APPENDIX 7: QUESTIONS TO COMPETENT AUTHORITIES AND APPOINTED INSPECTORS

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: GMO legislation in the MS (1)

Member State	Has Directive 2001/18/EC been implemented in national legislation in the MS? What is the name of the legislation?
France	Yes. Decret No. 2007-357 du Mars 2007 modifiant le decree no. 93-774 du 27 Mars 1993 (see www.ogm.gouv.fr), this was implemented in March 2007. Now integrated in the code of environment.
Germany	Yes. Directive 2001/18/EC was implemented in Germany in 2003 and there were further amendments in 2006. The national guideline for the BVL in the field of genetic engineering is the Genetic Engineering Act. It implements EU guidelines in national legislation and seeks to protect human and animal health and the environment from potential adverse effects of genetic processes and products. The genetic engineering law seeks to ensure that GM, non-GM and organic food and feed can be produced and placed on the market side-by-side. Furthermore, the act builds the legal framework for exploring, developing, using and promoting the scientific, technical and economic benefits of genetic engineering. Several national ordinances are made under the Act. The Environmental Protection Law is also relevant for GMO field trials. The Robert Koch Institute under the oversight of the Ministry of Health was responsible for GMOs until 2003 before BVL took it over. The Ministry of Health wanted to retain responsibility for clinical trials. BVL have implemented requirements for holding clinical trials under GMO Legislation as "Regulation on the implementation of good clinical practices with respect to investigation of medicinal products for human use in Germany, 9th August 2004" this implements Directive 2003/94/EC of 8 October 2003. Another Federal Agency is responsible for enforcing this. BVL is an incorporated CA for clinical trials, i.e. they have some involvement but are not the lead competence. The German Gene Technology Law does cover animals but it does not cover human medicinal clinical trials (the above-mentioned legislation covers clinical trials held under 2001/18/EC). The only thing not covered by the German Gene Technology Law is trials of medicinal products containing GMOs.
Hungary	Yes, fully implemented. Hungary has had legislation covering the regulation of biotechnological activities since March 1998 under the Act on gene technological activities (Act No. XXVII of 1998) (1998. évi XXVII. törvény a géntechnológiai tevékenységről). The Act on gene technological activities is dated 1998, and introduced enabling amendments are dated 2002 and 2006. The Act was amended by Act No LXVII of 2002 taking account of 2001/18/EC and by Act No CVII of 2006 taking account of 2001/18/EC and incorporating coexistence measures. Other related, implementing legislation (Government decrees) cover: the authorization procedure of the gene technological activity as well as on the liaison with the European Commission (132/2004. (IV. 29.); imposing gene technological penalties; the registering and supplying data as well as on the documentation which shall be enclosed in the notification regarding the gene technological activity; activities which shall be considered and not considered as gene technological activity as well as on authorities which are entitled to supervise the gene technological activity; certain rules of the gene technological activity in the field of agriculture and industry; co-existence of genetically modified, conventional and organic crops. A summary of most of this legislation can be found at: http://biodiv.kvvm.hu/cooperation/research/fol935505/magyar_jogszabalyok_angol_osszefoglaloja.doc

The Netherlands	Yes. Dangerous Substances Act 1990 with a subsequent amending decree, Decree on GMOs, which implements the Directive. Introduced 26th of April 2006 (Decree on GMOs).
Spain	Yes. Law 9/2003 on the legal regime of the confined use, deliberate release and placing on the market was introduced on 25 April 2003; Royal Decree 178/2004 for the regulatory development of the Law 9/2003 came into place on 30 January 2004 There is also the ratification Instrument for the Cartagena Protocol (BOE 181, 30.7.2003). Some Autonomous Regions also have their own implementing legislation for 2001/18. Details are at http://www.mma.es/portal/secciones/calidad_contaminacion/omg/legislacion_general/Legislacion_espaniola.htm.
Sweden	Yes. The GMO regulations have been in place since 2002. The Swedish Environmental Code (SFS 1998:808), Chapter 13 is the highest level; it defines deliberate release as "intentional introduction of genetically modified organisms into the environment without such containment measures as are mentioned in section 5" (chapter 13, section 6). The Genetically Modified Organisms (Deliberate Release) Ordinance (SFS 2002:1086) is made under the Environmental code and provides detail about administrative procedures, application requirements and running GMO field trials etc; the Ordinance also covers part C releases (but the coexistence regime is described under "Precautionary Measures for the Cultivation of Genetically Modified Crops (Coexistence) Ordinance (SFS 2007:273)". There is also i) The Swedish Environmental Code (Charges for Consideration of Matters and Supervision) Ordinance (SFS 1998:940) and ii) The Swedish Environmental Code (Supervision) Ordinance (SFS 1998:900), and "The Swedish Board of Agriculture's Regulations (SJVFS 2003:5) on the Deliberate Release of Genetically Modified Plants". There are also other authorities' Regulations e.g. for forest trees and aquatic organisms. All these documents are available at http://www.gmo.nu/gmoenglish/topmenu/legislation.4.52c6f10b903d789380002186.html. The actual legislation is in Swedish.
UK	Yes. Genetically Modified Organisms (Deliberate Release) Regulations 2002. Introduced in 2002.

Table 2: GMO legislation in the MS (2)

Member State	Is there any other national legislation that must be observed when a GMO DR field trial is conducted?
France	No, only the GMO legislation
Germany	Yes – the 'Environmental Protection law': a new paragraph was introduced 2 years ago which relates to the control of GMO field trials and states that, in certain cases, a specific risk assessment must be carried out (para 34a of Federal Law for Protection of Nature). This risk assessment is parallel to the risk assessment for the Gene Technology Law and must be done for trials that may affect certain protected areas, namely areas that are protected according to Directive 92/43 (Directive for protection of wild flora and fauna and natural heritage, which includes European Bird protection areas). GMO field trials that are proposed to be carried out near such areas must be subjected to an additional risk assessment. The CA consulted lawyers and it was decided that the CA rather than the notifier must do this risk assessment. The CA is trying to do the risk assessment, when it is necessary, within the authorisation time for a part B (90 days), but it requires a lot of information about the protected area that the notifier is supposed to provide and it can be difficult for them to get this information. The CA has had to determine the risk assessment procedure itself. The outcome of the risk assessment is whether the field trial represents a risk to the protected area; if there is evidence that there may be a negative effect the field trial cannot be authorised. The CA considers this additional procedure is disproportionate to the risk of the part B trials because the risk assessment according to the Genetic Engineering Act already covers any risks for the environment including protected areas - the following organisations are consulted on part B applications as part of the risk assessment process: the Federal Office for Protection of Nature, the Robert Koch Institute, the Former Federal Research Centre for Agriculture and Forestry (Braunschweig) and the Federal Institute for Risk Assessment; therefore there are already good procedures in place for the risk assessment of part Bs and this additional requirement is considered overly burdensome.
Hungary	Yes, Act Nr. LIII. of 1996 on Nature Conservation (1996. évi LIII. Törvény a természet védelméről). In particular, Article 9 of the Act, which prohibits the genetic modification of wild organisms and the spread or transfer of any resulting modified material to other wildlife communities.
The Netherlands	No
Spain	Yes - legislation on genetically modified plant varieties: - Law 30/2006 on seeds and plant genetic resources (BOE 178, 26.7.2006). - Royal Decree 1261/2005 on Plant Variety Protection (BOE 265, 5.11.2005) - Ministerial Ordinances on Plant Variety Registration (several)
Sweden	Not specifically, but all GMO releases must observe existing plant health and seeds legislation, and pesticides legislation.
UK	The Environmental Protection Act 1990

Table 3: Information and application procedures (1)

Member State	Do you have procedures in place for applicants seeking consent to conduct a GMO DR trial? How is this made available to applicants?
France	Yes. This information ("La procedure de demande d'autorisation d'experimentation de plantes superieures genetiquement") is available on request to the Ministry of Agriculture and is not available on the website.
Germany	Yes. The notification procedure includes the scientific evaluation of molecular, health, and ecological data by experts in these fields, involvement of the public over several weeks and consultation with further federal and state agencies like the Federal Agency for Nature Conservation, the Robert-Koch-Institute and the Federal Institute for Risk Assessment. In all notification procedures, the BVL asks for an opinion of the Central Commission for Biological Safety (CCBS). The BVL maintains the public registers including the GMO location register as well as the GMO notification register, which serves as an information platform on GMOs for the public. Application procedures are laid down by the legislation - there is a short description on the BVL website, not too much detail. Potential applicants are recommended to contact the CA to discuss their application before they go ahead. The CA will answer questions by telephone or email, or will have a meeting with the applicant to advise on their proposals. The CA will give advice on draft applications as to whether it is not likely to be approved, i.e. if sufficient information is provided etc. This is outside the 'formal' application procedure, but ensures that not too much time is wasted in assessing applications that do not meet key criteria. Unusual GMOs often go through this 'prior assessment' process. An applicant can apply for a programme of trials to be held in many locations under simplified procedures - the applicant must specify the location for the first year of the trials, and if the risk assessment is acceptable for releasing the GMO at this first location, additional locations can be notified later and it is much simpler than the original process, but it relies on the RA of the GMO at the first location being valid for the additional locations too. Subsequent sites can be notified at a later date, and in this case only site-specific information must be given by the notifier and not all the other information that was required in the initial application. The system works well and reduces the administrative burden. (Under the simplified procedures the Länder have 2 weeks to comment on the notification; the Länder have to inform all other interested parties - local nature conservation bodies, municipal and county administration, plant protection administration, chamber of agriculture etc, and 2 weeks is very difficult for them). To use the simplified procedures, the notifier must notify the intention to use the procedure at the outset, they cannot adopt it half way through the trial. As it is based on the original risk assessment for a programme it is suitable for ongoing development trials, for example variety development. The simplified procedure tends to be used more by the large companies. The simplified procedure (Decision 94/730/EC of 12/11/1994) was never transposed into German law so there have been problems with using it - at the start the government thought it was not necessary to implement the decision, then they decided that it was necessary so the CA was not able to use it; it is still not implemented fully (it should have been implemented into national legislation by 2006), however, as the process has started the CA and notifiers can use the simplified procedures again. Costs for applications are based on the amount of time involved in the assessment and are made up of the fees for official time involved plus costs (of adverts e.g. in newspapers, official journal etc). These are passed on to the notifier, and usually end up being €5000 - €8000 per site (the adverts can be very expensive). Public research institutes and universities do not have to pay; SMEs do have to pay, and for them the costs and political uncertainties have led to them dropping out, e.g. KWS dropped out, but have started back with trials recently (sugar beet trial for 2008 at four locations). This information is available on the BVL website (small amount of information plus contact details):

	http://www.bvl.bund.de/cln_027/nn_491826/DE/06__Gentechnik/gentechnik__node.html__nnn=true
Hungary	Yes. Applicants have to submit detailed documentation which complies with current national legislation which is in harmonization with Directive 2001/18/EC on deliberate release of genetically modified organisms into the environment. All elements of the regulatory system regarding GMOs are published in the Official Gazette as well on the Internet (http://biodiv.kvvm.hu). If applicants have further questions, the CA (Ministry of Agriculture and Rural Development) and the Ministry of Environment and Water can answer them by telephone or through arranged meetings. Furthermore, applicants can participate in the meeting of the Advisory Committee for Gene Technological Applications which evaluates their application. Depending on the outcome of the meeting, applicants have to provide further information, if necessary. When an application is received, the CA checks its completeness (including its format and content) within 8 days. If it is satisfactory, it forwards the notification to the Advisory Committee for Gene Technological Applications, which gives a scientific opinion within 30 days.
The Netherlands	Yes, guidance is available. An application form and covering guidance is available on the VROM website, at http://www.vrom.nl/ggo-vergunningverlening. Under Dutch national law there are two 6 week public consultation periods during the approval process for granting a Part B consent. Permit decisions are routinely challenged in court which can delay a decision. The consequence of these legal procedures is the Dutch Competent Authority cannot guarantee its obligation under 2001/18 (Article 6 (6b)) to issue a decision within 120 days from receipt of a notification. Although, they strive to stay within these 120 days.
Spain	Yes. There is a procedure published on the Ministry of the Environment website. Documents are available at the following website: http://www.mma.es/portal/secciones/calidad_contaminacion/omg/notificaciones_autorizaciones/index.htm
Sweden	Yes. An outline is provided on how to put in an application, requirements for field trials, how long the process will take etc. (Guidance on contained use of GMOs is also provided.) Links to information that is provided to the public about field trials is given, also generic information about GM plants. The information is at www.sjv.se/genteknik (all in Swedish) and at the website shared between several authorities, www.gmo.nu.
UK	Yes. Application procedures are available at http://www.defra.gov.uk/environment/gm/regulation/index.htm There is usually an informal initial meeting held between the notifier and the CA before the application is submitted. At this time the CA can offer guidance about the level of information required for an application. It is not compulsory but is useful. There is also a website with guidance which is currently being updated.

