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**GUIDELINES TO COMPILE THE PUBLIC DOSSIER**

**FIELD RELEASES OF TRANSGENIC PLANTS  
FOR EXPERIMENTAL PURPOSES (PART B)**

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**INFORMATION FOR THE NOTIFIER  
(VERSION OF 07/03/2003)**

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**GENERAL INTRODUCTION**

In Belgium, the Royal Decree (RD) for the deliberate release of GMOs of 18 December 1998, which implemented the European directive 90/220/EEC, stipulated in articles 8 § 1 and 16 § 1 that each application dossier of a deliberate release had to contain a **proposal of information** for the public: article 8 § 1 being of application for experimental purposes (part B) and article 16 § 1 for the placing on the market (part C).

Since 17 October 2002 the European directive 2001/18/EC repealing directive 90/220/EEC, is of application. The transposition of this directive into national regulation is still ongoing. Nevertheless, in the new regulation the public dossier will keep a central role in informing citizens and be of importance in the foreseen consultation procedure of the public.

As these regulations do not give any guidance to the notifier to compile the requested public dossier and in order to provide a clear framework to the notifier, to encourage a common homogenous approach to carry out the compilation of the public dossiers and to stimulate open and transparent public information, the Service of Biosafety and Biotechnology (SBB) in collaboration with the experts of the Working Group "Public Information" of the Biosafety Advisory Council developed guidelines for part B releases with transgenic plants.

The main objectives of the public dossier is to inform citizens about the activities of companies or research institutes in the biotechnology field and to stimulate public awareness and education. The delivered information should enable citizens to gather knowledge, to weigh up the risks and benefits, to form a proper opinion about these products, etc. To stimulate this process the notifier should not only address general and more technical information on the biosafety issues (risk assessment), but should also consider the concerns of the public in a transparent and open

way. People have ethical and moral concerns and have questions about the added value of the envisaged trials and used technology, trust, benefits, arguments of choice of technology, alternatives, training requirements, etc. It is clear that risk assessment is much too narrow to address people's concerns. Therefore, the guidelines and public dossiers should not only focus on the biosafety aspects but also draw a framework of people's concerns.

In addition, it is important to pay attention to the accessibility of these public dossiers. The public dossier should be readable and understandable. It is therefore important to use a comprehensible language, which is accessible to everyone. Scientific terminology and concepts should be explained, advertising messages and affirmative statements which are not scientifically founded should be avoided, as these are generally received by the public with suspicion and scepticism, and a good transparent argumentation should be used.

The public dossiers will be made available to the public by publishing them on the Internet in three languages (Dutch, French and English). For this reason the submission in electronic format (MS Word document) of the public dossier in the three mentioned languages (by email to [ydevos@sbb.ihe.be](mailto:ydevos@sbb.ihe.be)) is required.

These guidelines cannot be viewed as being static and will thus be reviewed and adapted as necessary.

## **CONTACT**

If you have any comment on the proposed guidelines or wish to obtain additional information on the guidelines, please contact us at the following address.

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web: <http://www.biosafety.be>

## **THE GUIDELINES**

The section below contains the guidelines to be followed (minimal requirement template) when preparing a public dossier.

# LOGO of the COMPANY or RESEARCH CENTRE

## INFORMATION FOR THE PUBLIC

NAME of the COMPANY or RESEARCH CENTRE

### Title of the experiment

European notification number  
B/BE/XX/YY

#### **(Short introduction about the regulatory framework and authorisation procedure.)**

The release of genetically modified organisms (GMOs) in the environment is strictly regulated at European level by directive 2001/18/EC of 12 March 2001 repealing directive 90/220/EEC and at Belgian level by the Royal Decree of 18 December 1998 "regulating the deliberate release and/or marketing of GMOs or products that contain GMOs into the environment". The transposition procedure is still ongoing for the moment.

To ensure the safe use of GMOs, the provisions of the Royal Decree above stipulate that the release of GMOs for experimental aims is prohibited without prior consent from the competent Minister. The decision is based on a thorough evaluation of the biosafety of the planned release, which is conducted by the Biosafety Advisory Council and which is composed of different Scientific Committees grouping independent experts from Belgian universities and governmental institutes.

