

Precautionary Expertise for GM Crops

National Report – Spain

Caution *versus* Precaution

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List of abbreviations

AESA	Spanish Agency for Food Safety <i>Agencia Española de Seguridad Alimentaria</i>
ANTAMA	Foundation for the Application of Biotechnology in Agriculture, the Environment and Food <i>Fundación ANTAMA – Fundación para la Aplicación de la Biotecnología en la Agricultura, el Medio Ambiente y la Alimentación</i>
AGPME	Spanish Association of Maize Producers <i>Asociación General de Productores de Maíz de España</i>
APROSE	Association of Selected Seed Producers <i>Asociación de Empresas Productoras de Semillas Selectas</i>
ASAJA	Association of Young Farmers <i>Asociación de Jóvenes Agricultores</i>
ASEBIO	Spanish Association of Biotechnology Companies <i>Asociación Española de Empresas Biotecnológicas</i>
CCAE	Spanish Confederation of Farmers' Cooperatives <i>Confederación of Cooperativas Agrarias de España</i>
CC.OO	Workers' Commission Trade Union <i>Comisiones Obreras</i>
CCU	Council of Consumers and Users <i>Consejo de Consumidores y Usuarios</i>
CECU	Spanish Confederation of Consumers and Users <i>Confederación Española de Consumidores y Usuarios</i>
COAG	Co-ordinator of Agricultural and Livestock Organisations <i>Coordinadora de Organizaciones Agrarias y Ganaderas</i>
CIB	Centre of Biological Research of the CSIC <i>Centro de Investigaciones Biológicas</i>
CIOMG	Inter-ministerial Council of GMOs, under the Ministry of the Environment <i>Consejo Interministerial de Organismos Modificados Genéticamente del MIMAM</i>
CNB	National Commission of Biosafety <i>Comisión Nacional de Bioseguridad</i>
CNBv	National Commission of Biovigilance <i>Comisión Nacional de Biovigilancia</i>
CSIC	Spanish High Council of Scientific Research <i>Consejo Superior de Investigaciones Científicas</i>
DGCEA	General Directorate of Environmental Quality and Evaluation of the Ministry of the Environment <i>Dirección General de Calidad y Evaluación Ambiental del MIMAM</i>
EA	Ecologists in Action – Spanish coalition of environmental groups <i>Ecologistas en Acción</i>
FAAE	Federation of Associations of Organic Agriculture <i>Federación de Asociaciones de Agricultura Ecológica</i>
GMx	<i>Grupo Mixto</i> Group of minority parties in the Spanish Parliament
IATA	Institute of Agro-chemistry and Food Technology of the CSIC <i>Instituto de Agroquímica y Tecnología de Alimentos</i>

IC	<i>Iniciativa per Catalunya</i> Political party linked to the Spanish Izquierda Unida – IU
INIA	National Institute of Agricultural Research <i>Instituto Nacional de Investigación Tecnológica, Agraria y Alimentaria</i>
IRTA	Institute for Agricultural Technology and Research of the CSIC <i>Institut de Recerca i Tecnologia Agrària</i>
MAPA	Ministry of Agriculture, Fisheries and Food <i>Ministerio de Agricultura, Pesca y Alimentación</i>
MIMAM	Ministry of the Environment <i>Ministerio de Medio Ambiente</i>
MSC	Ministry of Health and Consumption <i>Ministerio de Sanidad y Consumo</i>
OCU	Spanish Consumers' Association <i>Organización de Consumidores y Usuarios</i>
SEAE	Spanish Society of Organic Agriculture <i>Sociedad Española de Agricultura Ecológica</i>
SEBIOT	Spanish Biotechnology Association <i>Sociedad Española de Biotecnología</i>
UGT	General Workers' Union <i>Unión General de Trabajadores</i>
UPA	Small Farmers' Union

Abstract

Spain has been the only EU country with large-scale commercial production of GM crops so far. The first two GM crop varieties approved for commercial production, in 1998, were both from genetic modification 176 and both from Novartis (now Syngenta): Bt maize 950243 Jordi CB and Bt maize Compa CB. However, only Compa CB Bt maize has been cultivated commercially in Spain. According to the latest data available, the total area of Bt maize in Spain increased to 32,000 ha in 2003 and was expected to reach around 40,000 ha in 2004. Monitoring of Bt maize crops by several research institutes and universities has been carried out since the first season they were cultivated, as a result of an agreement with the Ministry of the Environment and because it was a condition of the market approval. The monitoring has provided data on issues such as: the efficacy of Bt maize in controlling target insects and the possible development of resistance to the Bt toxin; the effects on non-target entomofauna, mainly centred on the study of a natural predator of the corn borer, *Orius* species; the effects on soil microorganisms and their possible development of resistance to ampicillin (as a result of the presence of the antibiotic marker gene in the Bt maize); and potential effects on digestive bacterial flora with regard to resistance to ampicillin, based on trials of 70 chicks. According to these results, there have been no significant negative effects from Bt maize Compa CB, and the Bt maize was effective at combating the corn borer. Nevertheless, Spanish environmental groups, such as Friends of the Earth, have criticised the validity of the studies because they were funded by the biotechnology company (Syngenta) that produces the Bt maize, so in their view the study lacked the independence necessary to be judged credible. Another study, carried out by the National Centre of Biotechnology, on the impact of the Bt maize on soil microorganisms resistant to ampicillin showed no significant differences between those microorganisms in soil cultivated with transgenic crops and those in soil cultivated with non-transgenic crops, although some resistance was detected in both cases.

The introduction of the notions of precaution and the precautionary principle for the assessment and regulation of risks related to commercial GM crops is still relatively recent. Those terms hardly feature in the discourses and practices of policy makers and their expert advisors. Spanish regulatory bodies have tended to use the words 'caution' and 'cautionary principle' when dealing with GM crops. This was the case, for instance, in the transposition of the revised Deliberate Release Directive, where the terms precaution and precautionary principle were not included. However, environmental and consumer groups have always used those terms in their arguments to propose more stringent controls for GM crops. Thus Spain has two main accounts relating to precaution: one, a case-by-case 'caution', which is used within the regulatory bodies; the other, a systemic interpretation of precaution, mainly promoted by environmental and consumer organisations, and those farmers opposed to GM crops.

Main findings

This report explores the different accounts of precaution and of the precautionary principle as used and expressed by Spanish actors involved in the assessment of GMO crop risks and in the regulation of GM crops for commercial use. It also examines the extent to which present practices with regard to the assessment of risks and management of GM crops relate to different accounts of precaution, regardless of whether or not practitioners refer to them as precautionary. The implications of, and activities related to, precaution in the governance of GM crops in the Spanish context are also analysed. This study is part of a larger research effort within the framework of the EU-funded project *Precautionary Expertise for GM Crops* (PEG; 2001-2004). Our main focus of analysis is the period between March 1998, the time of the first authorisations of GM crops in Spain (under the conservative party), and March 2004, the time when the conservative party was defeated.

Bt crops in Spain: monitoring practices

Spain is the only EU country so far (2004) where the large-scale commercial production of GM crops has occurred. The first two GM crop varieties approved for commercial production, in 1998, both from Novartis (now, together with Ciba-Geigy, called Syngenta) were: Bt maize 950243 Jordi CB and Bt maize Compa CB. However, only Compa CB Bt maize has been cultivated commercially in Spain. According to the latest data available, the total area of Bt maize in Spain was 32,000 ha in 2003 and it was expected to reach around 40,000 ha in 2004.

In Spain, the Bt maize was first planted for commercial use and then its environmental effects monitored. The Ministry of the Environment (the competent authority for the Deliberate Release Directive) and the Spanish High Council for Scientific Research (CSIC), signed a collaboration agreement to monitor the ecological effects of such crops¹ (see Section 3.1.3). The first results were published in 2000. According to these studies, neither of the corn borer species monitored (*Sesamia nonagrioides* and *Ostrinia nubilalis*) developed significant resistance to the Bt endotoxin. Other GM crop-related risk research has been carried out by the National Centre of Biotechnology, on the impact on soil microorganisms resistant to ampicillin (since the GM maize has an ampicillin-resistance marker gene). Their results showed no significant differences in ampicillin resistance between the microorganisms in soils cultivated with transgenic crops and those in soils cultivated with non-transgenic crops, although some resistance in the microorganisms in both soils was detected (see Annex IIb). In addition, in February 2004 the IRTA (Institute for Agricultural Technology and Research of the CSIC) made public some results on gene flow between Bt maize and conventional maize. Bt maize pollen was found up to 40 m away from the Bt maize crop, although IRTA had previously recommended a minimum safety distance of 25 m between transgenic and non-transgenic crops, with a minimum barrier of four furrows of non-transgenic crop for GM crops grown in fields smaller than 1 ha.

On 20 June 2003, that is, five years after the first authorisations of Bt maize varieties, Syngenta produced for the Ministry of Agriculture the first report regarding the monitoring of the effects and the efficacy of Bt maize Compa CB crops in Spain. Scientists from two institutes of the Spanish Higher Council of Scientific Research (CSIC) and from two Universities in Catalonia participated in the research: IRTA, CIB, the University of Girona and the University of Lleida (Girona and Lleida are two provinces with large areas of Bt maize). The report included the results of four studies: the efficacy of Bt maize in controlling the targeted insects and the possible development of resistance to Bt toxin; the effects on non-target entomofauna, mainly centred on the study of a natural predator (*Orius* species) of the corn borer; the

¹ Convenio de Colaboración entre el Ministerio de Medio Ambiente y el CSIC: 'Evaluación de los potenciales riesgos ecológicos de los maíces transgénicos' (See Annex II).

effects on soil microorganisms and their possible development of resistance to ampicillin; and effects on digestive bacterial flora with regard to resistance to ampicillin, based on trials of 70 chicks. According to these results, none of the experiments showed any significant negative effects of Bt maize Compa CB, and the Bt maize was effective at combating the corn borer.

Environmental groups, such as Friends of the Earth Spain, criticised the validity of the studies because they were funded by the same company (Syngenta) that produces the Bt maize, so in their view they lacked the independence necessary to be judged as credible. Furthermore, some researchers participated both in the research carried out by the CSIC in the agreement with the MIMAM and in the agreement with Syngenta, while at the same time they were part of the CNB. Access to information and opportunities to question risk assessment and monitoring methodologies, for example, to ask for justification for the risk assessment criteria selected or the non-target species used in the monitoring, by other interested groups (such as environmental groups like Friends of the Earth or *Ecologistas en Acción*) or experts other than those involved in the CSIC or the CNB proved to be difficult or impossible. The lack of public discussion and transparency about the methods used in the monitoring has hampered the possibility of making such procedures more democratic, and of providing additional and relevant non-expert knowledge for policy makers, and has created further suspicion about the validity of the results. For instance, six months after the first results of the monitoring of the Bt maize crops were provided by Syngenta, neither Greenpeace nor FoE had had access to that document. In general, policy makers have preferred to avoid being too exposed to environmental and consumer groups who are against GM products and have kept a low profile on policy making so as to contain conflict that might jeopardise further GM crop authorisations.

Regulatory and risk assessment developments

In 1994, Directives 90/219/CEE and 90/220/CEE were transposed into Spanish legislation through Law 15/1994 of 3 June, and Royal Decree Regulation 951/1997 of 20 June that developed the application of this law, also known as the National Law on Biosafety. Nine years later, Law 9/2003 of 3 April transposed EU Directives 98/81/CE on Contained Use of GMOs and 2001/18/CE on Deliberate Release of GMOs at the same time. Inadequacies in Law 9/2003 resulted in some parliamentary controversy as well as protests by social and environmental groups. Opposition parties and NGOs denounced the conservative party, *Partido Popular* (Popular Party), on the grounds that the Spanish law did not adequately implement the risk safety, information and participation provisions of the Deliberate Release Directive (DRD). Furthermore, they criticised the new law for not adequately incorporating the precautionary principle, and for not guaranteeing the independence of the committees authorising new releases, those monitoring GMOs, and those establishing safety standards on risk assessment and management. Minority and left-wing parties, such as the *Iniciativa per Catalunya* (IA) and *Grupo Mixto* (GMx) played a prominent role in articulating the social unrest about the policy process (see Section 3.3.5), although due to their peripheral position they never succeeded in achieving substantial regulatory change. In particular, IA asked in the Spanish Parliament in July 2002 about the provisions for public information and consultation on new GM releases, and about the provisions previously. The response was that there had been no consultation with the public. On 13 March 2003, the European Court of Justice reprimanded Spain for not having implemented in time the obligations of Directive 98/81/CE. Furthermore, on 15 July 2003, the European Commission took 11 Member States, including Spain, to the European Court of Justice for having failed to meet the 17 October 2003 deadline for the adoption and notification of national legislation implementing Directive 2001/18/EC. In the national elections of 14 March 2004, the Conservative Party was completely defeated so can no longer push through its own ideas for policy reform.

So Law 9/2003 and the recent Regulation 178/2004 of 30 January now govern the release of GMOs. As explained in Section 3.1.1, these regulatory developments required several changes in the composition of the risk assessment and consultative body, the CNB, and the competent authority in charge of the authorisations, the

CIOMG (*Consejo Interministerial de Organismos Modificados Genéticamente*, a structure which also needs to consult and reach agreement with the Ministry of Agriculture). A larger number of members from different ministries and specialised agencies, such as the Spanish Agency for Food Safety and the Spanish Agency of Medical Products, are now also present. However, the new regulations and compositions have not resolved the problem of the lack of independence of the assessment and regulatory bodies, and they have not included any provision for consultation with the public *before* the authorisation of new GMO releases (nor for assessment or regulatory purposes).

Indeed, in Spain, as is apparent from the composition of the assessment and regulatory agencies, the relationships between the two could not be closer. The National Commission of Biosafety belongs to the Ministry of the Environment, and most of its members also belong to other administrative and regulatory agencies, such as the Ministry of Agriculture (MAPA) or the Spanish Agency for Food Safety. For instance, the president of the CNB is at the same time the main person responsible for regulatory issues concerning GM crops at the Ministry of the Environment, and has been so throughout the period of the transposition of the EU Directives on Deliberate Release into Spanish legislation.

After a period of relative non-decision and few important regulatory developments, the Spanish conservative government finally showed itself determined to join with the group of leading European countries trying to lift the *de facto* moratorium and engage in large-scale commercial GM agriculture. This position was favoured by the absolute majority in Parliament of the Popular Party (a party which in recent times has held views very close to those of the USA on these matters, not to mention on the Iraq war). While the permeability of the regulatory bodies to some social and environmental demands has proved very difficult, if not impossible, large agbiotechnology companies have managed to maintain a closer relationship with key policy-making agencies. Spanish regulatory agencies have shown increasing receptivity to corporate biotechnology claims about new GM authorisations but have remained relatively oblivious to demands from small and organic farmers on matters related to co-existence or the halting of new GM varieties until the safety, information and independence of assessment procedures have been sufficiently developed.

On 11 March 2003, five new Bt maize varieties were approved, together with nine more on 16 February 2004. All these new authorisations were for Bt maize varieties based on Decisions 97/98/CE and 98/294/CE and on the two original 1998 events CG 00256-176 and MON 810. As in the case of the 1998 varieties, the new authorisations are conditional on a compulsory plan for monitoring their possible risks and negative effects. However, the authorisations and the monitoring plans of the attendant Law Orders of 2003 and 2004 do not contain any explicit reference to liability in the case of non-compliance with the control measures or in the case of economic or environmental damage. The only provision in the new regulations is that if insect resistance is detected or if the measures in the monitoring plan are ineffective, commercial production of the authorised new BT maize varieties will have to stop, but only in the affected locality and its surroundings. In this respect, however, articles 34 to 39 of Law 9/2003 already establish the attendant liability regime in case of infringement of GMO-release conditions, including in serious cases a fine of up to 1.2 million euro.

A peculiar approach of progressively introducing GM commercial crops and at the same time carrying out a slow institutional evolution in risk research, assessment and regulation agencies seems to have characterised Spanish GM crop politics. The approach has also involved avoiding a strong regulatory framework or (precautionary) actions that could slow down agricultural growth and productivity or compromise the commitment to technological innovation. In this sense, Spanish institutional developments in the risk assessment and regulation of GM crops have appeared relatively late and have also adopted specific forms. Overall, they have tended to accommodate decisions taken *a priori* by the main Spanish regulatory agencies, namely MAPA, and have given way to pressure from certain biotechnology actors, mostly from industry and R&D institutions, in order to enhance agriculture's

competitiveness and test new forms of technological innovation in agriculture. The former conservative Minister of Agriculture, Mr. Arias Cañete, showed himself to be very much in favour of co-existence and the introduction of GM crops in Spain (see Section 3.1.1.). His policy in this respect appears to have been that of not creating too many institutional obstacles before an agbiotechnology sector was sufficiently established in Spain (that is, up to a point of no return). For instance, the Commission of Biovigilance (CNBv) was set up only in December 2003, five years after the Bt maize Compa CB variety was first planted commercially in Spain (the CNBv's first meeting occurred in early 2004). However, according to voices critical of GM agriculture in Spain, the Commission excludes important sectors of opinion – such as civic and environmental groups – and its legal text explicitly states that its aim is to guarantee the coexistence of GM varieties with both conventional and organic agriculture. That aim is explicitly opposed by a large part, in fact the majority, of the farmers' associations in Spain, who consider that coexistence will make non-GM agriculture unfeasible or irrelevant.

One illustration of the way that GMO risks or uncertainties have been understood and then incorporated (or not) into regulatory measures and institutions in Spain can be found in the approval, in March 2003 and in February 2004, of the new varieties of Bt maize. The laws APA/520/2003 (BOE 2003a) and APA/314/2004 (BOE 2004) state that the official labelling and the marketing catalogues for the new varieties containing genetic modification CG00256-176 or MON 810 must not only indicate that the varieties are genetically modified, 'but also that such modification protects against the maize borer'. That is, the wording expresses no doubt about their efficacy, and is supported by law. Furthermore, uncertainties about the possible risks of GM crops not only have been denied or set aside within the political or regulatory process (which lead to the new authorisations) but also have been compensated for, and balanced with, the 'certainties' of the economic profitability of Bt crops, as argued in Parliament in an official response by the government. A contradiction is apparent since, on the one hand, officials assert the certainties about the efficiency of Bt crops and on the other, they set up a monitoring plan to find out whether new resistances, loss of efficiency in insecticidal properties or other unexpected effects of Bt crops occur. One interpretation of this situation is that, in order to justify approval of new varieties, government needed to justify in an explicit and certain mode the public interest of the measure, but at the same time, implicitly, they needed to recognise the uncertainties by establishing the monitoring plan.

Under the new Socialist government, the new Agriculture Minister, Ms Elena Espinosa, showed a different attitude towards GM crops. Spain abstained in the EU Agriculture Council of 26 April 2004 on the vote about whether to allow the commercialization of Bt 11 maize. This vote marked a change from the previous Spanish government under the *Partido Popular*, which took a GM-favourable position.

Another significant change occurred as a result of EU-level advice. According to the EU Scientific Panel on GMOs, some antibiotic-resistance marker genes should be prohibited in commercial products because their spread to pathogenic organisms could undermine the clinical utility of the corresponding antibiotic. The list included the ampicillin-resistance gene originally used to construct Syngenta's Bt 176 maize, the basis of varieties commercialised in Spain since 1998. In April 2004 EFSA advised that such varieties should be withdrawn, and the new Socialist government followed that advice, with a ban on growing Bt 176 maize from January 2005.

Farmers', NGOs' and agbiotechnology companies' roles

In Spain, two main networks of farmers' organisations maintain two very different positions with regard to the opportunity, the usefulness, or the necessity of GM crops in agriculture. Some farmers and farmers' associations such as ASAJA, which represents around 35% of farmers (compared with the 48% represented by organisations such as COAG) want to promote the use of GM varieties in Spanish agriculture. However, the split among farmers in this respect cannot be understood without looking at the role played by the multinational biotechnology companies. Such companies have created new think tanks such as *Fundación ANTAMA* and have

fostered close relationships with ASAJA. They have funded the maize producers' organisation AGPME to organise annual forums for debate to try to manage public perceptions and encourage more favourable attitudes to the use of biotechnology in commercial agriculture. The ANTAMA Foundation was created in December 2000 by Novartis Seeds SA, Monsanto España, Agrevo Ibérica SA, and Semillas Pioneer SA (BOE, 2000). Biotechnology companies have also funded their own studies in order to prove that Bt maize is more profitable than conventional maize and reduces the use of pesticides at the farm level. In this respect, British economist Graham Brookes carried out one of the most widely quoted studies, in 2002. However, the costs of dealing with the possible environmental effects of GM crops and of taking precautionary actions in the first place were not assessed in this study. Biotechnology companies have frequently used the rhetorical strategy of referring to biotechnological agriculture as 'new and young' and conventional and other types of agriculture as 'old and *passé*' in order to gain support. This is why companies and *ad hoc* pro-GM crop organisations have funded, worked together with or sought the support of new associations such as ASAJA (Association of *Young Farmers*), even though there is no evidence that farmers in conventional or organic agriculture are older than those who use GM, and indeed the opposite may well be the case.

Opposed to commercial GM crops is a cluster of farmers' associations, and environmental and civic groups. These groups have also received some external support for their campaigns, from international environmental organisations such as Friends of the Earth and Greenpeace. Despite the visibility of some of their actions (see Table 5), these groups have not been able to create a nation-wide and sustained social debate on these issues and have failed to influence in any significant way the regulatory process so as to stop the approval of new GM varieties in Spain. Their activities may have contributed, though, to the postponement of some of the most controversial decisions, given the growing number of applications waiting to be approved for many years at the Ministry of Agriculture. Environmental groups have published reports, appeared in the national media, and revealed independent evidence of the lack of controls and of public information, and cases of contamination of organic farms by Bt crops in Spain. For example, the FoE-Greenpeace report *Al Grano* published in August 2003 claimed that Bt maize Compa CB was, on average, 9.5% less productive than conventional maize. On several occasions, farmers and civic and environmental organisations (mainly COAG, *Plataforma Rural*, *Ecologistas en Acción*, FoE Spain and Greenpeace) asked the Spanish regulatory bodies to open up the National Commission of Biosafety in their tasks of assessment and of providing verdicts with regard to new GMO authorisations (see Section 3.1.1). They also asked to be allowed to propose independent experts for the writing of reports on the contained use of GMO types 3 and 4 (moderate and high risk). However, these demands were not accommodated in Regulation 178/2004 on the development of Law 9/2003. The demands for greater independent expertise in the risk assessment bodies have come only from anti-biotechnology NGOs, in the form of allowing for the possibility of electing experts other than those proposed by government agencies.

Spanish consumer groups have often rejected the extensive introduction of GM products in the food sector and, particularly with regard to the case of Bt maize, argued for the need to implement precautionary measures first. Consumer groups have used the concept of the precautionary principle and have explicitly used the Spanish word for precaution (*precaución*) in their attacks on GM foods (see Section 2.3). Among their main reservations, besides those about risks, was the apparent lack of benefit to the end consumer.

Perceptions of risks and uncertainties associated with GM crops have also differed among the main stakeholders involved in policy making for biotechnological agriculture in Spain. For instance, the distinction between the risks associated with the *product* of GM crops and those associated with the *process* of creating them has been particularly criticised, probably for strategic reasons, by those stakeholders in favour of transgenic agriculture. Farmers with close relationships with biotechnology companies, such as ASAJA or other opinion leaders invited by ANTAMA, have repeatedly referred to as absurd the fact that Spain is allowed to import large quantities of GM crops such as soyabean but is not allowed to grow it. Furthermore, it

seems that the strategy of GM promoters has been to limit the number of issues discussed in relation to the assessment and regulation of risks in an attempt to focus the discourse on lower levels and types of uncertainties. The fewer the issues considered, and the smaller the time and space scale, the more manageable the uncertainties associated with GM crops could appear to be. A similar strategy could be said to have been adopted by the Spanish regulatory bodies, some of which have attempted to limit the amount and diversity of non-governmental stakeholders involved in the assessment and regulation of GM crops and hence have excluded important sectors of public opinion. At the same time, the number of ministries and agencies involved in the CNB and the CIOMG has grown substantially, hence there has been an increase in the intervention of official bodies in expert assessments. This strategy is relatively common in other areas of Spanish politics, such as environmental and conservation issues, in which problems and claims tend to be resolved within the state agencies rather than by negotiation with civic society or with private interests. This also could explain why Spanish GM crop politics do not seem to have sought public legitimacy as a main goal; rather the goal seems primarily to have been to develop the minimum institutional and regulatory means to make coexistence a reality in Spanish agriculture.