Table 4: Information and application procedures (2)

Member State	Is guidance on the information applicants are required to provide available?	Is guidance provided on the general principles that need to be considered for management of GMO DR trials?
France	Yes, guidance is available. The document "La procedure de demande d'autorisation d'experimentation de plantes superieures genetiquement modifies" provides details of the application process, including consultation with the public and the Mayor of the principality, also information that must be provided in the application dossier itself. The current document is dated November 2005 and has not been updated since implementation of the new law in March 2007. The Ministry of Agriculture is waiting for the new law to be put in place following forthcoming municipal elections (March 2008). It is not available on the web but it is available on request from the Ministry of Agriculture	Yes. The document is produced by the Commission du Genie Biomoleculaire "Recommandations pour la redaction du dossier scientifique et technique de demande d'autorisation d'experimentation de plantes superieures genetiquement modifiees". It provides guidelines on the general issues that should be taken into account when planning a field trial, and in annexes provides indicative guidelines for management of trials of sugar beet, oilseed rape and maize, based on biological characteristics of these crops. There is a section on measures to prevent gene flow for each of these crops, including isolation distances and monitoring plans. This is not available on the web but is available on request from the Ministry of agriculture.
Germany	Yes. A guidance document is available, however it is out of date and is currently being updated but is not yet ready.	No. The new guidance document will provide this information - as a recommendation. Each application is decided case-by-case so this is only 'guidance' for certain types of crops.
Hungary	Yes. Information on the legal framework including which kind of information is required in the notification (including formats for the notification as well as the principles of the ERA according to Directive 2001/18/EC) is available on the Internet. If applicants have further questions, they are answered on the phone or during arranged meetings. Relevant websites are: www.biosafety.hu and http://biodiv.kvvm.hu.	Yes. There is a general guideline on how to manage GMO DR trials which is available on Internet at: http://biodiv.kvvm.hu/cooperation/funding/doc684655 The consent also contains requirements the consent holder has to comply with, including isolation distances, handling of waste, etc. If applicants have further questions, they are answered on the phone or during arranged meetings.

The Netherlands	Yes. The guidance is provided to applicants at http://www.vrom.nl/ggo-vergunningverlening. Additional documents are provided covering for example trial location, confidentiality and category (area and number of locations) of GM field trials. In the application form guidance is given on numerous questions.	Yes. In the Netherlands, GM field trials are classified into three levels according to a GMO's properties and stage of breeding/market development. Mitigation measures are set in proportion to the level of perceived risk that their release could result in adverse effects on human health and the environment. Case-specific mitigation measures are also included in the permit conditions. The categories in short are as follows: Category 1. Small scale field trials with mitigation measures.which ensure that the possible adverse effects of the GMOs do not spread beyond the field plot (Maximum of 5 locations, no larger than 1 ha each). Category 2. Field trials. Mitigation measures are only prescribed if they follow out of the risk assessment and are necessary to decrease the risk to a minimum. (No limit on the number of locations but they cannot annually exceed 10 ha each). Dissemination need not be avoided. Category 3. Large-scale non-commercial trials. No restrictions on either the number of locations and size. Generally, no mitigation measurements are prescribed to prevent dissemination. Progression to higher categories depends on the extent of characterisation of the GMO, a more thorough knowledge of transgenic gene expression and the interaction with the receiving environment (including impacts on non-target organisms), and the conclusions of an up to date risk assessment. For further information see "Indeling veldwerkzaamheden met genetisch gemodificeerde planten" (http://www.vrom.nl/ggo-vergunningverlening). COGEM's draft advice is provided at the end of this appendix (pages 69 – 74). (This COGEM advice is currently under revision and will soon be replaced by the revised version).
Spain	No. Guidance is being developed	Yes. It is done case by case in the ERA report. http://www.mma.es/portal/secciones/calidad_contaminacion/omg/notificaciones_autorizaciones/liberac_voluntaria.htm
Sweden	Yes. Explanatory notes have been added to the application form. It is available on website at www.sjv.se/genteknik.	No. Guidance is not provided to applicants on general risk management principles - it is left to the applicant to propose.

UK	YES. http://www.defra.gov.uk/environment/gm/regulation/guide.htm The guidance is currently being updated.	Yes. The Advisory Committee on Releases to the Environment (ACRE) will advise on conditions for the consent, which are attached to the consent when issued. The GM Inspectorate will also advise on principles that need to be considered for management of GMO DR trials to ensure that an applicant is complying with consents.

Table 5: Assessment of applications to release a part B GMO deliberate release field trial (1)

Member State	Do you have any specific criteria for acceptance or rejection of applications to hold a part B trial?	Are there any crops, traits or crop/trait combinations that you would not authorise for a part B trial?
France	No – there are no specific criteria, all applications are considered on a case-by-case basis. If any information is missing it is returned to the applicant.	No. Each application is considered on a case-by-case basis
Germany	Yes. The notifier must prove that he/she is entitled to carry out the trial at the site specified - i.e. that the consent could go ahead if approved. If the notifier is not the owner of the site evidence must be provided that the owner agrees the trial can take place on his/her land (e.g. a letter must be provided by the owner). The applicant must specify exactly where the trial must be, even under the simplified procedures.	No. The CA would only refuse an application if the crop-gene combination was assessed to present some risks to the environment and it was not possible to identify adequate management measures to manage the risks. Generally, applications that fall in this category would not get as far as actually lodging an application because of prior discussions with the CA.
Hungary	No. The criteria applied are incorporated in national legislation on DR field trials according to Directive 2001/18/EC. Applications are accepted if the documentation is appropriate (according to the Directive). We also evaluate the plan as well as the methodology of the release/research.	Yes. Authorization decisions are made on a case-by-case basis where potential risks of the release and the management of those risks are taken into account, so there are no examples of crops, traits or crop/trait combinations that would not be authorised for a part B trial. It depends on the quality of information contained in the notification (e.g. thoroughness of the ERA), on the planned release site (for example if there is a GM maize producing pharmaceuticals, a larger isolation distance will be required. If the planned release site is not suitable, the release is rejected)), etc. Where wild species are genetically modified and thereby contravene Article 9 of the Act of Nature Conservation (1999) the application would also be rejected.
The Netherlands	No. Provided applications are complete, they are assessed on a case-by-case basis according to the potential risk they pose for harming either human or animal health or the environment, irrespective of the species, traits or crop/trait combination being considered.	No. We would not reject any crops, traits or combinations out of hand before an application was considered. To be authorised they would have to satisfy the criteria for a case-by-case evaluation set out in 2001/18. However in some cases (for instance with genetically modified forage grass), it would be very difficult, if not impossible to get an authorisation.

Spain	Yes: - Completeness check - Application form written in Spanish - Step-by-step criteria (information supporting the application increases with the stage of development of the GMO) - Appropriate isolation distances (physical, biological, temporal) - Presence of non GM border rows - Absence of local varieties in the proposed region of the release (in some cases) - No field trials in protected areas	Yes. Sugar beet in the South of Spain would not be allowed because of the presence of wild relatives (*Beta maritime*)
Sweden	No – there are no specific assessment procedures. The GMO must be safe from an environmental, health and safety perspective but apart from this all applications are assessed on a case-by-case basis.	No. All applications are assessed on a case-by-case basis.
UK	No. Acceptance or rejection of a trial is done on a case-by-case basis. Sometimes following the informal meeting the notifier decides not to go ahead with the application (e.g. doesn't have all the info needed and would not be able to gather the info needed etc).	No. There aren't any specific combinations that would result in an immediate refusal. Refusal will only occur after examination on a case-by-case basis and following advice from ACRE, the scientific advisory committee.

Table 6: Assessment of applications to release a part B GMO deliberate release field trial (2) – Scientific advisory committees

Member State	What is the name of the scientific advisory committee established for assessment of part B applications?	What is its composition and formal role?	Who else is consulted when an application is received?
France	The Commission de Genie Biomoleculaire (CGB) was in place until recently, however following the Grenelle review there is currently no Committee appointed to assess part B applications. The Ministry of Agriculture is currently awaiting the new law. Part B applications cannot be assessed until the new law is implemented. A new Committee can then be appointed; it is likely to be summer 2008 before any part Bs can be assessed.	The CGB comprised 12 government scientists plus 8 other persons who were representatives of: industries using GMOs, workers of these industries, farm production, consumers association, environment protection association, a member of parliament, a lawyer. Officials from the Ministry of Agriculture and the Ministry of Environment are in charge of the Secretariat but are not members of the Committee.	• No-one else is consulted - the CGB make the assessments

Germany	The Central Commission for Biological Safety (CCBS)	Non-government scientists, officials and lay persons. Scientists cover the disciplines of genetics, plant breeding, bacteriology, virology, environmental protection organisations, ecology committee, a representative of union (scientist), consumer protection. All discussions focus on safety. None of the authorities assessing applications are represented on the Committee. The CA prepares the papers and presents them to the Committee. The Secretariat for the Committee sits within the CA department. The Committee has existed for nearly 30 years (since 1978). The science focus is a very important driver for the applicants (rather than the desire to be on a Committee). The Committee gives advice on the applications and the CA actually makes the decision; there are very rarely occasions where the opinion of the CA and Committee differ very strongly. The Committee covers CU and DR, also part Cs under 2001/18. The CCBS meetings are closed meetings. Official representatives of the Länder are allowed to attend the meetings as guests, but do not participate. The CCBS issues advice on general opinions on GMOs - these are published on the BVL website and mostly concern CU of GMOs, very few relate to plants. The Committee's opinions on part Bs are not published. The public can have access to them if they apply for it under the Environmental Information Act.	These bodies are also consulted: • The Federal Institute for Risk Assessment • The Federal Agency for Nature Protection (formerly Environmental Protection Agency) • The Robert Koch Institute (main focus is human health) • Federal Research Centre for Cultivated Plants - Julius Kuehn Institute (main focus is plant health and agriculture) • NGOs are not consulted directly • The Länder in which the trial would take place must be consulted when the application is received. BVL contacts the local Ministry, and the Ministry contacts authorities within the Länder - how many other authorities are consulted depends on the Länder, it can sometimes be a lot. The Ministries also consult the GM Inspectors at this stage. The opinion of the Länders is not legally binding for the CA. These centralised procedures ensure harmonization of the conditions attached to field trials at different locations in different regions.
Hungary	The Advisory Committee for Gene Technological Applications	6 government scientists; 5 non-government scientists; 0 officials; 1 lay person. There are also 6 other representatives from non-governmental organisations dealing with environmental, health and consumer protection issues. The Advisory Committee may suggest further studies regarding the environmental or health risks of the particular GMO or special conditions for the release. The Advisory Committee is also entitled to ask for opinion of an independent expert (not member of the Advisory Committee) if it considers it necessary.	These bodies are also consulted: • Ministry of Environment and Water • Health and Safety Executive • Government scientists

The Netherlands	The Netherlands Commission on Genetic Modification (COGEM)	18 non-government scientists; 7 officials (the Secretariat comprises of 7 scientific staff). No lay persons.	These bodies are also consulted: • Conservation Agency/ies • Environment Agency/ies • Health and Safety Executive • Government scientist/s • COGEM • The GMO field inspectors are sent drafts of the consent as they progress through the approval process
Spain	National Commission on Biosafety (CNB)	7 government scientists; 49 officials (Central and Regional Government, attendance varies according to the notification); 1 lay person	These bodies are also consulted: • Conservation Agency/ies • Environment Agency/ies • GMO field inspectors • Health and Safety Executive • Government scientist/s • Other Regulatory Committee/s: • Spanish Agency for Food Safety and Nutrition (AESAN) • Spanish Agency for Medicines and Medical Devices (AGEMED) • Ministry of Agriculture: feed, plant varieties, and livestock.

Sweden	The Swedish Gene Technology Advisory Board (SGTAB) (established on 1 July 1994).	In total 28 persons (14 regular and 14 personal substitutes) are shown as being members of the SGTAB: 2 persons from each of the 7 political parties in the Swedish parliament and 7 (plus 7 substitutes) other members (scientists) who are university professors covering relevant topics such as botany, biochemistry, molecular biology, population biology, zoology, virology, ethics. There is also the Chair and co-Chair who are selected by Government, plus a Secretary and secretariat (2). The Board's functions are described in the Swedish Environmental code. It monitors national and international developments in genetic engineering, reviews ethical issues arising in this field, and gives advice aiming to promote ethically justifiable and safe use of genetic engineering, in order to protect human health and the environment. Under the Ordinance on Deliberate Release into the Environment of GMOs, the various sectoral authorities must consult the SGTAB when drawing up regulations and considering permit applications relating to the deliberate release in Sweden of new GMOs or of previously used GMOs under substantially new conditions. The CA assesses the part B applications, the SGTAB is consulted if an application is received for a trial with a crop &/or trait not previously placed in part B GMO trials in Sweden, or if there are circumstances not previously encountered. The meetings of the Board are closed - even the CA does not attend.	These bodies are also consulted: • Two environmental NGOs (Swedish Nature Conservation Organisation and Greenpeace) • Two farmer NGOs (organisations for organic farmers and conventional farmers), and sometimes others depending on the case. • The Swedish Food Safety Authority is consulted, which addresses health and safety issues. • The Ordinance on Deliberate Release into the Environment of Genetically Modified Organisms states that the Swedish Environmental Protection Agency (SEPA) must be consulted when a sectoral authority adopts regulations or takes decisions on new, untried releases. The Agency is also to be informed of decisions on consents under Directive 2001/18/EC. • SEPA also provides advice on how to design regulations of activities concerning GMOs, and is the focal point for the Swedish Biosafety Clearing House mechanism placed under the Cartagena Protocol. The SEPA provides nature conservation and environment protection roles. • The CA would seek advice from plant health experts if the trait was pest/disease resistance and would consult the chemicals inspectorate if the trait were herbicide tolerance. • Others may be consulted, depending on the case. After the consultation there is a structured procedure for assessment of the dossier and comments received, and issuing of the consent.

