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Review article

Field trials and tribulations—making sense of the regulations for experimental field trials of transgenic crops in Europe

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Summary

Transgenic plants that are being developed for commercial cultivation must be tested under field conditions to monitor their effects on surrounding wildlife and conventional crops. Developers also use this opportunity to evaluate the performance of transgenic crops in a typical environment, although this is a matter of commercial necessity rather than regulatory compliance. Most countries have adapted existing regulations or developed new ones to deal specifically with transgenic crops and their commodities. The European Union (EU) is renowned, or perhaps notorious, for having the broadest and most stringent regulations governing such field trials in the world. This reflects its nominal adherence to the precautionary approach, which assumes all transgenic crops carry an inherent risk. Therefore, field trials in the EU need to demonstrate that the risk associated with deploying a transgenic crop has been reduced to the level where it is regarded as acceptable within the narrowly defined limits of the regulations developed and enforced (albeit inconsistently) by national and regional governments, that is, that there is no greater risk than growing an equivalent conventional crop. The involvement of national and regional competent authorities in the decision-making process can add multiple layers of bureaucracy to an already-intricate process. In this review, we use country-based case studies to show how the EU, national and regional regulations are implemented, and we propose strategies that could increase the efficiency of regulation without burdening developers with further unnecessary bureaucracy.

Keywords: genetically modified organism regulations, experimental field trials, transgenic crops.

Introduction

In the early 1990s, the European Union (EU) introduced two Directives relating to the use of genetically engineered organisms (genetically modified organisms; GMOs). Ostensibly, these aimed to protect human and animal health and the environment, to guarantee consumers' freedom of choice and to create an internal market allowing the free movement of GMOs within the EU, thus avoiding unequal competition and trade impediments between and within member states. Directive 90/219/EEC, which was amended by Directive 98/81/EC and more recently replaced by Directive 2009/41/EC, covers the use of genetically engineered microorganisms in containment (many member states have broadened this to include all GMOs when implementing the legislation), whereas Directive 90/220/EEC pertained to the so-called deliberate release of GMOs into the environment, covering both research (Part B) and commercial use (Part C).

In October 2002, Directive 90/220/EEC was superseded by Directive 2001/18/EC, which also contains a Part B relating to experimental field trials and a Part C relating to commercial release (European Commission, 2001). This Directive remains in force, and to obtain an authorization for experimental release within the EU, the developer must submit an application containing the particulars required by Part B to the appropriate authority. Although this review focuses on the procedures for experimental field trial authorization in the EU, it should be noted that Directives were developed to cover the entire life cycle of a GMO product, including laboratory experiments in containment (2009/41/EC), then experimental releases (2001/18/EC) and finally commercial deployment (2001/18/EC, 1829/2003/EC covering genetically modified (GM) food and feed, and 1830/2003/EC covering traceability and labelling) (Plan and Van den Eede, 2010).

The current directive has a strict definition of 'deliberate release', which is '…any intentional introduction of GMOs into

the environment without specific containment measures to limit their contact with, and to provide a high level of safety for, the general population and the environment..'. The Directive explicitly adopts the precautionary approach as the basis for field release. Furthermore, a common methodology for environmental risk assessment has been established and risk assessment criteria have been broadened to include direct, indirect, immediate, delayed and cumulative long-term 'adverse effects' (Devos *et al.*, 2012). The following aspects were also introduced into the new 2001/18/EC Directive:

- Post-market environmental monitoring (PMEM) was made compulsory. Note that under Article 6 of the Directive, all field trial materials must be destroyed, usually by incineration or burying, once the trial is complete. This even applies to field trials of transgenic events that are already approved for import.
- Re-examination of risk assessment and management conclusions in the light of new scientific evidence was strengthened by limiting the duration of market consent to a maximum of 10 years.
- Specific considerations relating to the use of antibiotic resistance marker genes were introduced.
- Existing labelling provisions applying to food containing ingredients from GMOs were extended to all marketed products.
- The general concept of traceability at all stages of commercialization was introduced.
- Transparency in the decision-making process was increased by making it open to public scrutiny.
- Public consultation became mandatory in the approval procedure.
- The opportunity to consult an ethics committee was introduced.
- A requirement was added for the implementation of national cultivation registers to record the locations of experimental field trials of transgenic plants.

Authorization of experimental field trials—the role of the European Union

Authorization for the field cultivation ('deliberate release' in EU terminology) of a transgenic crop for research purposes begins when the applicant (known as the notifier) submits the particulars required in Part B of Directive 2001/18/EC (known as the notification). These particulars must include an environmental risk assessment carried out by the notifier. Although the regulations cover the EU as a whole, the notification must be submitted to one competent national authority, and the power to approve or reject the application rests solely with this authority, in some cases with additional input from regional authorities, technical advisory bodies (such as the Spanish National Commission for Biosafety), other member states and the European Commission (Hugo *et al.*, 2008). According to Article 6.5 of Directive 2001/18/EC, the national and regional authorities must respond to the notification within 90 days. The national and regional authorities also have the power to impose conditions under which the field trial may go ahead (Plan and Van den Eede, 2010). Therefore, the authorization of experimental releases differs considerably from the process undertaken to authorize commercial releases under Directive 2001/18/EC Part C, as the latter is authorized at the Community level and involves an initial evaluation by the European Food Safety Authority (EFSA) followed by a vote by the EU Standing Committee on the Food Chain and Animal Health (the Standing Committee). If there is no qualifying majority, which is invariably the case, a further vote must be taken by the Council of Ministers (Lee, 2008) (Box 1). Directive 2001/18/EC requires an initial risk evaluation by the member state where submission has been placed, but because objections from other member states are almost guaranteed, EFSA often carries out the evaluation again. Therefore, most applicants now use Regulation 1829/2003/EC (GM food and feed). Information about all experimental releases authorized by the EU member states is available to the public and can be accessed at the following URL: http://gmoinfo.jrc.ec.europa.eu/.

Authorization of experimental field trials—the role of national and regional governments

A decision taken at the Community level by the Standing Committee and (if necessary) the Council of Ministers is considered final, but in all but one case thus far, the Standing Committee and the Council of Ministers have failed to reach a qualified majority, leaving it for the European Commission itself to take the final decision. Even so, individual member states often flout this procedure and *illegally* ban the deployment of approved commercial transgenic crops by misapplying the 'safeguard clause' that allows member states to opt out if they provide compelling new scientific information that offers evidence of risk to health or the environment (Sabalza *et al.*, 2011). This, in turn, can lead to arbitrary and scientifically baseless coexistence legislation that has a de facto chilling effect on GM agriculture (Ramessar *et al.*, 2010). On 5 July 2011, the European Parliament approved a legislative proposal that eventually could allow member states to impede, restrict or ban the commercial cultivation of transgenic crops *legally* within their borders (European Parliament, 2011). The proposal has the ostensible aim of preventing tactical voting by committee members to achieve EU-wide bans (Casassus, 2011). This was the first reading of the proposal, and the European Parliament, the European Commission and the European Council of Ministers need to build a consensus before it becomes law (or returns to the European Parliament for a second reading). We and others have argued that the legislation will have the opposite effect to its intended purpose, that is, it will allow member states to introduce arbitrary bans that effectively prevent transgenic crops from being grown over large areas of the EU (Morris and Spillane, 2010; Sabalza *et al.*, 2011). The prior approach of certain member states in the decision-making process for experimental releases bears this out, because the legislation in many countries contains stipulations that, although not directly preventing applications, certainly make effective field trials very difficult, if not impossible, to carry out. We consider Spain as a key example because this country has approved the highest number of experimental field trials since Directive 2001/18/EC was introduced, and we also discuss Germany, the UK and Belgium as case studies. The status of summary notifications (SNIFs) for experimental field trials across all EU member states is summarized in Table 1.