Prevention, 'caution', or precaution?

Recourse to the precautionary principle, and the penetration of the notion of precaution in general, is relatively recent in GM crop politics in Spain, and to a large extent is still absent from many areas of discourse and practice with regard to the regulation of transgenic crops for commercial use. Nonetheless, a weak version of precaution exists and is frequently used by the regulatory agencies, mainly that relating to classical prevention and risk analysis. In particular, Spanish legal texts dealing with GM crops have not included the word 'precaution' at all, although it exists in other legal texts such as the Spanish translation of Principle 15 of the Rio Declaration on the Environment and Development of 1992. For GMOs another word, with a subtle, albeit very important, difference has been used in the development of the Deliberate Release Directive (DRD): that of 'caution' (*cautela*), which evidently avoids much of the environmental and sustainability-laden framework of many of the discourses on precaution. Spanish legal texts dealing with GM crops often refer to the 'principles of prevention and caution', without making any explicit distinction between them or mentioning the word precaution.

Nevertheless, whenever GM crop safety and risk discourses in Spain have mentioned issues related to prevention, caution, the precautionary principle and/or precaution, two main interpretative frameworks have appeared. Some Spanish actors have framed the governance of GM agriculture on the basis of a *systemic* conception of precaution, tending to look at interrelationships of GM crops and related risks with other social, environmental and equity issues, within broad time-space scales. This view has mainly been promoted by environmental, consumer and civic groups opposed to transgenic agriculture, who have employed the word precaution in very explicit ways when defending their claims. Other actors, such as the regulatory agencies and even some biotechnology corporations, have used and interpreted 'precaution' – that is, caution – from a case-by-case perspective, closer to traditional notions of prevention in risk analysis and management. In this interpretation, which is also representative of that used in risk assessment by the National Commission of Biosafety, actors have characteristically aimed to separate the issues, to reduce the time/space scale of GM crop problems, and to limit the involvement of non-governmental and other potentially critical actors in the management of GM agriculture. According to a key person in the CNB, the CNB is not interested in 'general questions', but only in case-by-case evaluation based on requested and provided technical information with regard to specific GMOs. So it is not surprising that in Spain, agro-business corporations, policy regulators supporting coexistence, and R&D researchers with high stakes in the biotechnology sector have used this approach, and that whenever they have mentioned the word 'caution' (or even, on rarer occasions, precaution) they have used it in this restricted sense. In accordance with the conventional management strategy of transforming a threat into a business

opportunity, the words precaution, precautionary principle or, more often, caution have been used to make sure that GM agriculture is both possible and profitable. The division that exists between farmers' organisations reproduces these differences in the interpretation and role given to caution, precaution and the precautionary principle (see Section 3.3.2). In our view, and following the EEA (2001) distinction between *prevention*, *preventative precaution* and *precaution*, in Spain the word and use of the term 'caution' relate mainly to the concept of prevention. At most, and when the words prevention and caution appear together in some legal texts, caution could be interpreted as referring to preventative precaution, although even then the meaning of *caution* is never made explicit and remains obscure. The ambiguous term 'caution' may have been used so as to appear to fulfil the requirements of the Deliberate Release Directive while avoiding the use of a contested term – that of precaution – that environmental groups could use to argue for more stringent measures than those finally adopted by the conservative party.

In general then, the terms caution, precaution and the precautionary principle have not received much attention in relation to GM safety and regulation in Spain. In cases where the terms precaution and the precautionary principle might be expected to appear – as in case of the recent regulatory texts on GM crops – the terms caution and cautionary principle have been used in their place. However, regulatory bodies have not differentiated 'caution' from prevention in any operationally distinctive way. Yet environmental and consumer groups have employed the terms precaution and precautionary principle often and have done so in an explicit manner and systemic sense. In the few occasions when discourse and practice have referred to the 'cautionary' or precautionary principle in Spain, they have tended to be centred first on the issues of human food safety and consumer choice, and secondly, on issues of environmental and social concern. Among those concerns, farmers' rights to the conservation and control of traditional knowledge about farm practices and plant varieties developed in the traditional manner and their attendant benefits have received increasing attention in recent times.

Evidence of the omission of any reference to the precautionary principle and the precautionary approach as 'caution' in Spanish regulatory discourse can be found in the recent regulatory texts dealing with GM crops. Quite simply, the word precaution, although it exists in the Spanish language, does not appear anywhere in the two most recent and important regulatory texts implementing the Deliberate Release Directive (Law 9/2003 and Regulation 178/2004). Furthermore, neither of these texts mentions Principle 15 of the Rio Declaration or the European Commission's communication on the precautionary principle. Although as early as January 2000 a coalition of agricultural organisations, trade unions, environmental and consumer groups, and cooperatives concerned with GM crop policy sent a letter to the President of the Spanish Government (then José Maria Aznar) asking for the strict application of the precautionary principle, (see Section 2.2), and although other regional organisations made similar moves, the word precaution never made it into Spanish legislation.

Thus, the most widespread accounts of 'precaution' and related risk management concepts used so far by relevant expert and policy makers involved in the assessment and regulation of GM crops in Spain have not differed substantially from the more traditional interpretations and framings of risk analysis and prevention. In Spain, expert and regulatory bodies have usually understood GMO risks as being similar in kind to those associated with mobile phones, chemical products, or pharmaceutical innovation. The term 'caution' has appeared as a compromise solution between the two extremes of prevention and precaution, although the regulatory implications of caution and the 'cautionary' principle (*principio de cautela*) are unclear. At first sight, case-by-case prevention or 'caution' seems to have satisfied Spanish regulatory bodies. However, on a closer look, one finds that it is precisely the use of such a restricted conception of precaution that has allowed the successful consolidation of GM agriculture in Spain. Spanish regulatory agencies are now fully committed (or, at least, were committed until the conservative party was defeated in March 2004) to the use of GM crops for commercial large-scale farming, even though they seemed somewhat hesitant initially (after the first authorisations in 1998). Some new institutions, such as the Commission of Biovigilance, have been set

up to ensure the coexistence of GM agriculture with other types of agriculture, and also to respond to criticisms and provide an image of compliance with the EU directives. But overall, it seems that the new institutional developments have mainly attempted to accommodate decisions already taken *a priori* by Spanish regulators and intended to secure a place for Spain in world agricultural R&D and the agbiotechnology market.

In sum, Spain's policy makers have not been opposed to the precautionary principle, or to precaution, with regard to GM crop policy. Instead, they have largely omitted it or, at most, have used it through the related but never explicitly defined notion of 'caution'. However, the 'cautionary principle', the meaning of which remains unclear, has not played a significant role in structuring Spanish GM crop policy, risk assessment processes or regulatory practices in a systemic sense. Furthermore, neither caution nor the cautionary principle has hindered the goals of coexistence and a profitable biotechnology innovation sector in Spanish agriculture.

Looking back, and to the future, on GM crop policy in Spain

Concerning the possible future development of Spanish GM crop policy and the role of precaution in it, four main forces have been identified that could either constrain or promote even further the favourable position towards biotechnological agriculture currently shown by the main regulatory bodies. From analysis of the empirical material gathered (especially that from the scenario workshops held in Barcelona and Madrid but also that from the analysis of secondary documentary sources and interviews), the following elements were seen as decisive:

- 1 A strengthening or weakening of the EU policy and regulatory regime with regard to the extent that it could support or impede the efforts of Spanish regulators to enable the coexistence of GM crops with organic and other types of conventional agriculture. An EU precautionary regime closer to the 'systemic' view of precaution might affect Spanish GM crop policy to the extent that it could adopt a less favourable position, and might boost risk assessment and regulatory institutional capacity before further GM varieties are approved.
- 2 Future development of corporate global strategies and alliances in the agbiotechnology sector, to the extent that they might exert substantial international pressure on the EU by creating a world GM market, isolating European non-GM agriculture, and making the EU *de facto* moratorium irrelevant at world level in the medium term.
- 3 The Spanish institutional capacity to put into practice (*via* further authorisations of GM products, public and international investment in ag-biotechnology R&D, and further evolution of risk assessment and management agencies) the full commitment of present regulators to promote agro-technological growth in agriculture.
- 4 The Spanish institutional capacity to resolve potential social conflicts, manage public perceptions, and convince consumers and producers of the added value and usefulness of GM crops, while showing that the new regulations and institutions are capable of guaranteeing the attendant health and environmental safety standards.

Thus, the role of the precautionary principle and of precaution in structuring Spanish GM crop politics and institutions is still ambiguous. Its effects may depend on the extent to which precaution, in its systemic version, is finally incorporated into Spanish legislation as a result of external pressures – for instance, if the European Commission initiated another sanction procedure before the European Court of Justice against Spain for not having correctly implemented the Deliberate Release Directive.

Moreover, and this may be a significant contrast with other European countries, Spanish regulators do not seem to have to seek either public legitimacy for, or public trust in, their GM crop policy. In fact, they have been able to authorise further GM commercial products in agriculture and increase the area of GM crops while at the

same time excluding a large part of the opinion of farmers, environmental groups, and consumer and civic society organisations. Changes in Spanish institutions seem to have responded more to EU pressures than to domestic forces, which to a large extent have not been able to find their way through the regulatory process or have not been able to mobilise sufficient resources to build up their risk and regulatory capacity. Spanish regulations and practices appear to have followed European directives and recommendations, but Spain has not taken any active or leading role in implementing extra precautionary measures in a profound or 'systemic' manner. A restricted case-by-case adoption of the many possible and different interpretations of precaution has allowed Spanish regulators to justify further authorisations of GM crops and to ensure coexistence with other types of agriculture. Nevertheless, it is likely that the Spanish position with regard to GM crops will change as a result of the recent election of a socialist government.

1 Introduction

Spain is the only EU member where large-scale commercial GM crops take place. The first two GM varieties (from genetic modification 176), for commercial use were approved in 1998: Bt maize 950243 Jordi CB and Compa CB both by Novartis (now Syngenta) although only Compa CB has been cultivated and commercialised. Also, GM soy resistant to Gluphosinate can be commercialised but not cropped. On the 11th March 2003 (BOE, 2003a) five more varieties of Bt maize were approved in Spain, and nine more on the 16 of February 2004 (BOE, 2004). In all cases, all these new authorisations were based on the Decisions 97/98/CE and 98/294/CE and derived from the 1998 approved modifications CG 00256-176 and MON 810. More specifically the five new Bt maize varieties approved in March 2003 were the following:

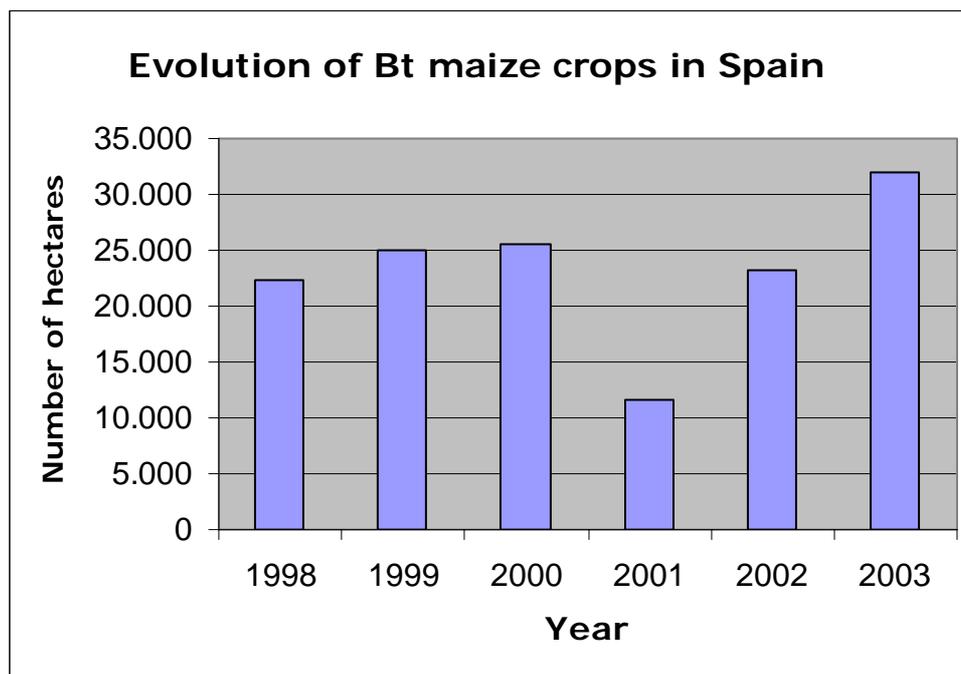
- (i) Derived from the genetic modification CG 00256-176:
 - BRAMA, commercialised by Syngenta Seeds,
- (ii) Derived from the genetic modification MON 810:
 - ALIACAN BT, commercialised by Limagrain
 - ARISTIS BT commercialised by Nickerson Sur
 - DKC6575 commercialised by Monsanto agriculture
 - PR33P67 commercialised by Pioneer Hi-Breed

All of the above modifications are designed for borer resistance and in the case of Brama also for increased tolerance to gluphosinate of ammonium. The nine new Bt maize varieties approved in February 2004 were:

- (i) Derived from the genetic modification CG 00256-176:
 - 19970357 SANSONE BT
 - 19970348 ESCOBAR
- (ii) Derived from the genetic modification MON 810:
 - 20000389 CAMPERO
 - 20000421 CUARTAL BT
 - 20000387 DKC 6550
 - 19970303 GAMBIER BT
 - 20000384 JARAL
 - 19980499 PR 32 P 76
 - 19980528 PROTECT

Both transgenic maize and soyabeans are brought into Spain as imports. Most of these crops are used for animal feed, mainly meat production. For instance, in 1999, the total imports of maize (both GM and non-GM) was 2.000.000 tons and the total imports of soy beans was 1.000.000 tons, where out of all the imports of maize and soy beans, 70 per cent was used for animal feed and 30 per cent for direct human consumption. During the period 1998-2003, the evolution of Bt maize in Spain has been the following:

- 1998: 22.360 hectares
- 1999: 24.952 hectares
- 2000: 25.516 hectares
- 2001: 11.540 hectares
- 2002: 23.280 hectares
- 2003: 32.000 hectares



(Source: Elcacho (2004) and our own data.)

Figure 1. Evolution of Bt maize crops in Spain

It is expected that the total hectares for 2004 will be around 40.000. (Agrohispana, 2004). With regard to the distribution of GM crops within the Autonomous Communities and provinces, during the first harvest in Spain of BT maize (1998), crops were distributed as such: 10.000 hectares in Aragón, 4.000 hectares in Castilla la Mancha, and 6000 hectares between Andalusia, Catalonia, Navarra, la Rioja, and Extremadura. Despite precise data on total GM crops distribution in Spain have been usually difficult to obtain, Table 1 shows Bt maize crops distribution of most of the crops (24350 hectares, over 95 per cent of the total) existing at the beginning of the process, although it only covers 24 out of the 52 Spanish provinces²:

Table 1. Approximate distribution of Bt maize Compa CB in Spain during the 1999-2000 season (Source: *Unión de Pequeños Agricultores (UPA)*, in Riechmann, 2002, p.28.)

Province	Area of Compa CB maize (ha)	Total maize area (ha)	Ratio Compa:total (%)
Albacete	2,399	22,961	10.45
Badajoz	2,513	41,337	6.08
Balearic Islands	28	552	5.07
Barcelona	8	2,360	0.34
Cáceres	226	20,994	1.08
Cádiz	186	2,117	8.79
Córdoba	578	5,857	9.87
Cuenca	254	2,130	11.92

² For instance, it does not cover any of the provinces of Galicia, none of the provinces in the Basque Country, only 1 of the 9 provinces of Castilla-Leon, and only 2 of the 3 of the Autonomous Community of Valencia.

Girona	974	10,000	9.74
Granada	225	3,891	5.78
Guadalajara	41	5,500	0.75
Huesca	4,284	42,371	10.11
Jaén	3	900	0.33
La Rioja	36	1,620	2.22
Lleida	3,856	21,940	17.58
Madrid	6,345	8,500	74.65
Navarra	231	14,306	1.61
Sevilla	619	9,900	6.25
Soria	290	1,000	29.00
Tarragona	1	207	0.48
Teruel	6	3,590	0.17
Toledo	119	12,700	0.94
Valencia	153	500	30.60
Zaragoza	4,289	32,845	13.06

Therefore, at that time, the Autonomous Community which had the largest area of Bt maize crops was Aragón, and in particular, the provinces of Huesca and Zaragoza. According to *El País* newspaper (24/III/01), farmers in Aragón, Basque Country and Navarra believed that GM cultivation would recede, although in the light of the recent figures of 2003, this has not been the case. However, in 2003, Catalonia was the Autonomous Community with the largest production of GM crops in Spain, with the 13 per cent of the total, followed by Aragón with 11 per cent in Aragón, and Madrid and Castilla La Mancha, both with 9 per cent (Agroinformación, 2004).

Spain is also the only cotton producer in the EU, together with Greece³. Total production of cotton in Spain is of 330 million euros, or 1,5 million day-wages that employ labour in 23 factories. According to the pro-GM agriculture opinion of Sanz-Magallón, Bt cotton produces an yield increase of the 12 per cent in Comparison with non-genetically modified ones, and a reduction of 15.8 litres of insecticides per cultivated hectare, as well as a reduction in labour demand due to less need in peste control (Sanz-Magallón, 2001:91-100, from Novillo, C. et al. 1999). Given that the total production of cotton in 1998 was of 97.499 hectares, with a total value of 39.053 million ptas (234,58 million Eur), he estimates, by simply extrapolating these results to current situation of the whole Spain, the possible effects of Bt cotton, if it was to be approved by the EU arriving to the conclusion that the introduction of such crop would result in:

- (a) Increase of Gross Added Value in agricultural production of nearly 42 million euros, out of 25 per cent of it would go the seed industries.
- (b) 1,5 million litres reduction of insecticides.

In 2003, Spain together with the Netherlands, forwarded favourable opinions to the EU on the new applications for commercial approval of GM crops, thus initiating, in line with the Deliberate Release Directive, the procedures for deciding whether to approve such applications. At present, Spain is the rapporteur CA for further commercial Bt maize products within the EU.

According to the Joint Research Centre, Spain has notified the placing on the EU market, including for cultivation, the GM products shown in Table 2.

³ According to Greenpeace (April 2000), Spain tried to import illegal GM cotton from Greece.

Table 2. Notifications of GM products placed on the market made by Spain before the European Commission (Source: JCR, 2004.)

Notification number	Notifier(s)	Name of the product (commercial and other names)	Date of publication of summary notifications (sn) or assessments reports (as)
		Genetically modified maize NK603 x MON 810, for import and use, including cultivation.	14/01/2004 (sn)
C/ES/03/01	Monsanto	Roundup Ready maize line NK603 for cultivation in the EU	22/07/2003 (sn)
C/ES/99/02	Monsanto	MaisGard/Roudup Ready maize GA21 x MON810	17/02/2003 (sn) (this summary has been withdrawn of the JRC web site)
C/ES/01/01	Dow AgroSciences Mycogen Seeds	Lepidopteran resistant and gluphosinate tolerant 1507 Maize	17/02/2003 (sn) 20/08/2003 (as)
C/ES/08/01	Monsanto	Roundup Ready maize line GA21	17/02/2003 (sn) (this summary has been withdrawn of the JRC web site)
C/ES/96/02	Monsanto	Insect-protected cotton line derived from Event 531	14/02/2003 (sn)
C/ES/97/01	Monsanto	Roundup Ready cotton line derived from Event 1445	14/02/2003 (sn)
C/ES/00/01	Monsanto	Roundup Ready (glyphosate tolerant) maize, event NK603	22/01/2003 (sn)

2 Precaution and GM crops in Spain

2.1 Biotechnology industry's views

As a general norm, in their public appearances, biotech companies operating in Spain on GM crops only mention the precautionary principle or the word precaution in very rare occasions. And whenever they do so, they usually refer to with distrust, as a threat or as an obstacle to their Research and Development objectives instead of as a tool to improve the management of their activities. Furthermore, the interpretation of the precautionary principle by the biotech industry is also peculiar. As summarised in the annual report of ASEBIO, the Spanish Association of Biocompanies of 2002 when defining precaution:

'Precaution: basic criterion which rules the environmental performance a priori, incorporated in the Maastricht Treaty of the European Union, by which every substance, organism or technology must show its compatibility with the environment and public health before its production and use are authorised' (ASEBIO, 2002a, p.271).

For its relevance in this context, it is worth mentioning how ASEBIO understand the difference between precaution and prevention:

'Prevention: basic criterion which rules the environmental performance a posteriori, incorporated in the Maastricht Treaty of the European Union, by which the original cause of an environmental damage already caused must be avoided, so that it does not occur again' (ASEBIO, 2002a, p.271).

Notice that in this understanding of precaution, for instance, there is no reference at all to the Principle 15 of the Rio Declaration, nor to the issues of uncertainty, of the scale of damage, or their implication with regard to public information and participation. Even the word risk does not appear. Such accounts are in line with the idea that it is somewhat pointless to try to apply the precautionary principle, or precaution in general, in areas which are possible future developments are already present 'facts', that is, which are already in motion or have already occurred. If this is the case, the reference to 'a priori' and 'posteriori' is everything but coincidental. It corresponds both with the discourse and practices of presenting GM products -not only in agriculture, but also in other sectors such as food or environmental technologies- as an unquestionable and unavoidable realities in which only prevention can therefore be applied.

One of the most common strategies carried out by industries while talking about the potential benefits of biotech products and particularly on GM crops and the role of the precautionary principle and precaution is the recourse to 'peer scientists' (see also sections 3.2.1 and 3.3.3). The recourse to opinions of scientists who share the same views of the agbiotech industry and support their activities has been a common practice in public conferences and stakeholder forums in Spain during the last few years. One of such early and relevant events in which some lobbying Spanish scientists, together with biotech companies, showed their positions in favour of GMOs was at the International Symposium on Transgenic Plants and Food held at the *Fundación Areces* in Madrid, on the 16 March 1999. One participant in the symposium was Dr. Emilio Muñoz, president of the Spanish *Consejo Científico de Bioempresas* (Spanish Scientific Committee of Biocompanies) a social researcher at CSIC, and also a strong supporter of biotech innovation. For him, it is not fair to invoke health and environmental issues, as the root of the problem is a commercial war amongst conflicting interests. To him, as ecologists accuse scientists that they are bought by multinationals, scientists could do the same to ecologists, saying that they have been bought by biological [organic] farmers. In particular, with regard to the precautionary principle, he said:

'We [scientists] also support it. But it is not the same the precautionary principle that the alarm principle'. (H. Iglesias, 1999).

According to the coordinator of the Symposium, and also a prominent pro-agbiotech speakers in Spain, Mr. Juan Ramon Lacadena, Professor in Genetics and self-acclaimed expert in Bioethics, while assessing risks to health and environment of GMOs he asserted that:

'To call on [and to resort to] biodiversity is nothing else but doing demagoguery'. (H. Iglesias, 1999).

Another influential person in Spain from the academic staff supporting biotechnology applications in Agriculture, is Francisco García Olmedo, Professor in biochemistry and molecular biology from *Universidad Politécnica of Madrid*. As it is usual in the discourses of promoters of GM crops, the only way to deal with the precautionary principle in agriculture is by looking each variety and applications case-by-case, and weighting both possible risks with their possible benefits.

"It only makes sense to talk about the risks associated to transgenic plants and the food derived from them (...) application by application. In fact, the approval of the crops and consumption of transgenic plants is being done case by case, following a strict process in which all the imaginable risks are taken into account (...). Never in the history of innovation such extreme precautions have been adopted" (Garcia Olmedo, 2001:41).

And with regard to precaution and risk assessment of GM crops he stated that:

"In synthesis, transgenic plants are subject to precautionary criteria which many non-transgenic plants would not comply, nor the products of the wrongly called biologic [organic] agriculture, nor many of the daily food products -such as sugar, tea, coffee, pepper, parsley or edible mushrooms- and of course many other of our daily lives, such as tobacco, cars or airplanes" (ibid. p.49).

His opinion on ethics and the public is also worth mentioning:

"From an ethical stand point, transgenic plants do not raise any controversy in the Spanish society, in contrast with other application of genetic engineering linked to human reproduction or livestock. (...) Social preoccupations have more to do with possible health safety and environmental problems. Spanish public often is not aware of the institutional mechanisms which act as guaranties of such safety and does not trust administrative agencies are in this respect protecting the interests of consumers" (ibid. p. 54).