UK	Advisory Committee for Releases to the Environment (ACRE)	12 non-government scientists plus 2 farming experts.	These bodies are also consulted: Conservation agency/ies Health and Safety Executive Government scientists Food Standards Agency and if applicable the Devolved Administrations. The GM Inspectorate is not formally consulted

Table 7: Assessing application dossiers

Member State	Information on personnel and training	Information about the genetic modification and the GMO	The environmental risk assessment	Risk management measures & rationale	Proposals for monitoring during and post-trial	Management of wastes from the trial	Emergency response plan
France	4	7	7	7	7	7	4
Germany	5[1]	7	7	5. The CA makes its own opinion on these and it is laid down in the consent; the CCBS also gives advice on this.	5[2]	5[2]	3
Hungary	6	7	7	7	7	7	6
The Netherlands[2]	5	7	7	6	6	4	4
Spain	6	7	7	5	7	7	5
Sweden	4	7	4. Because the CA considers its own ERA to be of higher importance	7	5 (Depends on the crop/trait)	5	4
UK	4	7	7	7	7	7	5

[1]The CA asks for details about the primary responsible officer for the trial, and the legislation lays out certain requirements for qualifications that must be met (specified in Gene Technology Law), also the Biological Safety Officer, who must meet certain qualification requirements. All other training for personnel is the responsibility of the notifier, but the CA does not ask for details of this.
[2]In reality all these points are important and necessary in an application dossier. The ranking of each component will also change according to the phase of the release.

Table 8: The consent / permit / authorisation

Member State	Is there a standard format for the consent document?	Is the consent document published, and if so where
France	Yes, there is a standard format for the consent.	Yes. All consents are published on http://www.ogm.gouv.fr/experimentations/dossiers/2007.htm. Authorisations are often contested in court by the NGOs; Ministry lawyers have to defend the authorisations, and this can go to Tribunal. The Notifiers recognise this is beyond the control of the CA.
Germany	Yes. The consent covers the GMO itself and the basis for the decision, the GMO, the trial site and the conditions that must be met. Anything that the applicant has stated in the application is binding so this is not repeated in the consent. The application is an integral part of the consent. The risk assessment and rationale is discussed. All objections from the public must be included and discussed, and reasons provided as to why they have not been observed. Sometimes the NGOs commission scientists to prepare science-based objections, or lawyers to prepare legally based objections, but usually they have been insufficient to prevent the trial going ahead.	The consent is advertised on the BVL website and in newspapers in the region where the trial is going to take place. In the advertisements, the summary of the consent is published detailing the crop and location, but not the conditions. Public access is provided for 2 weeks after the consent is issued. After 2 weeks it is removed, but would be available on request from the CA (a few Euros are charged). Anyone who has objected receives a copy of the consent when it is issued. If only very few objections are received (e.g. less than 150 objections) the CA is allowed to send the consent to the objectors directly to save on advertising costs. Most objections are against company applications, less so for university releases. Objections are often the same form signed by lots of different people - the CA can receive several hundreds up to thousands (>10,000), which puts a lot of political pressure on the CA and government. The number of objections is not the point, it is the reasoning behind why the objections stand or not that is important, and it is for the CA to do this in the consent.
Hungary	Yes, there is a standard format for the consent.	A summary of the consent document is published in the Official Journal as well as on the webpage (www.biosafety.hu) of the CA. The publication includes the name of the consent holder, the registration number of the consent, the goal and location of the trial and the genetically modified trait. The Competent Authority will also release the whole consent document in hard copy if a client requests it.
The Netherlands	Yes, there is a standard format for the consent.	Consents are published at http://www.vrom.nl/ggo-vergunningverlening (Vergunningendatabase - De database Zelf – Zoekresultaten)
Spain	Yes there is a standard format for the consent	Yes the consent is published (Central Government only) at http://www.mma.es/portal/secciones/calidad_contaminacion/omg/notificaciones_autorizaciones/index.htm

Sweden	Yes. The document is in more or less standard format. It is called a Decision Document, each document is structured in same way but there are changes between each Decision. All conditions are contained in the document, including the written risk assessment.	All Decision documents are placed on the CA website & can be downloaded from: http://www.sjv.se/amnesomraden/vaxtmiljovatten/genmodifieradevaxter/faltforsok/genomfordaforsok.4.1f85a8610dbb8e0d718000723.html The SNIF goes out for public consultation on the website of the Swedish Board of Agriculture. The CA very rarely receives a response (perhaps every other year). Interested parties can sign up to be informed each time a new SNIF is issued - a letter is sent to these persons informing them, but the CA does not tend to receive many responses. Objections are followed up if they are based on scientific grounds, and science-based risks that are raised would be reviewed.
UK	Yes there is a standard format.	All consents are published on the CA website and also in the statutory register (e.g. http://www.defra.gov.uk/environment/gm/regulation/pdf/07-r42-01.pdf)

Table 9: Information provided to the public

Member State	What information must be published about GM field trials that have been authorised, particularly with regard to location	Where is this information published			Are the public given opportunity to comment on applications	Are all application dossiers published for public review
		Newspaper	Website	Other		
France	The town must be given; the grid reference is not required. Although grid reference is not published, activists are very 'active' in finding the location of the trials. The lack of a grid reference delays activists finding trials, but they still find it.	No	No	Yes. In the town in which the trial will take place, it must be advertised in the town hall. It is also put in the official journal.	Yes. The public are given three weeks to comment on applications after the scientific committee has given its opinion that a trial may proceed. Most comments are from GMO protesters and are not based on scientific evidence. It has not been necessary to refer any trials back to the scientific committee based on any comments received. Comments are not published.	All applications are published

Germany	The whole application is published including location, the crop and the trait, but not commercial business information and personal data. The BVL must publish down to the smallest official category of land classification (the parcel of land) - the trial normally occupies only a small part of this. The notifier may not know exactly where on this parcel the trial will be over a 4-5 year programme & does not need to specify exactly where within this area the trial will be. The company must inform the inspection authority each year exactly where the trial will be to allow inspections. This information is not made available to anyone else.	Yes	Yes	Information is published in the communities in which the trial will take place.	Yes. The application is publicly available for 4 weeks when the application is complete and the CA will accept comments for a 4 further weeks after that.	Yes. There are no exceptions - all application dossiers are published.

Hungary	The Registrar keeps the following data on the GM field trial: a) registration number and date of the consent; b) description of the GMO, GMMO, plant or animal species, or variety); c) name and address of the applicant (company); d) description of the modified characteristic and relevant OECD code; e) the purpose and place of gene technological activity. Information indicated as being CBI is not published. All data is held on record for 10 years after the expiry of the term of the licence. Current practice is to publish site locations.	Yes. Draft consent - Official Journal of the CA	Yes. www.biosafety.hu, http://gmoinfo.jrc.it	Yes. The Registrar shall provide printed data from if it is asked for.	Yes – the public are given 15 days for sending comments to the CA. The CA sends the comments to the Advisory Committee within 10 days, which releases its opinion. The CA considers the opinion of the Committee and finalises, amends or rejects the application.	Whole dossiers are not published for public review (they always include confidential business information). A summary of the notification is published on the EC website for SNIFs in English. A draft of the consent is published in the Official Journal of the CA for public consultation in Hungarian
The Netherlands	The application, permit, risk assessment, advertisements are published. The exact location of GM research trials is not provided - instead a plot 100 times the exact size is made public.	Yes	Yes	Yes. Library of the Ministry of the Environment (Public Register)	The public can comment during two, six-week consultation periods. The first period is for the first draft of a permit and in the second period they can go to court if they don't agree with the way the competent authority handled their comments in the final, revised draft of a permit.	Yes, all application dossiers are published at http://www.vrom.nl/ggo-vergunningverlening

Spain	Summarised tables and SNIFs are published in the Web. Regarding to location only information of province (municipalities) where field trials are carried out is published. We do not provide the exact location of the site to prevent them from being destroyed, unless a specific public request for this information is made to the offices of the relevant Competent Authorities.	No	Yes[1]	No	Yes	Only SNIFs are published[2]

Sweden	The CA must make available the Decision, any new information that comes to light about the crop/trait, and the reports from the trial. The CA must have public register of sites available, and declare the detection of any unauthorised release. Maps showing the detailed location are mailed on request. The consent holder is required to publish locally that a trial will be held and inform the head of the administrative region. Decisions reached on applications considered by an authority are always to be made public. For notifications, the following information cannot be confidential: general description of the GMO, name and address of the person or organisation undertaking the activity; the purpose of the activity; the location; the risk category to which the activity is assigned; protective measures; plans for monitoring and for emergency response, and risk assessments. With regard to investigations, the granting of consents and supervision (inspection) relating to GMOs, confidentiality does not apply if the public interest carries such weight that the information concerned should be disclosed.	Yes	Yes[3]	No	Yes	Yes. A summary of the dossier (the SNIF) is published, but people can request to see the whole document if they want (minus the confidential aspects). It is very rare to receive a request to see whole dossier. Several NGOs are consulted during the consultation period & they see whole dossier, which may explain why the CA does not receive many requests for this.

UK	The information that must be published is laid down in the GM Deliberate Release Regulations in paragraph 34. Specifically applicants must advertise in a national newspaper with a 4 figure grid reference	Yes	Yes	Yes – the public register	Yes. The public can comment on applications through the website and they can also send letters	Yes. There are specific time limits. People may comment once the application is placed on the public register up to a date which is at least 60 days from the receipt of the application. The consent cannot be issued until at least 60 days after publication on website. All the dossiers are published but names, addresses and confidential information are not published.

[1] http://www.mma.es/portal/secciones/calidad_contaminacion/omg/notificaciones_autorizaciones/index.htm
[2] http://www.mma.es/portal/secciones/calidad_contaminacion/omg/notificaciones_autorizaciones/liberac_procedimiento.htm
[3] http://www.sjv.se/amnesomraden/vaxtmiljovatten/genmodifieradevaxter/faltforsok/genomfordaforsok.4.1f85a8610dbb8e0d718000723.html

Table 10: Management of part B GMO field trials

Member State	Has standard or best practice been developed for management of certain crops or traits or crop/trait combinations, or are management procedures applied on a case-by-case basis?	What are management measures based upon?				
		Crop biology	Previous experience	Published research	Other official guidance	Other
France	Yes. Indicative guidance has been produced ("Recommandations pour la redaction du dossier scientifique et technique de demande d'autorisation d'experimentation de plantes superieures genetiquement modifiees" dated December 2005 based on report by the Committee (January 2002) "Rapport de la Commission du Genie Biomoleculaire et du Comite Provisoire de Biovigilance sur l'experimentation au champ des plantes transgeniques", published jointly by the Ministry of Agriculture and the Ministry of Environment. Management procedures are applied generally along these lines, but as applications are assessed on a case-by-case basis, these may be modified.	Yes	Yes	Yes	No	Inspectors may make decisions about risk management, based on long term experience of GMO field trials
Germany	There is not any standard practice officially because each is decided on a case-by-case basis, but isolation and post-trial management procedures are crop-specific rather than trait-specific. In practice, although each application is considered on a case-by-case basis, management procedures tend to be comparable on a crop-by-crop basis. The CA does not require a fence around trials - a sign saying that it is a trial and that the plants are not authorized as food or feed is required. Humans can take fences down, so if there is a GMO that the CA believes to be dangerous and should not be eaten by humans they would not authorise the trial. The CA does not know if companies/consent holders actually put fences up - if they did it would be their own choice (e.g. to protect their property).	Yes	Yes	Yes	No	Monitoring reports from notifiers could be used to change management practices but this has not happened in practice
Hungary	Management procedures are applied on a case-by-case basis. Under Hungarian law the CA is entitled to define special requirements for the release, including the exact location and size of the release, the isolation distance, the size of the buffer zone and pollen control, restriction in the further use of the area, special waste management, post release monitoring of the field, if necessary. However, there are no crop-specific requirements, protocols or guidelines in Hungary in this regard. These requirements are incorporated in the consent.	Yes	Yes	Yes	No	No

The Netherlands	Yes. Taking account of the appropriate containment measures, GM crops are managed according to good agricultural practice in the same way as their non-GM equivalents.	Yes	No (No need to introduce new measures as a result of conducting Part B releases)	Yes	Yes (NAK isolation distances for agricultural seed and seed potatoes)	Yes. (Advice from COGEM)
Spain	Standard/best practice has been developed by the Plant Varieties Office (Oficina Española de Variedades Vegetales, OEVV), but management practices are still applied on a case-by-case basis.	Yes	Yes	Yes		
Sweden	No. Basic guidelines for crops are in place, but all applications are assessed on a case-by-case basis. The applicant proposes the management measures and the CA will only change the measures if they consider them to be inadequate, in which case they will decide on additional measures. No guidance is provided on management of wastes from trials. The measures given in the following tables have been approved for field trials. Other measures may be applied in the future on a case-by-case basis.	Yes	Yes	Yes	No	No
UK	No – management measures are decided on a case-by-case basis.	Yes	Yes	Yes	No	No