Field trials in Spain—national and regional authorities

Spain is divided into 17 Autonomous Communities and two Autonomous Cities that have the authority to establish their own regulations. Directive 2001/18/EC Part B is implemented through the Spanish national competent authority covering the

Box 1. Transition from field trials to commercialization in Spain

Following successful experimental field trials, authorization for the commercial cultivation of transgenic crops in Europe requires notification under Directive 2001/18/EC Part C or approval according to EC GM food and feed Regulation No 1829/2003. Notifiers must submit all the necessary documents in one member state, which submits the notification to EFSA in order to start the process (GMO Compass, 2011; MARM, 2011b). The data requirements for market approvals as well as requirements for the design (e.g. choice of comparator, receiving environment(s), and general statistical principles) of field trials are laid down in the EFSA Guidelines on the environmental risk assessment of transgenic plants (EFSA, 2010). If EFSA approves the application, its commercial authorization goes to a Standing Committee vote. If the vote is in favour, the application is approved throughout the EU. Approval by EFSA followed by either rejection by the Standing Committee or no qualified majority would result in the application being reviewed by the EC Council of Ministers. Here, a rejection would effectively kill the application because it would be returned to the Standing Committee for revision, which would likely involve further involvement from EFSA and a return to the early part of the application pathway. Either approval or no qualified majority in the Council of Ministers would result in the application being approved throughout the EU. In the future, this process could be subverted because member states might be allowed a veto to ban the cultivation of transgenic crops without scientific justification (Casassus, 2011). In Spain, only three notifications have been submitted under Directive 2001/18/EC Part C and all three applications are at very early stages of the process (Table B1), reflecting the unpredictable nature of approvals as discussed in the main text.

Table B1 Applications submitted to the Spanish National Competent Authorities for the commercial cultivation of a transgenic crop under Part C of Directive 2001/18/EC, from 1993 to 2010. Source: MARM, 2011b; genetically modified organism (GMO) Compass 2011

Notification	Crop	Notifier	Event	Trait	Date of submitted application	Status
C/ES/96/02	Cotton	Monsanto	MON531	Insect resistance (lepidopteran)	1996 (updated in 2003) Cultivation application discontinued in 2006	Positive opinion by the former Scientific Committee on Plants (http://ec.europa.eu/food/fs/sc/scp/out18_en.html)
C/ES/97/01	Cotton	Monsanto	MON1445	Herbicide tolerance (glyphosate)	1997 (updated in 2003) Cultivation application discontinued in 2006	Positive opinion by the Scientific Committee on Plants (http://ec.europa.eu/food/fs/sc/scp/out17_en.html)
C/ES/01/01	Corn	Dow AgroSciences Mycogen Seeds Pioneer Hi-Bred	1507	Insect resistance (lepidopteran) and herbicide tolerance (glufosinate-ammonium)	2001	No qualified majority (25/02/2009) in a Standing Committee vote

The only transgenic crop currently authorized for commercial cultivation and grown in Spain is the MON810 corn event, and Spain is the biggest grower of this crop in the EU (James, 2010). The Spanish Register of Commercial Varieties lists a total of 282 corn varieties, 110 of which are the MON810 event (MARM, 2011a). Farmers in Spain have adopted this variety because of the significant crop losses caused by the corn borer, against which the MON810 event provides resistance. The corn borer is a particular problem in the Autonomous Communities of Aragon and Catalonia, where these transgenic corn varieties are widely cultivated (Gómez-Barbero *et al.*, 2008).

The regional authorities in the Spanish Autonomous Communities of Asturias, País Vasco, Baleares, Canarias and Galicia have elected to become GMO-free territories. In other Autonomous Communities in Spain, specific cities, towns or locales have declared themselves GMO-free, although this currently has no legal basis and contravenes Directive 2001/18/EC. A list of all EU regions that have self-declared themselves as GMO-free is provided at the following URL: http://www.gmo-free-regions.org/.

entire territory of Spain, but the national regulations can be varied at the regional level through the establishment of additional regional competent authorities. The Directive was originally enacted through Spanish laws Ley 15/1994 and Real Decreto (RD) 951/1997, which have been superseded by Ley 9/2003 and RD 178/2004. These laws also establish a national consultative authority responsible for risk assessment and a common National Register for GMOs. In addition to the competent and consultative authorities, Article 19 of RD 367/2010 establishes a Participation Committee comprising stakeholders representing consumers, farmer organizations, syndicates, the pharmaceutical and agro-food industries and non-governmental organizations. This committee has no decision-making power but can present opinions to the national competent authority (Orden ARM/2616/2010). The different competent and consultative authorities in Spain, the registers and the transfer of information among them are summarized in Figure 1.

The national competent authority in Spain is the Interministerial Council of Genetically Modified Organisms (CIOMG, 2010a), which comprises representative members of different ministries from the Spanish National Administration and other members from the Spanish Agency of Food Safety and the Spanish Medicine Agency. At the regional level, 11 of the 19 regional governments have established their own competent authorities,

Table 1 List of summary notifications (SNIFs) circulated under Article 9 of Directive 90/220/EEC and Article 11 of Directive 2001/18/EC from 21 October 1991 to 30 August 2011 compared to permits and notifications in the United States over the same period (source: European Union Joint Research Centre, http://gmoinfo.jrc.ec.europa.eu/). Note that SNIFs do not correspond to approved field trial applications nor completed field trials, so the numbers shown in this table are generally higher than the actual number of field trials performed, although SNIFs can also represent multi-year field trials in which case the number of field trials (recorded as those in progress in each year) may also exceed the number of SNIFs

