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

The information requested in this questionnaire 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.

Data gathering:

There are two types of information to be gathered as part of this project:

1) Basic information from all MS,

or

2) Detailed information from seven selected MS

This questionnaire forms part of type 1, the gathering of basic information from all MS. Your MS will not be asked to provide more detailed (type 2) information.

Instructions to CA representatives for completion of questionnaire:

Please complete the attached questionnaire and return to eu-gmo-field-trials@csl.gov.uk. If you would prefer to provide your answers via a telephone conversation, please contact the project team at eu-gmo-field-trials@csl.gov.uk, telephone + 44 (0) 1904 462117 and we will arrange a time that is suitable for you.

On behalf of DG Environment, we urge you to please answer as much of the questionnaire as you can.

****If no GMO field trials have been conducted in your MS, please complete the questionnaire with a view to the procedures you would follow in principle****

PLEASE RETURN THIS QUESTIONNAIRE TO:
eu-gmo-field-trials@csl.gov.uk
BY 20th DECEMBER 2007

Questionnaire

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

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

Basic report of practices in: [MS]

Date of report: dd/mm/yyyy

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

Data gathered by: email / telephone / fax / other (please specify)

1. Competent authority (CA)

Primary contact:
Name: *name* [Note: use the tab key to navigate the form][1]
Address: *address*
Email: *email*
Telephone: *tel.*
Fax: *fax*

2. GMO legislation in the Member State (MS)

2.1 Has Directive 2001/18/EC been implemented in national legislation in the MS?
[use the space bar to tick] YES☐ NO☐

If your answer to this question is 'no', please go to section 3

2.2 If YES, please provide the name(s) of the legislation
enter 2001/18/EC-derived legislation

2.3 Does the national legislation include provision for part B GMO trials?
YES☐ NO☐

3. Summary of part B GMO deliberate release field trials

3.1 A summary of the GMO DR field trials held in the MS (since 17 October 2002) is provided in Annex A, does the CA confirm that this is correct: YES☐ NO☐

3.2 If NO: please provide updated information (either below or as a separate attachment in the spreadsheet provided[2]) *enter updated info.*

[1] Note: This document is protected to allow data entry to specific fields only. If, however, you consider it essential to add text outside these fields you can unprotect the sheet by selecting 'Unprotect Document' from the 'Tools' menu.

[2] 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.

3.3 Where a field trial was authorised but did not go ahead please indicate this either below or as a separate attachment in the spreadsheet provided [3]) *enter updated info.*

4. Information and application procedures

4.1 Do you have an authorisation procedure in place for applicants seeking consent to conduct a GMO DR trial? YES☐ NO☐

4.2 If YES, how is this information made available to applicants? *Please provide your answer here*, and please provide a weblink where possible *Enter weblink (if available)*

4.3 Do you provide guidance on the information applicants are required to provide in the technical dossier? YES☐ NO☐
If YES, please provide a weblink if possible *Enter weblink if available*

4.4 Do you provide guidance on the general principles that need to be considered for management of GMO DR trials? YES☐ NO☐
If YES, please provide a weblink if possible *Enter weblink if available*

4.5 Do you have established procedures for exchanging information with the European Commission on notifications in your MS? YES☐ NO☐

5. Assessment of applications

5.1 Do you have any specific criteria for acceptance or rejection of applications to hold a part B trial? YES☐ NO☐

If YES, please indicate what these are *summarise acceptance/rejection criteria*

5.2 Are there any crops, traits or crop/trait combinations that you would not authorise for a part B trial? YES☐ NO☐

If YES, please describe which ones and (briefly), why *crop/reason*

5.3 Is a dedicated scientific advisory committee established for assessment of part B applications? YES☐ NO☐
If YES, what is the name of the advisory committee? *name*
Does the Committee comprise any of the following? If yes, please indicate how many:
Government scientists NO☐ YES ☐ Number:
Non-government scientists NO☐ YES ☐ Number:
Officials (non-scientific) NO☐ YES ☐ Number:

[3] 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.