One of the main Spanish lawyers working in favour and assessing the introduction of GM plants and their commercialisation in agriculture is Enrique Marín Palma, lecturer at the University of Alcalá de Henares in Madrid and member of the Centre of Molecular Biology. With regard to the use of the precautionary principle in the regulation of GM crops, he interprets that:

'The application of the Precautionary Principle makes evident two [main] distinct aspects:

- (a) The political decision to act or not to act, linked to the factors that result from its utilisation [of GMOs].
- (b) The nature of the decided action, that is, how to act, taking into account the measures which are needed to be implemented as a result of its application [of the precautionary principle].

From these points, the recourse to the precautionary principle presumes that:

- (a) The potentially dangerous effects derived from a given phenomena, process or product have been identified.
- (b) The scientific evaluation impedes to determine the risks with sufficient certainty. This [is true], taking into account that the evaluation of risks encompasses four elements: identification of the

harm, characterisation of the harm, assessment of exposition, and characterisation of the risk.

- (c) The scientific uncertainty: depends on five characteristics of the scientific method (such as the selected variable, the measures taken, the samples taken, the models used and the causal relation employed), which stem from a controversy about the existing data or the lack of such needed data. Because of this, assessors use to take into account these factors of uncertainty using elements of caution.

(...) The application of the precautionary principle to genetically modified organisms is confirmed, as established by the European Court of Justice, not only by the proofs asked to the notification bodies in the release file, whatever its purpose, but also when the Commission sends to the Member State authorities the summary to make objections, and when it is established that the Company must communicate immediately to the Commission and to the competent authority of its State the new elements that may come up and which allow a better evaluation of the risks that the product may pose to human health or the environment" (E. Marín Palma, 2001:195)

This position could suggest that the question of uncertainty is mainly a scientific matter and thus a situation in which an improvement of the 'five characteristics' in which the scientific method depends on would reduce uncertainty. Under this view, public participation would become irrelevant to overcome or to manage the possible sources of uncertainties related to GM crops. Or else, that only when scientists say that there is not enough certainty, precaution should be applied. On the other hand, he still believes that PP is about to "act or not to act", in line with other recurrent arguments made by promoters of GM agriculture and against the PP who usually caricaturize detractors of GMOs as cowards who do not dare to act or assert that the PP is a 'conservative' principle.

Another early example on how biotech companies understand the precautionary principle and precaution in general was provided by Esteban Alcalde, (at that time, executive of *Novartis Seeds, SA* Spain, now Syngenta). In a short article published in 2000 used the discourse of scenario making (although only one 'scenario' was referred to) to express his position on the future evolution of GM crops and commercialisation and in particular, his views on the precautionary principle. He situated himself at the year 2025 describing how some past trends and facts had evolved with regard to GM crops, both at the international context and at the EU level, and provided his particular account on the precautionary principle. According to him, during this time:

- 1 There has been a mounting pressure in the world to expand the area dedicate to crops, due to growing world population and lack of food provision. This have resulted in large environmental impacts -e.g in developing countries- such as deforestation in places like the Amazonian rainforest.
- 2 European farmers had substantially lost world market competitiveness.
- 3 A growing number of consumers now prefer 'genetically improved food'.
- 4 Labelling in now is required for food which have used pesticides and a distinction of quality is now given to food produced with genetically modified organisms.
- 5 In 30 years no [health, environmental...] problem has occurred, but the thigh EU precautionary measures are still enforced (irony).
- 6 The gap in (bio)technological innovation between the EU and USA has dramatically increased.

For Alcalde, the precautionary principle is used to attack GM crops development:

'those who oppose to the use of this technology resort to the precautionary principle and ask that any product or technology that imply a risk, whatever minimum, should not be used. (...). Zero risk does not exist. There is no

human activity completely exempt of risk. If we were to apply this precautionary principle we should forbid electrical light, medicines, cars, ... including organic food, that is, everything. [So] the valid questions to be asked in relation to safety are: Are the genetically modified crops more or less safe than the conventional crops?; is the inherent risk associated in its utilisation compensated by the benefits which they yield?' (Alcalde, 2000).

2.2 Farmers' views – joint reactions with environmental groups and trade unions

In Spain there is a divide between the different the Spanish farmers associations with regard to the use of GM crops and the role of precaution in it (see section 3. 3. 2). However, in the present research, no references to the precautionary principle expressed by the Spanish farmers organisations in favour of the introduction of GM plants in agriculture has been found and therefore, this section concentrates in those who have used and which mostly coincide with those who oppose to GM crops.

According to J. Riechmann, lecturer at University of Barcelona and also working with an Institute for the trade union CCOO, in Spain the position of 'Agricultural unions COAG, UPA, the *Plataforma Rural*, *Sociedad Española de Agricultura Ecológica*, the workers trade unions CC.OO, UGT and environmentalist organisations such as *Ecologistas en Acción*, *Greenpeace*, *Amigos de la Tierra*, and *Adena-WWF* is the request for a moratorium in its production and commercialisation' (J. Riechmann, 2002:21). On the 12 January 2000 a coalition of agricultural organisations, trade unions, environmentalist and consumer groups and Third World countries support associations (namely, UPA, UGT, CCOO, Friends of the Earth, *Ecologistas en Acción*, *Asociación Vida Sana*, *CECU* and AC-SUR Las Segovias) send a letter to the President of the Spanish Government, José Maria Aznar, to make him aware of their preoccupation about the government policy adopted in relation to transgenic crops and foods. In this letter the following text was written:

(...) 'We write to you to ask you the *strict application* of the precautionary principle to genetic engineering by the Government and Administrative institutions, so that they incorporate the uneasiness and preoccupation of the majority of the European Union countries; this seems even more compulsory taken into account that Spain is, by and large, the EU country which the largest amount of transgenic crops. We also demand a *democratic debate about transgenic [crops and foods] with full public information transparency* and with guarantees that all voices are heard (including the most critical ones), a debate which has not occurred so far in the sufficient [right] conditions; and we denounce the present marginalisation in relation to the participation of the organisation in the different social spheres'.

(...) With regard to GMOs, in any case should commercial interests prevail before public health, food safety and the protection of the environment. This is one of the pillars which in our opinion should keep the Government in all international negotiations on food products.

(...) The below signatory organisations share the common four claims that should be the basis of a transgenic policy in our country, more in tune with the respect to the precautionary principle and the practice of democracy:

- 1 Moratorium in the authorisation, import, and production of GM varieties, to be conditioned to the approval of a binding Protocol on Biosafety and to the start of a set of mechanisms which incorporate the precautionary principle with regard to GM crops.
- 2 The *creation of a Food Safety Assessment Council*, with consultative character, in which the attendant Administrative agencies, trade unions, agricultural organisations, consumer groups, environmentalists and others representative social organisations are included together with the agro-food industry, the university, and

public centres of research. This Council should also be linked to and form part of the Biosafety Commission.

- 3 Rejection to the extension of the right of patents to live organisms.
- 4 Strengthening the public research system and the control with regard to food safety and biotechnology, in order to compensate for the meagre presence in Comparison with private research and the little degree of public control over GM crops' (2002, p.86-87).

Some days later, in a meeting held in Salamanca during the 22nd and 23rd of January 2000, both *Ecologistas en Acción* and the *Conferença Portuguesa das Associações de Defesa do Ambiente* signed another document to ask further application of the precautionary principle and tighter measures in relation to GM varieties

A similar manifesto signed by ten Andalusian organisations including farmer organisations as COAG, trade Unions, Green parties and Consumer Associations was produced in February 2002 in the Autonomous Community of Andalusia, asking for a moratorium in GM crops and its commercialisation. According to this document:

'Currently available on transgenic organisms contains serious uncertainties on the attendant risks both for health and the environment (...). Transgenic crops do not provide relevant advantages for the development of Andalusian agriculture (...).

Our bet for a sustainable, balanced, and social development of agriculture and for a responsible and save consumption is incompatible in transforming our land in an immense laboratory given the environmental, health and economic risks that this may imply.

For all these reasons, and in considering the precautionary principle, we believe that the Andalusian Government should approve a moratorium in the deliberate release of transgenic crops and that it should regulate the public information and control of the transgenic plantations for commercial aims'.

2.3 Consumer associations' and food dealers' views

As stated in O. Todt, & J. L. Luján, J. L. (1999), the initial debate over precaution and GM crops in Spain was framed over the issues of commercialisation. GM agriculture market expansion in Spain was not limited by production but consumption, and in particular, by the lack of confidence in such products for human consumption and the difficulty of assessment and regulatory agencies to provide adequate information and trust to the public (see also Sentmartí, et al., 2000). Nevertheless, all the supply of Bt maize has found its way into the market via meat production. Meat production grew nearly 150 per cent only in five years from 1995 to 1999 and most of the Bt maize was used as feed for livestock. It can then be understood why, and for similar reasons, Bt cotton trials and production has not find so many difficulties than other GM products that are intended to be for human consumption.

In May 2000, the results of an international review article on the safety of GM food products were published in the *Revista Española de Salud Pública*. (Domingo Roig & Gómez Arnáiz, 2000). The researchers, from the laboratory of Environmental Toxicology and Environmental Health of University Roviri i Virgili in Tarragona found that very few research and experimental studies had been carry out to prove the safety of GM food products. These results were then used by environmental and consumer groups to cast doubts about the safety of GM food.

Further controversies with regard to the safety and the image of GM food products lead, in Spring 2001, to several multinationals working in the food sector, to take out all their GM products out of the Spanish market. The main products rejected were those of biscuits, baby food, soups and puddings-, such as the company group Nabisco which includes Royal, Artiach, Oreo, Digesta, Marbú, Fontaneda,, Riera Marsá, & Fruco. The products from Nabisco, were the first to be taken from the

market, and this a multinational had already done so as reaction to a public campaign done by *Ecologistas en Acción* back in 1999.

Since the year 2002 some consumer associations were beginning to be more active and provide more visible public reactions in relation to GMOs and thus to carry some precaution/prevention practices. In October 2002, the Fundación Grupo Eroski, also linked to a distribution food store, carried out a study analysing 107 products sold in Spain that might contain GMOs. They results showed that only two of them for human consumption contained transgenic material, both with maize Mon-810: some sugar puffs cereals from *Kellogs* and other maize snack may by *Grefusa*. In both cases, the contamination was under the 1 per cent (0,032 % and 0,048 % respectively) and therefore it was assessed that the labelling of the product was correct according to present legislation (as it is not over 1%). Also six pet food product were analysed and two of them showed transgenic components with RR-soy (*Pedigree* dog food :0,09 %; and *Whiskas* cat food: 6,63%).

In particular, for the person responsible of the Health Programme of the Spanish Consumer Union, Rafael Urrialde de Andrés, the precautionary principle prevails above all in questions related to food safety. However, for him, it makes little sense, while talking about environmental or health risks associated to GMO for human consumption only to focus in food product and leave out other types as those produced for human medicines or animal health. For him, and in contrast with GMO produced by food industry, it seems that GM products elaborated by pharmaceutical industries:

‘Are completely accepted by the citizenship. This latter are no do not affect biodiversity, do not imply costs to cattle producers, are good for citizens, both for health and nutrition, do not imply allergies, nor imply antibiotic resistance and seem to have its innocuousness guaranteed. This situation is bizarre’ (El País Digital, 22. Sept. 02).

For Urrialde, in order to deal with uncertainty, to apply the precautionary principle and ‘to avoid suspicions and mistrusts, for each petition for authorisation of a GM variety, the mechanism to be implemented will ‘study and analyse it in a case by case, individual manner’. Thus, and taking into account consumer interests, such GMO products may be subject to six different possibilities:

- 1 When there is the slightest doubt of proven risk for consumer health, there will be neither notification or authorisation.
- 2 When there is no proven risk for consumer health and the genetic modification implies a social benefit for the citizens (as in the case the healing of an illness, eradicating gluten in food, reduction of the content of lactose in milk...), [such GMO products] will be notified and authorised.
- 3 When there is no proven risk for consumer health and the genetic modification implies a secondary benefit from the application of such products, they will notified and will authorised (e.g.: the *Kit* for analysis of antibiotics in milk; *Raboral*, which is a anti rabies vaccine in foxes)
- 4 When there is no proven risk for consumer health and the genetic modification implies a social benefit for the citizens, such as a nutritional improvement, they will be registered and authorised.
- 5 When there is only an economic benefit due to higher farm productivity and there is not any proven secondary negative effect for the environment, [these GMO products] will be notified and authorised (e.g. carnations with longer life span, or with colour changes).
- 6 When there is no proven benefit for the consumer health and there is only an economic benefit and there is an it is proven that there is an environmental risk, [GMOs] will not be notified nor authorised. (El País Digital, 22. Sept. 02).

Some large food stores, more noticeably linked to international chains, have already made public their position and practices with relation to GMOs. This is the case of

Carrefour Spain, which according to Antonio Arriola, from the store's quality department:

'We do not say that foods which contain GMOs are bad, as nobody can say that. We only apply the precautionary principle to the products that we produce with our own make. And we guarantee this with a complete traceability of the product, even with PCR techniques when necessary. We know where every product comes from and how it has been produced, and if we cannot guarantee that it has not used transgenic soy or maize, simply, we do not include it in our make' (Calvo, A. 2002).

Also, in May 2003, the president of the Spanish Consumers Association (OCU), Mr Carlos Sánchez-Reyes expresses his concern to the conservative Party *Partido Popular*, for the position of the Spanish Government in the EU Council of Ministers with regard to GMOs. He formally asks the Ministry of Environment, the Ministry of Health and the Spanish Agency of Food Safety (MIMAM, MSC, & AESA respectively) and to the main political parties in the Spanish Parliament not to lift the moratorium on GM products, or at least until labelling and traceability regulations become available to the Spanish consumers (OCU, 2003).

In conclusion, and in contrast to the years before 2000, there has been a growing number of public demonstrations by consumer groups expressing their concerns with GM food products. The recourse to the precautionary principle and precaution has been a relatively frequent -although not as a primary rhetorical resource- by consumer groups. In contrast to seeds producers or to manufacturers, consumers have objected to GM foods as not presenting clear advantages for the end consumer. Moreover they claimed that possible benefits of GM foods have not been proved enough when compared with non their non-GM equivalents. Actions done by environmental groups which were directly targeted to consumer have also increased consumer concerns with regard GM foods, as it was the case with the Greenpeace 'green and red list of GM products' (Greenpeace, 2003). A clear message of such campaign was to say that GM products are not necessary, can be substituted by other non-GM foods and furthermore pose a danger to health and to the environment. In the specific case of Bt maize, the only commercialised GM crop in Spain, benefits for the consumers were even less clear, a situation which added to the environmentalist concerns of the effect of such crops on the global environment and on biodiversity.

2.4 National Commission of Biosafety's views

Experts participating in the CNB usually say that they in their functioning they follow a protocol which is given by the Law, and in particular, by those recommendations given by the European Commission which already contain and are inspired by the precautionary principle. In order to get a positive assessment for the authorisation of a GMO trial field or for having GMO commercialisation approved a report containing the following information is needed:

- 1 List of related wild plants which the plant could produce cross-pollinisation.
- 2 Details about how the genetic modification has been taken place.
- 3 Detailed description of the modified plants.
- 4 How and where the trial will take place.
- 5 Control and monitoring measures, and in the case of a trial, specific plans for their crops
- 6 Potential impact on the environment derived from its release.
- 7 Risk assessment of its effects upon health derived from its release.

A general response to question on the way CNB members proceed in their assessments is that they tend to limit the issues at stake and to concentrate solely in 'scientific' issues related to risk and safety. General social, ethical or 'systemic'

questions are not of concern for the CNB. We interviewed three members of the CNB in order to get a inside view on these issues, and in particular on the understanding and role of the precautionary principle in their internal functioning. An expert of the CNB, interviewed in February 2003, asserted when asked about the precautionary principle:

‘There is a problem with the precautionary principle. I think that precaution can be understood in either a positive or negative way. You can understand precaution as fully avoiding any risk, but I don’t believe this attitude to be the right one towards transgenic crops. For the case of GMOs, the precautionary principle must be understood as a case by case, step by step, progressive consideration of the possible, potential risks, keeping an eye on the possible harms derived from risks for the first stages and avoiding its later spreading. However, I think also that the precautionary should be considered for any technology carrying possible impacts on the environment. If we make such an extension of the implementation of the precautionary principle nowadays, maybe we would realize that we should change our lifestyle because many current technologies couldn’t get through such a precaution filter’.

and particularly, on how it had been incorporated and used in the assessments of the CNB:

‘On the one side, every trial requires its possible impacts on the environment to be assessed. As this happens prior to further authorizations, this is an implementation of the precautionary principle. We have denied authorization for some environmental action as it haven’t got through this precaution filter. On the other side, there are some cases where risk assessment requirements are lower, for which authorization involves requesting information about the results which can be known, thereby we can know progressively the implications of those trials.

With regard to the burden of proof, this expert stated that:

‘For this case [of GM crops], the burden of proof is very difficult to be defined. It is impossible to demonstrate the inexistence of risks, it is scientifically impossible and logically inconsistent, we can’t demonstrate the absence of effects. Anyway, we would have to demonstrate the existence, not of risk but of its negative effects, though this requires us to determine what the risk situation is. I think that the best way to proceed is to progressively expose to the risk situation with the constant assessment of risk effects; this is what the precautionary advocates too. We mustn’t demonstrate the inexistence of risk, but we must evaluate for a long time, several campaigns or years, the effects of risk’.

According to this expert opinion, the ‘universal implementation’ of the precautionary principle in the case of GM crops needed to consider case-by-case local conditions, although at the global level no negative effects have been demonstrated:

‘There is a trouble about this. I don’t think that, for environmental issues, we must globalize the implementation of the precautionary principle. To demonstrate that some kind of maize is harmless for sort of Lepidoptera [e.g. butterfly] species in the US doesn’t mean that it harmless for other species in other countries. We can’t transpose those results either if we don’t make trials under the right conditions or if we don’t have the right information. The trouble with the environment is that many of its dynamics and possible effects happen at local scale, though this doesn’t mean that those aren’t important troubles. Then, the universal implementation of the principle can’t mean that we can be confident of what has happened elsewhere. However, so far, it hasn’t been demonstrated that the vast extensions of transgenic crops grown worldwide have any kind of negative effect. Therefore we live in a context determined by ignorance and incompatibility of the affirmations of ones and others’.

The role of participation of civic and other social stakeholders in risk assessment and management was also asked:

'They don't participate though they asked for it. The trouble is that though risk assessment has a social component, it isn't clear that any of this groups can have some kind of social representation for risk assessment, as neither enterprises nor farmers nor consumers do, though they all have as much legitimacy as those stakeholders [environmentalists?]. However, if such organizations were represented [in CNB], what currently are essentially technical assessments and decisions would become political contest issues, therefore we would be taking the place of the established political decision bodies. Something different is the social participation in media, debates and forums, which can never be contested. That helps to shape social opinion'.

And finally, when asked on how the CNB sorts out the issues of ethics and interests, the response was:

'Fortunately there aren't any conflicts for this case. CNB evaluations are made by pairs, thus there are several experts taking part in the evaluation process. When it is necessary, debate is raised, and its usual outcome is the acceptance of the arguments. When any member has got any doubt, he always asks for clarification, thereby there aren't any favourable reports while there is any remaining reasonable doubt. People in the CNB are reasonable, thus agreement is easy to reach. This is one reason why we don't incorporate agents with *a priori* clearly determined attitudes, as they would invalidate the working dynamics of the CNB. Thus these kind of considerations, ethical or religious, aren't addressed by the CNB. Sometimes, questions such as the background and the interests of the different projects applied for approval are brought out, though they aren't considered in the real evaluation process'.

Another central member of the CNB, was also asked about the role of precautionary principle and the procedures used by the CNB to assess the possible risks of GM crops. As stated in March 2003:

'Precaution is difficult to implement, because it can be done in its most strict sense. We try to implement it according to recommendations from European Commission. [...]. We do not interpret the precautionary principle like to do nothing. Our actions are based on scientific information. When there are any doubts we impose limitations for trials. But we are not supporters of the moratorium and of doing nothing' [...]. We are applying the precautionary principle as we had always been doing: with common sense'.

More specifically, when asked whether applying the precautionary principle would entail a different approach to scientific practices and procedures for the risk assessment of GMOs, the answer was:

'No, it does not'.

With regard to the specific criteria used in the CNB:

'CNB assessments aim for health & environment safety, thus they are based in scientific data. We usually apply our criteria thinking of the worst of the cases as a precautionary action'.

And whether comparison with non-GMO organisms is used in the CNB assessments:

No. We do not consider such aspects; we only attend to what is delivered to us. We will not negate any authorisation because there is something equivalent. We are only assessing risks.

for the role ethics and public participation in the CNB has taken the following position:

'different criteria will be taken into account to authorise products, though not within CNB because it only addresses safety. The EU Directive stipulates that ethical committees can be consulted to address general questions, though this will not be done case by case [...]. We are receiving many comments because of our files are delivered to the EU Commission, and which must remain open to public allegations for one month. When we read those comments we see: "we do not want transgenics"; "according to the precautionary principle we must not admit any transgenic"⁴; "transgenics are not necessary in EU"; "transgenics are dangerous for health"; "transgenics cause allergies". These comments are not well grounded. Are the people making these comments representative of the whole society? We have noticed that it is always the same people who are making the same comments on any file'.

As it appears from the above texts, and according to this member of the CNB, the protests and claims which social groups have tended to send to the CNB, have not been not as much related to the safety or the possible dangers which particular a GM crop may entail or to the methodologies used in assessing those risks. Such reactions have been more related to the type of agriculture, or even society which according to some NGOs is represented and enhanced by Agbiotechnology. Undoubtedly, these are kinds of questions, of a social and systemic nature, which the CNB is not designed to debate or answer.

In a similar guise responded our third interviewed expert of the CNB in January 2004, only two weeks before of the approval of the Regulation 178/2004 of the Law 9/2003 which transposes the DRD. When asked about the precautionary principle:

'For us, precaution means avoiding any risk for human health or the environment. We must apply precaution when there is a serious lack of information or scientific knowledge and thus to stop advancing. When we have some data, which will never be enough, and keeping in mind that the zero risk can't exist, our idea about precaution and risk assessment is to determine to what extent we can take on that risk, this is, to balance risk versus benefit. According to the state of the art of knowledge, and considering all of the scientific and technical information that we have been able to study and assess, we are not jeopardizing the safety neither of the environment nor of the people'.

And in relation to public participation of NGO and other social sectors:

'The CNB deals basically with environmental risk but also with some other issues because all of the related Ministries, many experts, and all of the ACs which have asked for it are represented there. There have been many complaints from social agents which are not represented in the CNB since it began to work on 1993. From a political point of view, the Ministry of Environment never accepted their representation in the CNB because this institution was meant to be a scientific one. It is supposed that there are other forums of participation to receive those social agents'.

Finally, it is interesting to note, according to the opinion of this expert, the difficulties which endures the CNB, and why many biotech companies chose Spain as a country to have their files assessed:

'I think it has played a right role while it can obviously be improved. There is a good representation of agents, as well as high quality, in the CNB. All files and notifications in Spain, or 99 per cent, are assessed by the CNB as it is enforced by the new Law, except for some notifications of null-risk contained use which are dealt by the ACs. The CNB evaluates the notifications in order that the CA decides anything later. However the CNB

⁴ Notice that the precautionary principle was therefore already acknowledged to be mentioned by persons at the MIMAM who were to develop the Regulation of the Law 9/2003 before it was approved on the 31 January 2004.

has overwhelming amount of work to do. There are many applications for trials in Spain because the terms are very favourable here. Due to the good acceptance of these crops in Spain, many firms apply their commercialisation files here too. Therefore we often lack of time and human resources to deal with all the remaining tasks’.

Which inevitably must influence both the understanding of the precautionary principle, its role in risk assessment and the actual practices eventually carried out.