Country/Year	91	92	93	94	95	96	97	98	99	00	01	02	03	04	05	06	07	08	09	10	11	Total
Austria						2	1															3
Belgium		26	16	17	11	7	7	6	8	16	5	8	1	2			1	2		2		135
Czech Republic															2	6	3	2	5	3	2	23
Denmark		5	1	5	4	5	10	4	5	1					1	2	5	2	4		2	56
Finland					1	3	6	3	3	3	1		1	1					1			23
France		1	35	57	69	91	72	70	64	34	17	3	17	11	14	32	2		1			590
Germany		3	1	8	12	17	20	18	23	7	8	7	9	10	7	11	12	5	3	3	1	183
Greece						1	5	7	6													19
Hungary															10	9	7	3	2			31
Iceland														1					1			2
Ireland							2	2				1				1						6
Italy			5	19	43	50	46	43	51	18	5	9	2	4								295
Lithuania																1	1					2
Netherlands	4	15	9	25	16	10	14	19	5		19	4	4	7	7	9	5	6	1	1	1	181
Norway									1													1
Poland														1	2	3	1	3	2	2	1	15
Portugal			2	2	1		3	3	1						4	5	2	2	1	1		27
Romania																	14	9	21	7	5	56
Slovak Republic																1		4	3	4	2	14
Spain			3	10	11	16	44	39	39	19	19	17	40	20	26	51	36	46	58	49	25	569
Sweden					8	10	9	8	19	6	2	2	1	14	4	6	5	5	6	1	4	110
UK		16	17	23	37	27	25	22	13	25	12	5	8	1		2	1	1	1	1	1	238
Total EU	4	66	89	166	213	239	264	244	238	129	88	56	82	72	78	139	95	90	110	75	44	2581
Total United States	90	160	301	579	711	612	763	1071	983	925	1083	1194	813	893	954	864	924	877	754	663	631	15 845

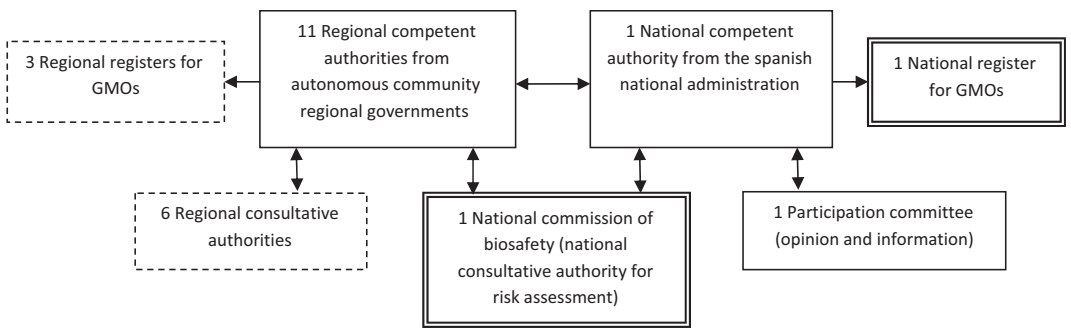

Figure 1 Authorities and registers in Spain covering field trials for transgenic crops, based on Ley 9/2003 and RD 178/2004. In Spain, there are 11 Regional Competent Authorities that make decisions regarding field trials in their Autonomous Community and some have also established their own Consultative Regional Authority and Register for genetically modified organisms (GMOs). There is also a National Competent Authority that is responsible for the National Register of GMOs, containing information from all the field trials in Spain. The Participation Committee reports to the National Competent Authority and provides opinions about notifications submitted to the National Competent Authority although these are not binding. The National Commission of Biosafety (the National Consultative Authority) is responsible for environmental risk assessments for all notifications submitted to regional and national competent authorities. Arrows show information exchange between authorities and registers. Boxes with broken outlines represent bodies that are optional and exist in some but not all Autonomous Communities. Boxes with double outlines represent bodies that are mandatory in all Autonomous Communities.

which share responsibility for the authorization of field trials with CIOMG (see Table S1). Notifiers submit their applications to the CIOMG and/or to the appropriate regional authority, if one exists in the notifier's locale (Figure 2). CIOMG can authorize field trials where the aim is to test a new crop variety for future commercialization, or if the notifier is funded by the Spanish National Administration, or if the GMO (or one or more of its components) is intended for medical or veterinary use,

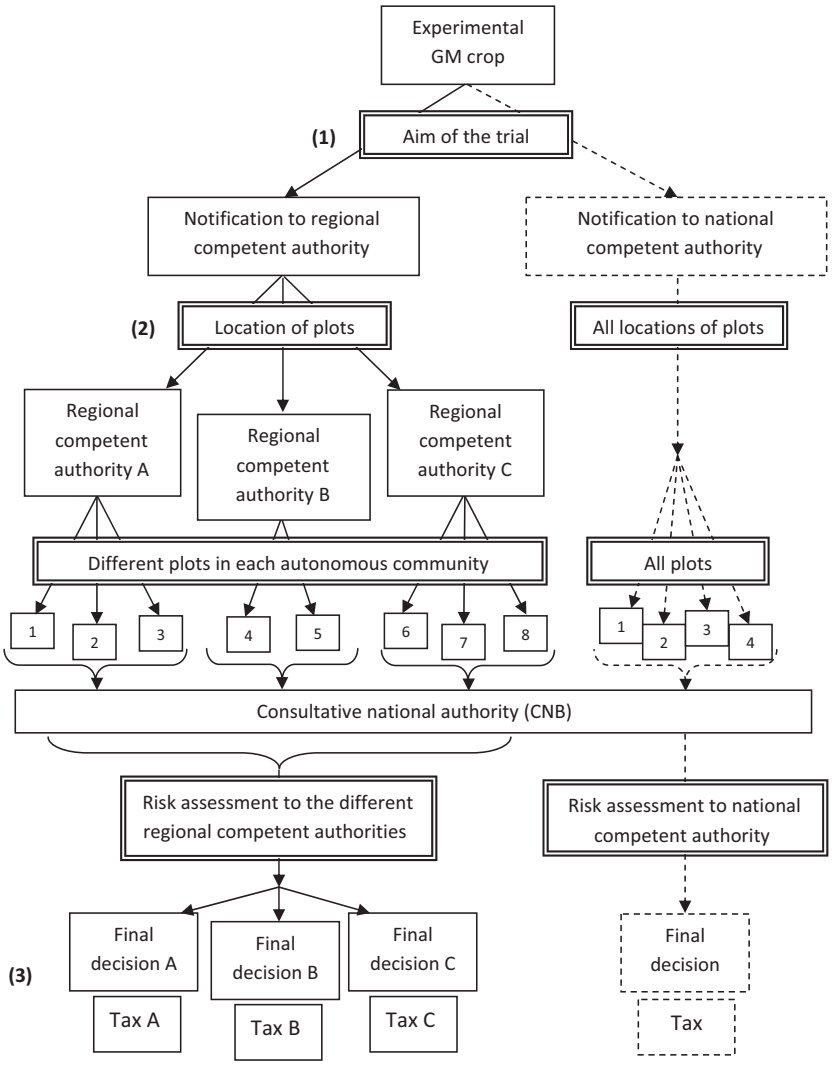

Figure 2 Schematic representation of the process for authorizing an experimental field trial in Spain (based on Ley 9/2003 and Real Decreto (RD) 178/2004) and situations where the same transgenic crop requires several authorizations from different competent authorities. (1) When different experiments (with different objectives) are planned using the same transgenic crop, different notifications must be submitted to the appropriate regional and national competent authorities. (2) A notification must be submitted to several Regional Competent Authorities when field plots in different Autonomous Communities are requested in a single notification. (3) An independent authorization is required from each competent authority, and several taxes (A, B, and C) must be paid independently to each Regional Competent Authority for the same notification.

but it will also take into account opinions offered by a regional competent authority if the field trial will take place in an area covered by that body. Regional competent authorities can authorize field trials in cases outside the remit of the CIOMG when the trial will take place within their territory, for example when the aim of the notification is 'evaluation and optimization of weed management programmes' or 'to obtain complementary data on the agronomic behaviour of the crop and take samples to analyse the composition of the plants and the expression of the transgenes during the life cycle of the crop under field conditions'.

