APPENDIX 10: QUESTIONS TO EU-WIDE NOTIFIERS

These tables should be read in conjunction with section 7 of the main report (Notifier experiences EU-wide)

Table 1: Application procedures (1)

Company	Do all of the MS competent authorities provide useful guidance for preparation of an application to conduct a part B trial?
A	No - not all. All provide information, but they do not all provide good guidance. Many MS lack a proper technical guidance document, we often have to go into national law and work it out for ourselves. One MS in particular was quite hard because the administrative arrangements are very complex: the technical dossier has to be duplicated for each entity operating the trials on behalf of the company. Another MS was hard but quite amenable, because they were new. In another MS there is no guidance, no response back from dossiers that are submitted and we don't even receive acknowledgement that our dossiers have been received. In another MS we had no response to our dossier the first time we submitted an application, the 2nd time the CA indicated they were amenable but then we received a large number of questions just before planting, so the trial did not go ahead; today the system works at least for submissions but to-date we have never received a permit from this MS. Under national law in one MS, trials must be 30km from a 'protected site' but there is no description of what a protected site is.
B	Yes. Generally speaking the CAs provide useful information.
C	No. In general guidance is OK in the countries we have experience with. The level of detail is different, e.g. level of instruction in one MS is very detailed, in another it is less so, in another it was OK. Where a CA does not enter into communication and advise us to what should be done this is unhelpful - this was the case in one MS. Timelines that must be observed are very important, the company needs to know what information will become public when, and what will be required when; the requirements for responding to information for the public must be known, plus the likely timeline for assessment of an application. CAs should make it clear what information MUST be provided, and what would be desirable. For a new MS - it is difficult to administer the first application, so possibly should consult another MS with more experience. In one MS management of the administrative processes were very good, but they struggled with the need to consult more than one Ministry, and ultimately political interference stopped the trial.

Table 2: Application procedures (environmental risk assessment)

Company	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?
A	Some are disproportionate, others are proportionate and are more interested in management of the trial. In one MS the risk assessment was difficult - there were too many questions; finally they did not provide a permit to the company but authorised the trial based on the same dossier, which had been submitted by a National University.
B	Some countries ask more questions than others, but they are generally proportionate and within requirements. There is one exception: two applications were lodged for exactly the same GMO, containing exactly the same risk assessment 'package', one trial was for efficacy studies, the other was for non-target organisms (NTO) studies. Consent was issued for the efficacy study, but consent conditions were disproportionate - for example additional studies were required to study NTOs, toxicology and economic impacts - and the consent was issued only in June, which is too late for maize planting. The other application for local NTO studies was not issued consent, i.e. the MS requested a NTO study to be done yet rejected the NTO study proposed by the company. It has to be noted further that other countries accepted the same risk assessment dossier, while this MS applied additional requirements to generate data on specific eco-zone and local economic impacts, which is not within the scope of the Directive.
C	In one MS the risk management measures were disproportionate to the risk assessment (potato, improved resistance to disease). The requirement for a feeding trial to be conducted after year 1 and results to be submitted before year 2 could proceed was disproportionate; also the fee requested was huge (€55,506K for each year of the trial (2006-2010) and a total of €3,600 per year for the years 2011-2014). In another MS (potato, improved resistance to disease), the reasons given for rejection were disease risks, but we believe the real reason for not allowing trial was due to objections from the potato trade.

Table 3: Application procedures (3)

Company	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?
A	Yes - this is similar across the MS. The files headlines are comparable as they are all based on the requirements of 2001/18/EC. The requirements for information about location are different. There are differences in what is considered confidential information, and the information that is published also varies. It is only in one MS that you have to present to the national Scientific Advisory Committee. We think that there is no need for the whole dossier to be published because it compromises competitive ability.
B	Yes. They are comparable but there are big differences in timelines. In general, the CAs do not appear to deliberately try to slow the process, although some exceptions exist. Through experience in certain countries, we know that it may be necessary to submit dossiers earlier. One MS is complex because we have to submit application for each party involved in the trial, so we have to submit several applications for the same field trial. Two other MS asked additional questions which appeared to be 'stalling' the process. The fees differ country to country.
C	1) Timelines are very diverse. In most countries the 90 days plus 30 days is not kept, especially in three MS in particular. It is too long in these countries, we can work around it because we know the timelines now, but it is still very difficult - it would be very difficult for a new applicant who did not know this. We have to get data for the application really early, which is a big hurdle for research and optimising line development. We should be able to submit the application in December, but actually we must submit it September /October so we have 2-3 months LESS for analysis of data. In one MS we must submit in July because application takes such a long time. In another MS it is necessary to get authorisation for each individual event, each year. 2) The methods of making information public is very variable, which is not necessarily a problem, but it is when the CA does not explain the system to applicants. Where there is a need for local consultation, discussions can be ongoing in local communities, but the discussions are not science-based and this can lead to problems, e.g. it can contribute to farmers having problems. The application process should prevent this - e.g. by not giving detailed information on the location. 3) In one MS, we must submit a separate application for each company involved - e.g. if we have 2 partners we would have to put in 3 applications. Also, if we employ e.g. a separate transport company, we would also have to obtain consent for that company. Each application must be paid for, assessed individually and each is issued with consent. Once we knew what had to do, the procedure itself was OK. Also in this MS, we must have an independent and CA-approved expert consultant who must be experienced in the field, with no political affinity. This person has to be paid. The purpose is to complete the risk assessment, which is submitted as part of the application, but he/she must sign the risk assessment. This system was not a problem, but was unusual - it is a requirement under national law. It worked OK, and the expert was helpful.

