APPENDIX 8: QUESTIONS TO MEMBER STATE-BASED NOTIFIERS

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: Application procedures in the MS (1)

Member State	Application procedures in the MS – ease and clarity	
	Are procedures for submitting an application to conduct a part B GMO field trial clear and easy to follow in this Member State (MS)	**Were you required to revise or to clarify any aspects of your application during the assessment process?**
France (Note: this response was provided by 1 notifier but the answers are collated from the key notifiers operating in France)	Yes. The procedure is clear but it is not necessarily easy. Problems are encountered with the requirement to advertise local information regarding the location of GMO trials. Dealing with the CA and inspectors is straightforward, but the system falls down with the publication of the location of the trial. It is not just companies that are targeted - even research institutes have not been able to proceed with a trial. For 2008 releases, the company sent all part Bs applications in December but has not received a response yet, which makes planning very difficult. It is the same for all companies in this France at present [because of the Grenelle review] and there are unlikely to be any new part B trials this year, only the ongoing programme.	Questions are quite often asked regarding the content of the application e.g. molecular aspects, toxicology study, but not often on management. When this happens the companies are invited to make a representation to the scientific advisory committee and then make adjustments to the dossier as appropriate, & re-submit for further assessment. It is normally not a problem to satisfy the questions, but companies do have occasional refusals. Companies consider it disproportionate to have to attend Advisory Committee meetings, it is not required in other countries, but they accept that this is the case in France.
Germany (2 notifiers)	1) Yes. 2) Yes. The company is able to maintain close contact with the CA and the people managing the applications. A meeting is held with the CA at an early stage, and contact is maintained. In Oct 2006 the CA held a workshop to discuss changes to the legislation re. changes to the nature protection legislation and this was helpful. The CA does not provide a strict application format, but the company is happy with this. The process takes much longer than 90 days, even with 'stopping the clock' it can take 5 -6 months. If the company wants the consent in March, applications are submitted in September of the previous year.	1) Yes. In most cases additional information regarding environmental protection areas has been requested (distances to release site, kind of protection goal, possible interactions, etc. 2) Usually at least once for each application. Generally these are sensible and reasonable questions. Questions relating to nature conservation risk assessment can be very detailed and difficult to respond to. If there is a 'Natura 2000' site within 1000m of the proposed trial site it makes gaining a permit difficult (same for all crops). Therefore, the company is looking for sites that are not within 1000m of these protected areas - in theory it should be possible to hold a trial within these, but in practice it would be very difficult to do this because of the level and complexity of the questions asked, resulting in an enormous time lag.

Hungary (1 notifier and a seed supplier)	Yes	Yes. Information has been requested covering relevant data from other countries where trials have already been done, more details for trial protocols, information on the interaction with GMOs and other organisms in the ecosystem and studies on the delayed impact on biogeochemical processes. The notifier has experienced difficulty in satisfactorily dialoguing with officials and members of the Advisory Committee when answering points of clarification, including the use of internationally-agreed test methods as part of the trial protocols and discussing applications that have been turned down. In our view, insufficient explanation has been given when our clarifications on dossiers have not been accepted and when applications have been refused. In some cases, agreement could not be reached over requests by the Competent Authority (CA) to change the original scope of research trials. An example of the reasoning for refusal of our 2007 GM HT maize applications, which were investigations on the impact of the GMO with non-target organisms, is as follows: "The documents also fail to answer the question how the distribution in the environment of the water-soluble glyphosate as well as of its slowing degrading metabolite (AMPA) will vary under the Hungarian soil and surface water conditions. Furthermore, no information is provided on how the hormone modulating effect of glyphosate as well as its degradation products will affect aquatic organisms and – through the abstraction of drinking water – animals and humans as well".
The Netherlands	Yes. The procedures are very clear, concise and can be easily followed	Yes. In practice the amount of revision has been very limited. Past examples have been: 1. Administrative clarification 2. Scope of the GMOs (breeding material) covered in the release 3. Information on the exact method to be used for backbone sequence detection prior to release.
Spain	Yes	Yes - to provide additional information following recommendations from the Advisory Committee with regard to molecular characterisation, safety data, and impacts on non-target organisms.
Sweden	Yes. The requirements are clear, but the CA sometimes ask for additional information e.g. on promoter expression profiles etc. Guidance is available. There is a standard form that has to be filled in with supporting guidance as to what the CA actually requires. The notifier thought a new applicant would find the process quite complicated (risk assessment in particular), but manageable.	Yes. Some clarification is most often requested e.g. on the data that is submitted on glasshouse trials, expression studies on promoters, information about the gene and the gene construct, i.e. generally about the GMO itself. When the CA asks for this information it is generally relatively reasonable and sensible. The notifier has never had the feeling that the CA is asking questions unnecessarily.

