

GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE) REGULATIONS - S.I. No. 500 OF 2003

GUIDANCE NOTE

Part B – Deliberate release of a GMO for any other purpose than for placing on the market

This Guidance Note has been prepared to provide assistance and guidance to users who wish to apply to the EPA for consent to carry out a deliberate release of a genetically modified organism (GMO), for any other purpose than for placing on the market (e.g. field trials/clinical trials). Nothing in this Guidance Note shall be construed as negating the user's statutory obligations or requirements under the Genetically Modified Organisms (Deliberate Release) Regulations S.I. No. 500 of 2003, Directive 2001/18/EC on the deliberate release into the environment of GMOs and repealing Council Directive 90/220/EEC, or any other enactments or Regulations.

The note is broken down into the following sections:

Section 1 – Legislation and Definitions

Section 1 provides information about:

- the legislation which should be consulted when preparing a notification;
- definitions; and,
- techniques which give rise to genetic modification as well as those which do not result in genetic modification and are therefore excluded from the scope of the legislation.

Section 2 – Part B notification - Deliberate Release of GMOs into the Environment for purposes other than placing on the market

Section 2 sets out the requirements for the submission of a notification to the EPA seeking consent to carry out a deliberate release of a GMO for purposes other than placing on the market i.e. clinical trials and/or field trials for purposes of Research & Development.

Examples of a deliberate release under a Part B notification include the growing of GM crops as part of a field trial, the administration of a GM vaccine or a GM virus which delivers a gene therapy product to animals or humans as part of a clinical trial.

SECTION 1 – Legislation and Definitions

Legislation

Directive 2001/18/EC repealing Directive 90/220/EEC on the deliberate release into the environment of Genetically Modified Organisms (GMOs) was transposed into Irish Law – GMO (Deliberate Release) Regulations S.I. No 500 of 2003 - on November 1st 2003.

A copy of this legislation is available on the [EPA website](#).

Definitions

Article 3 of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003 define **deliberate release** as *'any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their*

contact with, and to provide a high level of safety for, the general population and the environment’.

A **genetically modified organism** is defined as *‘an organism other than a human being, in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination, or by a combination of both’*, (Article 3 of S.I. No 500/2003)

An **organism** means *‘any multicellular, unicellular, subcellular or acellular entity capable of replication or of transferring genetic material whether by natural or artificial processes’* (Section 111 of EPA Act 1992).

Placing on the market means *‘any transaction in which a GMO is supplied or made available to a third party, whether in return for payment or otherwise, but does not include:*

- *supplying or making a GMO available for use in a GMO Contained Use activity (to which the GMO (Contained Use) Regulations 2001 to 2010 apply);*
- *supplying or making a GMO available for deliberate release into the environment for purposes other than placing on the market (i.e. clinical trial or field trial)*

(Article 3 of S.I. No 500/2003).

Product means *‘a preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market’*. (Article 3 of S.I. No 500 of 2003)

Environmental Risk Assessment (ERA) means *‘an evaluation of risk to human health or the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of a GMO may pose’*. The ERA must be carried out in accordance with the Second Schedule of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003, (Article 3 of S.I. No 500/2003).

Techniques which result in genetic modification

(Part I of the First Schedule of the GMO (Deliberate Release) Regulations 2003)

Genetic modification occurs through the use of the following techniques:

1. Recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;
2. Techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;
3. Cell fusion or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

Techniques, which do not result in genetic modification

(Part II of the First Schedule of the GMO (Deliberate Release) Regulations 2003)

1. The following techniques are not considered to result in genetic modification, provided they do not involve the use of recombinant-nucleic acid molecules or GMOs made by techniques/methods other than those set out in paragraph 2 below:
 - *in vitro* fertilisation;
 - natural processes such as: conjugation, transduction, transformation;

- polyploidy induction.
2. Organisms resulting from the following techniques or methods of genetic modification are excluded from the requirements of this legislation provided they do not involve the use of recombinant-nucleic acid molecules or a GMO other than those produced by one or more of the following techniques/methods:
 - Mutagenesis;
 - Cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

In accordance with article 7(b) of the GMO (Deliberate Release) Regulations 2003, these Regulations do not apply to the carriage of GMOs by road, rail, inland waterway, sea or air.