Table 4: Application procedures (4)

Company	Has an application that you submitted ever been rejected?	If yes, did you consider the reasons for this to be reasonable?
A	Yes – three cases (all maize)	No. 1) One MS rejected an application in 1 region, they said didn't have the pest and therefore there was no need to do the trial - the Scientific Advisory Committee had no objections - it was a local objection. The following year it was accepted. 2) In another MS in 2005 - 3 pages of questions on the dossier were sent back. We answered these but still the trial was not allowed to go ahead. We received a permit in 2006, which was submitted through a local university (2006 – 2008). We did not get authorisation for applications in 2007 - no reason was given and we received the refusal in June (too late to plant maize). 3) A MS refused us a permit in 2004 arguing that we did not provide enough data. This was an event from another company, which we had provided a letter of access. But the MS refused to use the owner-company data. Moreover at the same time, since we had applied for a GM variety registration, we provided the exact same file to the variety registration agency and that file got a permit: same file 2 different answers.
B	Yes – three cases (all maize)	No. The CAs were open to holding the trials at the outset. A favourable scientific opinion was given in two MS, but permit was refused. In another MS - for the same product, one permit was issued but with unacceptable conditions and too late to plant, the other was rejected.
C	Yes – two cases (potato and spring oilseed rape)	No. The reasons given were unreasonable because they were not based on science - a positive scientific opinion was given by the scientific advisory committee. In one MS we considered the reasons to be unacceptable because they were based on public acceptance: although in the letter received no reason was given at all, the official statement on the government website stated public opposition as the reasons (despite the fact that the CA had received 2 positive statements, from the GMO expert committee and the GMO steering committee).

Table 5: Trial management (1)

Company	Do all MS require information to demonstrate duty of care, particularly with respect to adventitious GM presence, comparable in all MS? If YES, is information requested similar across MS?
A	No. In one MS the inspection can check if the event announced is the one planted (i.e. by taking leaf samples in the field). In another MS we had to provide a seed sample of the GMO at planting time in order to test AP. Another MS requires a sample of grounded seeds at the time of dossier application as well as a detection method. Except for one MS the duty of care is not about AP but about verifying that the event tested is the one described in the application. We are always asked to label seeds. Some MS take samples and test; we think it is reasonable to ask for a sample to provide to the inspector, but this is not a realistic request for new events, only for established events like MON810 etc.
B	Yes. This is very similar across the MS for the countries we are working in. In one MS planting material must be provided at the time of submission of the dossier, it is part of national legislation.
C	Generally speaking yes, but not in respect to adventitious presence. Only one MS requested detail on adventitious GM presence - we found this very unusual because it was a part B trial.

Table 6: Trial management (2)

Company	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?
A	No - they are not. In one MS the distance for maize is 200m (which is consistent with the current seed production rules), in another MS it is 400m, in another the isolation requirement is 500m. Post monitoring is usually 1 year, but in one MS post release monitoring is 2 years.
B	Yes they are comparable - isolation distances, pollen barriers, border rows etc, but they are not identical - the detail varies. Destruction of the material - not familiar with the detail of this between countries.
C	Generally they are comparable - isolation distances are similar, conditions for monitoring are generally comparable in the countries where trials are actually taking place.

Table 7: Trial management (3)

Company	Is the rationale behind risk management requirements clear and logical to you in all MS?	If NO, can you identify MS in which this has not been the case?
A	The requirement is generally clear, but the logic behind it is some times disproportionate.	In one MS the isolation distance is too large; the 2 years PTM in one MS has no meaning in a country where winters are so hard. So far we have not identified any very 'relaxed' countries - generally MS are more rather strict than less risk adverse. Duty of care varies a lot - a requirement to test all the seed will kill the part B trials (cannot run PCR on each seed).
B	No. The measures themselves are generally logical, but the detail is not, and they are not always based on science - in particular isolation distances	No specific examples given.
C	Mostly yes, in principle the measures are comparable. Measures are not always based on science - e.g. 20m isolation for potato is not science-based but we can live with it.	One MS was exceptional - this example was completely disproportionate to risk.

