Checklist

for

Field trials in the European Union

Guideline for Inspections

A Proposal

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Introduction

During the meeting of the European Enforcement Project Deliberate Release of Genetically Modified Organisms in Helsinky (June 2001) it was agreed that the Netherlands would propose a checklist for GMO field trials.

Such a checklist can be used by inspecting field trials by supervising public servants. It can be seen as a manual and a guideline to harmonise the inspection of a field trial in the European Union.

I am aware of the fact that, although every permit holder in the European Union has to work under the EU directive 2001/18, the national or regional implementation of this directive can be different. So some countries may require certain information in advance in the application for a licence or before the start of a field trial. Nevertheless such items have been incorporated in this guideline because not all countries have such requirements.

On the other hand for some field trials certain information is not relevant or not possible ((i.e. 'flowering' in case of field trials with genetically modified micro-organisms).

This guideline has essentially three themes, describing 'Before the field trial' which is sent to the Inspectorate before the experiments with transgenic plants are carried out, 'During the field trial' and 'After the field trial'.

Describing information before the field trial, which is sent to the Inspectorate before the experiments with transgenic plants are carried out, is needed for the Inspectorate to have some basic information about the field trial. In some countries this information is already available with the application for the permit. Other countries give permits for releases taking several years which have to be put in concrete terms as described in the theme 'Before the field trial'.

During the field trial the licence holder has to keep up a logbook. All the subjects to inspect are written down in this logbook. This logbook is needed to control and to evaluate the described subjects, and the results of the findings, by the permit holder and the Inspectorate. The inspector should inspect all this items during the field trial.

When the field trial is finished it is sometimes needed to control and evaluate the obligations mentioned in the permit.

The purpose of this proposal for a checklist is to give an overall picture of what is possible to inspect before, during and after a field trial with genetic modified plants or other organisms. With the feeling that this checklist for some inspectors has to much subjects while other inspectors want to have a more detailed checklist, as a competent authority for field trial inspections you may use the relevant subjects.

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CONTENTS

I Before the field trial

Before the field trial is carried out the Inspectorate has to be informed by the permit holder about:

1. Responsible persons and addresses
   - Name and address of the notifier.
   - Name of the project leader and telephone number.
   - Name of the biological safety officer and telephone number.

2. Field trial
   - Number, code and contents of the permit.
   - Description of the released organisms and their genetically modification (general description e.g. sugar beet, herbicide tolerance to glyphosate)
   - Trial site's location. With the address of the field trial, the name of the farmer who owns the field, and a map of the area including a map/grid with reference to the nearest village so it is easy to find the transgenic field trial.
   - Distinction between transgenic field and the non-transgenic borders, and describing the way the transgenic field trial is recognisable.
   - Size of plots in m2 sown or planted.
   - Number of growing transgenic plants.
   - Proposed planting scheme (dates).
   - Destination of the surplus of seeds after the sowing/planting and the date of the eventual transfer back to the permit holder.

3. Logbook
   - Name and telephone number of the person responsible for this logbook.
   - Address where the log book can be inspected.
   - Items described in the logbook (logbook layout).
   - Period over which the data are being collected.

II During the field trial

During the field trial the licence holder has to keep up a logbook. All the subjects to inspect, and the results of the findings, are written down in this logbook. The inspector should inspect this logbook, the findings written down in this logbook and he should inspect the subjects in the field.

1. Description of the proposed work
   - See all the items under ‘I’, ‘Before the field trial’.
   - Description of the possible modifications in the subject which are sent to the Inspectorate before the field trial is carried out.

2. Other official documents
   - Any contract between permit holder and third parties (i.e. breeders) that ensure sufficient control and responsibility of activities and land hired.

3. Storage (before and after the field trial)
   - Location and dates of the beginning and end of storage.
   - Number or amount of genetically modified organisms which are stored.
   - How storage is taken place (packaging, distance non GMO, etc).