Although this multilevel system is complex, it is simplified by the existence of a single national consultative authority known as the National Commission of Biosafety (CNB), which is responsible for evaluating all Part B notifications received by any competent authority and performing environmental and health risk assessments prior to the final decision. The CNB includes representatives from different ministries of the Spanish National Administration, representatives of national agencies such as the Spanish Agency of Food Safety and the Spanish Medicine Agency, representatives from all the Autonomous Communities, and a panel of up to six experts from different scientific institutions. The body is responsible for public consultation about all field trial notifications in Spain that fall under the remit of CIOMG and has 30 days from the submission of a notification to consider public opinion on the risk assessment. Although CNB consultation is mandatory, its decisions are non-binding and can be overruled by regional competent authorities, especially those with their own regional consultative authorities. Some notifications are therefore assessed twice (MARM, 2011b).

Field trials in Spain—the notification process

Once a notification has been submitted to the appropriate competent authority or authorities, the documents are sent to the CNB, which provides an environmental risk assessment for the field trial. The risk assessment report is sent back to the compe-

tent authority, which then makes a final decision whether to authorize or refuse the trial. Additional environmental risk assessments or consultations may be carried out by regional consultative authorities.

The risk assessment looks at whether mitigation methods have been established in the field trial to avoid potential risks to the environment or human and animal health (e.g. cross-pollination with conventional crops or seed dissemination leading to experimental transgenic plants known as 'volunteers' growing outside the confines of the trial plot). The most common measures used to minimize outcrossing and volunteers are the implementation of minimum isolation distances and the planting of border rows of conventional crops surrounding the experimental field plot to absorb pollen, but such strategies are not prescribed. The notifier must suggest the most appropriate mitigation strategy for the field trial. This may vary according to the crop, the transformation event and the location, although there are currently no specific regulations covering experimental field trials in sensitive environmental areas in Spain (CNB, 2008, 2010). For example, the isolation distance recommended for transgenic corn is 200 m from a conventional corn crop with a minimum of four border rows of conventional corn used as a pollen trap. However, there is no minimum isolation distance for sugar beet (which is harvested in the first year without pollen production) although harvesting by hand is recommended to avoid root dissemination. The competent authority can accept the risk mitigation strategy suggested by the notifier or it can reject the application. It can also insist on stricter risk management and impose extra (and sometimes arbitrary) conditions on the trial.

The EU Commission strongly recommends that antibiotic resistance genes are phased out (Devos *et al.*, 2012), and it should also be noted that Directive 2001/18/EC requires member states and the Commission to ensure that GMOs containing genes providing resistance to antibiotics used for medical or veterinary treatment are taken into special consideration when carrying out environmental risk assessments. Therefore, this is another key aspect considered by the CNB for the assessment of field trial applications in Spain. EFSA has published two guidelines containing its scientific opinion on the use of antibiotic resistance markers in transgenic plants and considers marker genes assigned to groups I and II suitable for field trials (EFSA, 2004, 2009). However, EFSA opinions are not binding to member state competent authorities, and each national and regional authority makes its decision on a case-by-case basis. Furthermore, it is clear that the European Commission now strongly recommends the phasing out of antibiotic resistance marker genes despite overwhelming scientific evidence opposing the Commission's position (Ramessar *et al.*, 2007, 2010).

Despite the complexity of the Spanish notification system, Spain has one of the highest application rates for field trials in the EU (JRC, 2004). Table 2 shows the crops that have been notified in Spain from 1993 to 2010 and the total number of notifications per crop, with corn leading the field at 303 followed by cotton and sugar beet with 65 and 36 applications, respectively. Additional data showing the number of notifications submitted to different competent authorities in Spain, the different crop species and the total surface area that had been requested per year are provided in Table S2. The number of notifications submitted for field trials increased from three in 1993 to 49 in 2010, after peaking in 2009 at 61 trials covering an area of 212.96 hectares (including multiple field trials at the same site). Aragón (Aragon), Catalunya (Catalonia) and Castilla-La Mancha (Castile-La Mancha) had the largest number of authorized notifications (more than 100 in the last 5 years, predominantly corn) but field trials were authorized in 12 of Spain's 19 Autonomous Regions. These data are summarized in Table S3. No negative environmental effects have been reported in any of these trials.

Table 2 Transgenic crop species notified for experimental field trials in Spain (1993 to 2010) and total number of summary notifications (SNIFs) for each crop. The number of SNIFs is higher than the actual number of field trials approved and carried out. Sources: MARM, 2011b; JRC, 2004

Crop	Number of notifications 1993–2010
Alfalfa	1
Cantaloupe	1
Carrizo citrange	3
Corn	303
Cotton	65
Eucalyptus	1
Melon	5
Plum	3
Poplar	1
Potato	24
Rapeseed	2
Rice	26
Soybean	7
Squash	2
Strawberry	2
Sugar beet	36
Sunflower	3
Sweet Orange	4
Tobacco	6
Tomato	15
Wheat	10
Total (21 crops)	520

Field trials in Spain—unintentional consequences

If CIOMG and one or more regional authorities are involved in a field trial notification, then different and contradictory risk management measures can be imposed by each authority (MARM, 2011b). One example of such conflicting recommendations for a field trial involving transgenic corn is shown in Table S4. The overlapping roles of multiple competent authorities in Spain have in some cases resulted in farcical situations where several authorizations and notifications are required for the same experimental crop submitted by the notifier in the same year, and where the same crop was to be trialled in different locations. The notifier usually submits simultaneous notifications to the CIOMG (for technical tests to register new crop varieties for future commercialization in the Spanish Register) and to the regional competent authorities (to study other characteristics, such as herbicide tolerance). The CIOMG is competent to make a decision on the notification regardless of the field trial location, after receiving a risk assessment from the CNB (Figure 2). However, separate notifications must be presented to regional competent authorities based on the location of the trials, and independent authorization from each regional

competent authority is required, hence the possibility of final authorizations containing different risk management measures for different plots under the same notification. In other cases, the same notification can be approved by one region but rejected by another, for example B/ES/07/21, B/ES/07/22 and B/ES/07/23, which were authorized by the regional competent authorities of Castile-La Mancha, Catalonia, Madrid and Navarra but refused by Aragon (MARM, 2011b).