SECTION 2 – Part B notification –Deliberate Release of GMOs into the Environment for purposes other than placing on the market

A person intending to carry out a deliberate release of a GMO for purposes other than placing on the market (i.e. clinical trials or field trials) is required to submit a notification to the EPA under Article 14 of the GMO (Deliberate Release) Regulations, S.I. No. 500 of 2003. In accordance with Article 14 the notification must comprise the following;

1. Information set out in the Third Schedule of S.I. No 500 of 2003:
 - Part I of the Third Schedule concerns release of GMOs other than higher plants, e.g. a GM micro-organism;
 - Part II of the Third Schedule concerns releases of Genetically Modified Higher Plants.
2. A summary of the notification (i.e. **Summary Notification Information Format** or SNIF) in accordance with Council Decision 2002/813/EC as per the [download section](#) of the EPA website.
3. An Environmental Risk Assessment (ERA) carried out in accordance with the principles and methodology outlined in Parts B and C respectively of the Second Schedule of S.I. No 500 of 2003.
4. The conclusions arrived at by the notifier, on the potential environmental impact from the release of the GMO, in accordance with Part D of the Second Schedule of S.I. No 500 of 2003, together with any bibliographic references and details of methods used:
 - Part D.1. refers to GMOs other than higher plants;
 - Part D.2. refers to Genetically Modified Higher Plants.
5. In addition to the aforementioned information, the notifier may:
 - include or refer to data or results, from a notification previously submitted to the same or another Competent Authority, by another notifier. The other notifier must agree in writing and a copy of that written agreement must be enclosed with the notification. The data or results provided or referred to must not comprise confidential information.
 - provide additional relevant information.
6. The deliberate release of a combination of GMOs on the same site, or a GMO or a combination of GMOs on different sites, may be notified to the Agency in the same notification, provided:
 - the purpose of the proposed deliberate release is the same; and,

- the release will be carried out within a defined period of time.

Fee (Article 46)

In accordance with Article 46, a fee of €3,000 must be paid in respect of a notification under Article 14 i.e. deliberate release of a GMO for purposes other than placing on the market.

Register of GMO Users (Article 9)

The EPA is required to maintain a Register of GMO Users in Ireland. This Register is made available for public viewing at EPA Headquarters free of charge during office hours. The EPA must place details of the proposed deliberate release on the Register within 7 days of receipt of a notification or an amended notification

Notices (Article 15)

Under Article 15, within 14 days of receipt of the notification by the Agency the notifier is required to place an advertisement in a '*newspaper circulating in the area of the proposed deliberate release*' notifying the public of the proposed release. .

The required content of the public notice is set out under Article 15(1) of the Regulations.

In accordance with Article 15(2) the location of the proposed deliberate release given in the public notice must correspond with that placed on the public register in accordance with Article 9. The Agency advises that a draft of the advertisement be agreed with the Agency before publication.

In accordance with Article 15(3), within 14 days of the date of receipt of the notification by the Agency, a copy of the advertisement must be sent to:

- the owner of the site of the proposed deliberate release, (where the owner is someone other than the notifier); and,
- the Local Authority in whose functional area the deliberate release is proposed to take place.

Representations from members of the public (Article 16)

Members of the public may make representations in writing to the EPA at its headquarters¹, within 28 days of the date of publication of the newspaper advertisement. Persons making representations are required to pay a fee of €10 in accordance with Article 48 of S.I. No. 500 of 2003.

Representations found not to be not in compliance with these requirements will be deemed invalid and returned to the sender along with the accompanying fee.

Amended Notification (Articles 17 & 20)

If the notifier becomes aware of new information about the proposed deliberate release, or, if the proposed deliberate release needs to be modified in some way which could have consequences for the risks to human health or the environment, the notifier must inform the EPA in writing and must submit an amended notification.

- a Where the amended notification is received by the Agency prior to a decision being taken on the original submission, the Agency will cease review of the first notification and will consider the amended notification as if it were a new notification submitted under Article 14 (Article 17).
- b Where the amended notification is received by the Agency subsequent to a consent being granted, the deliberate release will not proceed and the Agency will commence review of the amended notification as if it were a new notification submitted under Article 14 (Article 20).