UK	Unknown. The application was submitted directly from the company HQ in Germany to Defra. Company HQ in Germany is responsible for biotechnology development within the company, which is why the application was submitted in this manner.	Not known. It is possible that the application may have been modified or further clarification provided but as the UK-based part of the company was not directly involved at this stage the answer to this question is not known.

Table 2: Application procedures in the MS (2)

Member State	Are the requirements for management and reporting a GMO field trial clear and easy to comply with in this MS?	Were trial management procedures required by the CA based on clearly identified and/or potential risks	In your view, were the requested management procedures appropriate to potential risks	In general, do you consider the regulatory framework established for holding GMO field trials in this MS to be consistent with the requirements of Directive 2001/18/EC
France (Note: this response was provided by 1 notifier but the answers are collated from the key notifiers operating in France)	Yes	Yes. Companies are used to them now - so they accept the requirements, but they don't necessarily think this is the best system. There is no consideration for reducing the risk management requirements as they become familiar with events. New events used to have 400m isolation requirement to start with, which was then reduced to 200m when experience of its behaviour in trials was gained. Companies would, therefore, like to see a response by the CA / scientific committee on reduced risk management measures with increased knowledge about the risks.	No. Risk management measures should be based on knowledge, e.g. in the 2nd part B for a known event, the company proposed reduced management procedures but this was refused and sent back to original management procedures, i.e. 400m isolation for maize. Pollen borders are no longer needed.	Yes. For maize it is (mostly) OK - it is not an easy system but the companies can work with it. It can be difficult to identify locations for field trials due to the 400m isolation requirement. The requirement to advertise the trials locally is also a problem.

Germany (2 notifiers)	1) Yes 2) Yes. It is clear what the CA want the company to do, and in principle it is OK. Some of the additional requirements imposed by the Federal Agency for Nature Conservation (BfN) can be difficult to comply with, but these are not generally unreasonable. In general it is fine doing trials in this Germany.	1) No. With increasing number of regulatory approvals of GMO-products one could conclude an increasing safety in risk assessment (NK603 maize, for example). As a consequence scientifically unfounded isolation distances are not based on an identified risk especially if they increase over time for identical GM-products. Furthermore, involved authorities ask for data which are beyond the identified and/or potential risks or objective of the trials. 2) Yes. In the past isolation distances varied for no apparent reason - e.g. for potato in 2005 and 2007 isolation was 10m, but in 2006 authorisations had an isolation of 10m, plus a control area of 10m around the trial site, i.e. total of 20m. In 2007 isolation went back to 10m.	1) No – see previous answer 2) Yes. Some of the conditions are difficult, but it is not fair to say no.	1) Broadly, yes, but it is too strict for domesticated plants such as maize when it has been approved for import and use in the EU (NK603 maize, for example). 2) Yes, with exception of the public register - there is a requirement to provide all details to the public. The exact location must be provided.
Hungary (1 notifier and a seed supplier)	Yes	Yes	Yes. Most of the management requirements are clearly set out in the permit conditions.	Yes, as far as conducting GM research trials. Greater openness and transparency in the approval/permit process would be welcomed.