Experimental field trials in Spain have been destroyed by activists, but commercial transgenic crops have largely escaped vandalism (only a small number of cases have been reported despite the many hectares of Bt corn grown in Spain). This almost certainly reflects the absence of a national register for commercially released transgenic crops in Spain, which makes the fields harder to identify. In contrast, the compulsory national register of experimental field trials presents an easy target for activists. An experimental corn field trial was destroyed by activists in Catalonia in 2003 in what was described as a 'symbolic and peaceful' protest, but there were no prosecutions. A wheat field trial in Catalonia was targeted in 2004, along with a field of conventional durum wheat that was apparently misidentified. In this case, the alleged perpetrators were prosecuted but the charges were dropped because of lack of evidence in court. More recently, Friends of the Earth published the locations of all Spanish field trials planned for 2010, again leading to the destruction of commercial corn crops in Catalonia owing to misidentification. These events are discussed in more detail in Box 2.

Box 2. Should field trial sites be kept confidential?

The number of experimental GM field trials in the EU is declining, and the total number carried out to date is five times lower than the number completed in North America over the same period, where the location of field trial sites does not need to be made public. The American approach cuts off the oxygen of publicity that activists require by preventing dramatic and newsworthy destructive gestures at field trial sites. The damage caused by activists in the EU goes far beyond the physical damage to experimental crops and actually contributes to the negative publicity, biased media coverage and unfavourable political environment as shown in the following case study.

In France in 2004, an application was submitted by Mr. Pierre Azelvandre to the Mayor of the Commune of Sausheim for information about the location of field trials authorized in the commune. The Mayor disclosed the public notices relating to field trials carried out within the commune but, based on a decision of the Committee on Access to Administrative Documents (CAAD), refused to disclose the specific planting records for the parcels of land, on the grounds that that disclosure would prejudice the privacy and safety of the farmers concerned. Mr. Azelvandre took the case before the Strasbourg Administrative Court which annulled the implicit decision of CAAD. Finally, the dispute arrived at the French State Council (Conseil d'État) which referred the following questions (reproduced verbatim) to the Court of Justice of the European Union in Luxemburg for a preliminary ruling (Conseil d'État, 2008):

1. Must 'the location where the release' of genetically modified organisms 'will be carried out may not be kept confidential' mean the registered parcel of land or a large geographical area corresponding either to the commune in which the release occurs or to an even greater area such as a cantor or department?
2. If the location is to be understood as requiring designation of the registered parcel of land, can an exception relating to the protection of public order, or other confidential matters protected by law, preclude the disclosure of the registered reference number or numbers of the location of the release?

In response to these questions, a Judgment of the Court on 7 February 2009 (Conseil d'État, 2009) concluded the following:
1. The 'location of release', within the meaning of the first indent of Article 25(4) of Directive 2001/18/EC, is determined by all the information relating to the location of the release submitted by the notifier to the competent authorities of the member state on whose territory that release is to take place in the context of the procedures referred to in Articles 6, 7, 8, 13, 17, 20 or 23 of that directive.
2. An exception relating to the protection of public order or other interests protected by law cannot be relied on against the disclosure of the information set out in Article 25(4) of Directive 2001/18/EC.

A ruling of the Court of Justice applies throughout the EU, so in response to this judgment other member states moved to adapt their national regulations. In Spain, field trial locations are listed in the Spanish National Register for GMOs (CIOMG, 2010a) and the public information about notifications on the CNB (MARM, 2011b) but this does not include the specific registered parcel of land (defined by an exact grid reference). The Judgment of the Court of Justice specified that all data should be made public although it was not specified whether this information should be included in the National Registers. In order to clarify the interpretation of the Judgment, the CIOMG consulted with the Spanish National Legal Services (CIOMG, 2009), which stated that any individual or legal entity requesting the information must have access to it with no restrictions. The CIOMG therefore agreed to provide information regarding the 'location of release' to anyone requesting it, including the registered parcel of land (CIOMG, 2010b).

Friends of the Earth subsequently applied for the location of field trials authorized in Spain, citing the above judgment, and published the entire list on their website on 5 May 2010, including the exact locations of all the registered parcels of land complete with directions and links to Google Maps. The next month, a campsite was established in the Girona province of Catalonia by a French anti-GM protest group, and on 12 May two corn fields in Girona were destroyed. Later, the destruction of 'field trial sites' in Girona was celebrated by anonymous posters on the Internet. However, there was no field trial in that location. The notifier had withdrawn the application (information that was not sought by Friends of the Earth) and the activists destroyed two valuable conventional corn crops owned by an innocent farmer. No individual or organization stepped forward to claim responsibility for this act of vandalism and no one was prosecuted by the Spanish authorities.

Field trials in Germany—national authority, application procedure and consequences

Unlike the situation in Spain, all applications under Directive 2001/18/EC Part B in Germany are handled by the national competent authority (The Federal Office of Consumer Protection and Food Safety, BVL), which implements the Directive under the Gene Technology Act (*Gentechnikgesetz*) (Gerdung, 2006). This came into force in 1992 concomitant with the first German experimental field trials of transgenic petunia plants produced by researchers at the Max-Planck Institute in Köln (Cologne). At the time of writing, there have been 214 applications for field trials in Germany, 188 of which have been granted with seven pending, and 49 were approved using a simplified procedure, where familiarity has been gained for a particular transgenic event through repeated experimental releases. The first field trial in 1992 attracted considerable media interest, and this has been sustained by the frequent protests and demonstrations that have become progressively more violent, often involving site occupations and the destruction of crops. More than 100 field trials have been destroyed in Germany to date (Figure 3).

The Gene Technology Act has undergone three major revisions reflecting parallel changes in the EC Directives and also additional stringent requirements implemented in Germany on a national level. The first major change was the 2004 First Act Reforming the Law on Genetic Engineering, which introduced a liability provision in case of damage caused by GMOs (based on existing provisions in the Environmental Liability Directive, 2004/35/EC). This made farmers responsible for any damage caused by GMOs, including a provision that farmers planting transgenic crops were collectively responsible for environmental damage should it be impossible to identify an individual culprit. After the second procedural amendment was blocked, the Third Gene Technology Reform Act came into force in Germany in 2005. This introduced a requirement that all sites used for the field testing of transgenic plants must be recorded precisely in a public GMO Location Register.