Table 11: Consent holder's duty of care with respect to adventitious GM presence

Member State	Does the consent holder have to demonstrate that adventitious GMOs are not present in planting material	If YES, what evidence is required					
		Production assurance documents from the consent holder	*GM testing results from the consent holder*	*Quality assurance documents from the consent holder*	*Provision of sample for official testing*	*CA takes official sample for testing*	*Other*
France	No. There is no formal requirement as such. Documents are required to declare that the GMO is the authorised GMO. There is a 'gentleman's agreement' in place under which the companies do not release anything other than the GMO that is authorised under the consent. It is not in the notifier's interests to do this deliberately and risk their reputation. There are already plenty of requirements on the notifiers to follow specified procedures at sites, therefore already many obligations on them.	-	-	-	-	Yes - Sampling may be done, depending on resources available, but it is not done systematically. Technically this does not present any problems, but it presents resource problems due to the expense - resources are allocated to where risks are higher (e.g. sampling for pesticide residues, toxins)	-
Germany	There is no requirement from the CA, but the inspection authorities are entitled to take samples and check this. The Länders have their own GM testing laboratories.	**Bavaria**: NO	**Bavaria**: YES	**Bavaria**: YES	**Bavaria**: YES[1]	**Bavaria**: NO	**Bavaria**: NO
Hungary	Yes	Yes	Yes	No	No	No	No
The Netherlands	No	No	No	No	No	No	No

Spain[2]	Yes, but for Plant Variety Registration Trials (OEVV) only, except in specific cases, e.g. where there has been a known seed contamination problem	Yes	Yes	Yes	Yes	No	No
Sweden	No.	No	No	No	No	Yes. In one location some sampling was done because the applicant asked for permit to release 9 events, but only 7 of these were finally authorised. Samples were taken and tested to make sure only the 7 authorised GMOs had been released. The consent holder was asked to provide a PCR test for the events and an external lab was commissioned to do the testing.	
UK	Yes	Yes	Yes	Yes	No	No	

[1]The Bavarian Agency for health and food safety (LGL) is the Competent body for this and takes official samples from the field trials. LGL decides how they want to sample/test and will approach the consent holder directly to obtain PCR primers etc. They generally take samples when the crop is growing, or they may sample seeds. The LGL informs the inspectors of the results.

[2]Spain. Maize Bt10 incident - as soon as Syngenta received the news of unintentional release of Bt10 maize in the United States, the company proceeded to implement the traceability of all Bt11 seedlots that had been imported since 2001 and determined that only in the years 2003 and 2004 had imported material contained the event Bt10 (Bt10 field trials B/ES/03/04 B/ES/04/09). This material corresponded to seeds of some pure lines and of a hybrid of maize destined for use in field trials only, authorized under Part B Permits.

The crop and vegetable waste of these trials were destroyed and buried on each experimental release site as specified in approved protocols before the incidents were communicated to the CA. In 2003, two samples were taken and sent to France by personnel of Syngenta. These samples were stored in authorised, contained-use storage facilities in France and were subsequently destroyed in January of 2005.

When authorization for the development of an experimental trial with Bt11 maize was requested in the year 2005, Syngenta was required by the Spanish Ministry of Environment to endorse a Bt10 maize absence certificate issued by a certified laboratory using the method of identification validated by the European Commission's Community Reference Laboratory (Joint Research Centre).

MANAGEMENT OF AUTHORISED PART B GMO FIELD TRIALS

Table 12a: Practical aspects of managing a field trial (MAIZE)

Member State	Are specific requirements described for any of the following activities associated with a GMO field trial					
	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**
France	No	No	No	No	Requirements are based on the guidance provided by the CGB. Recommend 1 year for volunteers but can change on case-by-case basis	Requirements are based on the guidance provided by the CGB. 1 year no maize but can change on case-by-case basis
Germany	No	None, except machinery must be cleaned afterwards and no GMOs must remain	Same as sowing	Must take place at the trial site	1 year with no volunteers, if any GM volunteers are found they must be removed and destroyed before flowering to prevent further volunteers. If this is done, PTM can then cease.	Anything can be grown that does not interfere with PTM for volunteers. Would allow GM maize on the same site for consecutive years, and PTM would commence when the final trial is harvested. It is normal to then go into normal crop rotation
Hungary	Yes. 500m isolation from a commercial maize crop is required.	Yes	Yes	Yes	Removal and destruction of sexually compatible or related crop found in the isolation zone	Limitation of further use of the field, special requirements for crop rotation for 1 year
The Netherlands	No. The management of field trials depends upon a GMO's classification (categories 1 to 3) and, on a case-by-case basis, any additional requirements that are set in the consent. Crop management requirements vary according to the trial category. Post trial monitoring is required.					

Spain	200 m isolation distance, use of border rows, One month temporal flowering isolation	No	Burial of seed and crop waste	Compulsory	1 year	Not the same crop. Specific conditions are set out in each risk evaluation report.
Sweden	None	Cleaning the machinery, and make sure seeds for sowing are destroyed/returned to originator. Consent holders state in end of year reports that they have done this.	'With care'. Maize must be chopped before it is ripe and left in the field with the cobs. It is then ploughed back into the land.	Yes.	Notifiers have proposed to monitor for 1 year post harvest and the CA has agreed	No maize for 1 year
UK	There is nothing laid down in specific guidance. General principles apply but this would be considered on a case-by-case basis for each application. The specifics are covered in the consent conditions.					

Table 12b: Practical aspects of managing a field trial (POTATO)

Member State	Are specific requirements described for any of the following activities associated with a GMO field trial					
	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**
France	No	No	No	No	Requirements are based on the guidance provided by the CGB. 3 years PTM is required.	Requirements are based on the guidance provided by the CGB.
Germany	No	None, except machinery must be cleaned afterwards and no GMOs must remain	Same as sowing	Must take place at the trial site	Minimum 1 yr PTM, if no GM volunteers are found monitoring can stop. If any GM volunteers are found PTM is extended. Must have 1 year with no GM volunteers before PTM can stop	Anything can be grown that does not interfere with post-trial monitoring for volunteers
Hungary	Yes	Yes	Yes	Yes	Yes	Yes
The Netherlands	No. The management of field trials depends upon a GMO's classification (categories 1 to 3) and, on a case-by-case basis, any additional requirements that are set in the consent. Crop management requirements vary according to the trial category. Post trial monitoring is required.					
Spain	20 m isolation distance	No	Removal of all tubers	Compulsory	2 years	Not the same crop. Specific conditions are set out in each risk evaluation report.

Sweden	None	Cleaning the machinery, and make sure seeds for sowing are destroyed/returned to originator. Consent holders state in end of year reports that they have done this.	With care. Potatoes must be removed and destroyed, unless they are propagating material	Yes	At least 2 years monitoring until 1 year with no volunteers	No potatoes until 1 year with no volunteers. Trial site must remain fallow for 1 year or in some cases cultivated with a crop where potato volunteers can be detected and destroyed (e.g. grain)
UK	There is nothing laid down in specific guidance. General principles apply but this would be considered on a case-by-case basis for each application. The specifics are covered in the consent conditions					

Table 12c: Practical aspects of managing a field trial (COTTON)

Member State	Are specific requirements described for any of the following activities associated with a GMO field trial					
	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**
Spain	40m isolation distance	No	Burial of crop wastes	Compulsory	1 year	Not the same crop. Specific conditions are set out in each risk evaluation report.

No GMO releases of cotton in France, Germany, Hungary, The Netherlands, Sweden or the UK

Table 12d: Practical aspects of managing a field trial (OILSEED RAPE)

Member State	Are specific requirements described for any of the following activities associated with a GMO field trial					
	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**
France	No	No	No	No	Requirements are based on the guidance provided by the CGB. 2 years monitoring for volunteers is recommended but can change on case-by-case basis	Requirements are based on the guidance provided by the CGB. 2 years is recommended but can change on case-by-case basis
Germany	No	None, except machinery must be cleaned afterwards and no GMOs must remain	Same as sowing	Must take place at the trial site	Only 1 application in the last 6-7 years. The applicant offered 5 years PTM, to be extended if necessary until 1 year with no GM OSR volunteers. This proposal was accepted.	Anything can be grown that does not interfere with post-trial monitoring for volunteers. The CA would probably not allow e.g. HT maize after HT OSR because it would make control of volunteers difficult.
The Netherlands	No. The management of field trials depends upon a GMO's classification (categories 1 to 3) and, on a case-by-case basis, any additional requirements that are set in the consent. Crop management requirements vary according to the trial category. Post trial monitoring is required.					

Sweden	None	Cleaning the machinery, and make sure seeds for sowing are destroyed/returned to originator. Consent holders state in end of year reports that they have done this.	Samples for analysis are cut by hand. Any material that will not be used in later trials or analyses shall be destroyed. When ready to harvest, the crop and seed is collected and burned on the trial site so it does not leave the field. The company may harvest the seeds and remove them from the field and send them for destruction, but they must be packed (double-bagged) and labelled on site and the machinery cleaned on-site.	Yes. If machinery is used in field while the crop is flowering, machinery must not be used for 48hrs in a crop of OSR.	At least 4 years monitoring until 1 year with no volunteers. Notes on the number of volunteers shall be sent to the CA	No OSR until 1 year with no volunteers. Trial site must remain fallow for 1 year. OSR sites must not be ploughed for 1 year after the trial to allow the seeds to germinate, shallow cultivation is permitted, but seeds must stay on the surface.
UK	There is nothing laid down in specific guidance. General principles apply but this would be considered on a case-by-case basis for each application. The specifics are covered in the consent conditions					

No GMO releases of oilseed rape in Hungary.

Table 12e: Practical aspects of managing a field trial (SUGAR BEET)

Member State	Are specific requirements described for any of the following activities associated with a GMO field trial					
	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**
France	No	No	No	No	Requirements are based on the guidance provided by the CGB. 2 years monitoring for volunteers but can change on case-by-case basis	Requirements are based on the guidance provided by the CGB. No sugar beet for 2 years but can change on case-by-case basis
Germany	No	None, except machinery must be cleaned afterwards and no GMOs must remain	Same as sowing	Must take place at the trial site	1 year minimum plus 1 year if anything is found in 1 year after the trial. It does not keep being extended provided sugar beet volunteers are removed. Bolters must be removed	Anything can be grown that does not interfere with post-trial monitoring for volunteers
The Netherlands	No. The management of field trials depends upon a GMO's classification (categories 1 to 3) and, on a case-by-case basis, any additional requirements that are set in the consent. Crop management requirements vary according to the trial category. Post trial monitoring is required.					
Spain	1000 m isolation distance (might not be required in some cases); inspection of bolters, only grown in regions where wild relatives are absent.	No	It is compulsory in Spain to harvest during the first year only for this biannual crop. Harvest before flowering. Burial of crop waste	Compulsory	2 years	Not the same crop. Specific conditions are set out in each risk evaluation report.

Sweden	None	Cleaning the machinery, and make sure seeds for sowing are destroyed/returned to originator. Consent holders state in end of year reports that they have done this.	With care. Chopped beet may be left in the field	Yes	1 year post-harvest	No sugar beet for 1 year.
UK	There is nothing laid down in specific guidance. General principles apply but this would be considered on a case-by-case basis for each application. The specifics are covered in the consent conditions					

No GMO releases of sugar beet in Hungary.

Table 13: Precautions to ensure isolation from sexually compatible crops and/or wild relatives

Member State	Maize	Potato	Cotton	Oilseed rape	Sugar beet
France	400m isolation (based on the guidance provided by the CGB)	No isolation distance specified	N/A	400m from a commercial crop (based on the guidance provided by the CGB). Inspectors do not monitor for wild relatives within the isolation zone for control purposes - it is not a mandatory requirement and is done when resources allow. It would be impossible for inspectors to say there are no wild relatives within the 400m isolation zone.	1000m from a commercial crop (based on the guidance provided by the CGB)
Germany	200m is the minimum isolation distance; other GM maize, or conventional maize may be allowed within the 200m but all maize within the 200m must be disposed of as GM maize i.e. not for food and feed or placing on the market. This is the responsibility of the notifier. A pollen barrier is not a requirement - the notifier may offer it, but the isolation distance must still be 200m (we used to require pollen barrier, but research suggests it is not that effective).	10m from a commercial potato crop	N/A	Case-by-case. BVL has not got a legally binding isolation distance. This is quite a sensitive issue. We do not yet have a general policy for OSR pollen barrier.	Non-flowering sugar beet = 10m. Sugar beet would not, on principle, be allowed to flower (Germany has a sugar beet seed industry, so it would be quite a sensitive issue to allow sugar beet to flower).