Table 8: Trial management (4)

Company	Is the management of different crops in part B trials comparable across MS?
A	Yes
B	Yes. Management of different crops in one particular MS is usually different because of the biology of the crop. Management of a certain crop between MS can be different (e.g. again for isolation distances).
C	Yes

Table 9: Control of field trials

Company	Are inspection procedures comparable across the MS?	Have you identified particularly good or poor practice in an Inspectorate?
A	Yes. The level of inspections varies across the MS. Some countries are not trusting companies monitoring: they require a biosafety officer to be in charge of monitoring on top of the current staff running the trials.	We cannot comment on this. We don't really see inspectors from other countries. In one MS inspectors can be 'difficult' (1 region specifies the times and dates the inspector can visit the crops and the company MUST comply with this). This MS also requires previous information of planting dates, harvest dates etc. We sometimes receive reports of inspections but we would like to receive these systematically.
B	Yes. All about notebooks and checklists.	No - they are all comparable. It is acceptable that the field trials are inspected; we have no negative comments about this.
C	Yes, basically they are comparable. i) In one MS we must submit plant material prior to planting for inspection control (but it would make more sense to sample leaf material from the trial). ii) In one MS the consent is issued and the inspectors interpret the conditions, which is also very unusual - adventitious presence is not mentioned in the consent, so this was a surprise and was quite difficult to meet because of the requests for information. These requirements not unreasonable but were unusual. The inspectors do a management audit, which is OK - more than other countries, but it is OK.	No. Basically they are comparable. We prefer that the inspectors only inspect and do not give rise to further conditions and/or requirements. Where there are countries with different [regional] arrangements political views could come into play and cause problems.

Table 10: Control of field trials (2)

Company	Is the documentation required to demonstrate compliance with consent conditions comparable across MS?
A	Yes. Reports are generally accepted in the EU format - sometimes dates by which reports must be provided are specified.
B	Yes. Generally it is comparable.
C	Yes, but it is difficult for us to say because we are using our internal field compliance guidelines in all MS and we set our own standards with this - so it might be a lot more than is needed in a lot of MS. In one MS autoclave records for disposal of material (in that MS) were required but we did not consider this to be unreasonable.

Table 11: Reporting to the competent authority

Company	Are consent holder reporting requirements similar across MS?
A	Yes. Reports are generally accepted in the EU format - sometimes dates by which reports must be provided are specified.
B	Yes. The EC report format is required. We have no negative comments about this.
C	Yes. All MS accept the European format. The timeline for submitting the reports varies - e.g. in one MS it must be provided 4 weeks after harvest or by the end of November - it is difficult to provide good reports within 4 weeks of the end of the trial. Some ask for the report at the end of year, which is OK. Some ask for the report by the end of February, which is also OK. We agree there should be sufficient time to consider the report before the next planting.

Table 12: Non-compliances

Member State	Of the consents you have been responsible for since October 2002, have there been any breaches of consent conditions?	Of the total consents issued since October 2002, in how many has there been a breach of consent conditions?				Were all non-compliances reported to the relevant competent authority?
		Technical non-compliance[1]	Number of cases where material has accidentally entered the marketplace	Number of fines or warnings issued	Number of prosecutions taken	
A	Yes	1	0	0	0	Yes
B	No. But would need to refer to Company MS reports for detail, where they are much more focussed on CAs and inspectors. The Company EU Regulatory Affairs Dept would be made aware by the local Regulatory Affairs Dep't if there are issues, and would be directly involved if there were observations of unanticipated adverse effects related to the GM crop.	0	0	0	0	N/A
C	No. We have reported cases where something did not go exactly as it should have, e.g. material was taken away from the field. We also ensure we have close contact with the local inspectorate and seek advice as to what to do.	0	0	0	0	N/A

Company A: A trial was destroyed in one MS because the border rows had not germinated & isolation was not correct - this would have become a non-compliance. There have been similar cases in another MS, but we replanted the border rows prior to inspection & the inspector agreed this was OK. In both these MS there have been cases where farmers have planted corn within the isolation distance - we had to ask the farmer to destroy the crop to re-establish correct isolation distance (involves compensation to the farmer)