Whereas the stated intention of these amendments was to improve transparency and accountability, there was considerable influence from environmental pressure groups and it is clear that both amendments erect obstacles to the effective field testing of transgenic crops. The second amendment specifically affects commercial crops by introducing a financial disincentive for farmers, whereas the third provides a means for activists to locate and destroy field trial sites (Box 2). As shown in Figure 3, the number of vandalized and destroyed sites rose dramatically once the third amendment came into effect, peaking at 25 sites in 2008. The number has fallen in subsequent years but not because activists are becoming less destructive or because field sites are better protected. The drop-off instead reflects the fact that the overall number of field trials in Germany has declined as companies and individual scientists move GM research out of Europe because of the slow and unpredictable authorization process, and to reduce their risk of financial loss when authorized trials are destroyed (Bullion, 2011; Table 3). However, two more cases of field trial vandalism in Germany were reported in July 2011, involving genetically engineered potato and wheat plots, showing that activism is still a pressing issue (BMBF, 2011). Such losses vary according to the nature of the crop and the scope of the trials. The destruction of a single test crop would cost a developer somewhere in the region of €20 000 ($28 000) but these costs can rise sharply if the crops are grown as part of a trial series taking several years. For example, activists destroyed a plot of transgenic apple trees in 2008, which was part of a multiple trial programme carried out by the Julius Kühn Institute, resulting in financial losses of approximately €700 000 ($980 000).

Activists do not even need to destroy crops to achieve the disruption of field trials. They can simply occupy the fields used by research institutes forcing the research to be abandoned or relocated. The most notorious German case involved the transgenic corn field trials carried out by Nürtingen-Geislingen University, which were routinely and persistently disrupted by activists occupying intended trial sites. After a prolonged field occupation in 2008, the university bowed to pressure and called a halt to field trials involving transgenic plants for 5 years (Miller, 2008). There is ongoing debate in Germany regarding the balance between the public's right to protest and the rights of scientists to carry out their research without impediment. In turn, researchers have appealed for the benefits of their research to be emphasized more strongly to avoid the climate of fear that underlies much anti-GM activism (Mönch, 2009).

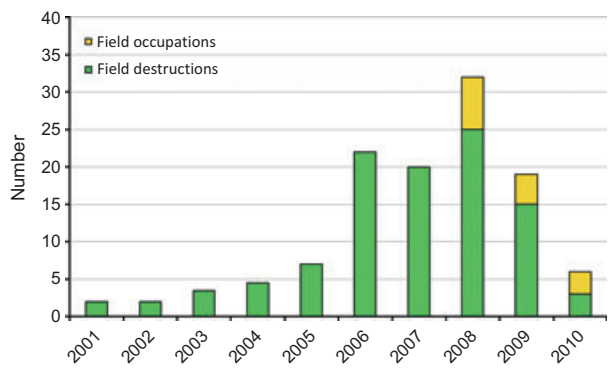

Figure 3 Occupations and destructions of experimental field trial plots of transgenic crops in Germany. Source: Federal Office of Consumer Protection and Food Safety (BDP).

Table 3 Approved experimental field trials of transgenic crops in Germany

	2007		2008		2009		2010	
Crop	Trait	Trial	Trait	Trial	Trait	Trial	Trait	Trial
Potato	14	36	6	14	6	13	5	13
Corn	7	37	5	18	8	17	6	7
Nightshade	2	2						
Rapeseed	1	1						
Petunia					1	1	1	1
Pea	1	1						
Soybean	1	1						
Sugar beet			1	6	1	2	1	2
Barley	1	1			1	1		
Wheat	1	1	1	1	1	2	1	2
Total	28	80	13	39	18	36	14	25

Source: German Plant Breeders Association (BVL) and the Federal Office of Consumer Protection and Food Safety (BDP).

Field trials in the UK—national authority, application procedure and consequences

Within the UK, England, Scotland, Northern Ireland and Wales have national laws that control the deliberate release of GMOs into the environment. In England, the Department of Environment, Food and Rural Affairs (Defra) is the competent national authority responsible for field trial approval of GM plants. All applications submitted to Defra are passed on to the statutory Advisory Committee on Releases to the Environment (ACRE) that was appointed under section 124 of the UK Environmental Protection Act 1990 (EPA) to provide advice to government regarding the release and marketing of GMOs. The committee works within the legislative framework set out by 'Part VI of the EPA', and within England, the GMO Deliberate Release Regulations 2002 Act, which together implement EU Directive 2001/18/EC. The principal role of ACRE is to consider each application on a case-by-case basis and evaluate the risks to human health and the environment. ACRE advises the UK Government and devolved administrations in Scotland, Wales and Northern Ireland. In England, ACRE returns advice to the Secretary of State for Environment Food and Rural Affairs, whereas in Scotland and Wales, they advise the Scottish Ministers and the Welsh Assembly Secretaries, and in Northern Ireland the Department of the Environment (http://www.defra.gov.uk/acre/).

The information required from researchers proposing an experimental release and the regulatory process for approval are directly comparable throughout the UK (Ball and Bainbridge, 2011). This must include details about the host plant, the introduced trait, the purpose of the release and details of the exact location and size of the trial, environmental impact assessments and details of the risk management strategies.

Under Regulation 20(b) of the GMO Deliberate Release 2002 Act, the Defra Secretary of State is required, on receipt of an application, to invite the public and others to make representations concerning potential risks to the environment from the proposed release. The notifier must advertise the release in a national newspaper within 10 days, and the SNIF must be posted onto the publicly accessible JRC website (http://gmoinfo.jrc.ec.europa.eu/) within 30 days (this is the responsibility of the national competent authority). Both must contain a four-figure grid reference for the trial site, but once the trial is approved, a six-figure grid reference must be made publically available prior to planting. The entire process from application to decision should take 90 days if no additional information is requested from the notifier. The legislation is designed to promote transparency: the application, consent and scientific advice provided by ACRE are published and made available to the public.

Under the EPA, Defra is required to 'recover its costs' associated with handling applications, which currently amount to £5000 ($8000) per application for a GMO field trial. Once approved, field trials are monitored by Defra's GM inspectorate annually at a cost of £850 ($1360) per inspection (Ball and Bainbridge, 2011). These costs are reasonable in comparison with the cost of generating and characterizing transgenic plants and testing them in containment, so why have so few GMO field trials been carried out in the UK?

The UK was among the first EU countries to conduct GM field trials, but unlike Spain the number of field releases in the UK has been declining since the turn of the millennium and most of the 229 trials approved thus far were carried out before 2000 (Table 1). The crops that have been trialed most extensively are rapeseed (106), sugar beet (43), potato (40), wheat (12) and corn (7). The decline in field trials coincided with the EU's *de facto* moratorium on GM food crops from 1998 to 2004, together with growing frustration at the unpredictable authorization process for commercial cultivation, mounting negative media coverage and field trial vandalism in other countries. This resulted in many retailers electing to become GM-free and politicians adopting a progressively more anti-GM stance under public pressure, leading decision-making bodies to reduce the amount of funding available for research involving field trials of genetically engineered plants. This self-reinforcing negative cycle has been described recently along with potential strategies to address it, such as better education and scientific communication, regulations to prevent media misreporting of scientific data and legislation to ensure that regulators are not put under pressure by partisan politicians and can thus operate independently (Farre *et al.*, 2011).