Hungary	1) Crop specific isolation distance is currently 500m plus some additional rows of non-GM varieties are required which should be demolished after flowering 2) Guarding of the trial site, safety requirements 3) Limitation of further use of the field, special requirements for crop rotation for 1 year. 4) Pollen control if necessary	1) Crop specific isolation distance has been 10 m with a 4m border plus some additional rows of non-GM varieties are required which should be demolished after flowering 2) Guarding of the trial site, safety requirements 3) Pollen control if necessary	No GM cotton releases in Hungary	No GM oilseed rape releases in Hungary	No GM sugar beet releases in Hungary
The Netherlands	The principal consideration is isolation from sexually compatible crops. Whilst there are no co-existence measures under the Decree on GMOs for Part B, if there are perceived risks of economic damage to neighbouring non-GM or organic crops, GM growers are encouraged to observe the national coexistence agreement for part C notification procedures and crop-specific isolation measures. Advice on this issue is being prepared.				
Spain	Isolation distance 200 m (compulsory), usually plus 4 border rows of non-GM. At least 1 month temporal isolation. Crop rotation	Isolation distance 20m (compulsory) Crop rotation	Isolation distance 40m (compulsory) Crop rotation	No GM oilseed rape releases in Spain	Spatial isolation 1000 m Inspection for appearance of bolters Harvest before flowering Crop rotation
Sweden	Only one maize trial has been held in Sweden, NK603, which is approved for food and feed (0.9% threshold), in which case isolation was 50m.	20m (it used to be 100m, but was reduced to 20m based on scientific advice) UNLESS it is seed production site then seed isolation rules operate.	N/A	500m - 800m. Must also remove wild relatives 50m from around the trial site, although it is not a requirement to report to the CA how many were found. Also require male sterile borders around OSR of at least 6m. The border is harvested with the trial and treated as part of the trial.	50m. Must remove bolters. At least 1km from any wild relatives. Wild relatives (*Beta maritima*) are very rare. Field trials are held at least 1km from locations where *B. maritima* grow.

UK	Crop-specific isolation distances	Crop-specific isolation distances (20m in recent trial)	N/A	Crop-specific isolation distances	Crop-specific isolation distances

What action would be taken if sexually compatible crops and/or wild relatives were found growing within the isolation zone?

France: Not prescribed, and not happened yet, but probably destruction of the trial, or another measure to prevent the pollen spread (e.g. elimination of male flowers to prevent pollen spread). Inspectors would discuss what to do and reach an agreement.

Germany: The Länder / Inspection authority would decide what should be done.

Hungary: Removal and destruction of sexually compatible or related crop found in the isolation zone; obligation on the controlling authority for official inspection. These requirements are incorporated in the consent. Furthermore, the controlling authority has a guideline on how to prevent gene flow from the GMO field release (see Annex II.A, available also on Internet: http://biodiv.kvvm.hu/cooperation/funding/doc684655).

The Netherlands: If action is necessary for sexually compatible crops, it would be prescribed in the permit.

Spain: Destruction of the trial. In other cases, the notifier has to buy the whole harvest that has been grown inside the isolation area.

Sweden: The requirements listed are the minimum requirements, if the notifier does not propose these at least, the CA will impose them. These are measures that have been approved for field trials - other measures may be applied in the future on a case-by-case basis. A related crop within the isolation distance is a violation of the conditions of the consent. It depends on stage of growth of the crop, but the situation would be remedied (probably destroyed).

- Potato: this has led to prosecution in one case (before 2001/18/EC).
- Oilseed rape: if it is just 1 or 2 plants the inspectors will pull them out and inform the consent holder. If lots of plants, the consent holder will be told and instructed to remove them. Inspectors may return to the site and check this has been done. It also depends on the stage of growth of the wild relative i.e. if it is at an advanced stage of growth & it clearly hasn't been inspected, CA/inspectors would be more concerned.

UK: No answer provided.

Table 14: Specific requirements for monitoring field trials

Member State	Generic crop inspection and monitoring requirements	Crop-specific monitoring requirements
France	The notifier is obliged to inspect the trial. Currently, each crop is inspected for control purposes once as a growing crop at an appropriate time, and once during the post trial monitoring period. The trial may be inspected more than this if resources allow. There is no specific requirement to inspect at sowing or harvest (depends on resources)	Flowering crops are generally inspected prior to flowering to ensure all controls are in place. Potatoes for example are visited when it is convenient in the inspector's schedule, as there are no issues with gene flow. All crops are inspected post-trial, mainly to ensure there are no volunteers at the site. To date no post trial monitoring period has had to be extended.
Germany	The CA expects to see plans as to how the trial will be inspected and how often, and this is followed up in the trial report. The Directive does not state exactly what is required for the monitoring plan for Part B trials, so the CA had to decide what is appropriate as monitoring for Part B trials in comparison to Part C monitoring. There is a requirement for environmental monitoring under 2001/18/EC; consents for field trials do not contain extensive requirements, but a general condition that says the notifier must observe the trial for any unexpected effects and/or unusual interactions - the CA does not expect to see a detailed monitoring plan in the application, or a detailed report.	Post-trial monitoring as described in table Xa-e above.
Hungary	No crop-specific requirements for monitoring - they are defined on a case-by-case basis. The monitoring obligation of the consent holder is incorporated in the consent and in the monitoring plan, which is proposed by the notifier and approved by the CA.	No crop-specific monitoring requirements other than no volunteers
The Netherlands	In general, monitoring requirements, including the recording of unexpected effects, are set in the conditions of the permit and are included on a case-by-case basis.	No crop-specific monitoring requirements - they are applied on a case-by-case basis. Post trial monitoring is required.
Spain	Yes	All crops must be inspected during: sowing, flowering and harvest. Sometimes post-trial monitoring. Specific conditions are set out in each risk evaluation report.
Sweden	Monitoring requirements are decided on a case-by-case basis, for example monitoring of germination may be required. The CA expects the notifier to inspect (=monitor) the crop at appropriate, regular intervals during the growing season, but the CA does not specify when this should be done. Inspectors visit at least once during the growing season. The CA does not specify to the inspectors when inspections should be done, other than to meet the requirements above. Post-trial monitoring for volunteers is the main requirement of the CA.	For all crops, inspectors must visit to ensure isolation. For oilseed rape, inspectors must visit to ensure isolation, and during flowering to check that the border is flowering at the same time.

UK	Yes. Specific requirements are written in the consent conditions and are done on a case-by-case basis. These will be both crop and trait dependent.	Yes. Specific requirements are written in the consent conditions and are done on a case-by-case basis. These will be both crop and trait dependent.

Table 15: Measures to minimise or prevent the dispersal of GM plant material (tubers, seeds, straw)

Member State	Maize	Potato	Cotton	Oilseed rape	Sugar beet
France	None are described. If the trial were vandalised, destruction of the trial would be requested. There are no specific requirements for transport or for storage of GM material - this is not part of the control plan and is not inspected. Isolation distance is the main measure to prevent dispersal. Straw is incorporated back into the soil.	Not an issue	N/A	None are described. If the trial were vandalised, destruction of the trial would be requested. There are no specific requirements for transport or for storage of GM material - this is not part of the control plan and is not inspected. OSR seed for sowing is generally provided in small size packages and there is no spare seed, so no issues regarding disposal of spare seed.	None are described.
Germany	None	After harvest of GM potatoes the trial site must be cultivated immediately to bring them to the surface and the area checked for tubers left behind. Tubers must be collected and destroyed. NGOs have been on former GMO site and collected tubers to demonstrate that not all tubers had been detected by the notifier.'	N/A	There must be no cultivation of the site immediately after harvest - OSR seed should be allowed to germinate and area should be watered if necessary to promote germination; germinated volunteers should be destroyed by shallow cultivation. The site can be sprayed, but generally the applicant chooses to shallow cultivate, and they may do this more than once. Deep cultivation of the trial area is not permitted during the whole PTM period.	None

Hungary	Crop specific isolation distances as already described. Destruction of the remaining material (seeds, stems, roots) usually by burning; cleaning of the machinery; guarding of the trial site, other safety requirements (fence, etc.); limitation of the further field use, special requirements for crop rotation; pollen control if necessary; removal and destruction of sexually compatible or related crop found in the isolation zone; official inspection		N/A	None described	None described
The Netherlands	Measures are designed to prevent the dispersal of GM plant material. They are case specific and crop specific measures.				
Spain	Isolation distance 200m (compulsory), usually plus 4 border rows of non GM. • Secure transport • Seed bags labelled • Cleaning of machinery • Chemical treatment Burial of unwanted seed and crop waste	Isolation distance 20m (compulsory • Secure transport • Seed bags labelled • Cleaning of machinery • Chemical treatment Burial of unwanted seed and crop waste	Isolation distance 40m (compulsory) • Secure transport • Seed bags labelled • Cleaning of machinery • Chemical treatment Burial of unwanted seed and crop waste	No GM oilseed rape releases in Spain	Spatial isolation 1000 m. • Secure transport • Seed bags labelled • Cleaning of machinery • Chemical treatment Burial of unwanted seed and crop waste
Sweden	The CA wants the applicant to take care of the material in a safe way but does not prescribe the methods other than to state that it must not enter the food or feed chain. The CA will accept any proposed measures that sound reasonable, and ask for confirmation that it has worked. Left over seed for planting the trials must be disposed of correctly. (Note: lots of methods have been approved for **potato**)				
UK	These will be specified in the consent conditions and include proper disposal of waste and control of volunteers following the trial.				

Table 16: Monitoring for gene flow around part B GMO field trial sites

Member State	Do you have a policy of testing for potential GM gene flow around a trial site? If YES, whose responsibility is it to do this	What happens if GM gene flow is found to have occurred?
France	No. This is not done - we would need to sample large numbers to detect even at 0.1% level, it is not part of the control plan.	This has not yet happened, the CA would refer to the Scientific Committee for advice
Germany	No. It is accepted that GM gene flow MAY occur beyond the isolation distance. Isolation distances are designed to minimize gene flow but not to prevent it 100% if the conclusion from the risk assessment was that gene flow does not pose a risk for the environment or human health.	If GM gene flow was found e.g. by a farmer then it is up to him to address this with the notifier and seek for compensation. Under German legislation, field trials are authorised on a risk basis, and GM gene flow is not a criteria to be addressed as part of the field trial itself.
Hungary	No. Exhaustive research was carried out on potential gene flow of maize in 2004. The results verified that the 500 m buffer zone is a sufficient requirement for avoiding potential gene flow around the trial site.	If GM gene flow occurred, which we consider unlikely, the contaminated material would be destroyed.
The Netherlands	No	N/A
Spain	No. Only done for specific trials and some research trials for testing GM thresholds, in these cases it is done by Plant Varieties Office (Oficina Española de Variedades Vegetales, OEVV),	The non-GM crop is managed as a GM crop
Sweden	No. The CA does not currently have a policy of testing for gene flow, but there is a study ongoing at present, as required by the CA, by Plant Science Sweden looking 500m around a trial site for presence of any wild relatives and feral OSR, and sampling & testing for the gene used in the trial, also testing any OSR plants found in the 500m zone.	It is accepted that GM gene flow will occur to wild relatives, but the GM gene (at least the ones used in trials that may have caused gene flow) is unlikely to persist or confer any benefit. However, the results of the PSS study MIGHT lead to an increase in isolation distance for subsequent trials.
UK	No	

Table 17: Post-release treatment of GM plant material, including GM and non-GM wastes

Member State	What methods are permitted for post-release treatment of the GM plant material, including wastes (GM and non-GM) from the trial?				
	Maize	**Potato**	**Cotton**	**Oilseed rape**	**Sugar beet**
France	GM material is generally destroyed in the field. Maize straw is ploughed back into the field.	GM material is generally destroyed in the field	N/A	GM material is generally destroyed in the field	GM material is generally destroyed in the field
Germany	Any proven destruction method. Decided on a case-by-case basis and is included in the conditions of the consent. If material is removed from the site it must be in closed containers. Some Länder have different requirements re. where the destruction can take place, there is some conflict between Länder and CA regarding point at which material is still covered by the Part B and when it must be in CU-licensed facility. Some Länder require that material be inactivated before it leaves the trial site if no CU licensed facility is available. **Maize** may be used for biogas - most maize is grown for silage, so it does not get ripe & is quite easy to incorporate.	Any proven destruction method. Decided on a case-by-case basis and is included in the conditions of the consent. If material is removed from the site it must be in closed containers. Some Länder have different requirements re. where the destruction can take place, there is some conflict between Länder and CA regarding point at which material is still covered by the Part B and when it must be in CU-licensed facility. Some Länder require that material be inactivated before it leaves the trial site if no CU licensed facility is available. **Potato** residues may be ploughed under.	N/A	Any proven destruction method. Decided on a case-by-case basis and is included in the conditions of the consent. If material is removed from the site it must be in closed containers. Some Länder have different requirements re. where the destruction can take place, there is some conflict between Länder and CA regarding point at which material is still covered by the Part B and when it must be in CU-licensed facility. Some Länder require that material be inactivated before it leaves the trial site if no CU licensed facility is available.	Any proven destruction method. Decided on a case-by-case basis and is included in the conditions of the consent. If material is removed from the site it must be in closed containers. Some Länder have different requirements re. where the destruction can take place, there is some conflict between Länder and CA regarding point at which material is still covered by the Part B and when it must be in CU-licensed facility. Some Länder require that material be inactivated before it leaves the trial site if no CU licensed facility is available.
Hungary	If GM material is required for other investigations, its transportation from the field to the laboratory has to be authorised using a transport consent. It has to be placed in appropriate packaging, which ensures that no GM material will be released into the environment. All other material remaining in the field after the harvest has to be collected and destroyed by burning (seeds) or by ploughing in (other materials).				

