Analysis of part B GMO deliberate release field trials management in Member States and prevention of accidental entry into the marketplace

The information requested is being gathered on behalf of EC DG Environment under research tender ENV.B.3/ETU/2007/0008.

Purpose:

The purpose of the project is, in the context of Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, to:

- Carry out an in-depth analysis of ongoing and completed Part B GMO field trials since October 2002;
- Get an overview of concrete measures in place in the EU Member States (MS) for the management of Part B GMO field trials, including inspection and control measures by the relevant responsible bodies;
- Assess the effectiveness of these management measures in the prevention of out-crossing and other means of accidentally entering the market place;
- Identify gaps and areas for additional guidance or follow-up work as well as examples of best practice.

Background:

This research is aimed primarily at the individual Member States and their procedures in place for managing GMO field trials. However, in addition to interviewing the competent authorities, GM inspectors and field operators, we also wish to gather feedback from the companies and organisations that have conducted Part B GMO field trials in more than one member state. The aim of this is to gain a perspective on comparability across the MS, and to assist in identification of areas of where the MS have implemented particularly good or poor practice.

Our records show that under Directive 2001/18/EC you have conducted GMO field trials in [x] member states. These are listed in the Excel spreadsheet provided separately to this document. Your company, therefore, has a good overview of conducting GMO field trials and we kindly seek your participation in the project.

Gathering information:

If you are willing to participate, it is entirely up to you how the information is gathered. A member of the project team can visit you, or gather your answers by telephone, or you can complete by email if you prefer. The following pages contain the questions we are seeking answers to – you may chose to answer all or just a subset of these.

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A study for EC DG Environment under research tender ENV.B.3/ETU/2007/0008

Detailed report from: [COMPANY CONDUCTING FIELD TRIALS]

Date of visit to company:

Name of company representative:

Date of report: dd/mm/yyyy

Report completed by: [name of project team member] / [name of person in MS CA]

1. Company details

Primary contact:

Name:
Address:
Email:
Telephone:
Fax:

2. Summary of part B GMO deliberate release field trials conducted

2.1 A summary of the field trials conducted by your company since October 2002 is provided in Annex A, do you confirm that this is correct: YES☐ NO☐

If NO, please provide updated information (either below or as a separate attachment in the spreadsheet provided[1])*enter updated info.*

2.1 This data shows that you have conducted field trials in the following Member States: [LIST MS]. Is this correct? YES☐ NO☐
If NO, please *update this list*

2.3 This data also shows that you have conducted field trials with the following crops: [LIST CROPS]. Is this correct? YES☐ NO☐
If NO, please *update this list*

[1] Where separate documentation is requested the preferred format is electronic, however hard copies can be sent to the address at the end of this questionnaire. In such cases please ensure the name of your Member State is clearly marked on the documentation.

3. Conducting a field trial

3.1 Do all of the Member State (MS) competent authorities (CAs) provide useful guidance for preparation of an application to conduct a part B trial?
YES☐ NO☐
If NO, *please indicate which MS do not provide useful guidance*

3.2 Do you consider the requirements for environmental risk assessment to be proportionate and in accordance with Directive 2001/18/EC in all the MS to which you have submitted an application to conduct a part B trial?
YES☐ NO☐
If NO, *please indicate in which MS environmental risk assessment requirements are disproportionate, in your view*

3.3 Do you find the process for assessment of applications to be comparable across the MS to which you have submitted a notification for a part B trial?
YES☐ NO☐

3.4 Has an application that you submitted to a member state ever been rejected?
YES☐ NO☐
If YES, do you consider the reasons for this were reasonable and acceptable?
YES☐ NO☐
If NO, please *explain why not*

3.5 Do all MS require information to demonstrate duty of care, particularly with respect to adventitious GM presence, comparable in all MS?
YES☐ NO☐
If YES, is information requested similar across MS? If NO, *please provide details if possible*
If your answer to question 3.5 was NO, please indicate which MS do not request duty of care information.

3.6 Are the procedures required to minimise the risk of physical dispersal of the GMO and to minimise gene flow to sexually compatible crops and relatives comparable across all MS for the same crop?
If NO, *please provide details if possible*

3.7 Is the rationale behind risk management requirements clear and logical to you in all MS? YES☐ NO☐
If NO, *can you identify MS in which this has not been the case?* (for example, where you consider MS risk management measures have been disproportionate to risk, or inadequate to manage potential risks)?

3.8 Is the management of different crops in part B trials comparable across MS?
YES☐ NO☐

3.9 Are inspection procedures comparable across the MS? YES☐ NO☐

3.10 Have you identified particularly good or poor practice in an Inspectorate?
YES☐ NO☐

If YES, please *please provide details if possible, and your reasons for thinking this*

3.11 Is the documentation required to demonstrate compliance with consent conditions comparable across MS? YES☐ NO☐

3.12 Are consent holder reporting requirements similar across MS? YES☐ NO☐

If NO, please *please provide details if possible*

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4. Non-compliances. *Note: non-compliances in this context are understood to mean a breach of consent conditions*

4.1 Of the consents you have been responsible for since October 2002, have there been any breaches of consent conditions? YES☐ NO☐
If YES, please complete the table below if possible:

Type of non-compliance	**Number**
Technical non-compliance (for example incorrect isolation distance, failure in monitoring, incorrect subsequent crop planted) (*please provide details of these if possible)*	
Cases where material has accidentally entered the marketplace (*please provide details of these if possible)*	
Number of fines or warnings issued (*please provide details of these if possible)*	
Number of prosecutions taken against your company (*please provide details of these if possible)*	

4.2 Of the non-compliances listed above, were all of these reported to the relevant competent authority? YES☐ NO☐
If NO, can you explain what were the reasons for this?

4.3 Of the consents you have been responsible for since October 2002, have there been any incidents of unanticipated problems YES☐ NO☐
If YES, please provide (brief) details of these
If your answer to question 4.2 was YES, were these reported to your Competent Authority?

4.4 Have you had field trial(s) vandalised in any of the MS? YES☐ NO☐
If YES, did this lead to the termination of the trial(s)? YES☐ NO☐

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5. The value of Part B GMO field trials

5.1 Have findings during part B releases prompted further research, either on the GMOs themselves, or their management? YES☐ NO☐

5.2 Have you submitted applications to place a GMO on the market on the basis of evidence gathered from part B trials? YES☐ NO☐

5.3 Which aspect of conducting a GMO field trial has presented the biggest challenge for you?

5.4 Are there any aspects of the current arrangements that you would change if you had the opportunity?

ADDITIONAL INFORMATION

Please provide any other information you consider to be of relevance:

Thank you for taking the time to participate in the study.
If you have any questions please contact:

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