¹ EPA, P.O. Box 3000, Johnstown Castle Estate, Co Wexford

Fee for amended notification (Article 49)

Where the notifier submits an amended notification under Articles 17 or 20, the notifier must pay an additional fee of €1,125.

Charges for monitoring (Article 54)

The notifier will be required to meet the costs of any monitoring or inspections carried out by the Agency in order to ensure that the proposed activity is in compliance with the Regulations, or in compliance with any consent or conditions imposed by the Agency.

Agency Investigations (Article 55)

The Agency may need to carry out investigations in order to enable it to properly assess a notification, amended notification or other related matter, in which case, the notifier will be required to meet or contribute towards the costs of such investigations.

Duty of the Agency following receipt of a notification under Article 14 (Article 18)

Following receipt of a notification under Article 14 - the proposed deliberate release of a GMO for purposes other than placing on the market - the EPA is required to:

- a acknowledge receipt of the notification in writing to the notifier. The notifier must be informed of the date of receipt of the notification by the EPA;
- b forward a copy of the Summary Notification Information Format (SNIF) to the European Commission within 30 days of receipt of the notification;
- c forward a copy of the notification to any EU Member State Competent Authority requesting such a copy;
- d review the notification and ensure that it is compliant with the requirements of the GMO (Deliberate Release) Regulations 2003, S.I. No. 500 of 2003;
- e review the Environmental Risk Assessment and ensure that it is appropriate;
- f assess the risks posed by the proposed deliberate release, for human health or the environment. This assessment must take account of:
 - the potential risks, whether direct or indirect, arising from the transfer of one or more genes from a GMO to another organism, the nature of the organism to be released and the receiving environment;
 - the potential risks arising from GMOs containing one or more genes expressing resistance to antibiotics which are used in human or veterinary medicine.;
- g consider any comments/observations received from the Competent Authorities of other EU Member States where such comments are received within 30 days of the European Commission notifying the Member States of the publication of the SNIF on the JRC website (<https://gmo-websnif.jrc.ec.europa.eu/main.asp>);
- h acknowledge receipt of representations received from members of the Irish public in accordance with Article 16 and consider these comments/observations in the final determination of the notification;
- i request further information from the notifier stating the reasons therefore (Article 19);
- j record its conclusions in writing;
- k inform the notifier of the decision taken by the Agency, in writing within 90 days of receipt of the notification.

Timeframe for decisions (Article 18(5))

The Agency must inform the notifier of its decision, in writing, within 90 days of receipt of the notification. The Agency may issue consent with or without conditions or refuse consent.

In accordance with article 8(1), any period of time during which the Agency is awaiting receipt of additional information on a notification or an amended notification, will not be taken into account i.e. the clock will be stopped.

Notification of decisions (Article 23)

Within 14 days of informing the notifier of its decision, the Agency shall also notify the following of its decision in writing:

- the owner of the site of the proposed deliberate release (where the owner is someone other than the notifier);
- the Local Authority in whose functional area the deliberate release is proposed to take place;
- The European Commission;
- Any person or body who made a representation under Article 16.

Duty to inform the Agency of new information (Article 21)

If, after consent has been granted to a Part B release, a change occurs or new information becomes available which could have consequences for the risks to human health or the environment, the notifier is required to immediately inform the Agency of the change or new information as appropriate and the protective measures employed.

Power of the Agency to modify suspend or terminate consent (Article 22)

If, after consent has been granted to a Part B release, the Agency becomes aware of information, or of a proposed modification, or a change to the Part B release which could have consequences for the risks posed to human health or the environment, then following an evaluation, the Agency may require the consent holder to modify the conditions or suspend or terminate the deliberate release. In either case, the deliberate release may not resume until such time as the notifier has received the written consent of the Agency and any additional conditions imposed by the Agency on foot of the changes, have been complied with.

Post Release Procedures (Article 24)

The consent holder is required to submit a report on the results of the deliberate release;

- at intervals during the release as specified in the consent conditions; and,
- on conclusion of the deliberate release.

The format of the report is set out in [Commission Decision 2003/701/EC](#) and will include:

- a post-release evaluation of the risks the Part B release poses to human health or the environment;
- a statement on the results of the Part B release, where the release has been carried out in respect of a product for which a consent to its placing on the market may later be sought.

Following receipt of this report a copy must be forwarded to the EU Commission by the Agency.

2012