The Netherlands	Case specific measures, which may include burial on site, ploughing in, removing material off-site for autoclaving, incineration or composting.
Spain	After completion of harvest, the plant residues will be chopped and then incorporated into the soil. The incineration of the remains is sometimes allowed.
Sweden	Any method is allowed providing it works. If it is a new/novel method the CA would follow up to check destruction was successful. Potatoes have for example been sent for destruction at biogas plants or incinerated.
UK	All the waste would be treated in the same way – this could be burial, incineration or autoclaving depending on the nature of the trial.

Table 18: Reporting and following up part B GMO field trials

Member State	Does the CA require the consent holder to provide formal monitoring reports?	Who assesses consent holder monitoring reports?	Is there an established procedure for following up observed or unexpected effects	Are any restrictions placed on a GMO field trial site following termination of a trial?
France	Yes. Reports are required in the EC format[1]	The CGB assesses all of the reports	No. This has not happened to date, but the CA would refer to the scientific advisory committee for advice	No, once post trial monitoring and subsequent cropping requirements have been met, the trial is officially complete and the land can enter back into normal cultivation.
Germany	Yes. A report is required from each site, for each year until the trial is declared complete. BVL uses the EC format, but don't consider it useful - there is far too much information listed, a lot of which is irrelevant depending if the format is used for annual reports about the progress of a trial or for PTM reports. There are still a lot of sites in Germany in PTM, so there are a lot of reports to deal with.	The CA assesses reports. Monitoring reports are also sent to the other Federal authorities involved in the assessment procedure, and the inspection authorities. The inspection authorities decide whether PTM must continue or if a trial can be terminated. The notifiers and inspection authorities liaise regarding termination of sites.	No. These would be assessed on a case-by-case basis. (There has been one example of an unexpected effect - poplar trees flowered before they were expected to, but there was a measure described for this in the consent (i.e. was unlikely but not totally unexpected))	No. The field is returned back to the farmer for normal agricultural use once the PTM is completed.
Hungary	Yes. The notifier has to submit a monitoring report to the CA on an annual basis, within 30 day after harvest. The EC format is used. Continuation is not permitted without submission and approval of this report.	The CA, the Ministry of Environment and Water and the Advisory Committee for Gene Technological Applications assess the reports. The submission of the notifier annual report on the monitoring is a prerequisite for further release.	Yes. Consent holders have to monitor the expected or unexpected effects of the release and submit a report within 30 days after the harvest every year. Unexpected effects or accidents have to be reported to the CA according to the emergency plan without delay.	All restrictions regarding the GMO field trial site following the termination of the trial are incorporated in the consent.

The Netherlands	Yes	Reports are assessed by the CA ("Bureau GGO", or GMO-office). The notifier has to submit a post-harvest report annually as a precondition for continuing a permit. This report is published on the site www.minvrom.nl/ggo-vergunningverlening. At the end of the trial programme, the notifier's final report is placed on the JRC Biotechnology and GMOs website (deliberate release).	Such effects are treated individually. If adverse effects were found emergency plans would automatically be implemented.	Yes. Restrictions are crop- and case-specific.
Spain	Yes.	The central Government: Inter-Ministerial Council for GMO (CIOMG) and National Commission on Biosafety (CNB) assess the reports, and the Regional Competent Authorities	Yes. It is mandatory for notifiers to submit a final report after the completion of a trial, which covers these two effects. Any reported effects would be followed up by the CA's Inspectors.	Crop rotation is compulsory, (restriction post-trial for 1-2 years)
Sweden	Yes. The report should be in the format as described Annex VII to 2001/18 (Commission Decision 2003/701/EC of 8/10/2003). The consent holders should also send in reports of volunteers found during post trial monitoring. The CA contacts the consent holder to inform them that the report is acceptable.	The CA assesses the reports.	No. None to date, but would be assessed case-by-case.	Only post trial cropping as already described. Once these conditions have been met, the trial can go back into the normal agricultural rotation.

UK	Yes	The CA assesses the reports. The GM Inspectorate also assesses the reports	No. The agreement between the GM team and the GM Inspectorate (GMI) states that the GMI will undertake inspection visits and produce reports for Defra to consider. It is expected that reports would highlight any unusual or unexpected circumstances and action taken.	Yes the restrictions are usually listed in the consent. The major restriction is usually not growing the same crop again within a certain number of years of no volunteers being observed.

[1] Commission Decision 2003/701/EC on establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council a format for presenting the results of the deliberate release into the environment of genetically modified higher plants for purposes other than placing on the market.

Table 19: Incidents of non-compliance

Member State	Are procedures in place for dealing with non-compliances, including criteria for initiating a formal investigation?	Of the total consents issued since October 2002, in how many has there been a breach of consent conditions?				Are details of non-compliances published?
		Technical non-compliance[1]	Number of cases where material has accidentally entered the marketplace	Number of fines or warnings issued	Number of prosecutions taken	
France	Yes	5 (see below)	0	0	0	No. The Ministry of Agriculture would not publish if there were a prosecution for non-compliances; this is the job of the Justice system.
Germany	No	1[2]	0[2]	0[2]	0[2]	No
Hungary	Yes. Under the Act on Gene Technological Activity, the controlling authority (inspectors) investigates whether the gene technological activity complies with the legislation in force as well as with the special requirements encountered in the consent on the spot. If any new information on the risks inherent in the activity, particularly those that pose a threat to human health and to the environment, becomes available to the competent authority (e.g. via the controlling authority), it may restrict or prohibit the activity.	0	0	0	0	Under the Act on gene technological activity, the competent authority publishes information (compliances and/or non-compliances) on the results of the official inspections in its official journal on an annual basis. This information would also be published on the website of the controlling authority
The Netherlands	Yes	0	0	0	0	No

Spain	Yes	1	0	1. Cases where either the isolation distance was infringed or crop waste material had not been incorporated into the soil	0	No
Sweden	Yes - procedures are very clearly laid out in the legislation	0	0	0	0	There might be a brief statement. It would not be published unless it is a matter of public interest.
UK	Yes	0	0	0	0	They are published in the public register and also in GMI annual report which is published on the GMI website.

[1]For example incorrect isolation distance, failure in monitoring, incorrect subsequent crop planted
[2]Note this report provided by the CA, but enforcement is the responsibility of the Länder and to get details of any incidents, we would need to consult each Länder. In the two Länder that were consulted one incident of technical non-compliance was reported (South Bavaria).

Further details of non-compliances

France

There was a problem with pollen barriers not being implemented when the isolation distance for maize was set at 200m (it was extended to 400m in 2006). If the pollen barrier was not in place it was treated as a legal non-compliance and the trial had to be destroyed by administrative measure - this was a risk management issue. Now the 400m pollen barrier is in place, this action is not necessary. Advice is not sought from the scientific committee where there are issues with the pollen barrier as 400m isolation is adequate to prevent gene flow. This is the risk manager's (= Inspector's) decision. In 2005, there were 5 cases of destruction of a trial due to absence of pollen barriers

Germany

In Germany, where there may be an issue, companies are open about it and inform the authorities of their mistake/s. To date all 'incidents' have all been unintentional, e.g.:

- spraying a pollen barrier accidentally
- during a PTM a farmer accidentally planted oilseed rape on a former oilseed rape GMO trial site.
- the GMO that was released was not the GMO that was authorised, there was a mix-up in laboratory - the crop was destroyed.
- a trial was planted in the wrong field, outside of the authorised area - the company had to remove the trial from the unauthorised area.

- In South Bavaria, Maize seed NK603 was contaminated with MON810 and MON863 (identified by the competent authority for analysing samples (Bavarian Agency for Health and Food Safety). Because these were approved events, it was considered not to represent a risk. The applicant was informed and the tassels of the male plants were destroyed so that pollen could not be released. There was no other penalty on the company.

INSPECTION AND CONTROL OF GMO FIELD TRIALS

Table 20: Practical arrangement for inspection and control of GMO field trials

Member State	Does the CA have an Inspectorate nominated specifically for GMO DR trials	What is the remit of the Inspectorate	Briefly, what powers do inspectors have	Do inspectors have guidelines /SOPs for inspection regimes and reporting mechanisms
France	National Inspectorate for Plant Protection. The Inspectorate is part of the Competent Authority. France is divided into 22 regions, within which are principalities. Each region has at least 1 GM inspector nominated, and dedicated to, part B trials.	Phytosanitary issues and part B GMO field trials.	Inspectors of part B field trials are legally 'sworn in' as inspectors. Inspectors have fairly 'standard' powers i.e. can seize and sample, can place prohibition on movement until further information is provided. To take any action regarding destruction of a field trial, an inspector must first inform the Minister, and get permission from Procurator.	Yes. Inspection services for phytosanitary and veterinary inspections are currently developing procedures and working towards accreditation for inspections. This is being led internally by the Ministry of Agriculture and will provide accreditation under a recognised French system

Germany	The CA does not have an inspectorate. In Germany the Federal Länder are competent for enforcement and are required to nominate specific authorities. In Bavaria it is the District Government of Upper Bavaria (southern part of Bavaria) and of Lower Franconia (northern part of Bavaria). In Schleswig-Holstein the Ministry for Agriculture, Environment and Rural Areas (Technical Environmental Policy Department) is responsible. It is unusual for the inspectors to be part of the Ministry, as the enforcement authority is usually a separate body, but Schleswig-Holstein is a fairly small Länder. BVL arranges a meeting for the inspectors (CU and DR) once each year, which is a useful meeting opportunity.	The key aim of all Länder is 'control' of releases in accordance with consent conditions. The key underlying basis of the inspectors work is environmental health and consumer protection. In Bavaria the remits of the District Governments are: i) Decision making procedure of contained use of GMO, ii) Supervision of contained use facilities, iii) Supervision of deliberate releases and iv) Supervision of products for placing on the market. In terms of 'control' inspectors must ensure that the applicant does what he/she states they will do in addition to any conditions required by BVL. This can lead to problems where the applicant states very specific requirements, which can happen particularly with University trials.	The inspectors have to supervise the releases. They can take samples from the field trial, create an order with specific obligations or can stop the releases, if necessary. The ultimate aim of inspection is protection of the environment and inspectors must assess this before taking any decisions with respect to taking any action. Any possible actions would first be discussed with BVL, and possibly regional lawyers. The course of action taken depends entirely on the situation and is considered on a case-by-case basis. The Bavarian regulation for supervision states that where mitigating measures are requested these must be based on science (e.g. published research).	There are not any general SOPs for inspectors - every Federal Länder has their own SOPs and they develop them case-by-case. The Guidelines produced by the European GMO Enforcement Project (EEP) are also used for DR inspections and sampling. Checklists are good guidance, but each case is treated on a case-by-case basis. In Bavaria there is a specific regulation of the Bavarian Ministry of Environment, Health and Consumer Protection: ‘Supervision of contained facilities and deliberate releases (frequencies, duty of information).

Hungary	Yes. Central Agricultural Office, Directorate of Plant Production and Horticulture, Seed Inspectorate	The inspectorate supervises seed production as well as Part B GMO releases	To carry out official control and to make a first level decision regarding imposing gene technological penalties. Inspectors can suspend the activity if: a) it does not comply with the consent; b) it is unauthorized or; c) there is new information regarding an increased risk on the human health or the environment of the gene technological activity. In case of a) and b), the controlling authority can impose a penalty and sends the report on the investigation to the CA within 3 days.	Yes - there is a special format for inspections on reporting on the supervision. The inspectorate supervises whether the consent holder complies with the legal requirements, including the legislative framework, the monitoring plan approved by the CA, the specific measures defined in the consent as well as other requirements incorporated in the guideline of the controlling authority. This is published on the following website: http://biodiv.kvvm.hu). There is an internal guideline for the inspectors.
The Netherlands	Yes. The VROM Inspectorate	Inspection of all GM related activities to verify compliance with the Decree on GMOs.	Access to deliberate release sites to conduct inspections and inform the Public Prosecutor of any suspected administrative or criminal infringements of the Decree.	Yes, principally guidelines for the three categories of GM field trials. There are also regular co-ordination meetings with the GMO Bureaus, GM policy staff and representatives of COGEM where inspection issues can be discussed.
Spain	Yes – but the regional CAs only, not the National CA	The three main functions are to ensure that: (1) GM Regulations are fulfilled (2) Records for inspection and control are developed and (3) Certificates of inspection are issued when undertaking inspections and controls	To request information, send inspection reports to the CA and to make the punishment fit the infraction by companies or farmers	European Enforcement Group Guidelines and other control criteria are used.