Table 13: Problems with field trials

Company	Of the consents you have been responsible for since October 2002, have there been any incidents of unanticipated problems	Have you had field trial(s) vandalised in any of the MS?	If YES, did this lead to the termination of the trial(s)?
A	Vandalism is the only unanticipated event (although we do anticipate this may happen).	Yes	Yes and no - it is not always necessary to destroy the trial, but sometimes the activists completely destroy the trials.
B	No unanticipated adverse effects have been observed. Vandalism has occurred.	Yes. In two MS. In one of those two MS 50% of trials were vandalised last year, while in the other MS metal bars were thrown at harvesting machinery & stones tied to maize cobs. It is increasingly hard to find farmers who will do trials. Trial destruction means we have insufficient data to generate a complete data package for the dossier.	If trials are vandalised early we get no/less data so they might be terminated early.
C	No. In the case of destruction (), we had to ensure that no material had been removed from the trial site. In one MS, where tubers were removed, signs were placed around the site showing where the trial was. The activists had removed the tubers and delivered them to the Regional Authorities; we then organised collection and destruction of the tubers.	Yes	No

Table 14: Value of Part B field trials

Company	Have findings during part B releases prompted further research, either on the GMOs themselves, or their management?	Have you submitted applications to place a GMO on the market on the basis of evidence gathered from part B trials?
A	Yes. The trials provide information on how the crops will be used at a commercial level. Field trials are still a very useful and essential part of developing a variety - comparing performance of a variety in many conditions etc	Yes. Part C applications are based on data generated in part B trials.
B	No. Usually our EU trials are confirmatory, since an elaborate data package exists already from field trials performed in other world areas. The EU field trials are performed to gather data for commercial release applications in EU. The trials therefore confirm what is already known about the product. Nothing new was observed. We realize, however, that this is not the case for all companies.	Yes. This is the main reason that part B trials are held, we need data from EU trials for cultivation applications, in addition to the data generated in other world areas. Trials are getting harder but we are hopeful for a change and are still planning trials. Sometimes we commission research with smaller companies - not necessarily for pure research but for data generation.
C	Yes	Yes

Table 15: Challenges of holding a Part B field trial

Company	Which aspect of conducting a GMO field trial has presented the biggest challenge for you?
A	i) Public information leading to vandalism. ii) Non-confidentiality due to requirements for publication
B	i) Public consultation - increases uncertainty in timelines, e.g. in one MS in particular this has become an issue. ii) Public information - publishing detailed information on the trials to be performed can lead to pressure on farmers, impacts on willingness of farmers to participate in trials, impacts the safety of the farmer and his family, facilitates trial destruction by activists, and thus overall limits locations that are available. iii) Part B approvals should be science-based - when applications are refused it is often for political reasons, not science-based reasons. iv) It would be useful to adapt the conditions for product approval depending on product familiarity e.g. where they have already been approved for food, feed, import & processing. For example, having to destroy the crop at the end of a trial costs a lot of money and it makes no sense to have to do this for products that are already being imported for food and feed - flexibility on disposal of authorised events would be sensible here. A framework of 'measures' for disposal could be proposed.
C	i) The requirement to make information public and the length of the consultation period in some countries. ii) Finding farmers to conduct trials, and a long way in advance of planting period - e.g. in the summer, and the need to find more than will actually be needed because some might drop out. iii) Maintaining the willingness of the farmers due to local pressure, and protecting the farmers and their families. iv) Getting approvals based on science-based evaluations only. It is hard to predict the outcome of the applications in some MS because of political and other non-science based pressures, which makes planning difficult.

Table 16: What would you change?

Company	Are there any aspects of the current arrangements that you would change if you had the opportunity?
A	i) Dossier structure - requirements in one MS are particularly 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. We consider the requirements to be disproportionate for a part B. ii) In one MS the main issue is on the need to apply the same dossier in each region. The dossier is then sent back by all concerned regions to the national CA for the scientific advice and then it goes back for decision to the regional authorities. Similar countries which have a strong regional organisation instead of centralised state have not transferred the decision to each region, it saves paper, time and administrative workload. iii) Reduction in requirements for stringency of management conditions with increasing familiarity with an event. iv) Requirements for publication of location of trials - can lead to dissemination of the GM material as well as vandalism.
B	1) Information that has to be published should provide appropriate safety to the persons that are conducting the trials for the companies. 2) In one MS in particular, the process is terribly complicated and a huge amount of paperwork. 3) Public consultation is OK, but it should not delay the process. 4) It would be useful to adapt the conditions for product approval depending on product familiarity e.g. where they have already been approved for food, feed, import & processing. For example, having to destroy the crop at the end of a trial costs a lot of money and it makes no sense to have to do this for products that are already being imported for food and feed - flexibility on disposal of authorised events would be sensible here. A framework of 'measures' for disposal could be proposed.
C	We would like the real possibility to perform part B field trials in all MS under the conditions of Directive 2001/18/EC