2.5 Analytical results: case-by-case versus systemic precaution

Our analysis of the empirical material found for the Spanish case study, provides an heuristic and empirically grounded distinction between *case-by-case* and *systemic precaution*, which was first traced during the first year content analysis of secondary written sources of the PEG research in Spain (Tàbara, et al. 2003) . This distinction is only aimed at giving an analytical tool to support the interpretation of the empirical material which has been collected on the interviews and secondary material. Our findings suggest that the following main traits characterise Spain with regard to the accounts and practices of precaution and of the precautionary principle of GM crops and their commercialisation:

- 1 Precautionary discourses and references to the precautionary principle are mostly absent from all the discourses carried by those actors and agencies most in favour of GM commercial crops. Thus, not only agbiotechnology companies but also some farmers associations and experts linked to them and regulatory agencies aiming to promote the use of large-scale transgenic agriculture in Spain have avoided to talk on the precautionary principle.
- 2 However, in the very few occasions which precaution, the precautionary principle and other related notions have been used by pro-GM crops opinion leaders and managers, these accounts are then used in very different ways than do those opposed to GM agriculture.. In particular, two main broad interpretations or approaches to precaution and the precautionary principle can be envisaged in Spain: one based on the insistence on ‘case-by-case’ and ‘single-issue’ risk assessment and management practices and the assertion that such practices are enough to deal with GMOs risks and integrate precautionary measures in them. In the Spanish language, and very likely for strategic purposes, this is called ‘caution’ (cautela) and often even the precautionary principle is also referred to as the ‘cautionary principle’ (el principio de cautela). The other conception, based on a systemic understanding of the GM issues, makes a number of references to a much broader issues and relations (see section 2.4). Moreover, such different conceptions of precaution seem to have also lead to different practices and judgements in order to deal with transgenic crops.
- 3 The actors who have mostly mentioned and used the notions of precaution and of the precautionary principle as rhetoric weapons to push tighter standards and regulations on GMOs -and denounce deficiencies in the implementation of EU regulations in Spain- have been mainly environmental, organic farmers and health and consumer groups, albeit only recently have they done so in a more structured and public manner. Other new actors have begun to appear in the debate on precaution and GM products such as supermarkets and food dealers.

From the analysis of the she several interviews, workshop recordings and content analysis of secondary written sources, it has been possible to observe that most of the risk assessment individuals, regulatory officials, corporate managers and biotech scientists involved in R + D GM crops in Spain, have tended to interpret precaution in a very similar guise as the traditional notion of risk prevention and risk analysis. For people in favour of a Agbiotech agriculture, the rhetorical recourse to the precautionary principle, to precaution or ‘case-by-case caution’ has been scarce if not absent in many occasions. As a contrast, other public opinion leaders from environmental and consumer groups, the issues of GM crops risks, costs and/or

benefits, precaution has been employed more often and have done so in different and broader interpretative frames. In addition, the latter have frequently included into the debate a larger number of options, not only underlying the economic benefits, and have questioned the inevitability of a single path to (technological) development and the real necessity or usefulness of the GM crops.

Hence, and from an analytical standpoint, two main approaches to the way 'cautionary' and precautionary accounts and practices in Spain with regard to GMs crops and commercialisation can be envisaged. This classification contains a multidimensional description on the way risk assessments, regulatory measures, safety implications, or the role played by other social actors among other issues are perceived by the different stakeholders and organisations analysed in Spain. In synthesis, for the case of Spain, the distinct precaution accounts and practices in current discourses of agricultural biotech crops and its commercialisation are described, and only for heuristic and communication purposes, as being more or less reductionist or single-issue based or more or less systemic.

Table 3 Case-by-case caution versus systemic precaution in Spain

Dimension	Case-by-case caution	Systemic precaution
Expert approach and strategies to risk assessment, costs and benefits	Single-issue focused, mainly on a particular crop or product. Towards reduction. Focusing mainly on benefits, usually only of the economic kind, and tending to ignore costs	Systemic, in a holistic and relational manner. Towards integration. Giving equal weight to costs and benefits and of different kinds
Trends and criteria to decide thresholds on commercialisation and its consequences	Increase thresholds, for reasons of feasibility, and economic profit	Reduce thresholds, for health, environmental or safety reasons
Main risk and benefit discourse; orientation	Towards natural objects or human subjects and towards specific issues.	Towards socio-environmental relationships and Systems
Risk management style and type of participation orientation promoted	Towards separated administrative bodies. Fragmentation.	Towards several agencies at the same time, in an integrative way; transversal management
Form of public consultation; encouragement and support for stakeholder participation	To specific stakeholders, one by one; without special support to participation	To a plurality of stakeholders at the same time, encouraging diversity
Main references to frame risks, potentialities and problems	Individual: e.g.: defence of consumer choice, personal health, or food taste	General: socio-political, structural and environmental aspects
Possibility of coexistence	Possible and desirable, with conditions, but to a large extent unavoidable	Not possible or desirable, mainly for social and environmental reasons
Main time and space scales taken into account	Short and medium term; local and national	Long term; global, international
Aim of evaluations, usually implicit in the different GM crop discourses	To reduce the number of elements, relations and issues to be considered	To increase the number of elements, relations and issues to be considered

Food discourses on global supply; public interest GMO justification	Food safety as dependent on increasing quantity and pushing technology; agbiotechnology is needed for 'survival'	Enough food is already available, food safety not dependent on quantity or corporate technology but on social and economic relations
Type of losses to be precautionary about	Mainly economic	Mainly social and environmental, but also some economic
Type of knowledge and expertise demands and sources to tackle uncertainty	Mainly natural sciences, although economics and law are also used in a disciplinary manner; limiting scientific expertise to 'experts'.	Mainly social and environmental sciences; interdisciplinarity; promoting the democratisation of expertise
Importance given to the burden of proof, to assess risks and inform decisions	Crucial, to argue that no evidence of negative effects has been provided on particular issues	Less important, although also present, as higher difficulties exist to prove systemic damage and negative outcomes.

In general then, either caution, precaution or the precautionary principle have not received much of attention in articulating the demands or institutions for GM safety and regulation in Spain. Nevertheless, and whenever precaution and the precautionary principle have appeared -as in case of the recent regulatory texts on GM crops- the terms 'caution', and the 'cautionary principle' have been used. While the meaning of caution remains largely implicit, opaque, and always intermingled with that of prevention, it appears that caution has been given a meaning close to the traditional approach of risk prevention and management. In other words, 'caution' has not been identified or differentiated from prevention in a operational and distinctive manner. Environmental and consumer groups, however, have employed the terms precaution and precautionary principle more often and done so in a more explicit manner and systemic sense. Indicative of the lack of official presence of the debate about precaution and of the precautionary principle in Spain can be found, for instance, in reviewing the only book published in Spain (and in Spanish) about these issues (J. Riechmann & J. Tickner, 2002). Despite it specifically deals with the role of the precautionary principle in the management of public health and of environmental issues, it does not devote a single line on the case of precaution in the Spanish context. In the few occasions the discourse and practices on the 'cautionary' or precautionary principle in Spain have appeared, such claims have tended to be centred in the first place on the issues of human food safety and consumer choice, and secondly, on issues of environmental and social concern. Among the later, farmers' rights to the conservation and control of traditional knowledge on farm practices and plant varieties developed in traditional manner and its attendant benefits have received increasing attention in recent times.

3 Three institutional practices

In Spain, there have been some confrontational practices, actions and activities carried out both by defenders and detractors of GM agriculture and in particular, with regard to coexistence (see Table 5 in section 3.3.1). However, the majority of the social actors who in general contribute to the creation of a public debate or conflicts around the GM crops in other EU countries have not played much of a significant role in Spain, as it could be expected from the only Community member where large-scale commercial GM agriculture is carried out. The coverage of GM crops related issues by the Spanish media has been very scant and only in very few occasions have they hit the national news. The lack of an environmental movement able to overcome the level of action of the Autonomous Communities explains partly the lack of collective action in this area and the inexistence of a green party with representation at the Spanish Parliament is indicative of this political fragmentation in relation to socioenvironmental issues. However and above all, it appears that Spain, having emerged from a situation of dictatorship and relative underdevelopment in the seventies and trying to catch up with the economic standards of living of its European partners, has grossly relegated some health risks and other environmental issues to the end of the political portfolio. And when these issues have penetrated political discourses, it has been as a reaction to external pressures, mainly from the EU directives and regulations or other international environmental policy process such as climate change in which Spain has adopted a position closer to the USA than to the EU.

Spanish administrative institutional capacity has showed great resistance to change and to the incorporation of complex regulatory issues associated with complex environmental and health risks where strong corporate interests are at stake⁵. In this respect, precaution and the precautionary principle in particular have not produced the expected effects in stimulating major institutional adaptation, but only in a relatively limited organisational areas of already existent administrative structures which inevitably had to introduce to some provisions contained in the EU directives though always in a peculiar way.

3.1 GM crops, regulatory practices and institutions

3.1.1 Main regulatory measures and institutional developments

In Spain, general activities related to risk assessment and regulation of GMOs are channelled through the Ministry of the Environment and are regulated in the Royal Decree 695/2000, of 12 May in which the organic structure of the Ministry is established. In particular, the responsible unit for managing the evaluation of environmental risks is the *Dirección General de Calidad y Evaluación Ambiental* (DGCEA; General Directorate of Environmental Quality and Evaluation) of the Ministry of the Environment. However, the CNB (National Commission on Biosafety) examines the petitions for the authorisation of the commercialisation of GMOs in order to inform the Ministry of the Environment. Until December 2003 far the Commission has held around 25 meetings, reacting in straightforward and synthetic manner to petitions made by private companies and public research institutes to allow the building of new biotechnology facilities, new trials and experiments with GMOs in Spain.

According to the official figures at the Ministry of the Environment, out of the 90 petitions for authorisation made to the CNB from June 1992 to February 2001, the results are the following:

⁵ In this respect, there are also close similarities with the case of climate change, D. Tàbara (2003).

Type of notification to the CNB	Approved	Rejected	Not answered	TOTAL
New facilities for contained experiments	28	0	13	42 (*)
Use of contained experiments	43	1	4	48

(*) one was not applicable of the Law 15/1994.

All the petitions between 1993 and 1998 -except one without answer- on use of contained experiments were resolved as positive, and all the petitions for new facilities between 1993 and 1998 were authorised. From this data, it can be interpreted that from 1998 on a different kind of response may have come up from this Commission, in delaying or not responding in positive way the petitions for new authorisations.

The main criteria followed so far seem to be those that allow only authorisations that remain as far as possible from the consumer preoccupations. This may explain that most of the authorisations for commercialisation of GM varieties have not been directed to human consumption but as livestock to feed or clothing material (cotton). However a link between meat production, environmental impact, and the pressures for further authorisations and expansion of GM agriculture, has not yet been widely made in public

According to E. Marin Palma (2001:204). him, the Biosafety National Commission, while studying the intentional releases of GMOs looked mainly at the following criteria:

- (a) Characteristics of the giving organism origin of the genetic material.
- (b) Characteristics of the receptor organism.
- (c) Genetic sequences introduced.
- (d) Type of environment in which the deliberate release is to be carried out.

For J. C. Blanco (2001), 23 seed transgenic varieties from five companies were waiting for over two years to have its authorisation passed. According to this source, which appeared in a business newspaper, all these varieties had already all the legal requirements passed but the Ministry of Agriculture, Fisheries and Food was delaying its approval because of social reluctance to these organisms. The five companies involved were: Monsanto, Syngenta, Aventis, Pioneer, & Nickerson. Such varieties have passed the proofs required by the National Commission on Biosafety and therefore, according to its president, Anna Fresno it was just a 'political decision'. For the subsecretary general of the Ministry of Agriculture, the strategy of Ministry is put all 'responsibility on the EU', in the hope that the EU will develop a consensuated regulation on these matters. Given this situation the *Asociación de Empresas Productoras de Semillas Selectas* (Aprose; Association of selected seed producers), proposed to reduce the number of approved seed from 23 to 5 (very likely, one of each Company), although again the response was to wait and see what the EU says. In 2003, the number of transgenic varieties waiting for authorisation being paralyzed by the Ministry of Agriculture grew up to around 30 (Elcacho, 2004). However, such position of the Ministry of Agriculture, which could be understood as precautionary, overly changed after the Conservative party achieved its absolute majority, a time when the necessary legislative and institutional developments could be easily put in motion for the approval of the 14 new varieties of GM crops.

The CSIC is the key institution providing expert judgements on GM from its large network of research institutes in Spain, an conforms a institutional structure parallel to those of Universities but only oriented to carrying out research. At the end of 2001, in Spain there were about 170 research groups in Biotech in Spain working in 17 different cities. Due to the structure of seed industry in Spain, most of the plant biotech innovation and use rights have been sold to international companies. The four

centres that now hold a largest number of researchers dedicated to plant biotechnology are the following (García Olmedo, 2001:51):

- (a) *Centro de Biología Molecular y Celular de Plantas*, in Valencia as a result of an association between the CSIC and the Universidad Politécnica de Valencia.
- (b) *Centro de Investigación y Desarrollo*: in Barcelona, of the CSIC.
- (c) *Departamento de Biotecnología de la Universidad Politécnica de Madrid*.
- (d) *División de Plantas del Centro Nacional de Biotecnología*, in Madrid.

Also, in Spain the only laboratory with sufficient conditions to carry out GMO activities with need contained uses of type P3 and P4 is the *Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria* (INIA) which part of the Ministry of Science and Technology and also the Centro Nacional de Biotecnología is building the same type of facilities.

In recent times, and specially following the two electoral victories of the conservative party *Partido Popular* which lead to its absolute majority since 2000, Spain has followed an open policy of clear support to GM crops development and implementation which has been defended both at home and at the EU institutions. The growing pressure exerted by Spain was clearly visible in the EU Council of Ministers in 2003 when Spain and five more countries asked for the end of the moratorium. Although in the year 2000 the Spanish Agriculture Minister still did not expressed such open opinions in public (and tended to say that a common position was being searched among the different Spanish Ministries involved in the regulation and management of GM crops), in May 2003 he finally stated that:

‘The future of the agriculture production goes with GMOs’ (Infoagro, 2003)

Interestingly enough, Arias Cañete also referred then to the need to apply the precautionary principle ‘given that in agriculture resources are limited and water is scarce’⁶. In his words, Spain should not ‘lose the train of history’, and ‘should not become a backward site in this issue... especially where there are countries where people dying of starvation’. (Infoagro, 2003).

For the case of Spain, two main types of regulatory developments should be distinguished: those related to the Administration of the Spanish State as a whole - Central Administration- and those being carried out by the Autonomous Communities’ Administrations. Indeed, regional diversity -not only in institutional practices but also in perceptions and agriculture traditions- explains largely the evolution and the history of GM crops and policy in Spain. In general, Spain has usually tended to adopt and implement EU directives, regulations and decisions without too much controversy, despite the deficit in many of its administrative agencies to comply effectively with them (more generally known in other Mediterranean countries as the ‘Mediterranean syndrome’). In the case of GM crop policy, however, as will be explained later, the usual ‘implementation deficit’ has been combined with a increasing favourable position by Spain in support of GM agriculture and development.

The table below (Table 4) shows the chronology of the main regulatory and institutional developments relevant to the governance and commercialisation of GM crops since 1971, a departing point in the modern seed and commercial plant regulation in Spain.

⁶ The link between ‘water risks’ and agriculture is usual in public discourses and by explain its inclusion here with regard to the precautionary principle.

Table 4 Chronology of main regulatory and institutional developments relevant to the governance and commercialisation of GM crops in Spain

Date*	Main regulatory/institutional development	Comment
30 Mar. 1971	Law 11/1971 – regulation of commercial seeds and greenhouse plants	<i>Competent authority:</i> Ministry of Agriculture Main modern regulation of commercial seed varieties starts in Spain
30 Nov. 1973	Order of the Ministry of Agriculture on the General Regulation with regard to the necessary conditions for the registration of commercial varieties of plants	<i>Competent authority:</i> Ministry of Agriculture. In this regulation GM varieties were not excluded for registration, and therefore GMOs were treated as any other type of commercial plant varieties
6 Dec. 1978	Approval of the new constitution	A major process of transference of agricultural competencies to the 17 new Autonomous Communities (ACs) starts. Central government keeps general state legislative powers, while ACs gain administrative competencies on management, regional implementation and enforcement of the attendant laws
3 June 1994	Law 15/1994 on contained use, deliberate release and commercialisation of GMOs This law establishes the creation of the <i>Comisión Nacional de Bioseguridad</i> (CNB) and the ' <i>Órgano Colegiado</i> ' as the Competent Authority for authorisations <i>via</i> the <i>Consejo Interministerial de OMG</i> (CIOMG)	Implements EU Directive 90/219 (of 23rd April) on contained use of GMOs and EU Directive 90/220 (also of 23rd April) on deliberate release into the environment of GMOs. All applications for GMO authorisations need to be accompanied with a risk assessment Central Administration retains the competence for the authorisation of commercial GMOs while ACs have competence for the authorisation of GMOs for contained use and non-commercial releases (and GMOs not to be used for human or animal consumption or drugs). Central Administration also has the competence for authorising GMOs related to national Spanish research (in several CAs) and CAs also have control and sanctioning capacities for the GMO activities in which CA have competences
4 Nov. 1994	Royal Decree 2163/1994 on utilisation of phytosanitary products	<i>Competent authority:</i> Ministry of Agriculture. Implements the European system for the authorisation and utilisation of phytosanitary products. All GMOs that use new herbicides need to comply with such a system and this regulation

21 June 1996	Royal Decree 1538/1996 creates the first Ministry of the Environment in Spain	The distribution of competences is further specified four years later in the Regulation Royal Decree 695/2000, of 12 May
20 June 1997	Royal Decree 951/1997, developing Law 15/1994.	Implements the technical issues of 90/219 and 90/200 Directives, and also the later 94/51 and 94/15 Directives (both of 7 November), which update the annexes of Directives 90/219 and 90/220. Directive 90/219 was almost completely modified by Directive 98/81 of 26 October on Contained Use of GMOs. Directive 90/220 was then repealed by Directive 2001/18 in 17 October 2002. The non-implementation of Directive 98/81 resulted in a case against Spain before the European Court of Justice (Pellicer, 2002)
26 Mar. 1998	First two Bt maize varieties approved for registration in the Commercial Plant Varieties Registry; Order of MAPA of 23 March 98	These varieties were authorised for commercialisation five years before the creation of the Commission of Biovigilance These varieties were based on the EU-wide Bt maize approvals of 1997 and 1998 of products by Monsanto and Ciba-Geigy based on the Decisions 97/98/CE and 98/294/CE
7 Jan. 2000	Law 3/2000 on the protection of plant varieties	Competent authority: Ministry of Agriculture and Autonomous Communities This law was modified in 12 March 2002 by Law 3/2002, as a result of pleas presented to the Constitutional Court by the ACs of Basque Country, Catalonia and Canary Islands in order to guarantee that ACs retain their administrative competencies for new plant files. New plant varieties legal regime is akin to the regime for the protection of industrial property
16 Jan. 2002	Spain ratifies the Cartagena Protocol on Biosafety and becomes a full party of it on the 11 September 2003. The Protocol was first signed by Spain on the 24 May 2000	Competent authority: the national focal point designed for the implementation of the Cartagena Protocol is the DGCEA (Environmental Quality and Assessment Department) of the Ministry of the Environment The Convention on Biological Diversity was first signed by Spain on the 13 June 1992. Spain became a party to the Convention on 21 December 1993
20 Aug. 2002	The proposal for the new law on contained use, deliberate release and commercialisation of GMO is published in the BOE for comments	Aimed to implement EU Directive 98/81/CE on Contained Use of 26 October and Directive 2001/18/CE on Deliberate Release of 12 March Comments on this law were published in the BOE of 22 October 2002. The final text of the law was approved in December 2002
26 April 2003	Law 9/2003, of 25 April, on contained use, deliberate release and	This law transposes the EU Directives 98/81/CE on Contained Use and 2001/18/CE on Deliberate Release at the same time (this is why Directive 98/81/CE is mentioned here), and repeals the

	commercialisation of GMOs	<p>former Law 15/1994. The former Royal Decree 951/1997 is to be applied, when it does not oppose Law 9/2003, for the following six months, which is the deadline to pass a new technical regulation (<i>reglamento</i>) to develop the new law</p> <p>Law 9/2003 is based on the following principles: prevention and caution (the word <i>precaution</i> is not mentioned); case-by-case; step-by-step; public information and participation; free access to information on authorised releases and commercialisation. It establishes that for any new GM variety to be registered for commercial uses, the Competent Authority will be the CIOMG, with the assessment of the CNB</p> <p>It does not set up any obligation to monitor the movement of GMOs within Spain as a result of commercialisation (after they have been harvested). It enforces dealers to keep the legally required data for traceability, and the ACs to notify the Ministry of the Environment of the location of fields growing GM crops (both non-commercial and commercial releases). The Ministry must keep a central register of these locations</p>
Date*	Main regulatory/institutional development	Comment
July 2003	The first draft proposal of Regulation (<i>Reglamento</i>) for Law 9/2003	Law 9/2003, in order to become operational needs to be further developed by a corresponding regulation. Originally, a deadline of six months was established for such legal development to come into force, but it did not appear until the 31st January 2004
27 Dec. 2003	Creation of the <i>Comisión Nacional de Biovigilancia</i> (National Commission of Biovigilance), by Royal Decree 1697/2003	Administratively belongs to the MAPA. One of its explicit functions: to ensure coexistence of conventional and organic agriculture with GM agriculture
11 Mar. 2003	Five new Bt maize varieties approved for registration in the Commercial Plant Varieties Registry; Order APA/520/2003 of 27 February	Competent authority: Ministry of Agriculture Based on Decisions 97/98/CE and 98/294/CE and derived from the 1998 approved modifications CG 00256-176 and MON 810
16 Feb. 2004	Nine new Bt maize varieties are approved for registration in the Commercial Plant Varieties Registry;	Competent authority: Ministry of Agriculture Based on Decisions 97/98/CE and 98/294/CE and derived from the 1998 approved modifications CG 00256-176 and MON 810

	Order APA/314/2004 of 4 February	
31 Jan. 2004	Regulation 178/2004, of 30 January developing Law 9/2003 of 25 April Creates the ' <i>Registro Central de OMG</i> ' (General Registry of GMOs) within the DGCA of the MIMAM	The proposal was sent for comments to a selection of relevant stakeholders, including biotechnology companies, environmental groups and Acs. However, it was not available on the AC web site as late as January 2004 and was approved by the council of ministries on 6 February 2004 Reforms the composition of the CIOMG as the competent authority for the authorisation of GM releases in the Central Administration
April 2004	Implementation of the EU GMO labelling regulations in Spain	Straightforward implementation of European regulation into Spanish legislation

(* Dates of publication in the Spanish Official Gazette – *BOE*.)

In Spain, all new plant varieties, in order to be commercialised, need first to be registered in the *Registro de Variedades Vegetales* (Commercial Plant Varieties Registry) being the Competent Authority the Ministry of Agriculture (MAPA). The present regulation dates back to the Law 11/1971 and the Regulation of 30 November 1973, hence, a set of regulations which were made in times of the Franco dictatorship. The regime change to democracy and the approval of a new Constitution in December 1978, despite it started a large process of decentralisation of agriculture competences to the Autonomous Communities, did not change, fundamentally, the regulatory conditions on the general registration of new plant varieties. At present, for a particular plant to be registered, either conventional or transgenic, it needs to verify that it is an distinct variety, it is stable, homogeneous, and has agronomic value. Applications for registration of new plant varieties also have to comply with a monitoring plan which needs to be approved by the Ministry of Agriculture. In the case of transgenic plants, each monitoring plan is specific for each transgenic variety. In particular, such plans need to cover the behaviour and the possible effects of the GM variety on the plant itself, on soils, on animal feeding behaviour, on other conventional crops nearby GM crops, and measures to be taken in case of 'adverse or unexpected consequences' (sic). Regulation 178/2004, of 30 January developing Law 9/2003 of 25 April created the 'Registro Central de OMG' (General Registry of GMOs) within the DGCA of the MIMAM

On the 3 June 1994 the Law 15/1994 on contained use, deliberate release and commercialisation was approved in Spain, its aim being at implementing the EU Directive 90/219 and the EU Directive 90/220. As stated in the texts, Autonomous Communities kept competences on the authorisation of contained uses and non-commercial releases, as well as on control and enforcement while authorisation for deliberate release on the environment for commercial use was competence of the central government. Royal Decree 951 was intended to develop the technical implementation of the Law 15/1994.