To acquire the necessary authorisation from the competent Minister, the company or research centre XXX submitted an application dossier to the competent authority, the Federal Service of Public Health, Safety of the Food Chain and Environment. On the basis of the advice of the Biosafety Advisory Council, the competent minister could grant a permission to the company or research centre XXX to conduct experiments with transgenic XXX during the year or years XXX, as stipulated in the application B/BE/XX/YY

The release will take place at one or more experimental locations in Flanders / Wallonia / Brussels in the municipality(ies) of XXX and will follow the normal growth period of crop XXX which is from month XXX to month YYY.

## **TABLE OF CONTENTS:**

The notifier should foresee a table of contents. This allows to have a general view on the structure of the public dossier.

## **GENERAL INFORMATION:**

### **DESCRIPTION OF THE GENETICALLY MODIFIED PLANT (GMP):**

Not everyone is familiar with the scientific language and jargon. It would therefore be useful to explain what transgenic plants are, how they were obtained (techniques used) and how they differ from actually bred crops. This means that a number of basic concepts should be explained (see topic "Glossary").

Further, the plant species that is being used, its (their) new traits and the environment where it will be introduced should be mentioned. This includes:

- the common and scientific name of the used plant species and/or varieties
- the nature of the new trait or traits (e.g. male sterility, fertility restorer, herbicide tolerance, insect tolerance, stress resistance, etc.)
- a comprehensible explanation about the function of the new genetic trait(s)
- a comprehensible explanation about the mode of action of the new trait(s)
- a description of the potential receiving environment (e.g. type of biotope)

The purpose of supplying this information is to teach citizens that every transgenic crop is a specific case, depending on the used species or variety, the introduced trait and the environment it is released into.

### **TYPE AND PURPOSE OF THE ENVISAGED TRIAL:**

The type of trial should be discussed and can be classified in research trials to test a concept, development trials to develop a working concept, biosafety research trials to study biosafety aspects or variety and seed trials for variety registration purposes (national list or recommended list trials), etc.

The purposes of the trial, independently of the type, should be explained in a understandable way e.g. selection of candidate elite lines in open field, evaluate tolerance of lines to (a)biotic stresses in open field, evaluate growth and yield performances, study pollen flow, volunteers, etc.

In this context, the notifier should also explain why the trial cannot be carried out in greenhouse, why it needs to be done in the open field, why these specific environmental conditions are needed?

It should be stated clearly that this notification concerns a deliberate release of transgenic plants for experimental purposes and that no feed and/or food purposes are aimed. For this reason the use of this material for food and/or feed is prohibited. Please explain that at that stage of development this prohibition is a common rule to follow and that this rule can not always be linked to risk/danger/toxicity aspects.

## **RESEARCH/DEVELOPMENT ACTIVITIES:**

### **PREVIOUS DEVELOPMENT ACTIVITIES**

The development of a new variety may be described as a long process, and that a long history based on the step-by-step approach precedes the foreseen field release. In this part the previous activities (history) undertaken by the notifier in the development of this new variety should be discussed. The experiments carried out in contained conditions e.g. laboratories, growth rooms, greenhouses, etc. and other deliberate releases carried out in Belgium or other Member States should be comprehensively listed and described. For the previously carried out field releases it could be very helpful to mention the European identification number of the concerned notifications.

### **KNOWLEDGE AND EXPERIENCE OBTAINED IN PREVIOUS DEVELOPMENT ACTIVITIES**

The gained knowledge of the previous undertaken activities under contained use or deliberate release should be addressed. It will indicate how knowledge and experience is cumulated through these different steps and could explain the necessity of the planned trial (see further).

### **FUTURE ACTIVITIES**

The trial should be placed in the whole development strategy of the company or research centre. Future plans, objectives, visions (e.g. the marketing of genetically modified crops) and the future steps in the research process that would be considered when the used strategy has proven to work should be discussed (outline of a vision for the future). Explain how the gained knowledge and experience will influence future development.

## **BENEFITS:**

In this chapter the notifier should give a good argumentation regarding the added value of the envisaged trial and used technology. Citizens need to understand why this GMO could be useful. The argumentation delivered by the notifier should not only be done in technical and environmental terms, but should also consider social and economical objectives.

