Scientific Institute
of Public Health

Service of Biosafety and Biotechnology

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GUIDANCE NOTE FOR

THE COMPILATION OF THE PUBLIC DOSSIER

WITHIN THE FRAMEWORK OF

THE DELIBERATE RELEASE OF TRANSGENIC PLANTS FOR EXPERIMENTAL PURPOSES

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Table of contents

Introduction

1. Introduction

In Belgium, the Royal Decree for the deliberate release of genetically modified organisms (GMOs) of 18 December 1998, which implemented the European directive 90/220/EEC into national law, stipulates in articles 8 § 1 and 16 § 1 that each application dossier needs to contain **a proposal of information** for the public: article 8 § 1 applies to experimental, research and developmental purposes (part B) whereas article 16 § 1 applies to the placing on the market (part C). Therefore, in Belgium notifiers are required to submit a public dossier, which is unique in the European Union.

2. Objectives

Guidelines to compile such a proposal of information were necessary, since the Royal Decree of 18 December 1998 does not give any guidance to notifiers to compile the requested public dossier. Moreover, the consultation of concerned stakeholders and other groups revealed the need to elaborate guidance in order to:

- provide a clear framework to the notifier to draft the public dossier,
- provide clear communication methods,
- encourage a common homogenous approach to carry out the compilation of the public dossier,
- stimulate open and transparent public information.

For these reasons the Service of Biosafety and Biotechnology (SBB) developed guidelines for part B releases with transgenic plants in collaboration with the experts of its working group on public information.

It was agreed that the main objectives of the public dossier should be to inform citizens in general about the activities of companies or research institutes in the biotechnology field and to stimulate public awareness and education.

The delivered information should also enable citizens to gather knowledge, to weigh up the risks and benefits, to form a proper opinion about GMOs or products derived from GMOs.

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 and meet 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 too narrow to address people's concerns. Therefore, the guidelines and public dossiers should not only focus on the biosafety aspects but should also address people's concerns.

In addition, it is found important to pay attention to the semantic accessibility of these public dossiers. The public dossier should be readable and understandable. It is therefore important to use a widely comprehensible language. 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.

3. SNIF versus public dossier

According to article 9§1 of the European directive 90/220/EEC the European Commission set up a system on exchange of the information contained in the notifications submitted under part B of this regulation. The exchanged information between the Member States is based on a technical summary of each notification, termed SNIF. The format of this summary was established by the European Commission in accordance with the procedure laid down in article 21 of the regulation.

Since 17 October 2002, the European directive 2001/18/EC repealing directive 90/220/EEC is of application. This new European directive reinforces the regulatory framework for the deliberate release of GMOs with a set of new provisions such as the obligatory information and consultation of the public. The information of the public is organised through the publication of the SNIF on the centralised website of the Joint Research Centre (JRC) of the European Commission (http://gmoinfo.jrc.it). The central idea is to use the SNIF to inform the public. According to the directive only the possible risks to the environment and human health can be taken into account in the risk assessment, and it is in this context that the information of the public should take place.

The Service of Biosafety and Biotechnology and the experts of the working group on public information were always of opinion that it is quite impossible to combine information for the public and information meant for the Competent Authoritie(s) of Members States in one single document, since the Competent Authorities demand 'scientific language and very detailed and summarised information' to be able to use the SNIF as an early warning system for potential risks, while information of the public implies 'clear language and general information also addressing their concerns'. The Service of Biosafety and Biotechnology and the experts of the working group on public information are of opinion that the way to fill in the SNIF does provide adequate information to citizens. The technical language used and its content that is limited to the topic of risk assessment are not targeting the general audience.

Since the SNIF is a EU obligation, already harmonised and intended to meet administrative needs of the European Commission and Members States, the Service of Biosafety and Biotechnology and experts of the working group on public information were of opinion that another independent tool was necessary.

The obligation laid down in the European directive 2001/18/EC to inform and consult the public makes this guidance note a valuable communication tool for the Belgian Authority.

The world wide consultation of the guidelines and public dossiers on the Belgian Biosafety Server (http://www.biosafety.be) supported the idea that the guidance note might at least be interesting and useful for a larger forum.

4. State of the art on transgenic plants

Since 2000, in Belgium the public dossiers for field trials with transgenic plants are made available to the public by publishing them on the database of the deliberate releases of the Belgian Biosafety Server (http://www.biosafety.be) in three languages: Dutch, French and English).
The first guidelines to compile the public dossier were drafted by the Service of Biosafety and Biotechnology and followed by notifiers in 2001.
In 2002, the notifiers used an updated version of the guidelines in order to meet the recommendations and concerns made by different actors active in this domain. Since 2002, the guidelines are updated in collaboration with the working group on public information. The previous guidelines, public dossiers (of experimental and marketing releases) and different reports were used to improve the quality of the existing guidelines.
The guidelines are downloadable from the site http://www.biosafety.be/TP/partB/public_info_dos.htm

5. Guidance notes for other GMOs

The Service of Biosafety and Biotechnology will in collaboration with the experts of the working group on public information draft guidelines for the compilation of the public dossier within the framework of:

- the deliberate release of genetically modified organisms other than plants for experimental purposes,
- the deliberate release of genetically modified organisms for commercialisation purposes.

Guidelines valid in 2003

The section below contains the guidelines to be followed by the notifier (minimal requirement template) when preparing a public dossier within the framework of a deliberate release of transgenic plants in the environment for non-commercial purposes.

These guidelines should be viewed as dynamically evolving as a result of permanent feedback of the public, notifiers, authorities and concerned stakeholders.

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[1]

(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.

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[1] X and Y to be filled in on for each notification.

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 cannot 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 cannot 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. By the elaboration of that report the notifier should take into account the 'format for the presentation of the report of deliberate release into the environment of genetically modified higher plants according to part B of Directive 2001/18/EC (article 10)' that is currently being drafted by the European Commission and should as well include the following topics:

- 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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List of experts

Within the framework of the Service of Biosafety and Biotechnology, which is the Secretariat of the Biosafety Advisory Council (the Belgian advisory board on genetically modified organisms), the working group on public information has contributed to the development of this document. The Service of Biosafety and Biotechnology of the Scientific Institute of Public Health carried out the drafting of the guidelines and report, the secretariat and the co-ordination of the working group on public information.

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Comments or questions on this report
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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