APPENDIX 9: QUESTIONS TO MS-BASED NOTIFIERS' FIELD TRIAL OPERATORS

These tables should be read in conjunction with section 6 of the main report (Detailed survey of seven member states: summary of responses)

Table 1: Field operator's understanding of the purpose of field trials

Member State	Did the consent holder explain the following to you					Did the consent holder explain why these risk management activities specified for the release were necessary
	The purpose of the trial	Essential management requirements	Requirements for record keeping	Requirements for reporting	Any other requirements?	
France	Yes	Yes	Yes	Yes	No	Yes. Day-to-day management is the same as for a conventional trial, including irrigation etc, so there are no specific requirements because it is a GM trial.
Germany (1 field operator)	Yes	Yes	Yes	Yes	All involved personnel are educated annually in all obligations listed in the application and the permission used at the specific site	Yes
Hungary	Yes	Yes	Yes	Yes	Yes	Yes
The Netherlands	Yes	Yes	Yes	Yes	Yes	Yes
Spain	Yes	Yes	Yes	Yes	Yes[1]	Yes
Sweden	Yes	Yes	Yes	Yes	Required to maintain the 'field compliance notebook which contains the regulatory compliance management requirements, transport documents, map, planting records, field visit records, reports, details of previous grown crops etc.- all information about the particular location.	Yes. The field plan is received from HQ in Germany, but how they actually plant is up to the field operator (and will depend e.g. on the local, prevailing conditions) as long as they act in compliance with set regulations and given they fulfil the written trial set-up. Any special agronomic requirements are also handled by HQ in Germany
UK	Yes	Yes	Yes	Yes	Both regulatory and technical aspects. The notifier provided guidance provided in easy to use format for operator.	Yes

[1]Standard operating procedures (SOPs) have been developed for some tasks. These are seen as key tools for the managing of research trials and ensuring compliance with consent conditions. They are updated annually for local needs with inputs from the company's European headquarters and the national office. They also include specifications required by the competent authorities and their inspectors. SOPs are an integral component of staff training programmes.

Table 2: Determining day to day management procedures

Member State	Were day-to-day trial management procedures:					
	Determined by you	Specified by the consent holder	Specified by the competent authority	Specified by GM field inspectors	Decided jointly	Other
France	Yes	Yes	No	No	No	
Germany	Yes	Yes	Yes	Yes	Yes	No
Hungary	Yes	Yes	Yes	Yes	Yes	No
The Netherlands	Yes	Yes	No	No	Yes. Some decisions are made with the consent holder	
Spain	Yes	Yes	Yes	Yes	Yes	The company undertakes the key operations by itself. Farmers perform certain agronomic services, e.g. irrigation and crop spraying.
Sweden	No The field operator advises on the best way to run a trial from his practical perspective.	Yes	Yes	No	No	No On a day-to-day basis the field operator does what the plan tells him to do; he does what the consent says, and what the research part of the company tells him to do for the trial.
UK	Yes	Yes	No	No	No	The pathology related technical aspects were determined by the field operator while the planting date and range of chemical products to be used determined by consent holder.

Table 3: Day to day management of the field trial

Member State	Were you provided with documentation to help you manage the trial	Were you requested to complete any documentation and keep records of your management actions	If yes, who held copies of this documentation			
			Field operator	Consent holder	Both	Other
France	Yes. A copy of the consent is not necessarily sent to the field operator - the Notifier prepares its own document with all the management requirements in the consent plus the notifier's own requirements, and this would be sent to all operators in the chain. The farmer would receive details on what he is required to do and is made aware of the requirements of a GM trial, and the post trial cropping restrictions. It is all written in the contract and is in the terms of the contract. Understanding of the need for compliance is good.	Yes. Forms for recording irrigation, weed control etc on the trial have been developed and the farmer must complete these			Yes	
Germany (1 notifier)	Yes	Yes			Yes	
Hungary	Yes	Yes			Yes	
The Netherlands	Yes. The notifier supplied protocols for maintaining the trial and a logbook. The logbook contains the permit, guidance from the VROM GM inspectors and reporting forms.	Yes			Yes. Faxed information sent by the field operator is retained by the consent holder	
Spain	Yes	Yes. Field operators keep a dedicated written logbook for every trial. On returning from the field, new entries are copied into an electronic copy of the logbook enabling the consent holder to view the management actions undertaken on every release site.			Yes	

Sweden	Yes. A field compliance handbook is established for each trial location. The originals of all documents are kept by the trial executor and the notifier keeps a faxed copy at the office.	Yes. The field compliance handbook established for each trial location. There is an emergency telephone number on all labels (storage / transport) - the number switches automatically to a notifier number. The field operators can always reach the notifier.	Keeps the originals	Keeps a faxed copy	Yes	
UK	Yes. Both regulatory and technical. A field compliance handbook was provided. The documentation provided by the consent holder made the whole trial process very easy to handle and work with.	Yes. Technical details such as inoculation dates, etc. were put in a report to the consent holder but paper copies were held by field-based operator. The regulatory and technical aspects were kept separate.			Anything in the field compliance notebook and the consent holder.	