Sweden	Yes - Inspection Division of the Swedish Board of Agriculture, established 2007. Prior to 2007 inspections were carried out by the Competent Authorities. Inspections are charged to the consent holder: all inspections are 2500 SEK per FIELD (approx €250), this has always been the case. Fees are due to be revised soon. The currently nominated inspectors are new to the GMO work and are trying to develop; they plan to look at the process in detail.	Inspection of all phytosanitary regulations, animal feed (including GMOs in animal feed), GMOs. Also quality control of fresh fruits and vegetables and import/export controls and with controls at the internal market.	Inspectors have quite strong powers i.e. sampling, prohibition on movement, demand access, demand provision of information. Inspectors can call the police if necessary to assist entry to premises. Inspectors record what they see and report this to the Head of Division, who then decides whether to take it further, if there has been a clear violation then it must go through the legal system.	The guidelines do exist but they are very brief and generic about the crop regarding isolation etc. These documents will be updated this year. For each trial site inspectors have a map and a protocol, which is created from the Decision document. Inspectors do not have SOPs as yet, but these will be developed. When inspections were done by the CA they did not have any SOPs but two people always went to ensure that one of the people always had done an inspection before. The Inspection Division recognises that this is a task that has to be developed for the Inspectors.
UK	Yes. The GM Inspectorate (England). There is also a GMI for Scotland. The GMI is made up of 1 full-time equivalent and there are 4 nominated inspectors.	Environmental protection and to ensure that material does not enter the food and feed chain.	Right of entry to premises if they have reason to believe a GMO is/was present (not domestic premises) and also to seize GM material which is potentially harmful. They also have the power to issue notices (including Enforcement Letters, Prohibition and Information Notices).	Yes. CSL is an ISO 9001:2000 accredited organisation and GMI SOPs are audited under this. The GMI use SOPs and basic checklists for all inspections and audits to ensure consistency between inspections and to ensure that the correct information is collected at each visit. This also enables the GMI to manage any non-compliance issues should they arise. The GMI is also active in the European GMO Enforcement Group, which develops protocols and checklists for inspection so they have access to the documents produced by this group.

Table 21a: Level of inspection at different stages of the trial (MAIZE)

Member State	How often is each trial inspected at the following stages			
	Sowing	**Growing crop**	**Harvest and disposal**	**Post-trial**
France	No specific requirement; as resources permit	Once	No specific requirement; as resources permit	Once
Germany	**Bavaria**: ONCE **Schleswig-Holstein**: Always visit at this stage (assuming it is possible) Inspectors must be provided with information from the consent holder that they will sow a minimum of 3 days before sowing.	**Bavaria**: 2 – 3 times (because of a problem with contaminated seed). Bavarian Agency for health and food safety (LGL) also takes samples at this stage. **Schleswig-Holstein**: at least once but depends on the trial and the circumstances	**Bavaria**: ONCE **Schleswig-Holstein**: Always visit at this stage	**Bavaria**: 2 – 3 times (more than usual because there was a problem with contaminated seed) **Schleswig-Holstein**: Always visit at this stage until PTM is completed
Hungary	1	1	1	1
The Netherlands	In general, the inspection strategy is to expect that companies will conform to permit conditions by documenting all trial activities in a log book. An important feature is that there is a statutory requirement for every company to have a licensed, environmental safety officer (MVF) whose role is to ensure compliance with the permit conditions. Inspections, therefore, operate at a higher level than just inspecting specific stages in a trialling cycle. Inspectors usually meet the ESO and inspect the logbook. Inspections are similar to an audit, in that they examine on the processes of managing a GMO trial. An annual inspection is usually sufficient. The number of inspections will depend on the circumstances being investigated.			
Spain	1	1 or 2	1	Random
Sweden	0	At least once	0. Destruction sites are visited.	Post-trial controls are made to all field trials in the next growing season, one visit/field. Also depends on the crop and the situation. Not really necessary for maize in Sweden, but depends on the crop and the situation.
UK	Possibly, depending on perceived risk and available resources. The GMI make recommendations re. inspection times/frequency to the CA, but the CA has the final say as to how many visits are undertaken.	Each trial will be inspected at least once during the growing season	Possibly, depending on perceived risk and available resources.	At least 1 inspection visit per year is carried out during the post trial monitoring phase of the trial.

Table 21b: Level of inspection at different stages of the trial (POTATO)

Member State	How often is each trial inspected at the following stages			
	Sowing	**Growing crop**	**Harvest and disposal**	**Post-trial**
France	No specific requirement; as resources permit	Once	No specific requirement; as resources permit	Once
Germany	**Bavaria**: ONCE **Schleswig-Holstein**: Never had potato trials Inspectors must be provided with information from the consent holder that they will sow a minimum of 3 days before sowing.	**Bavaria**: ONCE. Bavarian Agency for health and food safety (LGL) also takes samples at this stage. **Schleswig-Holstein**: Never had potato trials	**Bavaria**: ONCE **Schleswig-Holstein**: Never had potato trials	**Bavaria**: 1- 2 times **Schleswig-Holstein**: Never had potato trials
Hungary	1	1	1	1
The Netherlands	In general, the inspection strategy is to expect that companies will conform to permit conditions by documenting all trial activities in a log book. An important feature is that there is a statutory requirement for every company to have a licensed, environmental safety officer (MVF) whose role is to ensure compliance with the permit conditions. Inspections, therefore, operate at a higher level than just inspecting specific stages in a trialling cycle. Inspectors usually meet the ESO and inspect the logbook. Inspections are similar to an audit, in that they examine on the processes of managing a GMO trial. An annual inspection is usually sufficient. The number of inspections will depend on the circumstances being investigated.			
Spain	1	1 or 2	1	Random
Sweden	0	At least once	0	Post-trial controls are made to all field trials in the next growing season, one visit/field. Also depends on the crop and the situation,
UK	Possibly, depending on perceived risk and available resources. The GMI make recommendations re. inspection times/frequency to the CA, but the CA has the final say as to how many visits are undertaken.	Each trial will be inspected at least once during the growing season	Possibly, depending on perceived risk and available resources.	At least 1 inspection visit per year is carried out during the post trial monitoring phase of the trial.

Table 21c: Level of inspection at different stages of the trial (COTTON)

Member State	How often is each trial inspected at the following stages			
	Sowing	**Growing crop**	**Harvest and disposal**	**Post-trial**
Spain	1	1 or 2	1	Random

No GM cotton releases in France, Germany, Hungary, The Netherlands, Sweden or the UK.

Table 21d: Level of inspection at different stages of the trial (OILSEED RAPE)

Member State	How often is each trial inspected at the following stages			
	Sowing	**Growing crop**	**Harvest and disposal**	**Post-trial**
France	No specific requirement; as resources permit	Once	No specific requirement; as resources permit	Once
Germany	**Bavaria**: No OSR trials **Schleswig-Holstein**: Always visit at this stage (assuming it is possible) Inspectors must be provided with information from the consent holder that they will sow a minimum of 3 days before sowing.	**Bavaria**: No OSR trials **Schleswig-Holstein**: at least once but it depends on the trial and the circumstances	**Bavaria**: No OSR trials **Schleswig-Holstein**: Always visit at this stage (assuming it is possible)	**Bavaria**: No OSR trials **Schleswig-Hol**stein: Always visit at this stage - consider this the most important part of inspections for OSR
Hungary	No GM oilseed rape releases in Hungary	No GM oilseed rape releases in Hungary	No GM oilseed rape releases in Hungary	No GM oilseed rape releases in Hungary
The Netherlands	In general, the inspection strategy is to expect that companies will conform to permit conditions by documenting all trial activities in a log book. An important feature is that there is a statutory requirement for every company to have a licensed, environmental safety officer (MVF) whose role is to ensure compliance with the permit conditions. Inspections, therefore, operate at a higher level than just inspecting specific stages in a trialling cycle. Inspectors usually meet the ESO and inspect the logbook. Inspections are similar to an audit, in that they examine on the processes of managing a GMO trial. An annual inspection is usually sufficient. The number of inspections will depend on the circumstances being investigated.			
Spain	No GM oilseed rape releases in Spain	No GM oilseed rape releases in Spain	No GM oilseed rape releases in Spain	No GM oilseed rape releases in Spain
Sweden	0	At least once	0	Post-trial controls are made to all field trials in the next growing season, one visit/field. Also depends on the crop and the situation.
UK	Possibly, depending on perceived risk and available resources. The GMI make recommendations re. inspection times/frequency to the CA, but the CA has the final say as to how many visits are undertaken.	Each trial will be inspected at least once during the growing season	Possibly, depending on perceived risk and available resources.	At least 1 inspection visit per year is carried out during the post trial monitoring phase of the trial.

Table 21e: Level of inspection at different stages of the trial (SUGAR BEET)

Member State	How often is each trial inspected at the following stages			
	Sowing	**Growing crop**	**Harvest and disposal**	**Post-trial**
France	No specific requirement; as resources permit	Once	No specific requirement; as resources permit	Once
Germany	**Bavaria**: No beet trials **Schleswig-Holstein**: No beet trials (a consent was issued but not used) Inspectors must be provided with information from the consent holder that they will sow a minimum of 3 days before sowing.	**Bavaria**: No beet trials **Schleswig-Holstein**: No beet trials (a consent was issued but not used).	**Bavaria**: No beet trials **Schleswig-Holstein**: No beet trials (a consent was issued but not used)	**Bavaria**: No beet trials **Schleswig-Holstein**: No beet trials (a consent was issued but not used)
Hungary	No GM sugar beet releases in Hungary	No GM sugar beet releases in Hungary	No GM sugar beet releases in Hungary	No GM sugar beet releases in Hungary
The Netherlands	In general, the inspection strategy is to expect that companies will conform to permit conditions by documenting all trial activities in a log book. An important feature is that there is a statutory requirement for every company to have a licensed, environmental safety officer (MVF) whose role is to ensure compliance with the permit conditions. Inspections, therefore, operate at a higher level than just inspecting specific stages in a trialling cycle. Inspectors usually meet the ESO and inspect the logbook. Inspections are similar to an audit, in that they examine on the processes of managing a GMO trial. An annual inspection is usually sufficient. The number of inspections will depend on the circumstances being investigated.			
Spain	1	1 or 2	1	Random
Sweden	0	At least once	0	Post-trial controls are made to all field trials in the next growing season, one visit/field. Also depends on the crop and the situation.
UK	Possibly, depending on perceived risk and available resources. The GMI make recommendations re. inspection times/frequency to the CA, but the CA has the final say as to how many visits are undertaken.	Each trial will be inspected at least once during the growing season	Possibly, depending on perceived risk and available resources.	At least 1 inspection visit per year is carried out during the post trial monitoring phase of the trial.

Table 22: Inspection practices

Member State	Are your inspections scheduled, unannounced or both?	Is field inspection your only method of ensuring compliance?	Are you required to provide reports to the CA?	Are your inspection reports publicly available?
France	Scheduled. Inspections are usually scheduled and the inspector will arrange to meet the notifier at the site. There are two main points for control - before flowering and after harvest to ensure no volunteers are present, if more is needed they will be done - maximum number of inspections at one site is 5 to date. Last year on average each trial was inspected 2.5 times - because number of trials is reduced at present. Additional inspections (controls) are done on a case-by-case basis.	Yes	Yes	No. Reports are not published, but the CA annual report states number of inspections undertaken, what crops were in the trials and the outcome of the inspections

Germany	**Bavaria**: Scheduled Normally the inspection is announced; it must be scheduled according to the best time for the inspection (depends on season, crop, agricultural practice in order to look for volunteers). For taking samples (sowing, harvesting) the inspection is normally announced. **Schleswig-Holstein**: Both Normally sowing and harvest are scheduled, the consent holder informs the inspector and the inspector says he will come. Growing season inspections are unannounced.	YES – no other audits or inspections are undertaken.	The Länder competent authorities have to inform the BVL in case of: decisions, relevant safety information, violation by applicants, suspicion of violation by applicants (Art 28 GMO law) **Bavaria**: Internal reports are produced for the Inspection CA. These are held on the internal network, includes photos. No specified format is established at present – but this may be in the new handbook that is currently being developed. **Schleswig-Holstein**: reports are not required but they are prepared for the records. Under the Environmental Information Law persons can request access to this information if they wish to see it.	No reports are (formally) produced, and therefore not published.
Hungary	Scheduled	No. The inspection covers transport (seed, harvested material), storage facilities (seed, harvested material) as well as documentation and record keeping.	Yes. Official reports should be sent to the CA in cases of compliance &/or non-compliance, on the fulfilment of inspection requirements, on official measures such as imposing penalties. Under the Act on gene technological activity the inspection report must be sent within 3 days of the inspection.	No. Inspection reports are not available to the public. However, a short summary of the official controlling activity is published by the Competent Authority on an annual basis
The Netherlands	Predominantly scheduled, but unannounced visits are an option	No. Environmental safety officers are the main focus of inspection	Yes. The CA is informed of the outcome of inspection activities.	Yes. Inspection activities are summarised in an annual report. The information provided is not site specific.

