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

Detailed report of practices in: [MS]

Date of visit to MS:

Date of report: dd/mm/yyyy

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

PART I: QUESTIONS TO COMPETENT AUTHORITY ONLY

1. Competent authority (CA)

Primary contact:
Name: *name*
Address: *address*
Email: *email*
Telephone: *tel.*
Fax: *fax*

2. GMO legislation in the MS

2.1 Has Directive 2001/18/EC been implemented in national legislation in the MS?

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

2.3 When was this introduced?

If your answer to question 2.1 is 'no', please go to section 3

2.4 Is there any other national legislation that must be observed when a GMO DR field trial is conducted?

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

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[1]) *enter updated info.*

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[1] *enter updated info.*

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4. Information and application procedures

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

4.2 How is this information made available to applicants? *Please provide your answer here*, and *please enter weblink if available*

4.3 Is guidance on the information applicants are required to provide available? YES☐ NO☐

If YES *please enter weblink if available*

4.4 Is guidance provided on the general principles that need to be considered for management of GMO DR trials? YES☐ NO☐

If YES, *please 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☐

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5. Assessment of applications to release a GMO DR field trial

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	NO☐	YES ☐	Number:___
Lay persons	NO☐	YES ☐	Number:___

[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.

Other (*please provide details*)

5.4 Who is consulted when an application is received?

Conservation Agency/ies	YES☐ NO☐	
Environment Agency/ies	YES☐ NO☐	
GMO field inspectors	YES☐ NO☐	
Health and Safety Executive	YES☐ NO☐	
Government scientist/s	YES☐ NO☐	
Other Regulatory Committee/s	YES☐ NO☐	(*please provide details*)
Other (*please provide details*)		

5.5 How important do you consider the following information to be when assessing application dossiers? Please rank on a scale of 1 to 7 (1 = low, 7 = high):

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

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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*

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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☐

7.4 Are all application dossiers published for public review? *If yes, please provide weblink if possible*
If NO, which dossiers are not published? *Please provide details if possible*

ADDITIONAL INFORMATION

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

PART II: QUESTIONS TO BOTH COMPETENT AUTHORITY AND FIELD TRIAL INSPECTORS

Note: Where inspectorates operate on a regional basis, we appreciate that it may be necessary for the CA to collate responses from a number of Inspectors. If possible, we would like to meet with one inspector who would be prepared to participate in the study.

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, are management procedures applied on a case-by-case basis?
YES☐ NO☐

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 for official testing YES☐ NO☐
CA takes official sample for testing YES☐ NO☐
Other *please provide details if possible*

8.4 Are specific requirements described for any of the following activities associated with a GMO field trial:

Crop	**Maize**	**Potato**	**Cotton**	**Oilseed rape**	**Sugar beet**
Cultivation of a GMO field trial					
Sowing a GMO field trial					
Harvesting a GMO field trial					
Cleaning of machinery used for a GMO field trial					
Post-trial monitoring for volunteers					
Restrictions on post-trial cropping					

8.5 What precautions are taken to ensure isolation from sexually compatible crops and/or wild relatives?

Maize	Potato	Cotton	Oilseed rape	Sugar beet
Crop-specific measures to ensure isolation from sexually compatible crops &/or wild relatives	*Crop-specific measures to ensure isolation from sexually compatible crops &/or wild relatives*	*Crop-specific measures to ensure isolation from sexually compatible crops &/or wild relatives*	*Crop-specific measures to ensure isolation from sexually compatible crops &/or wild relatives*	*Crop-specific measures to ensure isolation from sexually compatible crops &/or wild relatives*
Action taken if sexually compatible or related crop is found growing within the isolation zone	*Action taken if sexually compatible or related crop is found growing within the isolation zone*	*Action taken if sexually compatible or related crop is found growing within the isolation zone*	*Action taken if sexually compatible or related crop is found growing within the isolation zone*	*Action taken if sexually compatible or related crop is found growing within the isolation zone*

8.6 Are there any specific requirements for monitoring field trials? YES☐ NO☐

If there are any crop-specific monitoring requirements please provide these below:

Maize	Potato	Cotton	Oilseed rape	Sugar beet
Crop-specific monitoring requirements	*Crop-specific monitoring requirements*	*Crop-specific monitoring requirements*	*Crop-specific monitoring requirements*	*Crop-specific monitoring requirements*

8.7 What measures are taken to minimise or prevent the dispersal of the GM plant (e.g. tubers, seeds, straw)?

Maize	Potato	Cotton	Oilseed rape	Sugar beet
Crop-specific measures to minimise or prevent dispersal of the GM plant	*Crop-specific measures to minimise or prevent dispersal of the GM plant*	*Crop-specific measures to minimise or prevent dispersal of the GM plant*	*Crop-specific measures to minimise or prevent dispersal of the GM plant*	*Crop-specific measures to minimise or prevent dispersal of the GM plant*

8.8 Do you have a policy of testing for potential GM gene flow around a trial site?
YES☐ NO☐

If YES, whose responsibility is it to do this?
What happens if GM gene flow is found to have occurred?

8.9 What methods are permitted for post-release treatment of the GM plant material, including wastes (GM and non-GM) from the trial?

8.10 Are any specific strategies established for post-trial monitoring?
YES☐ NO☐

If YES, please provide details of any crop-specific post trial monitoring requirements in the table below:

Maize	Potato	Cotton	Oilseed rape	Sugar beet
Crop-specific post-trial monitoring requirements	*Crop-specific post-trial monitoring requirements*	*Crop-specific post-trial monitoring requirements*	*Crop-specific post-trial monitoring requirements*	*Crop-specific post-trial monitoring requirements*

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

If YES, does the CA assess these? YES☐ NO☐
If consent holder reports are assessed by a different body *please provide the name of the body*

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

8.13 Are any restrictions placed on a GMO field trial site following termination of a trial?

9. Non-compliances. *Note: non-compliance in this context is understood to mean a breach of consent conditions*

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

9.2 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)*	
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 (*please provide details of these if possible)*	

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

ADDITIONAL INFORMATION

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

PART III: QUESTIONS TO FIELD TRIAL INSPECTORS ONLY

10. Inspection and enforcement

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

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

10.3 What is the remit of the Inspectorate?

10.4 Briefly, what powers do inspectors have?

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

10.6 Do you have guidelines for inspection regimes and reporting mechanisms?

10.7 How often is each trial inspected at the following stages:

Stage of trial	Maize	Potato	Cotton	Oilseed rape	Sugar beet
Sowing					
Growing crop					
Harvest & disposal					
Post-trial					

10.8 Are inspections:

Scheduled YES☐ NO☐
Unannounced YES☐ NO☐
Both YES☐ NO☐ (*(please explain)*)

10.9 What is inspected:

- Trial location and six-figure (or other) grid reference
- Crop planted
- Dimensions of trial area
- Presence of barrier crops if appropriate
- Proximity to other crops of same type
- Proximity to related crops
- Transport (seed, harvested material)
- Facilities for storage of material (seed, harvested material)
- Documentation and record keeping (*please provide details if possible*)
- Other (*please provide details if possible*)

10.10 Is field inspection your only method for ensuring compliance? YES☐ NO☐

10.11 Are you required to provide reports of your activities to the competent authority? YES☐ NO☐
If YES, *please provide details of the reports you produce*

10.12 Are your inspection reports publicly available? YES☐ NO ☐

If YES, *please provide weblink if possible*)

ADDITIONAL INFORMATION

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

QUESTIONS TO FIELD TRIAL INSPECTORS ON SPECIFIC TRIALS

Trial number:

Crop:

Date of release:

11.1 Did the field trial go according to plan? If not, how did it deviate from the plan?

11.2 Did any problems arise with the GMO that were not anticipated at the outset?

11.3 Were any incidents of non-compliance identified? If yes, what were these and what happened as a result?

11.4 Was any incident of spread of the GMO outside of the trial area identified?

11.5 If yes, how was this identified and what measures were taken to remedy the spread?

11.6 Was the origin of the spread of the GMO identified and analysed (e.g. out crossing or/and admixture)?

11.7 Were management procedures reviewed as a result of anything that happened with this release?

11.8 Were any lessons learned as a result of this trial?

11.9 Were the risk assessment and risk management plan judged to be appropriate for the trial, in particular taking into consideration any incidents of spread of the GMO?