Table 4: Interaction with the Competent Authority and field inspectors

Member State	Did you have any contact directly with the competent authority	How many times did a CA-nominated inspector visit the field trials	Was it clear what the inspector was looking at/for and why	Did the inspector examine, or request copies of, any documentation	Did you receive any feedback from the inspection/s?
France	No	On average a trial will be inspected 3-5 times. The field operator has direct contact with inspectors. There is contact with the inspector during the pre-planting visit and a post-planting control visit to verify location etc at least once when the crop is in the ground. Sometimes the inspector will visit at flowering if there is a specific requirement for bagging, also at or after trial destruction. Sometimes inspectors visit trials without any notice, but they normally announce the inspection and meet the operator at the trial.	Yes. The inspector asks to see the field compliance notebook, with maps etc, and checks this. They also check the isolation distances. He/she checks that waste straw (including the grain if this is left on the plants) is chopped and incorporated, then ploughed back into the field etc. Samples may be taken through the course of the trial and returned to the lab for analysis and disposal. There is then an inspection for volunteer control the following year but inspectors do not inform the notifier of this visit, unless there is a problem.	Yes	No. The field operator and notifier only have exchanges with the inspector in the field, if there is a risk of non-compliance it is discussed at the inspection, e.g. if there are insufficient border lines, the operator may need to plant extra rows etc to be compliant. The notifier would be pleased to have a report - this would be helpful and good for the records. End of trial monitoring reports are sent to CA, but there is no response unless there is an issue. No feedback is assumed to be good news.
Germany (1 operator)	Yes	Normally at planting and harvest time, plus potential visits during crop development or after trial destruction.	Yes	Yes	Yes. The type of feedback differs between the federal states. It ranged from oral comments up to detailed written reports of the results of a certain visit. The latter is regularly used when the results of a seed analysis are communicated.

Hungary	Yes	3 times - at pollination, harvest, transport of crop waste for incineration	Yes	Yes. Examples would be matching the seed labels with the permit and documentation that established how much seed had been sown, the amount of seed remaining and whether reserve seed had been destroyed.	Yes. Oral comments and a copy of the inspector's memo/records which are co-signed by the field operator.
The Netherlands	No	Once	Yes	Yes. Only examined records (logbook)	Yes. A copy of the inspection report
Spain	Yes. By fax to inspectors on critical operations with a copy to the consent holder	Inspections are made before planting, at planting and at harvest, plus potential visits during crop development or after trial destruction. Sometimes, inspectors can come unannounced	Yes	Yes	Yes. Verbal comments and/or a copy of the field inspection report taken in the field after planting and crop destruction operations.
Sweden	No	Each trial is inspected on average once. The Swedish Board of Agriculture tells their inspectors what they want them to look for. They check location, isolation distance and sometimes volunteers. They do not look at the field compliance notebook. They ask to meet the field operator but if he can't make it they still do the inspection. The field operator prefers to go with the inspectors to the trial.	Yes. The inspector does not explain what they are looking for, but the field operator understands anyway. A new operator of GMO field trials would probably have a full explanation, depending on prior conversation. If not - the executor would be on the phone to the notifier.	No	Inspectors only contact field operator again if there is a problem with the inspection. The inspection report is sent to the notifier. The field operator does not have a copy of the inspection report, but the Notifier does.

UK	No	3 inspections. The advice and guidance provided by the GMI was very useful. The GMI had a very professional manner with very fair questions being posed.	Yes	The inspector looked at the field trial notebook, the documentation that came with consignment and also documentation that went with harvested field trial material when it was returned to Germany	Formal feedback was provided indirectly via consent holder which included specific recommendations that were made. The recommendation was that in the event of the operator having to hold material for sowing or harvested produce, or material resulting from unauthorised action on the trial, it must be held in an enclosed container that is itself lockable and is kept in a facility that is locked outside working hours. This was requested for future use as a result of an incident. There was also general discussion with the CA-inspectors during inspections.