The following topics should be addressed:

The added value of the envisaged trial for the notifier, farmer, environment, society, citizen, etc. should be discussed as well as the added value of the technology in comparison with other existing technologies. The cost/benefit balance should be integrated in a more general framework including all the alternative methods. In this framework the notifier should also explain in which way the planned trial and technology contribute to a more sustainable development with a balanced attention to the three dimension of this concept: social, economic and environmental.

## **RISKS:**

In this chapter the relevant potential risks for the human health and/or environment that may result from the deliberate release needs to be identified. The relevant questions need to be identified and explained by the notifier. Available data on the impact of large-scale and long-term use of the specific plant should be addressed. Next to referring to relevant scientific literature the notifier should try to explain how these risks are investigated, how they arrive at certain estimations and conclusions and how uncertainty was taken into account at different levels in this risk assessment process. In this context the general principles, methodology or steps of the risk assessment procedure could be explained. Within this framework the notifier should compare the risks associated to the GMO technology as compared with the risks of existing and other alternative systems. Different risk scenarios could be compared.

Considerations about large-scale and long-term farming of the GM crop should be linked to the possible interference with other cropping systems. The argumentation delivered by the notifier should also consider social and economical aspects.

The following topics should be addressed:

The risks for the human health, dispersal of transgenic pollen, presence of sexually compatible plant species in the cultivation area, dispersal of transgenic seeds/fruit/nuts, dispersal of transgenic vegetative plant parts, selective advantage, presence of volunteers, horizontal gene transfer, interactions with target organisms, interactions with non-target organisms, changes in agricultural practices or farm management procedures (e.g. sowing, planting, growing, harvesting or transporting crops, crop rotation, disease and pest control, resistance management, agricultural practices, infrastructure of the farm, etc.), etc..

## **CONTAINMENT, CONTROL AND MONITORING MEASURES:**

In the previous chapter citizens were informed about the potential risks linked to the deliberate release and the way they were assessed. In this chapter the notifier needs to explain how the identified risks are addressed and limited in the scope of the release. Citizens need to be informed about the containment, control and monitoring measures taken to avoid adventitious presence of

GM crops in non-GM crops or wild relatives (avoidance of biological and physical mixing), adverse effects on human health and environment and to foresee nature preservation, etc. Trial design and protocols that determine how the plots of transgenic plants should be organised, monitored, harvested, managed and carried out and how transgenic material containing waste should be handled should be referred to. The public should also understand why such measures are required. In this context a link should be made to biodiversity, nature conservation and interactions with other agricultural systems.

**CONTROL OF POLLEN DISPERSAL (BIOLOGICAL MIXING):**

Explain the containment measures taken to control and avoid biological mixing (e.g. isolation distance, removal of flower buds, wrapping of flowering flowers with pollen proof mesh, installation of isolation cages, taking care that no compatible crops are being grown in the vicinity of the trial field, etc.).

**CONTROL OF DISPERSAL OF SEEDS/FRUIT/NUTS (BIOLOGICAL AND PHYSICAL MIXING):**

The spread of seeds from field to field by wind, insects and machines, mixing of crops after harvest, etc. can be sources of adventitious presence of GM crops in non-GM crops at farm level. Explain the different measures that will limit this (e.g. isolation distances, conditioning of the seed, emptying of the sowing machine, management of the seed residues).

**CONTROL OF VOLUNTEERS (FOLLOW-UP, MONITORING, POST-HARVEST TREATMENTS):**

It should be indicated that after the trial the field will be followed for 1, 2 or several years, depending on the type of cultivated crop, and checked regularly for volunteers. Explain what these measures are and why they should be taken? In this, the follow-up measures (monitoring) described in the trial protocols and protocols for transgenic sugar beet, *Brassica* and chicory can serve as a base.

Also the vegetative material that can result in the development of a new clone of the parental plant needs to be controlled. Also here the notifier must mention the proposed measures. E.g. the placing in plastic containers of bulbs that can be removed from the soil again after harvest, or to leave tubers in the soil to check the resulting volunteers.

**DESTRUCTION OF TRANSGENIC MATERIAL:**

It should be mentioned that both the harvested transgenic material that is not intended to be used in further product development or experiments and the transgenic material not being harvested will be destroyed. The transgenic seeds that are not going to be used for further product development or experiments will be destroyed. The way of destruction should also be explained.