4. Instruction
   - Employees involved in the (transgenic field trial) works referred to the permitted work in consequence of their jobs must be aware of the conditions in the licence and how these are complied with. For this purpose, written instructions (from the permit holder) must be prepared and made available to those persons involved in the works and be added to the log book.
   - The employee must know and understand the content of the permit.
   - A signed specimen by each employee that he or she has read and understood the instructions.
   - Subjects written in this instruction are for instance:
     - packaging
     - transport
     - labelling the field trial (or individual plants)
     - monitoring (flowering or other special instructions)
     - isolation distance
     - treatments during the field trial
     - cleaning harvest machines

- logbook obligations
- transfer to third parties
- emergency follow up action in the event of a breach of the consent.
- etc

5. Transport
   - Dates on which material is transported, where from and where to, stating the quantity of material, the dispatch address and the mode of packaging or transport (covered lorry, barrels, bags etc.). This transport referred to seeds, surplus of seeds after the sowing/planting, samples, yield after harvest etc).

6. Transfer GMO's to third parties
   - If genetically modified material is made available to third parties for follow-up research or waste processing, the permit holder must obtain a written statement from the recipient stating that the latter is aware that the material involved is genetically modified and that the products, such as milk and meat, derived from the animals fed with the genetically modified plants or parts thereof must not be made available for human consumption.

7. Checks of the permitted work
   - Dates on which checks were carried out for the appearance of flowers.
   - Wild relatives of the original transgenic host which are present in the area.
   - Ecological observations.
   - Non-compliance, referred to the contents of the permit and the information given to the Inspectorate before the field trial is carried out, must be noted in a log book.
   - The permit holder is obliged to maintain a regular and effective log book on the progress of the works.

8. Variations in phenotypes
   - Variations occurring during the experiments in the phenotypes of the GMO's by comparison with original non-genetically modified plants cultivated under the same conditions.
   - Period when the plants are flowering.
   - Dates when flowers were removed.

9. Treatments during the field trial

- All the treatments with dates made on the field during the experimentation, like used herbicide or insecticide with dose and cultivation's carried out.

10.Isolation distance

- If the permit required to observe isolation distances to fields with non transgenic plants that may cross fertilize, state the distance to the closest such field.
- If the permit includes a regulation on the observation of isolation distances to fields with plants of the initial organism which will be used for (sowing) seed production, state the distance to the closest such field.
- If the permit includes a regulation for a pollen barrier, state its size and whether it was flowering at the same time as the genetically modified plants.

11.Sampling

- Dates on which transgenic biological material was sampled and precise name by whom (by the inspection services or by the permit holder) and reason to analyse (e.g. the sugar content in sugar beets or the glucosinolates content in oilseed rapes) and attach the statement of sampling as mentioned before.
- In case of sampling of genetically modified crops (or part of crops like leaves, roots, etc) by the inspectors of the competent authorities, both parties (permit holder and inspection services) have to sign a statement of sampling. This statement of sampling for testing of transgenic crops has to mention at least: the date and location of sampling, the name of the sampled crop and of the line, the transgenic trait in question, the type of samples (e.g. leaves, roots, etc) and the approximate weight of the samples, the name of the permit holder and the notification number covering the experimentation.
- Date and the way of destruction of the transgenic samples after analyses.

12.Harvest

- Dates on which the crop or any product thereof is harvested and/or the plants are removed from the field.
- In the case of harvesting, the owners name of the machinery to be sure that the machine has been cleaned afterwards.
- A signed specimen by each employee that he or she has read and understood the instructions (see also under 'Instructions').

13.Waste processing

- State the dates on which the waste from the trial site was processed.
- If various possibilities for the method of waste processing are given in the description of proposed works, state the method of waste processing used.
- In the case of incineration in a waste incineration plant or deep burial in a landfill site, attach documentary evidence of destruction.

III After the field trial

When the field trial is finished it is needed to control and evaluate the obligations mentioned in the permit. For example the logbook with the findings has to be seen by the Inspectorate 5 years after the field trial. In other occasions in the permit written that the field trail needs ‘after care’.

1. Logbook
   - All the information described in the logbook because of the field trial in the year before.

2. Next crop
   - Date of sowing/planting of the type of crop(s) after the field trial.

3. Volunteers
   - Dates on which checks for volunteers (self sown plants) were carried out.
   - Numbers of volunteers per 100 m2 (approximately).
   - Manner in which these plants were removed and the manner in which the waste was processed.