Table 5: Unanticipated problems and non-compliances

Member State	Did any unanticipated problems arise either during the field trial or in the post trial monitoring period	Did any potential non-compliance incidents arise during the trial	Were these incidents be reported to the consent holder / would they be reported
France	No. Activists are the greatest problem at field trials	No	Where trials have been destroyed it is always reported to the CA.
Germany (1 operator)	No.	No	N/A
Hungary	Yes. Extreme weather conditions (drought) and extreme pest infection.	No	Yes, the unanticipated problem was reported to the consent holder.
The Netherlands	No	No	N/A
Spain	Some neighbouring farmers planted conventional maize within the 200m isolation distance, and in one case over a release site where there had been a GM trial the year before.	No	Yes, the unanticipated problem was reported to the consent holder.
Sweden	None found. In one trial, mini tubers did not grow well and some lines had fewer tubers than others, the trial was for starch quality, but this problem did not affect the trial as such. The problem occurred depending on too short interval between harvest and planting.	No. The trial executor follows the compliance handbook closely, therefore no non-compliances should arise - it is very important to follow the rules. There are emergency telephone number on all labels (storage/transport) - the number switches automatically to the notifier or another nominated (notifier) mobile number (24h). So field trial executors can always reach the notifier or another representative for the notifier.	Yes

UK	Yes. The trial was extensively damaged by unauthorised personnel entering the site and pulling up plants. The incident was reported within 2-3 hours of discovery by the field operator's staff. For such incidents there is a chain of events which is outlined in the field trial notebook. In addition the consent states that the CA must be notified within 36 hours of incident. If an incident happens over the weekend it is difficult to ensure that this time limit is complied with and in this specific instance there was a problem with the GMI receiving the message. This has been addressed by the consent holder and the GM Inspectorate.	No because the procedures in the emergency plan were followed as detailed. Non-compliance was interpreted as being a deliberate release of material by not following the specific consent procedures, for example, a tractor leaving the site without being washed down.	Yes

Table 6: Challenges and changes (1)

Member State	Which aspect of managing a GMO field trial has presented the biggest challenge for you in this MS?
France	Finding a farmer to run the trial, and a field with suitable isolation distance is a significant challenge. The local political situation of the farmer is the most difficult issue. At present, potential locations must be found 7 - 8 months before planting, the field operator may start with lots of possible sites but end up with only 1 field suitable for planting after 'problems' have arisen. Once the trial is established, it is quite straightforward unless there are problems with activists. On some trials it has been necessary to put barriers around them (2005) where there is threat of activists but barriers have not always worked in the past – there was a dog and police, and lights around one site but it was still destroyed.
Germany (1 operator)	The public register and the prescribed isolation distances impose quite harsh restrictions. The listing in the public register facilitates trial destructions which, besides the illegal nature of such actions, might also reduce the biological safety. The isolation distances force the trials to be held in regions which are not ideal for the crop being tested.
Hungary	Receiving annual permissions (prolongation and seed import permits) before mid-April so that sowing occurs at an optimum time for maize.
The Netherlands	The only challenge was the inconvenience of having a security guard permanently on site to deter vandalism.
Spain	Giving notice of release sites 6-7 months in advance of planting can be problematic as farmers and their neighbours can change their minds according to grain, prices, water availability etc.
Sweden	There are no challenges - the customer decides, so the field operator does what the customer tells him. The actual contract is a problem, the field operator has to read it in English and translate it to Swedish. Converting documents to Swedish is time-consuming and difficult, and the field operator needs to make sure everything has been covered. There are a lot of rules to be followed but as a specialist in agriculture trials the field operator is used to fulfilling the customers needs.
UK	Security against vandalism.

Table 7: Challenges and changes (2)

Member State	Are there any aspects of the current arrangements in this MS that you would change if you had the opportunity?
France	The public information requirement - because it makes the job very difficult to do where anti-GM activists are opposed.
Germany (1 operator)	New regulation for the public register (as described above) and reduced, more realistic risk-based isolation distances. Also, grain destruction when the maize (such as NK603) has been approved for import and use, should not be required.
Hungary	The level of regulatory oversight is appropriate and there is no need for changing the current arrangements for conducting GM research trials.
The Netherlands	The current system works well and is fit for purpose. The system accounts for the inherent risks of releasing GMOs and there is no need to change it.
Spain	A more flexible approach to site notification, allowing a larger number of potential sites (locations) to be notified whilst recognising that only a few sites will be planted. Also, grain destruction when the maize (such as NK603) has been approved for import and use, should not be required.
Sweden	Nothing would change - only practical aspects of planting potatoes etc. The field operator would not change safety aspects of the GMO trials.
UK	From a field operator's point of view the public knowledge of where a trial is creates the biggest security problem. Differences between 4 and 6 figure grid references are not likely to make a big difference. If a 6 figure grid reference is not supplied it is possible that the consent holder may be found not to be complying with conditions.