The Netherlands	Yes	Yes. The CA procedures are based on clearly identified risks, which are based on independent, science-based advice. Sometimes the CA has departed from this practice. This break in continuity can come about by having to implement different management procedures from those recommended by their own advisers, this has resulted from judicial rulings when permit authorisations have been contested in court.	Yes	Yes. Documentation is very clear and precise, as is the guidance that is provided for submitting a notification and conducting field trials.
Spain	Yes	Yes	Yes the management measures are appropriate, however two practices deserve further consideration: (1) Where flowering dates differ by at least a month between GM maize varieties and neighbouring non-GM varieties, the company would welcome a relaxation of the recommended minimum isolation distance of 200m. (2) For GM events that have been approved for commercial importation and processing, the requirement to bury harvested seed and waste crop material should be reviewed.	Yes

Sweden	Yes. Management procedures are proposed in the application, the CA will assess these and respond based on their assessment. These procedures have been developed with years of experience with breeding potato and OSR. Templates are provided for yearly reports and final reports. Post-trial monitoring is separate and is requested yearly and reports must be submitted to the CA. Potato material might be requested for testing but this is *ad hoc* rather than an ongoing requirement. In addition, the notifier has contracts with its growers specifying how the trials should be executed. The notifier goes through the "Field compliance notebook" with each grower and all sign to say that they have read and understood the information given. Yearly a 3rd party auditor visits each site to check each party is doing the compliance job correctly. The auditor visits each site at least once a year. Internal management of documentation is a very important activity and aspiration for management of GMO trials.	Yes. Trial management procedures are generally, but not always, totally science based. Sometimes they are mediated with the need to satisfy the community, e.g. OSR isolation distance increased from 500 to 800m recently, it is not entirely clear that this is based on science, but it will keep the community less concerned about the trials. To date there have not been any management procedures that the company thought: "we really can't do this". There is a recent requirement (2006) to monitor for wild relatives around OSR trials and check for gene flow - this is a large block trial and during the 2007 trial, not enough wild relatives were found within the surrounding area to allow a reasonable investigation. The scientific value of such investigation with the current set-up is questionable, but the company is being asked to do it.	Yes. They were appropriate for the present legal safety requirements within EU for GMOs and for e.g. minimizing gene dispersal, but they are disproportionate relative to other new trait introductions and introduction of other new genetic resources (e.g. new garden species or foreign seeds in wild bird feed during winter). But CA requirements are reasonable with respect to legislation.	Yes
UK	Yes. The procedures outlined in the initial consent were clear but not particularly detailed. With advice from the GM Inspectorate it was possible to set up more specific procedures for management and reporting.	Yes	Yes	Yes

Table 3: Inspection and reporting of field trials in the MS

Member State	Were procedures for inspection and monitoring of your field trials for regulatory purposes clearly explained to you and easy to comply with?	Were any unanticipated effects of the GMO noted during or after the trial?	If YES, was the risk assessment reviewed in response to this?	Where any changes or extensions applied to the post-trial monitoring period	If YES, did you consider these changes to be reasonable
France (Note: this response was provided by 1 notifier but the answers are collated from the key notifiers operating in France)	No. It is clearly explained in the consent what must be done, but it is not always easy to comply with these requirements, e.g. it is very difficult to find 400m isolation from a commercial crop of maize in the main maize growing areas. The Inspectors are reasonable and companies have good exchanges with them. There can be slightly different approaches to inspections with respect to timing, but all inspectors operate in a similar way and to similar standards.	No. None of the companies operating in France has identified any unanticipated effects during a trial	N/A	No. Post trial monitoring for maize has always been 1 year, and there have never been any extensions to this	N/A

