Pt. 1 s. Apara. 4 words substituted in earlier amending provision S.I. 2019/90, reg. 9(6)(b)(ii)(bb) by S.I. 2019/1229 reg. 5(2)
- Annex Pt. 1 s. Apara. 6 words substituted in earlier amending provision S.I. 2019/90, reg. 9(6)(b)(iv)(bb) by S.I. 2019/1229 reg. 5(2)
- Annex Pt. 2 s. Apara. 4 words substituted in earlier amending provision S.I. 2019/90, reg. 9(7)(a)(ii)(bb) by S.I. 2019/1229 reg. 5(2)
- Annex Pt. 1 s. Apara. 5 words substituted in earlier amending provision S.I. 2019/90, reg. 99(6)(b)(iii)(bb) by S.I. 2019/1229 reg. 5(2)