The Law 15/94 created the *Comisión Nacional de Bioseguridad* (National Commission on Biosafety, CNB). The CNB sets criteria for the approval of trials and facilities based on a review of petitions made by private companies or public institutions under a 'case by case' and 'step by step' procedure. According to the structure established in the Law 15/94, a total of 11 experts are called for to participate in the CNB six proposed by Autonomous Communities and other five who belong to the Spanish Scientific Research High Council (CSIC), the largest scientific cluster of research institutions in Spain. Originally, and according to the article 45 of the Royal Decree 951/97 developing the Law 15/94, the composition of the National Commission on Biosafety, which was given the role of a consultative body part of the administrative organisation of the MIMAM, was designed as follows:

- President: A representative of the Ministry of the Environment.
- Ministry of Environment: up to 6 members.
- Other ministerial members: 1 from the Ministry of Health and Consumption; 1 from the Ministry of Agriculture, Fisheries and Food; 1 from Ministry of Industry and Energy, 1 from the Ministry of Education and Culture;
- Up to 6 experts.

However, in practice, by the year 2003 (and before the approval of the Regulation 178/2004) the National Commission of Biosafety had grown substantially and was finally composed by the following members:

- Ministry of Environment: 6 members, including the chairman.
- Ministry of Health and Consumption: 5 members
- Ministry of Agriculture, Fisheries and Food: 4 members.
- Ministry of Industry and Energy: 4 members. One worked in CSIC.

- Ministry of Economics: 1.
- Ministry of National Interior Affairs: 1
- Ministry of Education, Culture and Sports: 2
- Experts proposed by CA (competent authority): 6. One worked in the National Centre of Biotechnology, five work in universities.
- Other specialized experts: 5. Three from the High Council for Scientific Research (CSIC), one in a university, one in a research centre of Andalusia government.
- Representatives of Autonomous Communities: 1 each, although some Communities such as Ceuta and Melilla did not have a representative.

Making it very clear the growing interlinkages between assessment and regulation procedures making it impossible to assert the independence of the CNB to the political agencies and transforming it mostly into a place where both expert assessment and policy interests mix together and in very close way. For instance, only 11 out of nearly 50 of the members of the National Commission on Biosafety (in practice there were less, as some Autonomous Communities were not represented) were scientists, while the rest were mostly civil servants representatives from the various State and ACs public administrations.

The regulation 178/2004 approved in January 2004 has not resolved the problems of lack of independence of the CNB. In fact it has strengthen is political functions and has weaken the expert consultative ones. Although the main function of CNB is to work as a consultative body in order to inform in a perceptive way on the authorisations, then many of the same Ministries appear again in the Competent Authority in charge of authorisation of commercial GM varieties. Article 8 of such regulation establishes the composition of the CNB and again, it is stated that the president be a civil servant from the *Dirección General de Calidad Ambiental* (DGCA) of the MIMAM, together with:

- 1 vice-president, nominated by the Ministry of Environment.
- 1 civil servant from the Ministry of National Interior Affairs.
- 1 civil servant from the Ministry of Education, Culture and Sports.
- 4 civil servants from the Ministry of Agriculture, Fisheries and Food.
- 4 civil servants from the Ministry of Health and Consumption
- 2 civil servants from the Ministry of the Environment, experts in biosafety and biodiversity.
- 1 civil servant from the Ministry of Economics, expert in international trade.
- 4 civil servants of the Ministry of Science and Technology, experts in agro-food technology.
- 1 member of each CA asking to become part of the CNB
- Up to 6 members of scientific institutions
- A Secretary without vote capacity of the DGCA of the MIMAM

As shown in the table 4, Law 15/1994 of 3 of June on contained use, deliberate release and commercialisation of GMOs first established the structure, functions and composition of the *Consejo Interministerial de Organismo Modificados Genéticamente* (CIOMG), competent authority for the GM authorisations. However, Regulation 951/1997 developing Law 15/1994 specified that an inter-ministry structure named '*Organo Colegiado*' (OC) would deal with the authorisations of those GM releases which competence is restricted to the Central Administration. Art. 44 of Regulation 951/1997 established the composition of the OG by a president from the

DGCEA (MIMAM) and one member of four ministries: Health, Agriculture, Industry and energy (later the Ministry of Industry would disappear) and Education. Therefore, not only the number of Ministries involved in the CNB increased in relation to its first composition but also the number of ministries participating in the authorisations of GM releases did so. The Regulation 178/2004, of 30 January has further clarified the procedures for GM authorisations which now are channelled through the CIOMG, although it still does not resolve the problem of lack of independence between assessment and regulatory bodies. For instance, it states that the president of the CIOMG be also the president of the DGCA of the MIMAM, and several Ministries which participate in the CNB also participate in the CIOMG. Moreover, the CIOMGs also needs the conformity of the MAPA in order to obtain the authorisation of GM varieties for commercial use. According to Art. 6 of the 178/2004 regulation, the current composition of the CIOMG is as follows:

- 1 President: who is also the president of the DGCA.
- 1 member of the Ministry of National Interior Affairs.
- 1 member of the Ministry of Education, Culture and Sports.
- 2 members of the Ministry of Agriculture, Fisheries and Food.
- 1 member of the Ministry of Health and Consumption.
- 1 member of the Ministry of the Environment
- 1 member of the Ministry of Economics
- 2 member of the Ministry of Science and Technology
- 1 member of the Spanish Agency of Food Safety (AESAs)
- 1 member of the Spanish Agency of Medical Products.

On the 26 March 1998 (BOE, 1998) and despite the lack of the institutional developments able ensure the independence of expert risk assessments in Spain at that time, the first two varieties of Bt maize were approved. The approval of these varieties were based in the Decisions 97/98/CE and 98/294/CE on the EU-wide Bt maize approvals of products by Monsanto and Ciba-Geigy made in 1997 and 1998.

Later, on the 5th June 2000 ended the term for the Spanish authorities for adapting its regulatory bodies in tune with the Directive 98/81 on Contained Use of GMOs. However Spain failed to introduce new assessment methods in relation the deliberate release of GMOs nor provides high safety laboratories or containers for its repository (Fundación Grupo Eroski, 2000). As far as in 2001, and even for the pro-agbiotech lawyer E. Marin Palma:

“National legislation still has not adapted to the latest modifications established in the Community instruments which have to be deemed in any deliberate release, such as the establishment of general and uniform principles for the evaluation of risk, the creation of monitoring plans and pests control, labelling of products according to their aims, the application of precautionary principle in the applicable rules, the differentiation established between procedures of part B and part C [of the Directive], the need of Bioethics councils and of scientific assessment councils, the incorporation of public opinion, and the establishment of the term between the date of commercialisation authorisation and its later renewal (10 years)” (E. Marin Palma 2001:204).

The ‘implementation deficit’ and difficulties of the EU Directives on GMO issue have been shown in several occasions. On the 13th March 2003, the European Court of Justice sentenced Spain for having failed to implement in time Directive 98/81/CE on Contained Use of GMOs. And again, in 15 July 2003, the European Commission took action against eleven Member States, including Spain, to the European Court of Justice for having failed to meet the 17 October deadline in the adoption and

notification of national legislation implementing the Directive 2001/18/EC on Deliberate Release of GMOs (Tribunal de Justicia, 2003, Seedquest, 2003).

Both directives are mentioned here because, finally, on 25th April 2003 came into force the Spanish Law 9/2003, which set the legal regime *at the same time* for the contained use, deliberate release and commercialisation of GMOs in Spain. This law transposed the EU Directive 98/81/CE of 26th October 1998 and the Directive 2001/18/CE of 12th March 2001. Law 9/2003 derogated the previous Law 15/1994 law and the Royal Decree 951/1997. Opposition parties and NGOs attacked the passing in the Parliament the law 9/2003 on the 3rd of April for 'allegedly failing to transpose safeguards contained in the underpinning of EU deliberate release directive' (ENDS, 2003). The *Partido Socialista Obrero Español* (PSOE) and Izquierda Unida (IU) claimed that conservative government had used its absolute majority to 'bypass the precautionary principle contained in the directive' and Greenpeace said to have excluded clauses referring to risk assessment, and independence of committees authorising new releases and monitoring (ibid).

The Law 9/2003 of 25th of April, derogated the two former laws and such law had already been announced by the Ministry of Environment on the 2 August 2002 in the form of a law proposal, which would take into account the European regulatory measures being approved since 1994 (when was passed the current Law). The principles which are the basis for the Law 9/2003 are *literally*:

- Prevention and caution. (that is, the word *precaution* is not mentioned in the text)
- Case by case.
- Step by step.
- Public information and participation.
- Citizenship access to information related to authorised trials and commercialisation.

Other modifications relate to the inclusion of traceability and labelling requirements, which were largely neglected by the previous law. Fines for serious infringement and negligence of the law, such as the commercialisation, import, export of GMOs without the attendant authorisation, can be up to 1.200.000 euros and possible suspension of the activity or the closure of facilities where such products are being produced. Another aspect regards to the impossibility for Autonomous Communities to authorise a GMO trial or if there is not agreement among European countries on that specific GMO in the first case.

However, the law 9/2003, in order to become operational needed to be further developed by the corresponding Regulation (as 951/1997 regulation did with the 15/1994 law). Its first draft appeared in July 2003 and originally, it was established a deadline of six months for such legal development to become into force, although it was not until 31 January when the attendant Regulation 178/2004 came into force. In the final text:

- The word *precaution* is not used (as it was the case of the Law 9/2003), despite it exists in Spanish, only 'caution' [cautela], and in some cases 'prevention' is mentioned. Furthermore, precaution is used in the sense of traditional risk prevention (as EEA, 2001), and assumes that is possible to estimate probabilities and the consequences of possible risks of GMOs crops as if they were not fundamentally different from other risks.
- The composition of the CNB is modified, but still does not include any member from civic, farmers, or environmental organisations.

- Aimed at reducing the Autonomous Communities' competences in the regulatory capacity of GMOs (mainly contained use and deliberate release authorisations)⁷.

Some environmental and civic organisations reacted and were given access to the draft text of the Regulation in order to give their views on this document. This was the case of Friends of the Earth – Spain (AdT, 2003a, 2003b). In their opinion, the proposed Regulation, among other issues:

- Did not contain some definitions and did not specify adequately, as it is stated in the directive, some concepts related to GM risks. In particular, the concept of what is understood as 'product' is not defined nor there is no mention to *direct and indirect* or to *immediate and delayed* risks.
- Did not transpose adequate the obligation of providing an independent scientific report with regard to environmental effects of GMOs.
- Lacked adequate provisions for the information, consultation, participation of civil society in the competent authority before authorisations are made.
- Did not mention in the possible long term effects in the monitoring plan of deliberate releases of GMOs-.
- Reduces substantially the number of requirements needed for the use and commercialisation of GMOs, since the labelling and traceability conditions to localisation of GM crops.
- Showed the intention of the Spanish government to make two types of procedures for authorisation of deliberate releases one 'simplified' and the other 'differentiated' (the latter did not exist in the Directive):
- Did not clarify issues about liability in cases of damage and losses to third parties which are still largely undefined;
- Did not regulate the possibility of actions to be taken in case non-authorized GM products are deliberate released or commercialised in Spain.
- Did not included the obligation of stating the location of crops and register of crops and liabilities in case of non compliance with such obligations. Furthermore, FoE-Spain argued that on the one hand there was a contradiction in stating that in some parts of the Regulation asserted that the location of releases will be specified while in other places it said that such location will not necessarily be made public. FoE asked for an additional obligation to state all the locations of GM crops and releases, as well as the list of holders which have authorisations and the farmers who use them.

The farmers' coalition 'Plataforma Rural' (PF) also reacted to the Regulation proposal of the Law 9/2003 in September 2003. This coalition, which together with COAG set up the Campaign 'Transgénicos, ¿Alguien me ha preguntado?, La libertad del agricultor, el derecho del consumidor' (GMOs, has anybody asked me?, freedom for the agriculture farmer, a right for the consumer) asked MAPA to follow the precautionary principle and expressed that transgenic agriculture was incompatible with organic and other types of agriculture. Among some of their demands were the following:

- To make public the names of the authorisation holders and agriculture farmers of GM crops, as well as the location of the fields with GM varieties -either for commercial and non-commercial purposes.

⁷ According to our interview at the Ministry of the Environment (MIMAM) this was one of the main obstacles which led to postpone this Regulation.

- To open up the participation of social organisations to the National Commission of Biosafety in order to have a say in the process of new authorisations. Independent experts proposed by social organisations should be included when carrying out reports of contained use of type 3 and 4 (moderate and high risk).
- To set up more severe measures in case non-authorized GMOs are released into the environment.
- Further specification of monitoring and control of GMOs, and that such controls be efficient, independent and complete. (Agroinformación, 2003b)

In this respect, and despite the Directive/18/CE explicitly stated the obligation of public consultation with the public of all the procedures for authorisation of deliberate releases of GMOs, previous obligation is not contemplated in the new Regulation 178/2004, of 30 January, and consultation still remains discretionary to the attendant Competent Authority. Particularly, with regard to public information and consultation issues, and although the preamble of the Law 9/2003 states that the Law will 'guarantee the consultation with the public *before* the authorisation of some activities of contained utilisation [of GMOs] and all of the voluntary releases and commercialisation', in fact, art. 20 of the law limits this public information to the authorisations, assessment reports and results from other scientific committees *already* provided by the Competent Authority and expert bodies. Regulation 178/2004 which regulates public information of the Law 9/2003 has not resolved this problem and maintains the same position: This article 49 of Regulation 178/2004 on public information -no consultation is mentioned- did not change these matter despite the comments to the draft text given by farmers and environmental organisations.

With regard to public information and consultation with stakeholders and the development of the Regulation 178/2004 during the previous months of its approval, two interviewed experts of the CNB who participated in its elaboration, asserted in January 2004 that:

Expert 1: 'I think that industrial and agrarian associations have been the most influential ones [in the elaboration of the Regulation]. NGOs hold such rigid standpoints that it is very difficult to discuss with them. We haven't been able to talk with them in many forums where we have been presenting the regulations on GMOs. Although I personally think that it would be very interesting that they were represented, we have always said that things have to be argued according to some scientific and technical basis. We have asked them for it but they have never answered to us in those terms'.

Expert 2: 'We have a forum in the web page of the MIMAM though it doesn't work properly because the whole web site is under reconstruction. [...] It is not going to be available before the final approval of the Regulation [on the 31 January 2004]'.

Expert 1: 'The information exchange with these NGOs had taken place through the Advising Council on the Environment though it hasn't worked too fine for some reasons during the last years, thus there hasn't been any institutional exchange of information with them. However we have always given some answer to them when they have requested information⁸. Moreover they are always interested to know the exact place the GM crops are, and we give them that information with the precision of municipal

⁸ This doesn't always mean that the requested information was effectively provided to NGOs. For instance an interviewed Greenpeace activist (on January 2004) told that they haven't been delivered the report on the monitoring plan of Compa CB maize (published on June 2003) though they have been requesting it for more than half a year and it is supposed to be a public access file.

scale when they make a formal request and it is not confidential information⁹. However they usually don't like our answers'.

On the 27th December 2003 the *Comisión Nacional de Biovigilancia* (National Commission of Biovigilance CNBv) was created via the Royal Decree 1799/2003 as an initiative of the Ministry of Agriculture (MAPA; BOE, 310:46235-46237, 2003). Its aim being to become a unit in charge of assessing the MAPA on the GM crops on the monitoring plans, traceability and labelling as well as on the coexistence between GM crops and conventional or organic agriculture¹⁰. Having said so, however some of the traits of this new regulation are remarkable and worth mentioning:

- Just at the beginning of the exposition of motives the new law on the Commission of Biovigilance explicitly states in that 'there is no reason for genetically modified varieties crops to be less safe than the crops of traditional varieties and they [GM crops] can be less harmful for human health, animal health or the environment when such genetic modification aim to diminish or prevent the attack of certain pests or illnesses with the attendant reduction of the use of phytosanitary products' (p.46236).
- Similar to the Regulation of the Law 9/2003, this Decree did not mention the word precaution and only (explicitly) *prevention* and (again) *caution*.
- The article 3 on functions, section f) explicitly states that the NC of Biovigilance will have to 'inform about the agriculture practices in order to make Compatible the coexistence of the conventional and organic agriculture with the agriculture which uses genetically modified varieties'.

The composition of the new National Commission of Biovigilance is the following:

- The president, who will be also the General Secretariat of Agriculture and Food;
- 3 representatives of the Ministry of the Agriculture, Fisheries and Food;
- 1 representative of the Ministry of the Environment;
- 1 representative of the ministry of Science and Technology;
- 3 representatives of the Autonomous Communities;
- 6 representatives of 'interested parties' (sic) selected by the MAPA;
- 1 representative of each of the professional agriculture organisations in Spain and from the *Confederacion of Cooperativas Agrarias de España* (Spanish Confederation of Agriculture Farmers' Cooperatives);
- 1 representative of the Consumer organisations, designated by the *Consejo de Consumidores y Usuarios* (CCU);
- Up to 6 experts of recognised experience, designed by the Ministry of Agriculture.

Thus, in a thrust to limit the number of agents involved in the CNBv, no explicit room was given for environmental or other civic NGOs, apart from farmers only 'interested parties designed and selected by the Ministry of agriculture. Moreover, regional representation was given to only three people selected out of the 17 Autonomous Communities in Spain¹¹. Moreover, it can easily be seen that such commission is

⁹ The Spanish environmental legislation establishes a public access regime for this information.

¹⁰ In Spanish, organic agriculture is referred to as ecological agriculture.

¹¹ This is line with other attempts -e.g. in environmental policy or others- of the current conservative party to strengthen the role of central administration and weaken the role of Autonomous Communities, even though a lot of them have almost full competences in the agriculture issues.

mainly an institutional mechanism to guarantee and make possible coexistence of GM agriculture with other types of agricultures (hence *case-by case precaution* based on the belief that coexistence is both possible and desirable, and to a large extent unavoidable).

An interviewed expert of the CNB when asked in January 2004 about the National Commission of Biovigilance (CNBv) reacted by saying:

'It was an original idea arisen from the experience of the CNB; we were aware of the necessity to solve some gaps in vigilance and control issues mainly from an administrative perspective. First we thought of creating a subcommission on vigilance within the CNB and it was proposed to the MIMAM though it didn't succeed because, from a juridical standpoint, vigilance and control tasks are to be developed by ACs. Then the issue was recast due to the designation of the new director of the Spanish Office of Vegetal Varieties; the most important products we have are GM plants, and the MAPA needed such a commission to address all the elements relating to vigilance'.

The CNBv will have an additional perspective, this is, that of coexistence, and it will also assess the monitoring plans of GM commercial varieties. We made some comments to MAPA intended to avoid the duplication of tasks. The CNB has to assess the monitoring plans enforced by our Directive, and so far it has been reporting on monitoring plans for commercial varieties. The idea remaining is that tasks will not be duplicated but complemented; the CNB will make a first assessment of the monitoring plan, which will become the basis of the later monitoring plan of the vegetal variety. I think that the members of the CNBv will be the same, or almost the same, of the CNB and the CA ones. The CNBv membership has a General Director level as it happens with our CA.

On the 11th March 2003 five new Bt maize varieties were approved, together with nine more on the 16th February 2004 (see introduction). As it was the case with the authorisation of varieties Compa CB and Jordi CB of 1998, all the new authorisations of 2003 and 2004, MAPA asked that they needed to be accompanied with a compulsory monitoring plan. In particular, in such monitoring plan of the varieties approved in 2003 and 2004 it is stated that:

- 1 It has to have a minimum duration of five years.
- 2 It needs to deliver the data of each GM variety sold in each municipality and in all Spanish territory to the MAPA and to the CIOMG, including the list of buyers. The same information needs to be delivered to the Autonomous Communities in their territories.
- 3 All of what the monitoring plan has to include with regard to the Bt varieties is the following:
 - (a) An evaluation of their insecticide efficiency;
 - (b) An study of their possible resistance to the protein Cry1Ab (Bt toxin);
 - (c) Their possible effects on entomofauna and soil microorganisms;
 - (d) With the exception of the modifications derived from the genetic modification MON 810, the possible effects on the evolution of bacterial digestive flora in those animals which consume them with special attention to ampicillin resistance;
 - (e) Indication of the areas to be used as refuges; (f) programmes to inform farmers on how to control adventitious pests.

However, in these authorising Orders APA/520/2003 and APA/314/2004 there is no explicit reference to liabilities in case of non-compliance with such plan or with the wrong-doing of the already authorised Bt maize varieties in case of third party or environmental damage. However, whenever insect resistance would be detected, this

situation needs to be communicated to the CIOMG, to the CNB and to the attendant Autonomous Community authorities. In case resistance is proven to be of special relevance, besides informing these public agencies, the applicants will have to assess farmers how to apply palliative measures of the detected harm and how to destroy the rest of the crops. Furthermore, if the aforementioned measures stated in the monitoring plan for the new authorised plants are ineffective, the only additional anticipated action is that the new BT maize varieties will have to stop being commercialised, but only in the affected localities and their surroundings.

The texts specifying the monitoring plan for the new varieties of Bt crops approved in 2003 and 2004 are identical, although they differ from the text approving the varieties of 1998. In particular, the orders APA/520/2003 and APA/314/2004 add the following texts:

- 1 That yearly data of the amount of GM crops planted in the whole of Spain need to be delivered to the MAPA and to the *Organo Colegiado* before the 15th of June of each year.
- 2 That the programmes of information and education to farmers need to include that farmers 'need to plant by the side of the GM crops a band of conventional variety of maize, with the adequate width and characteristics in each case' (neither the purpose of this refuge area or the dimensions of it are specified).
- 3 Excludes the monitoring requirement of checking the possible effects on the evolution of bacterial digestive flora in the animals which consume Bt maize and on the ampicillin resistance to the Bt maize variety MON 810.
- 4 In the order of 2003 (not in the one of 2004), they assert that the points (a), (b), (c) and (d) of the monitoring plan mentioned above have already been 'fully carried out' (*completamente realizados*) with regard the genetic modification CG 00256-176, as such monitoring had been carried out for the Bt maize Compa CB.
- 5 With regard to the need to carry out extra actions in case of resistances, the order of 2003 and 2004 add, that such measures will be taken if *such identified effects are of special relevance*. Among the extra measures, the orders of 2003 and 2004 add the following three new points:
 - (i) That such effects need now to be communicated also to the *Secretaria General de Agricultura*, (besides the *Órgano Colegiado* and the Autonomous Community).
 - (ii) That the customer (that is, mainly the farmer) need to be assessed on the measures to be taken in order to mitigate the identified adverse effects.
 - (iii) The rests of (GM) crops need to be destroyed by the most adequate means in each case.

Notice then, with regard to this last point that the order of 1998 only asserted that in case of detected resistances, the rests of the crops should be incorporated to the soil. In the new legislation also it can be interpreted that it is accepted that some kind of resistances to Bt crops might appear, but the need to take extra (precautionary?) measures are only necessary in case of such resistances are significantly enough (without specifying the yardstick to assess so). It is also quite remarkable the fact that the Order approving the new varieties refers that the monitoring plan for the previous varieties has been fully carried out, implying that such monitoring has been carried out in a satisfactory manner.

In addition to all these internal regulatory developments, the Convention on Biological Diversity was first signed by Spain on the 13 June 1992. Spain became party of the Convention on the 21 December 1993. Spain was first signed the Cartagena Protocol on Biosafety on the 24 May 2000 and ratified it on the 16 January 2002, although at the end of that year Spain still had to notify to the Biosafety Protocol Clearing House (BSCH) the domestic use of Living Modified Organisms for Food, Feed or Processing (LMOs-FFP). Spain became full party of the Protocol on the 11 September 2003. The

focal point and the Competent Authority for the implementation of the Cartagena Protocol is DGCA of the MIMAM.

In summary, and in the light of current Spanish regulations, any reference to the precautionary principle has been included in the most recent Spanish regulatory instruments with regard to the governance of GM risks. Only 'prevention and caution' have been mentioned in the Law and Regulation implementing the DDR. Even in the Spanish translation of the Decision C(2002) 2715 of the Commission on additional orientation to carry out deliberate releases of GMO (Annex II of Directive 2001/18/CE) the precautionary principle is translated as the 'cautionary principle' while in other Spanish legal texts precaution is simply translated as 'precaución'. This is the case, for instance, of the principle 15 of the Rio de Janeiro Declaration on the environment and development in which appears, in Spanish, the translation of the precautionary principle as the 'principio de precaución'¹². In practice, this subtle but important 'weakening' of the principle means that every new GM variety will have to be evaluated by a 'case by case' and 'step by step' procedure but without the inclusion of other sources of non-expert value or knowledge. And also, that those procedures of expert knowledge will be intermingled with policy values in the several political forums – as between the same Ministries which are present both at the CNB and the CIOMG. Such apparently 'preventative' (not precautionary) approach seems to be sufficient for many of the GM agriculture promoters, producers and legislators, so far very clearly in favour of coexistence of commercial GM crops with other agricultures. In addition, and especially, from the analysis of material obtained in our meetings in Madrid at the Ministry of Agriculture and at the Ministry of the Environment, it became clear that Spanish GM crop regulation and policy aim above all to:

- 1 To allow and to provide strong support for biotech technological development and innovation in the agriculture sector¹³.
- 2 To avoid conflict, particularly with consumer and environmental organisations.