Germany (2 notifiers)	1) Procedures have been explained clearly but it is not always easy to comply with, e.g. large isolation distances are difficult to establish in the main growing regions of the crop – where the trials should be from an agricultural point of view. 2) In principle it is OK, but the Federal system means there will be slightly different approaches between the Bundes Länder. Not all of the health and food safety agencies have a lot of experience with sampling and analysis. The company provides protocols for detection on request etc. The inspectors have discussions with the Company, and generally resolve any issues. Where inspectors and/or Länder do not have experience of GM field trials it can be problematic. But generally, even if it is a new trial, the Inspectorates are understanding of GM trials etc and are sensible.	1) No 2) No	1) N/A 2) N/A	1) No 2) No. Potato trials must be 1 year with no volunteers, so PTM is not necessarily extended - it is part of the authorisation agreement.	1) N/A 2) N/A
Hungary (1 notifier and a seed supplier)	Yes	No	N/A	No	N/A
The Netherlands	Yes	No	N/A	No	N/A

Spain	Yes	No. Phenotypic behaviour other than modified genes has been no different from their non-GM equivalents.	No. As Spanish permits are only given on an annual basis, if there was a need to change the post-monitoring conditions, permit conditions for the following year would be altered. To date this has not proved necessary.		N/A
Sweden	Yes. The applicant proposes what they will do in terms of their own inspection and monitoring of the trial, and the CA will request changes as appropriate. There has recently been a change in requirements for OSR monitoring.	No	N/A	Yes. Potato fields in 2007 continued to have volunteers because winter was not cold, so monitoring has been extended.	Yes
UK	Yes. The company already has detailed procedures for carrying out GMO field trials, which were used. These were approved by the GM Inspectorate who also provided further advice, which was appreciated.	No	N/A	No	The notifier is still in the post-trial monitoring period so there is still scope for changes but it is not considered very likely that changes will have to be made.

Table 4: Unanticipated effects and incidents of non-compliance

Member State	How many incidents of unanticipated problems have you reported to your Competent Authority?	How many potential non-compliance incidents have you reported to your Competent Authority?
France (Note: this response was provided by 1 notifier but the answers are collated from the key notifiers operating in France)	None	Nothing to report in France
Germany (2 notifiers)	1) None. There had been no unanticipated problems or incidents during all part B releases in Germany. But several trial destructions occurred which have been all reported to the CA immediately. 2) None. The company anticipates that problems of vandalism may occur, which is why they have fences and a guard on each site. There are a number of options available for disposal of wastes from the trial and we will adopt the most appropriate methods, in discussion with the inspectors. The company has many years of experience and good understanding of the GMOs, and a good understanding of the German system.	1) No such incidents have happened. 2) The company reports all things that happen in the field, in case it is necessary to take action. The company provides the facts to CA and inspectorates directly; the company proposes the course of action and discuss with the CA and inspectors; the company does not comment on legal aspects. The company awaits telephone, email or written OK from the CA. The CA decides if it is a compliance issue.
Hungary (1 notifier and a seed supplier)	None	None
The Netherlands	In early 2007 the notifier's potato permits were annulled. At that time, there was an active, over-wintering trial in the ground. This produced a practical dilemma; how could the trial be safely terminated when permission to work on the site had been withdrawn? In the meantime, a member of staff had taken the initiative to harvest and destroy the over-wintering tubers but had omitted, initially, to inform the Inspectorate, who would normally be notified of the harvest date. The issue was resolved as documentary and photographic evidence could verify that the harvest and crop destruction were performed according to the permit conditions.	None

Spain	In the last 3 years, where 19 permits have been granted involving 41 notifications, only two unanticipated problems have occurred	Two incidents in 2007: 1) A neighbouring farmer felled an apricot orchard and planted the area with conventional maize. This compromised the 200 m isolation distance 2) Despite contractual requirements, a farmer planted conventional maize over a GM maize release site the following year These incidents were communicated to the Spanish Authorities and resolved with the farmers involved in agreement with the conditions of the Part B Permits.
Sweden	None to report	There was an incident in 2004 with a potato field trial (planted under 90/220/EC) - a farmer planted a crop of seed potatoes within the isolation distance for the potatoes in the trial. An Inspector from the Board of Agriculture observed it, the company responded by putting everything correct (i.e. isolation distance corrected) and the field trial continued as planned. The Board of Agriculture reported the incident to the authorities and the farmer was prosecuted and fined. As a result of this incident the company increased its inspection of trials.
UK	There was 1 major vandalism incident. The trial was attacked and vandalised. The consent had required an emergency plan to be drawn up before the GMO field trial began. Following the incident the plan was put into action. Although damage was caused the trial was still able to continue.	None