Spain	Both. Scheduled visits are arranged to check the site before planting (sometimes), sowing, flowering and harvest (including disposal). Unannounced inspections can be used to check monitoring	Yes	Yes. Inspection reports (Acta de control de campo) are forwarded to the relevant Competent Authorities.	No
Sweden	Scheduled. Inspectors do not meet the notifier / field operative at the site. Inspectors have a discussion with the field operator before going to the field to check crop has grown etc. When the CA was in charge of inspections, the inspections were unannounced because they felt it should be unknown UNLESS it was in a restricted area and permission had to be obtained to get on to the site.	No. An administrative inspection is undertaken by the CA in which the notifier is required to send details of managing the field trial to the CA, this includes instructions to the field operator, a report to CA on how the field trial performed, and a report to confirm conditions such as the absence of wild relatives have been observed. Inspections are therefore split quite clearly between in-field compliance and administrative compliance	Yes. Inspectors provide a report to the notifier and the competent authority. These go on the Swedish Board of Agriculture intranet but are not published externally.	The reports are not published externally but are available to the public on request. Generally these can be shown, but aspects of confidentiality must be addressed - e.g. name of persons involved must be removed.

UK	Both. In general inspections are scheduled but if the GMI had concerns, they would consider unannounced inspections.	No. The GMI carry out a management audit of the consent holder and their management of the trial. In particular it is to ensure that the consent holder has set up the appropriate contracts, e.g. secured land for a 5 year trial, identified all the people involved in the chain and established clear lines of communication with them. The audit also checks the documentation for various stages of trial and that the consent holder is exercising appropriate duty of care. The audit is usually undertaken in advance of planting; if it is a multi-year trial an audit would be undertaken each year in advance of planting. The audit can also be used to address any concerns about how the consent is managed (particularly for a multi-year trial) and the GMI would seek to resolve these with the consent holder. The audit establishes effective communication between the GMI and the consent holder. A report of the management audit is always sent to the CA not to the consent holder as it is seen as an internal check. In the past the GMI has also received 'concerned' feedback from the public (e.g. about some of the FSE trials), and they have a duty to follow these up.	Yes. Reports of all inspections and audits are provided to the Competent Authority.	All field inspection reports are published. The reports must be produced within 5 working days of the inspection and are sent to the CA and the notifier who have 20 working days to comment on the factual content of the report. The report is then published on the GMI website at http://www.gm-inspectorate.gov.uk/ Management audit reports and post-trial monitoring reports are not published but could be released in the event of an FOI request An annual report is published summarising all inspections and audits undertaken during the year.

Table 23: What is inspected

Member State	What is inspected?									
	Trial location and grid reference	Crop planted	Dimensions of the trial area	Presence of barrier crops (if appropriate)	Proximity to other crops of the same type	Proximity to related crops	Transport (seed & harvested material)	Storage facilities (seed & harvested material)	Documents & record keeping	Other
France	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes. Notifier must be present at inspection to provide this information.	
Germany	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes. Labels on seeds are checked. The field operator & consent holder are seen; their documents are checked, the label/s on the seed are checked. Every person who is dealing with the GMOs must be trained, including the farmers and inspectors check to see that this training has been completed.	If the consent holder does not own the land contracts are checked. This is laid down in German Law - the applicant must show the letter of confirmation when they announce their intention to sow (= 3 days in advance of planting)
Hungary	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
The Netherlands	This will depend on the consent. But – the log book for the field trial is especially examined.									
Spain	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes. Permits and trial diaries	Volunteers, follow-on crops
Sweden	Yes. GPS is used where possible	Yes	Yes	Yes	Yes. Must check for bolters in sugar beet	Yes. In OSR trials, must check 50m around the trial for wild relatives	Yes	No	No. Inspectors do not meet with the field operator and therefore do not check documentation etc.	No
UK	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Field boundaries; anything unusual

Title: Classification of field experiments with genetically modified plants[1]

COGEM advice: CGM/050929-03

Introduction

COGEM has been asked to advise on the revision of the classification of field experiments with genetically modified plants. In the Netherlands, a classification of field trials with genetically modified plants is used (1) as implementation of the “step-by-step principle”, as set out in the European Directive 2001/18/EC (2). In its advice entitled "COGEM guidelines for the assessment of field trial applications" (1), the COGEM distinguished five classes of field experiments, ranging from small-scale experiments with containment measures (class one and two) to large-scale trials for which restriction is no longer deemed necessary (class three to five).

The classification is based on the steps taken in the pathway of the development of a new variety, from glasshouse experiment to market introduction. At the start of this procedure, many, not fully characterised, transgenic variants of a plant are often tested for their properties in the field. During the process, a few transgenic plants are selected from this group and characterised with the properties suitable for an approval for marketing by the applicant. For this, fewer different transgenic plants are tested, but often over a larger area. For each class, requirements are described for the characterisation of the genetically modified plants, the number of locations and the surface area of field trials.

When sufficient information has been gathered in previous experiments about possible environmental effects, work can be scaled up to a higher class. These experiments do not necessarily need to have been conducted by the applicant, but may also have been carried out by others. Results can also be obtained from the literature.

In the classification, as described in the COGEM advice of 1999 (1), the difference between grade one and grade two is the obligation to deliver more information about the possible effects of the expression of the genes in question and the increase of the number of locations from one to five. The difference between grade three and

[1] This paper was translated into English by the Project Team and is an unofficial COGEM translation.

four consists of the provision of more information on specific constructs that have been used for the modification and on any effects of the expression of the genes in question and an increase in the total area from five hectares in class three to ten hectares in class four.

The advice request

From the experience with licence applications for field trials gained so far, it has become clear that it is desirable to review the advice given in "COGEM guidelines for the assessment of field trial applications" (1). The field trial classification has largely functioned to everyone's satisfaction in the past and the environmental safety is also guaranteed with the old system of classification. However, with the increased experience gained nowadays, it is possible to simplify the system so that it becomes easier to apply in practice. The difference between some of the classes has been shown in practice to be too small causing some classes not to be requested. In addition, it has become obvious that the restriction of the size and number of locations per class cannot be strictly applied in practice. This restriction is partly based on the practicality of the containment measures potentially imposed. However, when a permit holder can meet the containment measure using a larger area or more locations than the allowed maximum, a motivated deviation from the prescribed area size or the number of locations should be able to be allowed upon request.

The COGEM has been asked to advise on a new interpretation of the class system for field trials, prepared by the Ministry of Housing, Spatial Planning and the Environment (VROM).

Proposal for the new classification

The new classification presented for advice includes three categories which are related to the level of uncertainty about possible harmful environmental effects of the GMOs. Where the term 'harmful' effects is used, the following meaning is given to it by the COGEM: unwanted effects that significantly differ from the reference framework. The reference framework used by the COGEM for the effects of GMOs is current agricultural practice and classical breeding (3).

For all three categories, a monitoring plan to detect the effects of the GMO on human health or the environment should be submitted in accordance with Article 6 (2) of the European Directive 2001/18/EC (2). The three categories are briefly described below:

Category 1. Small scale field experiments with containment measures

In this category, work is classified which is allowed to be carried out at up to five locations. Each site must be no larger than one hectare. The following data are required on the characterisation of the GMO:

- The following should be indicated regarding the open reading frames (ORF) and the regulatory elements:
  - the abbreviation used for genetic element;
  - the donor;
  - the expected function or functions after expression of the genetic element in the plant;

- In addition, results from previous experiments with the same or similar GMOs should be evaluated for the possible effects of the expression of the relevant genes. Potentially harmful effects should be limited to the experimental site. This means that the dispersal of the GMO should be prevented by, for example, removal of the flowers.

Category 2. Field trials without containment measures

In this category, no maximum is set for the number of locations, but there is for the size. Annually, this may not exceed ten hectares. Dissemination need not be prevented. The following data are required on the characterisation of the GMO:

- The same requirements as for category 1.
- After the assessment (in category 1), there should be no reasons to believe that the genetically modified organism itself is harmful for humans or the environment, either through its offspring, or via transfer to other organisms.
- A map of genes used for the modification should be provided. It must show which combinations of the sequences to be expressed, regulatory sequences, or other selection elements have been used for the modification.
- In addition, an assessment is requested of the effects of the expression of the genes in question on the basis of results from previous trials with similar or other plants.

Category 3. Large-scale non-commercial field trials

In this category, there is no longer a limit on the number of locations or the size. No containment measures are required to prevent dissemination. The following information is required on the molecular characterisation:

- The same requirements as for category 2.

- The molecular characterisation of each transformant (actually inserted elements). A full assessment on the safety for humans and the environment should have been carried out. Following this assessment, there should be no reasons to believe that the genetically modified organism itself is harmful for humans or the environment, either through its offspring, or via transfer to other organisms.

Review and advice

The new classification has to,- just like the old classification -, fit within the European Directive 2001/18/EC (2). Consideration 24 of this Directive (2) states that "the introduction of GMOs into the environment should take place step by step". This consideration is meant to avoid that negative effects of deliberate introduction of a GMO harm humans and the environment. The step-by-step principle during the development of a GMO is aimed at managing the degree of uncertainty attached to the environmental risk assessment and the possibly unforeseen effects of the GMO. During the progressive successive steps in the development process of a GMO, more information becomes available and the uncertainties in the environmental risk assessment decrease. Uncertainties may lead to the imposition of additional requirements to a permit, such as the prevention of flowering. With diminishing uncertainty and if the environmental risk assessment permits, the number of prescribed measures for limiting the risk can then be reduced over time.

The new classification is based on a simplification of the old classification and is an implementation of the step-by-step principle. For example, in category one, data are collected which are needed to carry out a category two experiment, and in a category two, experimental data are collected necessary for a category three experiment. The criteria and requirements for each category have both in the old and new system been assessed on the basis of practical experience and expertise of the COGEM members.

For all categories, a survey requirement (monitoring plan) is in place, to detect the effects of the GMO on human health or the environment. If it is shown that, during an experiment or after assessment of the data from the monitoring plan, there is still some uncertainty regarding a harmful impact of the GMO, emergency measures can be imposed. This could mean that the GMO itself and/or any seeds must be destroyed.

The first category consists of small-scale work with genetically modified plants that have not yet been fully characterised. It is a combination of the old class one and two field experiments. There is still insufficient certainty about possible environmental effects should cultivation takes place. The activities are therefore small scaled and containment measures may be imposed. From this point of view, it remains important to attach a maximum number of locations and/or surface area to this work. Data from laboratory experiments, glasshouse experiments or experiments with similar GMOs should sufficiently map possible effects. The experts from the COGEM are of the opinion that, in this category, the maximum number of five locations and the maximum size of one hectare per location are so small that, with containment measures, human and environmental safety can be guaranteed. These containment measures may include, for example, that flower heads should be removed, or that a double isolation distance should be used.

The second category consists of work with genetically modified plants for which more characterisation data are available and about which more knowledge has been gathered on the basis of previous experiments. Category two is an amalgamation of the old classes three and four. In this phase, often still several, GM plants are tested in the field for the development of a new variety, so that it is not yet a case of large scale experiments with a single transformant. Data on the characterisation are requested and reviewed after which a better judgement can be made on the possible environmental effects of the GMO. The maximum number of sites is no longer limited, but the maximum surface area is set at ten hectares. These are activities without containment measures.

For a category two experiment to be carried out, data from a category one experiment, data from the literature or results of experiments abroad on the same or similar GMOs are needed. Such data must be able to demonstrate that the harmful effects on humans and the environment arising from the GMO itself, or after crossing over, are negligibly small. For this reason, containment measures are not necessary. When the risk analysis shows that there are uncertainties and that there is therefore a need for containment measures, classification of the experiment in category two is not allowed. In that case, the experiment has to take place in category one.
In category two, additional data are collected about the GMO itself and the GMO in interaction with the environment. These may, among other things, be data regarding the effects on non-target organisms. These data are, in addition to the already

available data, essential to assess whether a field experiment can take place in category three.
It should be noted that the aforementioned area size of ten hectares is a guideline and that, if necessary, deviation from this size may be possible. A possible deviation must be supported by the environmental risk analysis.

The third category includes large-scale non-commercial activities with genetically modified plants. Category three is equivalent to the old class five. At this stage of the development of a new race, the applicant has often reduced the number of transformed plants to one or a few, which are then tested on a large scale in the field. The transformants are molecularly fully characterised in accordance with a marketing consent, and harmful environmental effects have not been demonstrated in a category two experiment or a similar experiment abroad.
The work is not limited in advance with respect to the number of locations and the surface area. In addition, no containment measures are required. In this category, data can be collected during several seasons on possible unforeseen environmental impacts on a large scale, which are necessary for market approval. Should any foreseeable uncertainties about harmful effects on humans and the environment exist, then the experiment cannot take place in this category.

The COGEM is of the opinion that a classification of field experiments with genetically modified plants into three categories is an improvement, because the new classification is simpler and COGEM expects it will prove to be easier to implement in practice. The COGEM is of the opinion that the safety of people and the environment will continue to be safeguarded with this new classification system.

References

(1) CGM/990518-41, COGEM guidelines for the assessment of field trial applications.
(2) Directive 2001/18/EC of the European Parliament and the Council of March 12, 2001, on the deliberate release of genetically modified organisms into the environment and repealing Council Directive 90/220/EEC.
(3) CGM/021017-06, Standing agriculture and traditional breeding as a frame of reference.