Despite the usual argument and rhetoric that Spain tends to 'follow suit' to EU regulations, Spain has proven to have had a distinctive aim and a clear long-standing policy position on GM agriculture, which has led to the new authorisations of Bt maize varieties and in particular a strong defence of coexistence. Furthermore, in all this time, the word *precaution* has never made it into the Spanish legislation.

However, under the new Socialist government, the Agriculture Minister, Ms Elena Espinosa, showed a different attitude towards GM crops. Spain abstained in the EU Agriculture Council of 26 April 2004 on the vote whether to allow the commercialization of Bt 11 maize.¹⁴ This vote marked a change from the previous Spanish government under the Partido Popular, which took a favourable position, although it is too early to assess the possible change in policy.

Another significant change resulted from the EU level. According to the EU Scientific Panel on GMOs, some antibiotic-resistance marker genes should be prohibited in commercial products because their spread to pathogenic organisms could undermine the clinical utility of the corresponding antibiotic. The list included the ampicillin-resistance gene, which was originally used to construct Syngenta's Bt 176 maize, the basis of varieties commercialised in Spain since 1998. In April 2004 EFSA advised

¹² As example, see in Spanish the 'Declaración de Rio de Janeiro sobre el Medio Ambiente y el Desarrollo', In Francisco Delgado, José Antonio Moreno & Nuria Garrido (1995) Legislación de Medio Ambiente. Madrid: Ed. Tecnos.

¹³ Hence as expressed by an interviewed high executive from the Ministry of Health 'we want and it's always good to provide technological support and development in relation to biotechnology'. To this statement an environmentalist lawyer asked, 'but why?', it can also provide some harm', to find out a response asserting that technological innovation is always good.

¹⁴ The Council reached no qualified majority for or against the product, so the decision was then taken by the Commission, which decided in favour of its commercialization in May 2004.

that such varieties should be withdrawn, and the new Socialist government followed that advice.

Moreover, according to the new Environment Minister Cristina Narbona, the government would now seek the advice of independent researchers. She questioned whether it was wise to continue the country's extensive cultivation of GMO crops, and went on to accuse the previous conservative government of authorising a massive extension of GMO crops without waiting for scientists to reach a definitive opinion.

We want to reinforce independent research in this area, and I underline the word independent, because in this country, where there is little scientific investigation, many researchers are privately financed by companies that want the research to have a specific conclusion (23.06.04).

3.1.2 The role of the autonomous communities (ACs)

Agriculture policy is highly de-centralised (as many other issues) in Spain. Autonomous Communities (17 in total) have the competence to regulate agriculture and, or whenever be the case, put penalties to producers. This will have an important effect in understanding the application of the PP in Spain, as although private companies work at the international and state level, control capacity are set at regional level. Autonomous Communities have also many other competences in relation to food regulation and eco-labelling. In relation to contained use of GMOs and intentional release into the environment for trials, it is only required the authorisation of the utility by the competent body of the Autonomous Community, although it can also be asked through the Central Administration at the Spanish Ministry of the Environment. Thus, in this two cases, control and responsibility is a competence of Autonomous Communities. For commercialisation the only competent body for its authorisation is the Central Administration. Nevertheless there are two exceptions in which the authorisation of deliberate releases of GMOs is not a responsibility of Autonomous Governments but of the Central Authorities:

- (a) GMOs which are incorporated in medicines for human or veterinary use.
- (b) Biotech research projects of national scope.

Given the current administrative structure in Spain, in practice, the Spanish National Law on Biosafety obliges the Autonomous Communities to develop their own regulations with regard to biosafety measures, procedures and responsibilities. For instance, and in order to provide assessments on those authorisations which the Competent Authorities correspond to the Autonomous Communities, some ACs have created their own autonomous biosafety commissions. Out of the 17 Autonomous Communities governments existing in Spain, by the end of 2003 the following ACs had already designed Competent Authorities to deal with GMOS and thus developed specific regulations on laboratory and field trials of GMOs: Andalucía, Aragón, Castilla-La Mancha, Castilla-León, Extremadura, Madrid, Navarra¹⁵. Regulation is in process in Catalunya, País Vasco, La Rioja and Galicia. All of these governments have been assisted by the Biosafety National Commission (consultative body), and have designated vocal member for this commission.

In 1999, the Basque Country announced a five-year moratorium for the production and commercialisation of GMOS in its Autonomous Community. According to the director of the Natural Environment of the Basque Government, this position was justified on 'precaution' (sic) given the Central Government was just about to approve the commercialisation of several GM products. To him, 'before authorising them one must check out the effects such crop technologies have on biodiversity' (E. Azumendi, 1999).

¹⁵ Andalucía: Decreto Foral 204/98 of 22 June; Aragón: Decreto 142/98 of 7 July; Castilla-La Mancha: Decreto 1/2000 of 11 January; Castilla-León: Decreto 255/98 of 3 December; Extremadura: Ley 8/1998 of 26 June; Madrid: Decreto 109/2000; Navarra: Decreto Foral 204/98 of 22 June).

In June 1999, the regional parliament of Andalusia approved a resolution asking a moratorium of 5 years to authorise trials of GM varieties in this Autonomous Community and also to exert pressure onto the Spanish government to do so in all the Spanish territory. Similar propositions have been approved in other autonomous parliaments such as Castilla-La Mancha, and the Balearic Islands, as well as in some local municipalities such as Adra, in Almeria (Riechmann, 2002: 27-28).

Therefore, in Spain, Autonomous Communities play an important role in the control of GM risks once they have been authorised by the central administration. With regard to these issues, a member of the CNB reacted in March 2003 by saying that:

‘The vigilance & control issues are always difficult in Spain. Central Administration has little power over vigilance & control activity; power is only over issues which are regulated by the research laws. Autonomous Communities are competent for most of these issues. In order to reinforce coordination for vigilance & control duties, we are discussing this question within Spanish act which transposes the new EU Directive. We can not create any new body because this issue is a competence of Autonomous Communities, but we must somehow coordinate these vigilance duties. Nowadays, most of the Communities which have proceeded with experimental liberations are assisting to CNB sessions, as they are very interested to know about the new monitoring, traceability & labelling regulations. We will develop these regulations in an harmonised way, either with specific instruments or with voluntary actions’.

Another expert and a technical assistant working at the CNB, interviewed in January 2003, were asked about what were the most conflictive issues in the development of proposal of the regulation of the Law 9/2003 and mentioned the tensions between Central and Autonomous Communities Administration agencies:

‘Basically, some procedural issues as well as the distribution of competences between the central Administration and ACs. If you have compared the two Laws¹⁶, you’ll have found that the most recent one reduces some of previous competences hold by the ACs because the experience of last years shows that it generates many problems. [...]Through the Law 9/2003, the central Administration wanted to assume some competences, especially relating to some specific field trials, that is, releases to the environment in an experimental stage when being on record in a commercialisation file. We’ve had several cases in Spain which there is a commercialisation file under study and the promoter is required to do some field trials in our country. Those field trials would be under competence of ACs because of their experimental character according to the old Law 15/1994, and sometimes the trials haven’t been authorised by ACs not because of biosafety issues – the CNB¹⁷ report was usually favourable – but for other reasons. This is a quite contradictory situation’

And with regard to the representation of the Autonomous Communities into the CNB they said:

Expert 1: ‘The CNB deals basically with environmental risk but also with some other issues because all of the related Ministries, many experts, and all of the ACs which have asked for it are represented there. There have been lots of complaints from social agents which are not represented in the CNB since it began to work on 1993. From a political point of view, the Ministry of Environment never accepted such representation in the CNB because this institution was meant to be a scientific one. It is supposed that there were other forums of participation to receive those social

¹⁶ The old and repealed Law 15/1994 and the recent Law 9/2003.

¹⁷ Comisión Nacional de Bioseguridad.

agents'. [...] In some ACs have sometimes made decisions without considering the reports of the CNB.

Expert 2: In some cases the CNB has reported the inexistence of risks but the ACs haven't authorised the trial.

At present, however, it is difficult to provide a general assessment on to which extent the 17 Autonomous Communities have influenced the final outcomes of the recent GM crops in Spain. Such assessment is even more difficult to provide after the defeat of the Conservative Party on the 14 March of 2004, given that some of regional forces now represented in the Spanish government -such as Iniciativa per Catalunya or even Xunta Aragonesista- have repeatedly shown their opposition towards GMOs (see section 3.3.5).

3.1.3 Monitoring practices and control measures

Following the EU approvals of Bt maize produced by Monsanto and Ciba-Geigy in 1997-1998 based on the Decisions 97/98/CE and 98/294/CE, Spain authorised in 1998 the Bt maize varieties 950243 Jordi CB and Compa CB both from Novartis (now Syngenta), although only Compa CB was finally cultivated and commercialised. The authorisations were subject to a compulsory monitoring plan which had to be delivered by the promoters and which was formally described in the Resolution published in the Official Gazette in March 1998 (BOE, 1998). According to this Resolution, the monitoring plan:

- 1 Had to be initiated at the time of registering the new varieties and should last for a minimum period of five years.
- 2 At the end of each season, the promoters should deliver to the MAPA data on the total amount of seeds sold, their distribution by municipalities and the list of buyers.
- 3 Before the second year after publication of the Resolution -that is March 2000- a prevention plan (sic: 'plan de prevención) should be elaborated which should include:
 - (a) Evaluation of the effectiveness of the insecticide properties of the genetic modification included in the maize variety.
 - (b) Study of the possible resistances which the corn borer could develop to the protein CryIA(b).
 - (c) Possible effects on entomofauna and microorganisms derived from these Bt varieties.
 - (d) Possible effects on the evolution of bacterial populations of the digestive flora in the animals which consume such Bt varieties, and in particular with regard to ampicillin resistance.
 - (e) An indication of the extension of non-GM crops that needed to be planted in relation to that with GM varieties as refuges for the corn borer.
 - (f) A information programme to farmers with regard to the cultural practices alternative (sic) to the use of transgenic varieties.
- 4 Whenever resistances be detected, the 'Organo Colegiado de OMG' (at that time the CA on GMOs) has to be informed as well as the 'Dirección General de Producciones y Mercados Agrícolas' (General Directorate on farm production and markets) and the Autonomous Community in a maximum period of 30 days. However, in that case, no liabilities were regulated, and only, if the measures proved to be ineffective, the Bt seed had to stop been sold.

As a result of the monitoring plan mandate which was established in the Resolution of March 1998, on the 20th June 2003 Syngenta presented to the Ministry of Agriculture a report regarding the monitoring of the effects and efficacy of Bt maize COMPA Cb crops in Spain (Alcalde, 2003). The experiments and research trials were carried out by scientists from two institutes or the Higher Council of Scientific Research

(CSIC), that is, the IRTA at Tarragona, and the CIB in Madrid, as well with the University of Girona and the University of Lleida (the latter two provinces hold large areas of Bt maize crops, around a 900-1000 hectares in the case of Girona in 1999). The report contained the results of the following four studies carried out in Spain:

- 1 The efficacy of Bt Maize to target insects and the possible development of new resistances to Bt protein Cry1Ab by the corn borer in the Bt maize crops areas. Baseline populations of borer were taken in 1998 and 1999 from six areas before Bt maize was planted and both borer species MCB and ECB were taken from fields with Bt maize for comparison for a period of four years 1999-2002. Results showed that no significant susceptibilities to protein Cry1Ab appeared in the areas where such study was carried out. Furthermore that after five years of harvesting Bt maize it is still efficient in controlling the borer attacks and no resistances to toxin Cry1Ab have been developed.
- 2 Potential effects on non-target entomofauna: based during three years 2000, 2001 and 2002 of two observation fields Bt maize Compa CB was compared with non-transgenic maize Dracma. Visual observation and traps were used to assess the presence of natural predators to the corn borer and the study centred on the species Orius spp. No relevant negative effects were observed in the Bt maize fields in such populations of insects.
- 3 Potential effects on soil microorganisms: Soil microorganisms resistance to ampicillin was compared from samples taken in 2000, 2001 and 2002 in field of both Bt maize Compa CB and non-transgenic Dracma maize. Despite there is a population of bacterial organisms to ampicillin detected in the study (between 1 and 32 per cent) no significant differences between the two varieties of maize nor in the four different regions were the samples were collected.
- 4 Potential effects on digestive bacterial flora in the digestive system of animals fed with Bt maize, in order to detect ampicillin resistance, based on chicken trials: seventy chicken chicks one-day old were used to carry out a test to assess the sensibility to antibiotic Enterococcus Spp (Gram +) and Escherichia coli (Gram -) and also to study the nutritive value of the maize Compa Cb in comparison with the non-transgenic Dracma. Results showed that no significant changes could be observed in the resistance to ampicillin and the daily weight growth of chickens were similar in the both varieties.

Therefore, and according to the Syngenta report none of these studies observed any significant negative effect Bt maize on the researched issues and it remains effective to combat the corn borer pests. However from the information contained in the report it is difficult to follow with sufficient detail how these surveys have been carried out, the justification of the selected methods or indicators used specific quantitative data is missing and the scope and number of samples and researched issues are also limited. Furthermore, and inevitably, long-term effects on the environment or effects on human digestive systems have not been assessed, so the results only correspond to the timeframe of the years since the crops were first harvested, and in the case of health hazards, to chicken trials. It is interesting to note, that some environmental and civic organisations did not have access to these studies, so an informed debate or public criticism (that is, democratisation of expertise) could not be carried in this respect. For instance, six months after the Syngenta report was handed in to the MAPA (that is January 2003) neither Greenpeace-Spain nor FoE Spain had seen such report. The same has occurred with the later studies of Farinós et. (2003) or of the Centre National of Biotechnology where a scientific methodological criticism could not be carried out by proposed experts of such organisations. These organisations have repeatedly argued that no sufficient independence and separation exist between the promoters and scientific experts assessing GM crops risks and also between them and the Spanish regulatory agencies. Furthermore, we have not found any programme, measure or indication given to farmers in relation to the points 3e and 3f of the 1998 Resolution. That is, those which regard to the information on the extension of non-GM crops that needed to be planted as refuges for the corn borer or to the information programmes directed to farmers on the cultural practices alternative to transgenic varieties.

In parallel to the report presented by Syngenta in 1998 the Ministry of the Environment and the Spanish High Council for Scientific Research (CSIC) signed an agreement to carry out risk research on the possible ecological effects of the COMPA CB maize¹⁸. Monitoring started since the first harvest at selected sites and the first results appeared in 2000. The aim of the monitoring program was to detect at an early stage insect resistance to Bt maize and susceptibility to the Cry1Ab delta-endotoxin from *Bacillus thuringiensis* (from now on Bt toxin) for the Mediterranean corn borer (MCB, *Sesamia nonagrioides*) and to the European corn borer (ECB, *Ostrinia nubilalis*). In addition, the research aimed at assessing potential environmental impacts on several non-target arthropods. After two years of monitoring in six regions, their results showed that there were no significant difference between both species of corn borer of the same geographical area in their susceptibility to Bt toxin. Also with regard to environmental impact on non-target insects they found that no detrimental effects on beneficial arthropods were observed in the year 2000 (Farinós et al., 2001). Similar results were presented in several publications (González-Núñez et al. 2000, Castañera et al. 2000) and extended following further monitoring in the following years. For instance, for Castañera et al. (2004) none of the two corn borer species (MCB, ECB) monitored for five years in Spain has developed any significant resistance to Bt endotoxin and thus susceptibility to Bt endotoxin remains as reported in González-Núñez et al. (2000).

Other monitoring studies were also carried, on the one hand, by the Department of the Environment of the Autonomous Community of Navarre on the impact of Bt-176 maize Compa CB on the associated populations of insects and on the other, by the *Centro Nacional de Biotecnología* (National Centre of Biotechnology) on the genes transfer to the populations of microorganisms in the soil. In particular, the study of the National Centre of Biotechnology aimed at 'assessing the presence of genes of possible environmental risk in soils where Bt maize was being cultivated as previous step to the assessment of the this gene material transfer to micobiological flora of these soils, and to assess the possibility to implement the traceability of the molecular traceability of these soils'. According to their results, which covered a period of almost three seasons, no significant differences in the resistance to ampicillin of the bacteria's genes Gram-positive used as markers in the studied soils were detected, and in those cases differences appeared these were not significant compared to soils cultivated with conventional maize (Pérez Mellado, R. 2003, Annex 2). In contrast, in October 2001, the *Instituto Técnico y de Gestión Agraria* of the Autonomous Community of Navarre made public a study in which Bt Maize Compa CB crops were compared with conventional varieties. Results were based on the follow-up of three years of Bt crops and asserted that farmers from Navarre did not notice any significant advantage of Bt maize crops and that production was similar and even inferior than conventional varieties. Bt maize was therefore not advised in areas where the corn borer was not a major hazard to the maize crops.

The IRTA (a CSIC research institute on agriculture and food technology and also funded by the Catalan government), also carried out further research on coexistence between GM and non-GM crops. This research was partly funded by Syngenta, was made public in February 2004 and aimed to know the extent whether genes escaping from GM crops were pollinating non-GM crops. In the test Bt maize and non-transgenic maize Brasco were used. Transgenic flow was also wind-dependent, and one transgenic pollen point was found 40 metres away from the Bt maize field. Nevertheless, IRTA recommended a minimum distance of 25 meters between transgenic and a minimum of four (plough) furrows of non-transgenic crops of separation in the field smaller of one hectare. The association of selected seeds producers APROSE regarded these results with satisfaction and stated that they meet their own guidelines on good practices for cultivation of GM maize (agroprofesional, 2004). The *Oficina de Variedades Vegetales* of the MAPA together with the INIA were initiation in October 2003 another study on co-existence of Bt and

¹⁸ Convenio de Colaboración entre el Ministerio de Medio Ambiente y el CSIC: "Evaluación de los potenciales riesgos ecológicos de los maíces transgénicos" (See Annex II).

conventional maize from 700 samples taken from two locations in Aranjuez and Albacete and now likely to be coordinated by the Commission of Biovigilance.

3.2 Expert judgements

3.2.1 Expert judgements

In this respect, it is also interesting to observe some of the values, perceptions, or prejudgements that such researchers who carry GMO risk research in Spain maintain with regard to GM crops in general and how or to which extent their expert knowledge intermingles with some ethical and political values in their assessments. In order to understand how their risk research and results are framed, as well as their own views on the role of development of GM crops, it helps to look at the way their research is publicly justified. For instance, the introduction of the first paper by Farinós, de la Poza, Ortega, and Castañera, on GM crops presented in the year 2000 they asserted that:

‘The use of genetically engineered corn plants expressing delta-endotoxins from *Bacillus thuringiensis* (Bt maize) offers a rational strategy for the control of these two pests and can reduce at the same time environmental costs associated with the use of conventional insecticides’ (Farinós et al., 2001 (2000), p.114)¹⁹.

That is, only after two years of monitoring Bt maize in Spain, they already stated that GM crops was a ‘rational strategy’ to manage the corn borer pests. The same sentence was almost literally reproduced in paper by Farinós et al (2003:1) after five years of field monitoring (four years of sampling Bt maize crops, as 1998 was for baseline comparison):

‘Bt maize can effectively control these two major maize pests, at the same time reducing environmental costs associated with the use of conventional insecticides (Shelton et al. 2002)’ (Farinós et al., 2003, p.1)

Notice that the word rational has been changed by ‘efficient’ and the argument now adds a scientific reference of 2002. In this respect, it is also worth mentioning, that Dr. Castañera who has participated in all of the publications of the agreement between the MIMAM and the CSIC (Annex 2) to assess the environmental effects of Bt maize in Spain and he is also a member of the group of experts of the CNB. Furthermore, Drs. Pedro Castañera and Félix Ortego who participated in the aforementioned studies of the agreement between the MIMAM and the CSIC, also participated in the studies 1 and 2 of the Syngenta report.

Another member of the CNB, Dr. Daniel Ramón, has also given his opinion with regard to the development of GM foods in several occasions. For instance, in an article published in 2001 he and M. Dolores Calvo stated on the use of Bt maize that:

‘the use of this transgenic plant constitutes an example of profits for the producer who sells the seeds as for the farmer who sees his crops protected. On the contrary, it does not offers nothing new for the consumer, as the organoleptic and nutritional properties of this transgenic maize are the same as those of a conventional maize’ (Ramon & Calvo, 2001:174).

And with regard to GMO food risks they said that:

‘It is not possible to generalise when talking about transgenic food risks (...). As in the case of farmaceutical products, the most rational way to study them is by a case-by-case assessment, transgenic product by transgenic product (Ibíd., p.175).

And ended by asserting that:

¹⁹ An almost exactly the same text (and results) can be read in González Núñez et al. (2000)

'Transgenic foods are an unquestionable reality. It is evident that in the present they are a problem, but it is not a scientific problem, nor a social one, but an economic one'. (Ibid., 184).

Opinions which corroborate the case-by-case framework of GM risk assessment and precaution detailed in section 2.4.

In relation to bioinvasions, herbicide resistant crops another expert lobbying for further authorisations and applications of Biotechnology in Agriculture, Francisco García Olmedo, Professor in biochemistry and molecular biology from *Universidad Politécnica of Madrid* argued that:

'The possibility of appearance of "superweeds" as a result of crops being resistant to certain herbicides lacks of any basis [...] The possibility of appearance of resistant [new pests and pathogens] does not justify that a given system of production should not be used while it works, in the same way that because an antibiotic is going to be ineffective we are not going to use it [now] while it can save millions of lives' (García Olmedo, 2001 p.45- 46).

In relation to crops which use antibiotic resistant markers, he stated that:

'Despite there is no objective risk and the fact that the employed antibiotics have no longer clinical use, there have been an agreement not to use such genes and to substitute by other auxiliary ones' (Ibid, p.43-44).

In Spain, the latest findings made public in 2003 by the Royal Society²⁰ with regard to field trials in the UK by do not seem to have produced any major changes in the scientific dominant opinion on the issue of possible biodiversity impacts of Bt crops. José Ignacio Cubero, one of the experts called to participate in the CNB, and professor of Genetics and Plant Improvement at the University of Córdoba, stated in a bulletin of the *Fundación ANTAMA*, funded by the biotech corporate cluster of biotech companies that:

'Results can be summarised with a quote from the executive report: the scientists who have carried out the work found that the results do not depend on the genetic transformation or improvement was done. In other words: being transgenic or not did not intervene in the effects that growing any variety can have on the environment.'

Also, Emilio Muñoz from the *Consejo Científico de Bioempresas*, commented the results of the Royal Society fields trials on the effects of broad-spectrum herbicides on farmland biodiversity in a public debate on biotechnology and public opinion held in Barcelona organised by the *Fundación ANTAMA* (November 2003):

'On the issue of field trials in the UK: [...] The only thing that is demonstrated is the effects due to herbicides on biodiversity, both for conventional and transgenic crops.[...] In two cases, sugar beet and rape, wild plants disappear due to the use of herbicides and, consequently, the diversity of insects decreases. In the case of maize, which also implies trazine, an herbicide which will probably be banned, the effect was the opposite. Thus, results have been diverse, as it usually happens with science. Scientific issues must be addressed with care and attention. So this is the absolutely scientific fact as it is now.'

These opinions were latter contested by several people of the public, clearly showing an environmental position, arguing that those results proved the existence of uncertainties with regard on the effects on GM crops on biodiversity, an issue which is increasingly receiving more attention in some media in recent times. (As it is the case of the Catalan television with a debate on GM crops held in March 2004, between a member of Greenpeace and a representative from ASAJA which lasted about 20 minutes)

²⁰ Philosophical Transactions of the Royal Society: Biological Sciences (October 2003).