11.10 Did data gathered from this trial contribute to an application to place a GMO on the market?

THIS SECTION MAY BE REPEATED DEPENDING ON SPECIFIC TRIALS IDENTIFIED FOR THE MS

PART IV: QUESTIONS TO MEMBER STATE-BASED NOTIFIER

12.1 Please confirm which of the trials listed in Annex A that you were responsible for. Please confirm that this information is correct.

12.2 Are procedures for submitting an application to conduct a part B GMO field trial clear and easy to follow in this Member State (MS)? YES☐ NO☐
If NO, *please explain why not*

12.3 Were you required to revise or to clarify any aspects of your application during the assessment process? YES☐ NO☐
If YES, *please explain which aspects and why*

12.4 Are the requirements for management and reporting a GMO field trial clear and easy to comply with in this MS? YES☐ NO☐
If NO, *please explain why not*

12.5 Were trial management procedures required by the CA based on clearly identified and/or potential risks? YES☐ NO☐

12.6 In your view, were the requested management procedures appropriate to potential risks? YES☐ NO☐

12.7 Were procedures for inspection and monitoring of your field trials for regulatory purposes clearly explained to you and easy to comply with? YES☐ NO☐
If NO, *please explain why not*

12.8 Were any unanticipated effects of the GMO noted during or after the trial? YES☐ NO☐
If YES, was the risk assessment reviewed in response to this?

12.9 Where any changes or extensions applied to the post-trial monitoring period YES☐ NO☐

If YES, did you consider the changes were reasonable? If not, *please explain why not*

12.10 How many incidents of unanticipated problems have you reported to your Competent Authority? If you have reported any such incidents, please provide (brief) details of these.

12.11 How many potential non-compliance incidents have you reported to your Competent Authority? If you have reported any such incidents, please provide (brief) details of these.

12.12 In general, do you consider the regulatory framework established for holding GMO field trials in this MS to be consistent with the requirements of Council Directive 2001/18/EC?

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

12.14 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:

PART V: QUESTIONS TO FIELD-BASED OPERATORS

13.1 Contact details:
Name:
Address:
Email:
Telephone:
Fax:

13.2 Please confirm which of the trials listed in Annex A that you were responsible for managing in the field.

13.3 Did the consent holder explain to you:

The purpose of the trial	YES☐ NO☐
Essential management requirements	YES☐ NO☐
Requirements for record keeping	YES☐ NO☐
Requirements for reporting	YES☐ NO☐

Any other requirements (*please provide details*)

13.4 Did the consent holder explain why the risk management activities specified for the release were necessary? YES☐ NO☐

13.5 Were day-to-day trial management procedures:

Determined by you	YES☐ NO☐
Specified by the consent holder	YES☐ NO☐
Specified by the competent authority	YES☐ NO☐
Specified by GM field inspectors	YES☐ NO☐
Decided jointly	YES☐ NO☐
Other	YES☐ NO☐ (*please provide details*)

13.6 Were you provided with documentation to help you manage the trial? YES☐ NO☐

13.7 Were you requested to complete any documentation and keep records of your management actions? YES☐ NO☐
If YES, who held copies of this documentation?

Field based operator	YES☐ NO☐
Consent holder	YES☐ NO☐
Both	YES☐ NO☐

13.8 Did you have any contact directly with the competent authority? YES☐ NO☐

13.9 How many times did a CA-nominated inspector visit the field trials?

13.10 Was it clear what the inspector was looking at/for and why? YES☐ NO☐

13.11 Did the inspector examine, or request copies of, any documentation? YES☐ NO☐

13.12 Did you receive any feedback from the inspection/s? YES☐ NO☐
If YES, *please provide details*

13.13 Did any unanticipated problems arise either during the field trial or in the post trial monitoring period?
If YES, *please provide details*
Did you report these incidents to the consent holder YES☐ NO☐

13.14 Did any potential non-compliance incidents arise during the trial?
If YES, *please provide details*
Did you report these incidents to the consent holder YES☐ NO☐

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

13.16 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 Sarah Hugo or James Blackburn at:

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Sand Hutton
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North Yorkshire
YO41 1LZ, UK

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