Since 2006, only five experimental field release applications for GM plants have been received and authorized in England. In 2006, application B/GB/06/R42/01 was approved for BASF Plant Science GmbH to conduct trials of potatoes engineered to provide resistance to *Phytophthora infestans* (late blight). This trial, which took place in Cambridgeshire, was vandalized by activists in 2007, but the company were able to continue with the trial and successfully replanted the experimental crop in 2008. A second application by BASF for the same crop was approved for Yorkshire in 2007 but the field trial was not carried out. Similarly, BASF aborted a successful application for field release in the Republic of Ireland, possibly due to the onerous conditions imposed by the regulators. In 2008, the University of Leeds also suffered destructive protests when a field trial of GM potatoes engineered for resistance to potato cyst nematodes was also targeted by activists (this trial recommenced in 2009, with heavy security co-funded by the BBSRC and Defra, who also funded the initial research). In 2010, the University of Leeds received approval for a further trial of GM potatoes, which was carried out again with security funded by the BBSRC. In 2010, the Sainsbury Laboratory received approval for a small-scale field trial of blight-resistant GM potatoes in Norwich. The trial involved 192 GM plants and non-GM controls in a small plot surrounded by a 20-m buffer zone imposed by the regulators. The cost of security to discourage potentially-destructive protests was £70 000 ($112 000), comprising a security cage 3 m in height fitted with an alarm system, security lighting and closed-circuit television cameras, as well as patrols by security personnel (Figure 4). Most recently in July 2011, an application was submitted from Rothamsted Research for a GM wheat trial to study field performance of wheat engineered to produce an alarm pheromone to repel aphids (http://www.defra.gov.uk/environment/quality/gm/). This was the only UK field trial notification received in 2011.

Field trials in Belgium—national authority, application procedure and consequences

In Belgium, there is a cooperation agreement between the Federal State and the three regional authorities (Flemish, Walloon and Brussels Capital) concerning the administration and scientific evaluation of GMOs. The Federal state is the competent authority for the evaluation of GMO field trial applications, but the regional authorities have a veto for field trials in their territories. Therefore, regional authorities can prevent the

Figure 4 Sainsbury Laboratory experimental field trial site for blight-resistant genetically modified potatoes, showing the 3-m security cage required as part of the £70 000 ($112 000) security costs added to the research project. Photographed by Andrew Davis, John Innes Centre, Norwich, with kind permission from Prof. Jonathan Jones and Dr. Simon Foster, Sainsbury Laboratory, Norwich.

Federal State granting a permit for field trials in their territory, and the Federal State can refuse a permit even if a regional authority is satisfied. The cooperation agreement also forms the legal basis for the Belgian Biosafety Advisory Council (BAC), the members of which are appointed by the Federal Ministries of Health, Science Policy and Employment, in combination with members appointed by the three regional governments. This body evaluates the applications on the basis of risk to human health and the environment. The administrative procedure for field trial applications closely follows the rules set out by Directive 2001/18/EC. An application is filed with the federal competent authorities and this is forwarded to BAC. The notifier must provide details about the host plant, the introduced trait, the purpose of the release, details of the exact location and size of the trial, an environmental impact assessment and details of the risk management strategies. A public consultation is launched at the same time, involving the municipality in which the field trial will take place, and this lasts 30 days. The federal authorities need to make their decision within 90 days. This period can be extended to give an applicant time to respond to questions from BAC. After approval, field trials are monitored without charge by the inspectorate of the Federal Public Service Health, Food Chain Safety and Environment according to the Royal Decree of 18 October 2006.

The first Belgian field trial was carried out in 1986 and the number and size of the trials has grown since, peaking with more than 100 ha of field trial sites in 2000 (Figure 5). The leading crops have been rapeseed (50), corn (28), sugar beet (13) and chicory (13). More than 70% of Belgian field trials are carried out in Flanders, partially reflecting the implementation of regionally unique coexistence regulations. In Flanders for example, the minimum isolation distance between GM and non-GM maize is 50 m, whereas in Walloon it is 600 m.

After 2002, the number of field trials dropped to zero, reflecting the destruction of field trials in 2002 by activists, and regulatory uncertainty about the implementation of Directive 2001/18/EC by the responsible federal minister. In 2003, there was one field trial application for GM apple by the Catholic University of Leuven, but the permit was vetoed by the Flemish minister for the environment (Flachowsky and Hanke, 2011).

The next field trial application was submitted by the Flanders Institute for Biotechnology (VIB) in 2007 to test GM poplar trees whose wood composition was more suitable for biofuel production. This was the first application after the implementation of Directive 2001/18/EC in Belgian Law by the Royal Decree of 21 February 2005. The application was approved by BAC, but the federal ministers ignored the advice and illegally refused the permit causing political uproar. Questions were raised in the European Parliament and VIB approached the Council of State to overturn the decision, resulting in a permit begin granted in 2009. The trial is still underway.

In November 2010, a consortium of four Flemish research institutes (Ghent University, Institute of Agricultural and Fisheries Research, VIB and University College Ghent) requested permission to conduct 2 years of field trials with potatoes engineered for resistance to *Phytophthora infestans* (late blight). After two rounds of additional questions, the application was approved in March 2011. Less than 1 week later, a local activist group launched a campaign and website announcing the 'liberation' (destruction) of the field trial site on 29 May 2011. Security was therefore improved, including the installation of fencing and permanent surveillance, requiring an extra €100 000 ($140 000) in funding. The 'liberation' went ahead and was partially successful; 40 activists were arrested and prosecuted, and the event received major coverage in the media. This increased public awareness and stimulated debate about the value of GMOs and their role in future agricultural systems, their sustainability, the impact of intellectual property and the balance between civil disobedience and scientists' rights to carry out research. The field trial was restored and preliminary results have now been collected.

Problems and solutions

The number of experimental field trials is declining in the EU in terms of both applications and authorizations (Joint Research Centre, 2004). As discussed in the case studies above, there are many overlapping reasons for this phenomenon, including the increasing complexity of the application procedure, the increasing stringency and variation of national and regional regulations

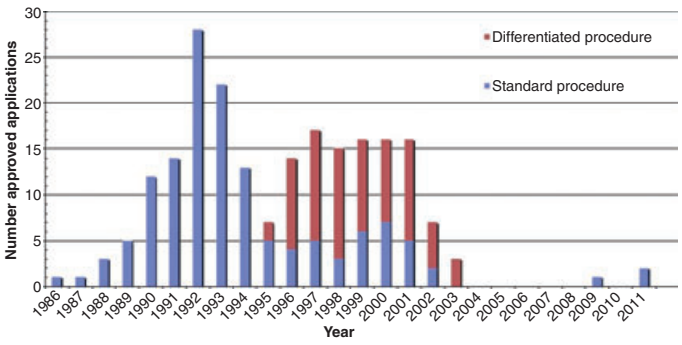

Figure 5 Field trial applications in Belgium 1986–2010, approved following the standard or differentiated procedures (source: WIV-SBB). The notifier may apply under the 'differentiated procedure' if, for certain types of genetically modified plants, sufficient knowledge, data and experience have been obtained concerning the necessary safety prerequisites for human health and the environment.