Finally, it is interesting to note the general position of the several members and ministries who participate CNB with regard to GM crops, according to an expert of the same CNB interviewed in January 2003:

‘Six Ministries are represented in the Spanish CA, thus there are different points of view within this political body. In general, I think that in Spain we are neutral or slightly favourable to GMOs while there are many differences, for instance among the Ministry of Agriculture (which is pressing for liberalisation of GM crops), the Ministry of Health (which is very cautious) and the Ministry of Environment (which has adopted an equidistant position)’.

3.2.2 Links and relationships between experts, regulators and the public

In Spain, close links exist between expert GM crops risk assessment bodies and regulatory bodies. For instance, the president of the National Commission of Biodiversity, Ms Anna Fresno, is also the main responsible person in charge of GM crops regulatory issues at the Ministry of the Environment, as it is the case of the development of the technical regulation of the Law 9/2003. Other persons of the National Commission of Biosafety also work at the Ministry of the Environment, or in other Ministries as the Ministry of the Agriculture or the Ministry of the Food and Public Health. In this respect, while asked about relationships between experts and regulators as well as with other social groups such as GMO promoters or environmental groups, a central member of the CNB stated in our interview of March 2003 that:

‘We don’t have bad relationships. Companies provide us with the information we need. There have not been any tense moments, they always answer to our requests for further information. I do not know what happens with research centres; I think that some research issues are being promoted by companies. Our poorest relationships are with NGOs and consumer associations, though we will formalise this soon. We try to attend them, but there is little relationship because they do not a member of our established bodies to discuss GMO authorisations’.

The same person, however, denied that lack of independence exist in the CNB:

‘About independence: members are mostly working in research centres, can not have any link with enterprises, and must keep confidentiality of the data’.

However, there are some indirect links which vary at different stages of the risk assessment and management process as well as depending on the issues at stake. Research institutes and biotech corporations have an almost exclusive role at early stages, as their information and practice remain almost completely close to external inspections. Once authorisations are asked for, new window for public agencies, other science approaches and some public participation, are open. In the case of Spain, the possibilities for public intervention in the different stages of such process still remain very low. According to environmentalists and consumer associations the links between innovators, research institutes and regulators couldn’t be closer. For instance, Dr. Daniel Ramón, member of the CNB and researcher at the *Instituto de Agroquímica y Tecnología de Alimentos (IATA-CSIC)*, working in GMOS in wine yeasts forms, has publicly shown his position in support of GM crops and its commercialisation. However, the fact that scientists represent a smaller proportion of members at the CNB may result that they tendency to have passed most of the trials petitions, may have been stooped in recent years.

In 2003, the Spanish Agency for Food Safety (*Agencia Española de Seguridad Alimentaria*, AESA) began to work within the Ministry of Health and Consumption. It was created by the Law 11/2001, and was legally embodied by the 709/2002 Regulation. But only in September 2003 it became funded and operational. It has

become the agency responsible for actions linked to food safety. Its main functions are, in relation to GM crops and food products:

- To ask for executive and normative actions from the Competent Authorities, especially in the case of crises or emergencies.
- To coordinate the current alert networks in the field of food safety.
- To advise the design and development of food policies.
- Monitor market stage of products containing GMOs.

AESA is already present in the CNB through the membership of José Ignacio Arranz, the executive manager of the AESA. The main expert body informing risks related to the GMOS in food (as other foods risks) is *Centro Nacional de Alimentación* formerly a institution which was part of the *Instituto Carlos III*.

At present, however, and according to our interviews both at the MIMAM and at the AESA, there is still a general feeling of competence confusion about the specific relationships to be maintained between these institutions, as well as with the recently created *Comisión Nacional de Biovigilancia* (CNBv) within the Ministry of Agriculture. The functions to be developed by each of these bodies (CNB, AESA, CNBv), and the Autonomous Communities too, is still under discussion; moreover the interviewees think that functions relating to the monitoring of GM crops will be distributed in general as follows:

- CNB assesses the applications for authorisation of new varieties (and renewal ten years after). As the monitoring plan for potential environmental harms is demanded in the authorisation file of new varieties, CNB will then determinate the requirements of the monitoring plan. The CNB has not executive political competences, and thus it produces recommendations for the Competent Authority, which is the CIOMG (*Consejo Interministerial de OMGs*).
- CNBv assesses the monitoring plans for potential agricultural harms, this is, effects on non-GM varieties affecting the coexistence of GM and non-GM crops. The CNBV has not executive powers thus it produces recommendations for the Ministry of Agriculture and the Spanish Office of Vegetal Varieties (within the Ministry of Agriculture).
- AESA assesses the monitoring of the market stage of GM products, and it has the executive competence to directly implement any required action to ensure the food safety. However its basic function during the following years will be to take care of the correct labelling of GM products.
- The Autonomous Communities, which have administrative competences too, will also be competent for some vigilance actions as well as sanctioning.

In short, in Spain it is difficult to separate or to assert the existence of independence between the assessment bodies of risk assessment and those in charge of the regulatory functions with regard to GM crops. In fact, the CNB includes several members of several Ministries through the CIOMG and therefore, these people are both risk assessors *and* regulators.

3.3 Stakeholder roles and practices

3.3.1 Introduction

The amount of actions taken by different stakeholders aimed at influence not only public opinion but also directly both assessment and regulatory bodies involved in GM crops since they were authorised in Spain for the first time is quite large. However, during all this time, most of the main groups have tended to express relatively clear and polarised ideas in their public appearances and seem to have

reinforced their positions instead of finding a common ground. Some of them have incorporated new issues and discussions but without any sign of approximation between the different positions in conflict. In order to show the type of practices and actions taken by the relevant private and civic actors in Spain, table 5 summarises a selection of public events carried out by farmers' associations, environmental groups, consumer groups, biotech companies' and pressure groups associated to these companies, as well biotech scientific organisations with regard to GM crops and their commercialisation. Given its illustrative character of this table -it does not pretend to be exhaustive and only indicative- it only contains information from actions taken since the year 2000 onwards and does not include measures taken by public regulatory bodies (for that, see Table 3).

Table 5 Recent stakeholder roles and practices (a selection of recent events carried out by farmers' associations, environmental groups, consumer groups, biotechnology companies' pressure groups, and biotechnology scientific organisations with regard to GM crops and their commercialisation in Spain)

Date	Event
Jan. 2000	A coalition of agricultural organisations, trade unions, environmentalist and consumer groups, and Third World countries support associations send a letter to the President of the Spanish Government, José Maria Aznar, to express their preoccupation about the government policy adopted in relation to transgenic crops and foods and asking him to apply the precautionary principle
Jan. 2000	First 'Foro de Biotecnología del Valle del Ebro' (Forum of Biotechnology of the Ebro Valley), promoted by ASAJA, the farmers' association which at the same time asks the forum to be organised by AGPME with the support of ANTAMA, which at the same time receives the support of companies such as Syngenta
Jan. 2000	World Wide Fund (WWF) Spain , Ecologistas en Acción, Greenpeace and members of the Spanish Association of Organic Agriculture produce a 'giant butterfly' signed with 40,000 signatures collected in only two weeks for the Ministry of the Environment at the time of the Biosafety Protocol negotiations and ask the Spanish government for tougher regulations and the withdrawal of the existing authorised GM crops in Spain
Nov. 2000	Law Proposal Initiative publicly presented at the Food and Lifestyle Fair Biocultura in Madrid, with a 'Manifiesto in favour of Farmers' Rights on the Conservation and Use of Biodiversity' based on the refusal of GMOs
Feb. 2002	A manifesto is signed by ten Andalusian organisations including farmer organisations such as COAG, trade unions, green parties and consumer associations, asking for a moratorium on GM crops and their commercialisation in Andalusia
July 2002	ANTAMA organises the 5th National Congress of Biotechnology (Biotec 2002) as part of its long-term campaign to increase public acceptance of GM crops and includes a visit to two Bt maize fields of the companies in Seville
Sept. 2002	Study published on the 'farm level impact of using Bt maize in Spain', funded by six large biotechnology firms (Brookes, 2002) in order to justify the benefits of growing Bt maize crops. A similar study presented by Jesús Urel with the same title at the 3rd Forum of Biotechnology of the Ebro Valley
Oct. 2002	Fundación Grupo Eroski, linked to a food distribution store, carried out a study analysing 107 products sold in Spain that could contain GMOs. Their results show that only two of those products intended for human consumption contained transgenic material

May 2003	The president of the Consumers Association (OCU), Mr Carlos Sanchez-Reyes, expresses his concern on the position of the Spanish Government in the EU Council of Ministers with regard to GMOs. He formally asks the MIMAM, MSC, the AESA and the main political parties in the Spanish Parliament not to lift the moratorium on GM products, or at least not until labelling and traceability regulations become available to Spanish consumers (OCU, 2003)
May 2003	A book supporting GM crops, Los Transgénicos: conózcalos a fondo, coordinated by Ramon Tamames, a well-known professor of Economics at the Autonomous University of Madrid, is published. The Fundación ANTAMA, together with the Instituto de Cuestiones Agrarias y Medioambientales collaborate in its production.
May 2003	Greenpeace prints 100,000 copies of its first list of 'red and green GM food products' in Spain, which is widely publicised (it is also available via the Greenpeace web site). The second version, in December 2002, reaches 160,000 copies

Date	Event
July 2003	The farmers coalition Plataforma Rural asks for the immediate revocation of all the Bt maize authorisations, as a follow-up to their campaign 'Transgénicos ¿alguien me ha preguntado?' (GMOs, has anybody asked me?), arguing that the necessary conditions to prevent the negative effects of these crops and in particular those related to coexistence are not in place. It also asks the government to allow GMO-free zones and to establish liability in case of contamination and to ensure that the monitoring plan assesses the efficiency and effect of the Bt insecticide
August 2003	Greenpeace-Spain and Friends of the Earth launch a joint report on the situation of GM crops in Spain, Al Grano, denouncing several cases of contamination and of insect resistance to Bt maize toxin in Spain. It carries out a field activity in the town of Villanueva de Gállego, Aragón. Their campaign receives media coverage in the national news and in several CAs' newspapers. Syngenta, AGPME and some scientists respond energetically against the report and the action
March 2003	Just after the new Bt maize varieties are approved by the Spanish Government, the Catalan farmers' trade Union Sindicat Unió de Pagesos initiates an information campaign in order to 'alert farmers to the dangers of growing transgenic varieties' of maize, while the trade union ASAJA in Catalonia asserts the opposite, that 'GMOs are an improvement, as their greater productivity and lesser production cost is indisputable, besides their environmental advantages' (Elcacho, 2004)
Nov. 2003	COAG, Plataforma Rural, FoE-Spain, Ecologistas en Acción, Asociación Vida Sana and other Spanish organisations react against the European Commission's proposed regulation on coexistence, arguing that it only responds to economic interests, that the controls to prevent damage are insufficient, and that it threatens GM-free agriculture
Dec. 2003	The Fundación ANTAMA funds a one-day conference on Public Opinion and Biotechnology in Barcelona, together with the Barcelona Council and the 'Observatori de la Comunicació Científica' (OCC) of Pompeu Fabra University. At the end of the day the meeting is boycotted by environmental activists, who give a completely different view of the conclusions of the meeting. Mr Vladimir de Semir from OCC and the Barcelona Council, who

	supports ANTAMA's views on biotechnology R&D, immediately ends the debate.
Dec. 2003	5th Forum of Biotechnology of the Ebro Valley, supported by ANTAMA and AGPME, with the participation of ASAJA and representatives of MAPA and AESA. The president of AGPME congratulates the new authorisations of Bt maize, and the president of ASAJA reiterates his position of allowing both 'the consumer and the producer choice' (Agrohispana, 2004)
Jan. 2004	The Spanish Union of Small Farmers UPA criticises the Spanish Plan for Organic Agriculture (Plan Estratégico de Agricultura Ecológica) presented by the MAPA as it does not mention the issues of GM crops. For UPA, the presence of GMOs should not be allowed in organic products at all and liability measures should be clearly established in case of contamination, economic loss and environmental damage resulting from such contaminations (UPA 2004)
Jan. 2004	The left-wing political party Izquierda Unida joins the movement against extending the moratorium on GMOS in Spain and such a position is contested by ASAJA
Feb. 2004	FoE, Ecologistas en Acción, Greenpeace, CECU, COAG, Plataforma Rural and SEAE send out a press release against the possible commercialisation of maize NK 603 in Europe, arguing that there is a lack of capacity to control their potential health and environmental risks
March 2004	Greenpeace assaults a cargo ship suspected of carrying GM soya and receives large media coverage in Spain. This also provokes several debates in some national and regional television channels, such as one between Greenpeace and ASAJA on Catalan television

3.3.2 Farmers and farmers' associations

Two main farmers organisations in Spain maintain two very divergent positions in relation to GM crops: ASAJA, (*Asociación de Jóvenes Agricultores*) close to a right wing orientation and representing around 35 per cent of the sector is in favour of GM crops, and COAG (*Coordinadora de Agricultores y Ganaderos*) close to the left and representing the 48 per cent of farmer which is opposed to them 'unless it is proven that they are save' (Sic, *El País*, 25.11.99). With regard to the latter, Javier Sánchez, a representative of the COAG stated, against the publicity provided by Monsanto and Novartis (now Syngenta) that the transgenic crops showed lower levels of productivity than conventional ones. Furthermore, that Bt Maize from Novartis were paid at a lower price in Spanish farmer cooperatives, given that it shows a higher level or humidity retention.

On the one hand, leaders of opinion talking on behalf of farmers who have accepted GM agriculture tend to underline the greater economic value and profitability of the crops while those opposed emphasize the possible risks and uncertainties. Moreover, it is interesting to notice that the distinction between the risks associated with the *product* and the risks associated with the *process* of making GMOs seem to have been explicitly avoided particularly by farmers in favour of GM crops and close interests with biotech companies such as ASAJA. For instance, the president of ASAJA-Seville, Mr Ricardo Serra, in order to support his arguments in favour of GM crops give some examples of what he believes are the current uses of Bt cotton in Europe. For him, Euro notes are to a large extent printed in GM cotton (a point which has not been prove indeed) as well as are most of our cotton clothes. In his view, economic competitiveness is crucial when considering the authorisation of new Bt cotton varieties:

'I believe that the attendant precautions need to be taken, we need to listen to experts and establish rules, but to deny progress in a systematic way while others compete with us, they sell us their products and progress, is simply a non-sense' (Agroinformación, 2003c)

At the BioSpain conference of Biotech companies held in Madrid in February 2003, a representative of ASAJA argued that Bt maize was more productive and that no problems have had occurred until then. In his words:

'About Bt maize, we are actually growing it, and has proven to be efficient. We have quantified the economical and non-economical benefits of growing Bt maize. I must say also that not the whole of Spain is affected by the corn borer pest; Aragón is currently affected, but not other northern places. In those places where the borer pest is present, we have made the following economical estimation: the over-costs due to [more expensive] seeds are about 30 €/ha, while the saving due to the reduction of using pesticides is about 50 €/ha. The average result of the last campaigns in affected places is a productivity increase of 150 €/ha; this is equivalent to one tone per ha, about 10% of productivity increase. These numbers may look to be small, but they are outstanding when compared with agrarian standards.

I will talk now about non-economical impacts. For example, the farmers' health benefits of a reduction of the amount of pesticides used to grow. There is also an environmental benefit because many Bt fields fully avoid the use of insecticides, which have been 100% replaced. Hitherto, we have commercialized Bt crops without any troubles because our dealers, most of which are feeding stuffs processors, haven't found any problem to worry about. Surely this is due to the precedent of transgenic soy, which has also been broadly commercialized to make feed stuff. So far in Spain, the Bt crops occupy 5 per cent of maize surface in Spain, therefore we don't have any coexistence trouble because there is a separation between different areas. Also, 80-85 per cent of consumption of Spanish maize is to make animal feed, 15 per cent is for human consumption mainly in the form of starch. Relating to this latter use, our [Spanish] food processing companies don't accept to use Bt maize'.

Furthermore, one of the most common strategies followed by defenders of GM crops -either biotech companies and sympathising farmers- which is to present their development as inevitable, unquestionable and as 'fait accompli'. In this sense, the president of ASAJA, Mr. Esteban Andrés, while criticising the proposal of the political party *Izquierda Unida* (IU) for extending the moratorium on GMOs states that:

'In all the world, also in Europe, and in Aragón, the growth in the production and commercialisation of GM crops is a fact. [...] We want to remind IU that we always have been and are net consumers of transgenic soy and maize, grown abroad. It would be absurd to keep on being consumers and not been able to have the advantages of being producers'. (Agroinformación 2004)

Another recurrent claim usually provided in many documents of those in favour of GM crops and how to deal with safety measures is the recourse of biological isolation. Characteristically, at the Feria de Zaragoza 1999 the official documents of organisation stated that:

'From a standpoint of environmental preoccupation, GM crops such as maize, soy or cotton do not have in Spain close species which can interchange genes with. Besides a very careful plan to follow them has been approved, and a strict monitoring with no Comparison never before is being put in place for a technology which offers an excellent history of safety. However, most of the burden of the monitoring plans falls onto the seed producer and the farmer has to collaborate in them". (FIMA, 1999).

And added that the farmers would have little trouble in using such seeds in their properties. This is important as this farmers' meeting was being held in the Autonomous Community where most of the GM crops are cultivated. Moreover, the promoters of the technology advised farmers to tell consumers that their GM products had undergone a double amount of safety controls than 'traditional' ones so and that the new environmental and consumer advantages could be summarised by a specific labelling saying 'genetically improved'. According to the same source:

'There is no reason why the genetic modification should change the sensibility of the crop to herbicides, and this has been the case so far, so that the precautions that farmers must take (some voluntary others compulsory) will be oriented to:

- Avoid or postpone the transmission of the resistant gene to sexually compatible plants that may exist in the area (spontaneous sugar beet).
- Control the later germination of the fallen seeds (by using an alternative herbicide or mechanical means)'.

Thus, some of the measures to deal with GM crops which were disseminated in this farmers meeting asked them to use even more pesticides (on top of the one used to kill weeds and insects) but also at the end of the crop, to kill the actual GM seeds. The burden of the safety control is then put on mainly farmers, both in terms of time and effort to control possible risks and also of future responsibilities, in case some things go wrong. In fact, and from an interview carried out to a farmer who grew Bt maize we found that some farmers were not given specific indications on precautions on how to grow this transgenic variety at all, nor the farmer in question found it to be more profitable (See appendix A2).

On the other hand, farmers against GM agriculture have usually mentioned the dangers of GM varieties to biodiversity and the loss of control and cultural knowledge in the improvement of local seed varieties. In this guise, in November 2000 a Law Proposal Initiative (*Iniciativa Legislativa*) was publicly presented at the food & lifestyle Fair Biocultura, held in Madrid, with a 'Manifiesto in favour of Farmers' Rights in the Conservation and Use of Biodiversity' based on the refusal to GMOs. This document was the result of the opposition by a network of farmers -mainly the FAAE - *Federación de Asociaciones de Agricultura Ecológica*-, as well as consumer associations, and researchers, to the Spanish Law on New Vegetable Varieties (*Ley de Protección de las Obtenciones Vegetales*) approved in January 2000. To their view, the new Law only favours large companies and collaborate in the loss of agricultural biodiversity, and favours transgenic crops. This actors' network, now called *Red Semillas* (seed network) has been campaigning for the establishment of a rights of genetic resources access and economic compensation system for local farmers, and particularly those who work in the improvement of new varieties without genetic intervention, as well as protecting them from transnational 'biopiracy'. Its early motto was 'No transgenic [seeds], nor multinationals, local varieties'. Moreover, the Association of Small Farmers, UPA has repeatedly defended its position against GMOs and finds inappropriate the terminology about 'coexistence' -as it found it impossible in organic agriculture and is in favour of zero GMO presence threshold (UPA, 2003).

Farmers from several Autonomous Communities have also reproduced the existing conflict of Spain as a whole. Just after the new Bt maize varieties approved by the Spanish Government in March 2003, the Catalan farmers' trade Union *Sindicat Unió de Pagesos (SUP)* initiated an information campaign in order to 'alert farmers of the dangers of growing transgenic varieties' of maize. In particular, this trade union questioned the safety in the use of such crops and they warned farmers on the potential economic losses that could result from Bt maize. As a counter-response, again, the trade union ASAJA in Catalonia asserted that 'GMOs are an improvement, as its greater productivity and lesser production cost is indisputable, besides its environmental advantages' (Elcacho, 2004). Also, the Union of Basque Farmers, as expressed by one of its representatives, Ms Helen Groome, criticised the Spanish

Government for failing to implement the adequate controls of GM crops (Biomed Scientist, 2003). According to Greenpeace (Greenpeace & AdT, 2003), the farmers' trade Union Euskal Erriko Nekazarien Elkartasuna (EHNE) which operates in Navarre and the Basque country carried out an investigation on farmers who planted Bt crops. They found out that Syngenta did not provide the adequate information to farmers on what precautionary measures had to be taken, alternative management procedures or refuges and that the names of the farmers were not asked either. The same trade union also denounced that organic crops had been contaminated by Bt maize crops (AdT, 2002)

In conclusion, on the one side, there are arguments defended by those farmers close to the positions of ASAJA, ANTAMA and to a large extent AGPME, which work in close collaboration with Agro business corporations such as Monsanto and Syngenta, while on the other there are a number of other organisations such as UPA, COAG, SUP and others which work with the help of other international environmental organisations such as Greenpeace or Friends of the Earth. For the former higher improvements in productivity, competitiveness and technological progress appear to justify the use of GM crops at a commercial scale. For the latter, GM varieties are in fact less productive, entail unnecessary risks and jeopardize both organic and conventional agriculture. In any case, and from the recent GM varieties authorisations carried out in Spain, as well as for other peculiar forms of regulatory developments in Spain, it seems that those farmers opposed to GMOs have had less access and less resources to have their claims incorporated by the regulatory bodies than those in favour of extending large scale GM commercial agriculture.

3.3.3 The role of the agbiotechnology industry

In Spain, the *Fundación ANTAMA (Fundación para la Aplicación de nuevas tecnologías en la Agricultura)*, is a key actor in the defence and promotion of biotech development and applications in agriculture. ANTAMA organises regularly number of annual public conferences, funds studies and creates liaisons with key local, regional actors such as local authorities and biotech R + D researchers and universities. A usual strategy of ANTAMA is to invite experts and regulatory officials to these conferences and Symposium in order to make the frame their discourses in accordance to their audiences. Also, and as part of the public campaign of the Spanish Society of Biotechnology, together with ANTAMA has published several pro-GMO book-pamphlets, as in the case of the one entitled "Biotech in few words. Transgenic Plants, questions and answers". For instance, the Vice-rector of Strategic Projects of the Autonomous University of Barcelona is also the President of the scientific Spanish Association of Biotechnology (SEBIOT). According to Professor Garcia Olmedo, the role of SEBIOT has been the following:

'The Spanish scientific community in general, and the Spanish Society of Biotechnology in particular, have adopted clear position of support to the introduction of this technology. This association (...) is carrying an active public information campaign' (Garcia Olmedo, 2001: 56).

Another key actor is ASEBIO – *Asociación Española de Bioempresas*, a R + D biotech industry organisation which in the year 2002 was composed by 71 biotech companies in Spain. One of the main objective of ASEBIO is to establish alliances between companies of the biotechnology sector and also with public officials. For instance, in the presentation of their '10 accomplished results' since their creation only three years before they stated to have achieved:

'Excellent relationships with the distinct European institutions, ministries, regional governments, local councils, trade unions and a consolidated position as a interlocutor in the sector between all of them" (ASEBIO, 2002b)

In the summer of 2001, ASEBIO sent a manifesto to the Ministry of Agriculture, together with other pro-transgenic organisations, asking for the approval of genetically modified seed varieties (L. Cecilia, 2001).