Table 5: Challenges and changes (1)

Member State	Which aspect of conducting a GMO field trial has presented the biggest challenge for you in this MS?
France (Note: this response was provided by 1 notifier but the answers are collated from the key notifiers operating in France)	1) The requirement for public consultation is preventing trials - it is possible to envisage part B trials falling to zero (Bayer has pulled out of trials in France; Syngenta pulled out for a couple of years but have returned; Limagrain (Biogemma) is reducing its activity significantly). Removal of the requirement for public consultation could reverse this. 2) Publication of application dossiers and lack of commercial confidentiality of Company programmes means all companies know exactly who is doing what, so it is very difficult to be competitive: transparency = loss of competitive edge.
Germany (2 notifiers)	1) Public information of the field site in detail often led the way to trial destruction. 2) By the large and scientifically unfounded isolation distances the company is forced to conduct the trials at sites which are not really typical for the crop. 3) It is difficult to find farmers - they are personally interested and financially it is beneficial for them, but they can encounter problems in their local village and they either don't want to host trials, or agree to do it and pull out later. So, in addition to the 1000m from nature conservation sites, the company has to find farmers willing to hold the trials on their land.
Hungary (1 notifier and a seed supplier)	Obtaining approval to conduct GMO field trials, in particular resolving the scope of GM research trials.
The Netherlands	The most challenging aspect has been the unpredictability of the approval process due to the imposition of judicial rulings when some permits have been challenged in the courts.
Spain	1) Neighbouring farmers can change their minds over planting plans, which can affect isolation distances. This can make the choice of sites problematic, especially as notification of sites has to be given 6 to 7 months before planting. 2) Damage from wild animals, either by grazing or providing shelter. 3) Finding sites with sufficient water throughout the growing season.
Sweden	Anticipating what information the CA is going to request each time, and having all the data available that they will ask for, and which will satisfy them (e.g. promoter activity, which tissues is it active in and which tissues is it not active in etc). The notifier thinks that it is not altogether reasonable to expect such high levels of detail to be known about the GMO for part Bs.
UK	1) The security, which is linked to the grid reference, which must be made publicly available. 2) The interpretation of the specific consent conditions. Maybe the advisory role played by the GM Inspectorate could be more clearly stated in the consent.