(often with no scientific basis), the high costs of security and protection for field trial crops and the researchers working on them, and the risk of financial loss through the destruction of crops by activists (Bernauer *et al.*, 2011; Rauschen, 2009). There is evidence that some EU member states are being targeted for field trials because their regulatory system is more approachable and transgenic crops are more accepted by the public (e.g. Spain), but increasingly companies interested in genetically engineered crops are taking their field trial research overseas, where procedures and political environments are more favourable (Bullion, 2011).

The complexity of the application procedure can be addressed by looking at precedents for simplifying and streamlining notifications under the current system. For example, simplified procedures as set out in Article 7.6 of Directive 2001/18/EC are currently applied in Germany where familiarity has been gained for a particular transgenic event through repeated experimental releases. Therefore, a lengthy evaluation process should not be necessary where a previously released variety is being notified in a different location, or where previously tested traits are being stacked in a single plant line. In Germany, repeat notifications for different locations can be processed in as little as 14 days. One disadvantage of this fast-track procedure is that EU-level participation is limited and local authorities have little time to assess the suitability of additional field locations. State authorities in Germany have therefore criticized their lack of involvement in the information-sharing process required for basic applications because the first trials were carried out in a different state. It is necessary to resolve the conflict between accelerated approval and appropriate evaluation of additional field sites in different regions without going to the excesses witnessed in Spain, where the same application can receive multiple approvals with different conditions, or a mix of approvals and rejections.

Further simplification could be implemented in cases such as the Spanish system, where there are multiple authorities with overlapping roles, by dividing the assessment responsibilities into different areas of competence (e.g. agricultural practice, nature conservation, human health, food and feed safety) rather than along national/regional lines. Similarly, a harmonious set of evaluation criteria would be useful, rather than the idiosyncratic and irrational mix we are faced with at present (Ramessar *et al.*, 2008, 2009). This might be achieved by the separation of risk assessment and risk management, and a strict adherence to science-based evaluation. The involvement of stakeholders is also another important strategy for simplification, because this would allow the integration of local knowledge (e.g. protected areas, local wild plants and their compatibility with transgenic crops). In this way, member states could contribute further to and benefit from information on the field releases of their neighbours.

Conclusions

There has never been any negative environmental impact reported from any GM field trial carried out in the EU. The present system for GM field trial notifications in the EU is haphazard, unbalanced and overly complex, strongly discouraging investment in the EU's much-touted bioeconomy. Furthermore, the constant challenges to and modification of the regulatory system, as most recently seen with the approval of a legislative proposal for a member state opt out on 6 July 2011, do nothing to improve consumer confidence. It is interesting to note that the EU public is not generally against biotechnology and that there have been very few representations against medical applications involving genetically engineered microbes (Gaskell *et al.*, 2011). However, faced with unwieldy application procedures, conflicting regulatory demands, long delays, irrational decision-making processes and the threat of interference and destruction from activists, there is ample evidence that many academic and industrial developers are scaling back their research into transgenic crops or moving that research overseas where the political climate is less hostile (Bullion, 2011), and that the EU risks being left behind as the rest of the world embraces GM agriculture and moves forward with a more diversified and less regulated system in which the public sector and industry can play a substantial role driving innovation (Areal *et al.*, 2011; Tait and Barker, 2011).

At the same time, EU regulations forbid member states from preventing the import and marketing of GMO-derived food products from overseas, which means effectively that the EU is driving researchers overseas so that products can be developed and commercialized outside Europe and then imported back into the EU at a much-inflated cost. It is striking that approximately 2500 notifications for GMO field trials were received in the EU since Directive 90/220/EEC came into force, many of which have not progressed to actual trials, whereas the number of applications received in the United States over the same period exceeds 15 000 (Table 1).

In order to restore order in this chaotic system and redress the balance between apparently irrational, non-scientific decision-making and rational, science-based evaluation, we need to inject some much-needed consistency and rationality into the regulatory system governing experimental field trials and harmonize the regulations throughout the EU, in line with international regulations and agreements. Only harmonized regulations based on sound and scientifically justifiable principles can provide a climate that supports research, development and innovation, and the eventual commercialization of beneficial transgenic crops, while offering reliable safety assessment for consumers. Regional differences, in terms of agriculture and ecology, can still be taken into account, but this should not distort the scientific basis of risk assessments and unduly influence opportunities for cooperation, trade and economic growth. The implementation of risk assessments by competent authorities only makes sense if these authorities base their assessments on the same information and use the same evaluation criteria and scientific benchmarks to reach their decisions. We also face the increasing problem of activism-based politics, in which the unsubstantiated and in many cases deliberately misleading views of activists are not only given higher visibility than they deserve in the name of 'balanced debate' but are, because of the disruption and destruction of field trials, preventing the very research that is necessary to provide scientific evidence to dismiss many of the concerns that underlie the activism. In short, the freedom of the scientific community to present its case is being curtailed, thus preventing the fair and balanced discussion of issues lying at the heart of the debate, whose rational and rigorous investigation is in the best interests of all parties involved.

In addition to the development of an overall strategy to harmonize the regulations governing the authorization of experimental field trials, we also recommend certain specific changes to the application procedure that will maintain transparency while helping to prevent the destruction of field trial sites by

activists. We recommend that precise grid references for field trial sites should not be made publically available until after the field trial is complete, because these are not part of the risk assessment process and only serve to facilitate illegal action by activists. This is the system currently applied in the United States and Canada, where field trial destructions are almost unheard of, but this does not reduce the effectiveness of the risk assessment process carried out by the regulatory bodies in those countries. Complete secrecy for field trials in Europe will be impossible because the Aarhus Convention on the right to environmental information (Rodenhoff, 2002) lays down principles on how detailed certain information should be, and the European Court of Justice has ruled that the location of a field trial should be indicated precisely (Box 2). However, these principles could be amended so that the full information is released only after completion of the trials.

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Supporting information

Additional Supporting information may be found in the online version of this article:

Table S1 Regulation of experimental field trials for transgenic plants in Spanish Autonomous Communities.
Table S2 Number of summary notifications (SNIFs) and range of crop species notified, and total surface area requested, for Spanish field trials (1993–2010).
Table S3 Summary notifications (SNIFs) for field trials with transgenic crops authorized both by the corresponding Regional Competent Authority and by the National Competent Authority in Spain, arranged by Autonomous Community.
Table S4 Two notifications for the same herbicide-tolerant transgenic corn event notified in 2010 for field trials in Spain.

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