It should clearly be stated that this notification concerns a deliberate release of transgenic plants for experimental purposes and that no feed and/or food purposes are aimed. For this reason the use of this material for food and/or feed is prohibited. Please explain that at that stage of development this prohibition is a common rule to follow and that this rule can not always be linked to risk/danger/toxicity aspects.

**TRAINING REQUIREMENTS:**

In this subchapter the undertaken measures (training requirements) regarding the farmer who will cultivate the GM plant should be discussed. Working with a trained and experienced staff can be discussed within this framework. Will the training requirements for this technology be different than for existing or alternative systems? Will additional equipment or change in practice be required? Will standard practice remain adequate for handling these GM crops?

**EMERGENCY SITUATIONS:**

Here the notifier should explain how unexpected events will be identified at an early stage and how these will be managed. It should be mentioned as well that in exceptional cases the plants can be destroyed (e.g. by treatment with an appropriate herbicide).

**OTHER CONTAINMENT, CONTROL AND MONITORING MEASURES:****RESPONSIBILITIES OF THE NOTIFIER:****(to be literally copied by the notifier)**

The consent that could be given to the notifier by the competent Minister stipulates that the notifier takes complete civilian liability regarding the damage that could be caused by the deliberate release to the health of humans, animals, products or environment.

**INSPECTION BY THE PUBLIC AUTHORITIES:****(to be literally copied by the notifier)**

Inspectors are in charge of inspecting the trials for compliance with the conditions specified in the consent and specific protocols for growing GM crops and to investigate potential breaches of the consent. Therefore, checklists are used during the inspections. In order to organise its inspections the notifier is obliged to submit the exact locations of the field trials and to inform the competent authority about the date of sowing and the date of harvesting in advance. In addition, the inspectors take samples of the plant material that are analysed in official laboratories. After harvest, the field trials are inspected on the presence of potential volunteers. In case where mismanagement or fraud is identified specific sanctions will be imposed.

**ACTIVITY REPORT:****(to be copied literally by the notifier)**

At the end of the growing season an activity report prepared by the notifier needs to be delivered to the competent authority, before the end of that year. This activity report includes at least the following data:

- a copy of the logbook,
- the site and period of release,
- the precise nature of the actually released transformants,
- the actual surface of the trial plot,
- the aim(s) of the trial,
- the frequency and nature of the observations on the trial plot,
- the measures that were taken to prevent unwanted release of transgenic material outside the trial plot

- the method used for the destruction of the harvest and the efficacy of this,
- the results obtained during the trial,
- an overview of the surveillance of the trial plot.

## REFERENCES:

Research pointed out that the use of affirmative, not scientifically underpinned statements and advertising messages have a negative effect on the public. These are received by the public with suspicion and scepticism. Therefore, the notifier should provide a scientific base for its statements and findings by referring to relevant scientific literature or websites etc.

## GLOSSARY:

Since not all citizens are as familiar with the issues discussed, it is recommended to explain particular concepts, terms, etc.

## CONTACT:

### NOTIFIER:

Citizens who want to address any comments on the public dossier or want to obtain additional information on the public dossier or deliberate release need to be able to contact the notifier. Therefore, the address, a telephone and fax number, an email address and if available the web site of the company or research centre should be made available.

Notifiers are encouraged to react on the comments and requests raised by citizens as an absence of reaction or constructive reply creates a climate of mistrust. It is desirable to appoint a contact person within the company or research institute who can answer to the raised questions. This contact person should be able to inform citizens about the activities of the company or research institute and to make the link between the notifier, press, public and concerned public. This as well implies the co-ordinates of the contact person.

The SBB would be very interested to be kept informed about the requests raised by the citizens. The feedback of citizens and notifiers in this matter could allow the reassessment of the actual guidelines.

### **(to be literally copied by the notifier)**

If you have any comment on the public dossier or our activities or wish to obtain additional information on the public dossier or the deliberate release, please contact us at the following address.

You can also have access to a technical summary of the notification (SNIF) on the web site of the Joint Research Centre (JRC) of the European Commission (<http://gmoinfo.jrc.it>). Comments can be addressed to the Commission via this website.

**Notifier:**

Name of company or research centre:

Address:

Phone:

Fax:

Email:

Web site:

**Contact person:**

Name of contact person:

Address:

Phone:

Fax:

Email:

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