Lay persons NO☐ YES ☐ Number:
Other (*please provide details, including numbers*)

5.5 How important do you consider the following information when assessing application dossiers? Please rank on a scale of 1 to 7 (1 = low, 7 = high; please do not assign the same value more than once):

- Information on personnel and training *enter 1 to 7*
- Information about the genetic modification and the GMO *enter 1 to 7*
- The environmental risk assessment *enter 1 to 7*
- Risk management measures & rationale, including day-to-day management of the trial *enter 1 to 7*
- Proposals for monitoring during and post-trial *enter 1 to 7*
- Management of wastes from the trial *enter 1 to 7*
- Emergency response plan *enter 1 to 7*

6. The consent

6.1 Is there a standard format for the consent document? YES☐ NO☐
[*If possible, please provide an example*].

6.2 Is the consent document published? YES☐ NO☐
If YES, where is it published? *Please provide weblink if possible*

7. Information provided to the public

7.1 What information must be published about GM field trials that have been authorised, particularly with regard to location? *Information published*

7.2 Where is this information published? *Please provide weblink if possible*

Newspapers YES☐ NO☐
Websites YES☐ NO☐
Other YES☐ NO☐ (*Please provide details if possible*)

7.3 Are the public given opportunity to comment on applications? YES☐ NO☐

8. Management of authorised deliberate releases

8.1 Has standard or best practice been developed for management of certain crops or traits or crop/trait combinations YES☐ NO☐
If yes, *please provide details if possible*

If NO, how are management procedures determined? *Insert details of how management proceddures are determined*

8.2 What are the reasons for the specific management procedures proposed?

Crop biology YES☐ NO☐
Previous experience YES☐ NO☐
Published research YES☐ NO☐
Other official guidance YES☐ NO☐ *Please provide details if possible*
Other YES☐ NO☐ *Please provide details if possible*

8.3 Is there a requirement for the consent holder to demonstrate 'duty of care' to ensure adventitious GMOs are not present in planting material? YES☐ NO☐
If yes, what evidence is required:
Production assurance documents from the consent holder YES☐ NO☐
GM testing results from the consent holder YES☐ NO☐
Quality assurance documents from the consent holder YES☐ NO☐
Provision of sample(s) for official testing YES☐ NO☐
CA takes official sample(s) for testing YES☐ NO☐
Other *please provide details if possible*

8.4 Does the CA require the consent holder to provide monitoring reports? YES☐ NO☐

If yes, does the CA assess these? YES☐ NO☐ (*or another body*)?
If reports are assessed by another body, *please provide the name of the body*

8.5 Is there an established procedure for following up observed or unexpected effects? YES☐ NO☐
If yes, *please describe this briefly*.

9. Inspection and enforcement

9.1 Does the CA have an Inspectorate nominated specifically for GMO DR trials? YES☐ NO☐

9.2 If YES, what is the name of the Inspectorate? *Inspectorate name*

9.3 If there is not a nominated inspectorate, *how is regulatory compliance achieved?*

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

10.1 Are procedures in place for dealing with non-compliances, including criteria for initiating a formal investigation? YES☐ NO☐

10.2 Of the total consents issued since October 2002, in how many has there been a breach of consent conditions? Please complete the table below:

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)*	*number*
Cases where material has accidentally entered the marketplace (*please provide details of these if possible)*	*number*
Number of fines or written warnings issued (*please provide details of these if possible)*	*number*

Number of prosecutions pursued (*please provide details of these if possible)*	*number*

10.3 Are details of non-compliances published? YES☐ NO☐
If YES, where are they published (*Please provide further information and a weblink if possible*)

11. Any other information:

Please enter any other information you feel would be useful concerning prevention of accidental entry into the marketplace: *further information*

Thank you for taking the time to complete this questionnaire.
If you have any questions please contact Sarah Hugo or James Blackburn at:

Central Science Laboratory
Sand Hutton
York
North Yorkshire
YO41 1LZ, UK

Tel: + 44 (0) 1904 462117
Fax: + 44 (0) 1904 462740
Email: eu-gmo-field-trials@csl.gov.uk