Table 6: 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 (Note: this response was provided by 1 notifier but the answers are collated from the key notifiers operating in France)	1) Dossier structure - requirements in this MS are quite heavy in terms of information requirements, too much data and testing is required. Companies do not understand why [the CA] are asking for so much information about molecular and toxicology data for experimental trials, which are heavily managed. It is difficult for smaller European-based companies to gather sufficient data for the dossiers (US based companies already have a lot of the requested information so it is easier to provide). Risk management and conditions are the most important things, and if these are correct then detailed information about the event is not really necessary – we believe the CA should be more interested in knowing that the trial is managed well and that proper arrangements are in place for this. The companies consider the requirements to be disproportionate for a part B. 2) Reduction in requirements for stringency of management conditions with increasing familiarity with an event. 3) Requirements for publication of location of trials - can lead to dissemination of the GM material by vandalism.
Germany (2 notifiers)	1) For events already approved for import and use (NK603, for example), change the crop destruction requirement by the use of grain as GM maize properly labelled (GM maize containing MON-ØØ6Ø3-6). 2) For safety reasons, do not include the exact location of trial sites in the public information. It increases the risk of trial destructions. 3) Details for trial locations should not become public at the level of detail currently specified. 4) A public register is not needed for part B trials. It would be safer for the farmer if this information was not available on the public register - it would prevent the farmer from getting threatened. 5) The requirement to inform the CA & local inspectorates of the intention to sow 3 days prior to planting can be difficult. It becomes a problem when, at short notice, the company has to move the trial to another approved location (e.g. because a farmer has pulled out). It is possible to achieve, but makes it difficult. The company does not see why they need to inform the CA with such strict requirement of the planting date. The company would prefer to inform the CA after planting which consents have been planted and which locations. 6) The CA sometimes refers decisions to the upper Ministry (Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz, BMELV = Federal Ministry of Food, Agriculture and Consumer Protection) The company feels the CA can make these decisions and does not need to refer it higher - it adds more time. In the past 2 years many of the consents have been referred upwards - but it is not clear why they are doing this. 7) In the past the Gene Technology law permitted use of the simplified procedure; a recent application was submitted under this procedure and the notifier was hopeful that it could be used again. 8) Distance to Natura 2000 sites. 9) The definition of a GMO is handled differently in different MS. In Germany all plant lines that may be released must be listed in the application, but the risk assessment is based on the construct not on specific lines. The application therefore lists all the lines, not all of which are planted. If a consent is e.g. for 5 years, notifiers are constantly developing new lines but cannot trial these under the consent. It would be preferable that the consent would allow planting of any plant lines based on the specific construct, with assurance provided that all analysis of new lines is done on the same basis as in the consent.
Hungary (1 notifier and a seed supplier)	1) More communication, cooperative approach and partnership in favour of clarifying outstanding issues and finding acceptable solutions. 2) In wishing to resolve these issues, the notifier and their seed supplier would welcome a forum which encouraged greater listening, dialogue and interaction between officials and notifier parties during the approval process for authorising GM research trials (Part B applications). 3) For the seed supplier, the hurdles encountered in obtaining permits for GM research trials in 2007 has the led the company to apply to a different MS to continue their deliberate release research trial programme in 2008.

The Netherlands	The current system is fit for purpose. However, in view of recent annulments of the notifier's permits, the company would recommend that the administrative procedures undertaken by the CA during the approval process are sufficiently robust and defendable so that they cannot be easily undermined by legal challenge. Withdrawal of permits by the CA as a result of judicial rulings is costly for the company and delays our research programme.
Spain	1) The notifier supports openness and transparency in the publication of information on research trials. However, in doing so it wishes to ensure the safety of farmers conducting research trials and protect the trials from vandalism. To this end, the notifier would not reveal the exact location of field trials during public consultation as part of the permit approval process or when members of the public specially request this information. 2) For GM events that have been approved for commercial importation and processing, the requirement to bury harvested seed and waste crop material should be reviewed.
Sweden	1) There is no opportunity for fast-tracking similar applications, i.e. where the data and gene construct and risk assessment is very - still the formal approval process takes the same time as a totally new application. It is possible to apply for new locations for an approved gene construct/event under a fast-track procedure. But it would be very helpful if there were opportunity to streamline applications where we have knowledge and experience about the gene constructs/events with very minor modifications. The company is happy with clearly defined steps but with a little bit more flexibility. 2) Given that the part Bs are based on 2001/18, the system is OK. But - we would like the time periods for assessment to be shorter. 3) The competitive nature of the industry means time lines are sharply defined, therefore there is not always time to gather all data before a dossier is submitted and flexibility on submitting data at a later stage during the assessment period would be helpful. Because of the lengthy assessment process, the Company would like the option to submit the basic application well in advance, and submit data on the actual material that will be used in the trial as they get the results of the previous year's trials etc, or as material is developed (e.g. in the glasshouse).
UK	The four figure grid reference. The notifier appreciates that it has to be publicly available but it does lead to potential problems, e.g. vandalism.