Apart from continuous direct pressure and lobbying to regulatory bodies, one of the main strategies of the agbiotechnology industry at present is to carry out opinion polls in order to 'proof with numbers' the growing acceptance and favourable public opinion toward biotechnology and to agbiotech products in particular²¹. For instance, and following the pro agbiotechnology judgements of F. García Olmedo (2001), and according to an poll carried out in 1997 (details not provided) to 600 farmers in five Autonomous Communities representatives of maize production, only 39 per cent had heard about the Bt maize. Among them, 76 per cent had a favourable opinion about it with regard to higher yield production, easiness in handling, and environmental impact. Only 5 per cent had an unfavourable opinion, as a result of fears of not being able to sell their crops, and 19 per cent was indifferent. (So far, there have been other polls carried out by companies and pro-biotech lobbies to farmers, with smaller and dubious samples, and even more dubious results, which are not worth mentioning). Also, the polls consulting Company GABIOTEC was created by pharmaceutical companies in order to carry out studies on public perception of biotechnology and is dependent on the *Centro de Estudios para el Fomento de la Investigación* (J.L. Garcia & F. Ferrandiz, 2003). Also the annual report of ASEBIO 2002 dedicates on chapter to analyse the public communication in the press on biotechnology and in particular the public acceptability of this technology. Their conclusion point out that the most accepted applications of biotechnologies are on the medical sector, while in agriculture the public perception is the least favourable. At the same time, they found out that public administration yield very little trust while guaranteeing food safety. In this sense, ASEBIO invests a notable effort in social network research, and in particular, to the analysis of actor's alliances, possible conflicts and strategies followed by the different relevant organisations which could enhance or limit the development of biotechnologies in Spain. In this report, for instance, one full chapter and an annex is devoted to the study and quantification in great detail of these issues. Interestingly enough, however, the electorate is not considered as relevant actor in this report.

With regard education, in Madrid there is the school *Bioforum -Escuela Internacional de Negocios* which now carries out a masters degree in biotechnology company management in order to promote the biotech sector in Spain which is assessed and coordinated, among other people, by a member of the CNB, and the vicepresident of the CSIC.

In the same line of public education, on the 25 November 2003 the same Fundación ANTAMA organised, together with the *Observatori de la Comunicació Científica* of the Pompeu Fabra University (mainly lead by Mr. Vladimir de Semir, a journalist and science communication adviser of the Barcelona Council and with close links with Syngenta) a day-conference in Barcelona called "Biotechnology and the Public Opinion" (ANTAMA, 2003). Such meeting, which was open to the public and also publicised in the Barcelona council newspaper was attended by about 60-80 people. However, at the end of the official speeches, several environmental activists were able to provoke a number of dialectical rows against the arguments and conclusions provided by the speakers which made the organisation to immediately resume the debate and conference.

Increasingly competition of the global agriculture marked has also opened new opportunities to agrochemical and seed giants operating in Spain. These are now offering new options particular to larger farmer and meat producers, framing GMOs in a kind of producer and seed provider win-win situation where final consumer still do not see the clear benefits of the new technology. Furthermore, as four of the largest biotech companies in the world merged into two -Novartis and Zeneca into Syngenta, and AgrEvo and Rhone-Poulenc into Aventis- it is expected that this new clusters will also have stronger arm in negotiating new introductions into the Spanish market, and in particular Syngenta. On its part, and according to *Greenpeace* in 2001 Monsanto

²¹ For a discussion on the inadequacies and deficiencies of quantitative polls to represent perception on complex environmental uses and the serious political implications derived from them see D. Tàbara, 2001.

has 150 workers in Spain and produces an annual turnover of around 40 millions dollars. Monsanto holds a experimental station in Andalusia in the town of Los Palacios, with apart from the previous crops includes also sunflower. Monsanto has done in Spain 124 trials with transgenic seeds, mostly in Andalusia, mainly on cotton, due that this area produces the 80% of all the EU cotton.

With regard to the economic importance of the Biotech sector in Spain is also worth mentioning that the Autonomous Community with the largest number of Biotech companies is Catalonia, with an annual turnover of 945 million euros, that is 35 per cent of the total in Spain. companies share in biotech companies and investment in Spain, according to Asebio in L. Cecilia (2001):

	Number of companies	Economic turnover share
Agriculture:	80	40 per cent
Food processing:	30	15 per cent
Human health:	28	14 per cent
Environment:	18	9 per cent
Bioprocesses:	16	8 per cent
Animal health	16	8 per cent
Other:	12	6 per cent
	200 companies	100 per cent

Therefore, in Spain, agriculture stands out as the most important area of development for the biotech sector and stands as a very important pressure group sector in Spanish politics. However, the real number of biotech companies in Spain may be smaller as many of them are the result or participate in the bigger ones. Also, around 25-40 per cent of public funding in biotech is directed to agrofood industry, that is around 3 and 3,6 million euros per year (Sanz-Magallón, 2001:82). On the other hand, during the last decade the organic food (referred to in Spanish as *ecológica*) has experienced a huge increase, and in particular organic agriculture has grown a hundredfold from only four thousand hectares in early nineties to four hundred thousand hectares in the year 2001, mainly in Extremadura and Andalusia (J. Romera, 2001).

Also the seed sector is very important in Spain. Seed for all kinds of crops, are provided in Spain by approximately 350 companies, being the largest ones part of multinational corporations. The international seed trade of Spain in 1996 was the following (selected deficit crops, in tons):

	Export	Import	Deficit
Oily seeds (mainly for feed)	10.683	105.781	- 95.098
Potatoes	3.768	77.042	- 73.274
Maize	4.535	67.728	- 63.193

Thus agroindustrial production in Spain is dependent of many seed imports. According to Sanz-Magallón (2001), the main problem that explains this situation:

“is not the lack qualified personnel, but the lack of participation of the Spanish seed companies [in agro biotech due to] the conservative character of such companies and of it small size”, as well as “the current risky situation of being liable to boycotts”.(Sanz-Magallón, 2001:84-85).

In particular, and in relation to maize, and due to the losses in this crop being attacked by the corn bore pest the expansion of Bt maize crops have not been limited by the demand of its seeds but on the ground of availability of supply by Syngenta. However, at the same time, to Sanz-Magallón:

“given that the new transgenic maize crops have not had the expected effects on the prices as perceived by farmers, the improvements in productivity have mainly benefit to the seeds producers” (p. 91).

A very controversial report funded by six large biotech firms on the productivity, the use of pesticides, and the economic potential benefits of growing Bt maize in Spain was published by British economist Graham Brookes in 2002, although such study did not consider long-term or environmental effects (Brookes, 2002). This paper was used by the Europabio's plant biotechnology director, Simon Barber, as to show and prove the evidence of such potential benefits and thus adding further pressure on the irrelevance of EU GM moratorium. According to this study, yields using Bt maize had increased their yields up to 15 per cent, increasing 150 per cent euros per hectare. In those areas where the problems with the corn borer were less of a problem, such increases in revenues did not occur, although for Brookes, it was favoured by farmers as it improved the stability of their yield and reducing the time spent in the inspection of crops, (see ENDS, 2002). If the moratorium was to be lifted, according to this study, Bt maize planting would increase up to 36 per cent, the use of pesticide would be reduced by a third in comparison with conventional crops. According to Brookes, the halt in the expansion of area planted with Bt was due to a 'voluntary arrangement by the seed supplier Syngenta' (p.3), although according to one of our sources, farmers did not find differences in profit in the new varieties and simply there was no demand for them. In fact, in the words of our local source, Novartis/Syngenta was given the Bt seeds free to some farmers in order to promote their use. The extent of this practice -although recorded in our interview with a farmer (see Appendix 2) needs to be confirmed with further research. No references to the economic costs of taking precautionary measures were included in the Graham study either. Mainly because, according to our own sources consulted, no indications were given to the farmers on taking them and they were told to plant such varieties as if they equal to conventional ones.

In sum, industries working on biotechnology have created their own lobbying organisations in Spain such as the *Fundación ANTAMA*, and have organised their public forums with some local authorities in order to frame GMOs debates in accordance to their interests. Increasing amount of resources have also been placed by biotech corporations to fund social research in order to explore and influence general public, consumer and farmers' opinions with regard to GM products. However, and against this background, an increasing opposition carried out by the environmental and social movement is being built up around GMO crops and their large-scale commercialisation, although such groups have proven to be unable to penetrate into the regulatory bodies in a substantial way. On the other, biotech industry, together with some farmers and regulators, mainly interested in increasing productivity, test GM crops innovation in the field while setting aside other risk and environmental considerations have shown sufficiently strong as to have new varieties approved and avoid public controversy. GM crop issues have not entered into the public opinion discussions in any significant way and multinationals have succeeded in 'de-politicizing' the issue. To a large extent due to the receptiveness of the conservative party *Partido Popular* to their claims, but also because the strategies of the biotech companies have proven to be better coordinated and effective, in March 2003 and February 2004 new Bt maize varieties were approved, a situation which can be understood as a success of the biotech lobby. As put by a executive of Monsanto Spain at the BioSpain conference in Madrid in February 2003:

'I think that, in Spain, we can and we must continue growing the authorized transgenic crops, as so far, the first results have been positive. We must also be allowed to grow new varieties which are being demanded by farmers'.

3.3.4 Environmental NGOs

In Spain, and previously to 2002 (before the ratification of the Cartagena Protocol, among other events), GMOs issues tended to be mainly framed within the discourses of food safety and did not focus as much on the environment although this situation has been changing in recent times. One can explain this situation as an strategic bet done consciously by the civic advocacy groups, such as Greenpeace, in order to obtain greater attention by the general public, and in particular consumers. To a large

extent, for many Spanish conservation groups, neither at the state or Autonomous Community level (such as the largest in Catalonia -DEPANA), the issues of biosafety and threats to biodiversity with regard to GM crops are still are not on the agenda²².

The main strategies followed by Spanish environmental groups so far with regard to GM crops have mainly aimed at building networks of relatively broad and diverse organisation which make strong use of electronic and new communication media and usually organise meetings and write public 'manifestos' and other documents which are later handed in to Central or Autonomous regulatory bodies. Actions on the ground where Bt maize are grown have been quite exceptional although some of these demonstrations have been of relevance in recent years.

Among the main environmental actors involved within the GM crops protests have been those with links with international organisations, namely Friends of the Earth and Greenpeace- while local or regional conservation groups have been almost absent from the public discussions on these issues. An exception to this has been the coalition of Spanish environmental groups *Ecologistas en Acción (EA)*. For Gregorio Álvaro (2000) from EA, the authorisations of the Bt maize in Spain in 1998 were done at a time that the potential risks that this crop were known, although adequate information was not given to the Parliament, to civil society or to farmers, and non-transgenic crop refuges had not be requested. To him, the main aim for multinationals, such as Monsanto operating in Spain was to expand and consolidate GM markets, and in the case of commercialisation, doing it fast, so their opposition to labelling and their practice of mixing transgenic seeds with non-transgenic ones is a necessary result of mounting pressures to sell their seeds as soon as possible.

As shown in table 5, environmental groups have engaged in a series of actions and campaigns to make their words of opposition heard with regard to the process of the increasing authorisation and growing area dedicated to Bt maize crops in Spain. In November 2001, the Spanish environmentalist group *Ecologistas en Acción* publicly criticised the Spanish Law Proposal on contained use of GMOs (now the Law 9/2003) and on the deliberate release of GMOs. In the words of one of its representatives, Gregorio Alvaro:

'It may seem that the Law regulates something, but in a closer look, allow us to understand that what it really the Law attempts to do is to have a 'sieve law' [a law that everything can go through easily], full of accomplice winks and [friendly] looks at multinationals and absolutely full of juridical lagoons [omissions]'. (Rebelión Ecología, 2001).

According to him,

'Risk is basically evaluated by the promoter himself, who logically, a priori holds the largest of the [vested] interests in saying that there is nothing wrong [with GMO], despite afterwards in some cases, there is not even a monitoring follow-up and the most interesting part of the information which companies could provide to the Administration, as it is well specified in the Law Proposal, has a confidential character, and we the citizens do not have the right to know it'. (Rebelión Ecología, 2001).

²² This is not surprising as, on the one side, Spanish conservationist groups have tended to focus on single-issue demands -such as saving a particular species or place- and have usually resisted to introduce into their discourse more systemic and global issues into their programmes and actions. On the other side, ecologist parties, which usually bring in such broader framings, have been very weak or inexistent in the Spanish politics. Furthermore, the fact that the cluster of farmers and environmental associations against GM agriculture has not been able to create a nation-wide social debate on these issues is in line with the weakness and fragmentation of the Spanish Environmental movement as a whole. Spanish environmental organisations, as well as the Spanish ecologist parties have resisted to engage in State-wide politics and have remained in the sphere of the local and of the Autonomous Communities politics (D. Tàbara, 1999).

Ecologistas en Acción also criticized the notion of risk used in this Law Proposal to the extent that it did not consider the possible synergies and interactions that may come up and occur from different GMOs (that is, systemic consequences), and that it did 'not follows the precautionary principle' (sic), as well as the way authorisations were made. In this respect, EA believed that the final decision on to authorise or not to authorise is falls mainly on the grounds of the main interested party or on a Inter-ministry Committee, and that citizen participation in blocked in this matter. Furthermore, such final decisions can only be revised at the Courts. For Gregorio Alvaro, the law:

'pretends, by means of juridical lagoons, by permits given simply by [administrative] silence, and by the lack of Administrative Recourses, to make citizens' rights without effect (...) What use does it make to denounce a transgenic experiment which can put health in danger if the only way to do so is to initiate a litigious procedure that can perfectly be delayed six or more years?' (Rebelión Ecología, 2001).

In March 8th 2002, Friends of the Earth Spain sent a letter to the President of the Spanish Government, during the Spanish Presidency of the EU (first semester 2002) summarising their requests in relation to GM crops. Their petition concentrated on 5 main points:

- 1 To continue the moratorium on new GM crop authorisations.
- 2 Provision of adequate responsibility regime within the EU and inclusion of the damages provoked by GMOs within the Directive of Environmental Liability.
- 3 Strengthening the regime on traceability and labelling of GMOs and to reject the possibility of 'adventitious ' or 'technically inevitable' presence of GMOs in food products.
- 4 Implementing the necessary mechanisms to prevent the possible costs, damage and risks derived from the coexistence of two models of agriculture.
- 5 Ratification of the Cartagena Biosafety protocol.

In August 2003, Greenpeace launched together with Friends of the Earth – Spain the report *Al Grano* denouncing several cases of GMOs contamination in and of insect resistance to Bt maize toxin in Spain. According to this report, which is aimed to question the results of the Brookes report and other claims provided by Biotech companies, the Bt maiz Compa CB by Syngenta produce up to 9,5 per cent average less than conventional varieties. And also argues that the corn borer incidence in many areas of Spain is very low and thus that such Bt varieties are of little help and make little sense as to justify their use when Compared with their possible risks. The document also provides information of GM contamination in the Autonomous Community of Navarra, and denounces the lack of attendant controls and of information measures which in their view should have been put in place since the first moment when these GM crops were planted.

Also in August 2003, Greenpeace carried out a field action in the town Villanueva de Gállego, Aragón. Greenpeace occupied a Bt maize field with a large badger with the words 'Stop: transgenic contamination' and also put the mocked face of the Minister of Agriculture, Mr. Arias Cañete. Greenpeace had previously asked the CSIC the analysis of some field samples of maize in this area, finding GMOs in them. According to Greenpeace, samples were taken from a field 800 metres away from a known Bt maize field and found that such contamination had been taken place (Martinez, 2003).

In many public hearings and documents, environmentalists usually argue that the authorisation of GMOs products and therefore the application of the precautionary principle in this matter should also consider and include the 'polluter pays principle'. In particular, environmentalists ask themselves who will pay for the damage produced by GMOs to third parties and whether the European Commission really acts for the public well-being or only for the sake of the multinational profits (Ecoportal, 2002). As stated in the Friends of the Earth newsletter of January 2004:

“The prevention of contamination [of GMOs] to non-GM crops is not legislated and there is not any concrete measure in this respect. Liability is a business of the member states, so biotech companies and farmers who use transgenic seeds will have more or less the right to pollute of the countries which they operate. Liability is not regulated either, in particular when economic losses appear: the norm which prevail will be: ‘those contaminated will pay’ (Amigos de la Tierra, 2004).

3.3.5 Recent parliamentary activity on GM crop policy

The seventh legislative term of the new Spanish democracy, which started in the year 2000 and ended in March 2004, was characterised by the absolute majority of the conservative party *Partido Popular* and the difficulty of opposition and minority parties to introduce an open debate on the Spanish GM agriculture policy. Nevertheless, some minority parties, namely from the left *Izquierda Unida* (IU) and *Grupo Mixto* (GMx) made some Parliamentary Questions to the Government aimed at getting some official responses on the existing situation, developments, and governmental goals of the GM crops in Spain. (See section 3.1.1). However, most of the answers were largely incomplete and did not address the main points contained in the questions.

For instance, MP Francisco Rodríguez Sánchez from GMx made two set of questions in February and in March 2001 to the Government asking for the Spanish plans to authorise new GM varieties. However, he did not receive any answer on this (BOCG, 2001a, 2001b). Another question was put forward by Mr Joan Saura Laporta, of *Iniciativa per Catalunya* (IA), now linked to *Izquierda Unida*, with regard to how public information mechanisms on GM releases had been provided by Spanish authorities. The answer, given in July 2002, simply stated that those projects of deliberate releases in which the attendant authorisations corresponded to the General Administration of the State (and not the ACs):

‘No consultation with the public has been carried so far’, (BOCG, 2002)

While in those authorisations in which the competences belong to the Autonomous Communities, they are also the competent authorities with regard to information and so no answer was provided. The same answer stated that:

‘So far, the reports of the CNB were not made public, although they were available for those who asked for them. In the future, and as response to the new Law requirements in this respect, it is planned to include in the MIMAM web site the reports of the CNB of those files in which the competence corresponds to the State. Corresponds to ACs to decide whether the reports made by the Autonomous Commissions of Biosafety are to be made public. No the web site of the MIMAM contains the following information:

- Notifications of the facilities.
- Notifications of the contained releases carried out in Spain.
- Notifications of voluntary releases carried out in Spain.
- Notifications of commercialised products in the EU containing GMOs’ (BOCG, 2002).

However, during all this time such web site has been operating in a peculiar way, and far from being a institutional mechanism to channel the opinion of relevant stakeholders has only been a way to provide, with the attendant delay, results and decisions already made by the Spanish assessment and regulatory bodies. For instance, as late as January 2004 the MIMAM web site still had not included for public consultation of the new draft Regulation of the 9/2003 despite it was approved by a Council of Ministers some days later on the 6th of February. Furthermore, at that time, such web site had the information on the summaries of the CNB with a delay of six months. According to FoE – Spain the draft text of the Law 9/2001 which was

approved by the Popular Party in December 2002, only incorporated 3 of the 122 amendments proposed by parliamentary groups (AdT, 2003c).

In September 2003, the Member of Parliament of the 'Grupo Mixto' (group of MPs of small parties) Mr. José Antonio Labordeta Subías from *Chunta Aragonesista* asked again in Congress about the situation of GM crops in Spain and in particular with regard to public information provided to farmers and evaluation of effects. The official answer mentioned that besides Compa Cb maize, the varieties 'PR33P67', 'Aristis Bt' and 'Aliacan Bt' were already been cropped in Aragon where at that time, had about 11800 hectares of Bt maize. Also the response stated that enough information was given to farmers in the label of the GM seeds and that profitability was between 15-20 per cent higher than conventional crops. According to this official response, the notifiers of the GM varieties are responsible for the monitoring of possible negative effects each season and no problems had been detected until then. Furthermore, it asserted that farmers:

'demand such varieties as they resolve the serious problem of these pests [corn borer]. Besides, these crops eliminate the application of insecticides that used to be employed to kill such insects' (BOCG, 2003).

And finally, in November 2003, MP Carlos Aymerich Cano, from GMx asked about the Government Plans to approve 30 new varieties of GM maize and 14 of GM cotton and the fact that no co-existence legislation or institution were still created in Spain or the UE at that time. Again, the response avoided any reference to the GM maize varieties and only mentioned the GM cotton varieties by saying that the latter are still not allowed to be inscribed in the national Commercial Plant Varieties Registry until they are approved in the EU (BOCG, 2004).

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Annexes

Annex I: Interviewee list and workshop participants

This is a list of those people who attended either of the two sessions of the workshop (w), those who were directly interviewed (i) and those who responded the questionnaire (q). There were many other relevant sources of secondary qualitative material from other people used in the writing of this report. All the workshop discussions and interviews (except one) were recorded, transcribed and translated into English. All the personal names cited in this report have been obtained from written and public secondary sources while the anonymous quotes are from personal interviews, questionnaires or recorded speeches.

- 1 An executive from a large agbiotechnology company operating in Spain, responsible for regulatory and public issues in southern Europe (Portugal, Spain, Italy, Greece), (q, w)
- 2 An executive manager of the *Agencia Española de Seguridad Alimentaria*, (AESAs, Spanish Agency of Food Safety) (i)
- 3 An activist anti-GMO campaigner of *Ecologistas en Acción* (environmental organization) and a lecturer and researcher of the Autonomous University of Barcelona (w, i)
- 4 A member of the International Institute of Environment and Law (NGO, Madrid) (w)
- 5 A senior executive in the Food Planning of the Ministry of Agriculture (w)
- 6 A member of the *Greenpeace*-Spain campaign against GMOs in agriculture (i)
- 7 A responsible person of *Organització de Consumidors i Usuaris de Catalunya* (consumer organisation), who works in its Department of Environment and Responsible Consumption (w)
- 8 A senior executive of the SEBIOT (Spanish Biotechnology Scientific Association) (i)
- 9 A member of the Spanish Commission on Biosafety (i)
- 10 A researcher of the IRTA (*Institut de Recerca i Tecnologia Agrària* – Institute for Agrarian Technology and Research) (w)
- 11 Another researcher of the IRTA. Both researchers at the IRTA work on gene flow from rice crops (w)
- 12 A senior official of the Spanish Office of Vegetable Varieties, Ministry of Agriculture. Member of the National Commission of Biosafety (w)
- 13 An expert and manager of the Department of Environmental Quality and Assessment, Ministry of Environment (MIMAM) and member of the National Commission of Biosafety. This interview was attended by two more people also working on GM crops at the MIMAM, who at times participated (i)
- 14 An activist from Friends of the Earth Spain, working on their anti-GMO campaign (w)
- 15 An expert of the of the Spanish *Consejo Científico de Bioempresas* (i)
- 16 An Autonomous Community policy maker dealing with GM crops from the *Departament d'Agricultura, Ramaderia i Pesca Generalitat de Catalunya*. (q).
- 17 A researcher at the *Dept. Biologia Fonamental i Ciències de la Salut, Universitat de les Illes Balears* (q)
- 18 A researcher at the *Instituto de Agroquímica y Tecnología de Alimentos*, Valencia (q)

19 A farmer who grew Bt maize in Aragón (i)

Recorded speeches cited in the report

20 A farmer from ASAJA with experience of GM crops

21 An executive of Monsanto Spain

Annex II: Monitoring of Bt maize crops in Spain

(A): Agreement between the Ministry of the Environment and the Spanish High Council for Scientific Research (CSIC) in order to monitor the ecological effects of Bt maize

In order to monitor the ecological effects of Bt maize crops in Spain, the Ministry of the Environment asked the CSIC to carry out a series of studies. The results have been published in the following works:

Publications:

González-Núñez, M., Ortega, F., and Castañera, P. 2000. Susceptibility of Spanish populations of the corn borers *Sesamia nonagrioides* (Lepidoptera: Noctuidae) and *Ostrinia nubilalis* (Lepidoptera: Crambidae) to a *Bacillus thuringiensis* endotoxin. *Journal of Econ. Entomol.* 93: 459-463

Castañera, P. and Ortega, F. 2000. El maíz transgénico en España. *Mundo Científico* 210: 43-47

Farinós, G.P., de la Poza, M., Ortega, F., and Castañera, P. 2001. Monitoring corn borers resistance to Bt-maize in Spain. Proceedings EU Workshop: Monitoring of Environmental Impacts of Genetically Modified Plants, Berlin, 9th and 10th November 2000. pp: 114-118. Miklau, M., Gaugitsch, H., and Heissenberger, A. (Eds.). German Federal Environmental Agency, Berlin, Germany

Castañera, P., and Ortega, F. 2001. Environmental implications of Bt-maize in Spain: monitoring corn borers resistance and nontarget impacts. Internet-Forum about monitoring of genetically modified plants. Center for Gene Technology. Robert Koch Institut. <http://www.rki.de/GENTEC/G E N ENG/FORUM/FORUM. HTM>

Farinós, G.P., De la Poza, M., Hemández-Crespo, P., Ortega, F., and Castañera, P. 2003. Resistance monitoring of field populations of the corn borers *Sesamia nonagrioides* and *Ostrinia nubilalis* after five years of Bt maize cultivation in Spain. *Entomología Experimentalis et Applicata*, 108 (in press)

Conferences

Farinós, G.P., De la Poza, M., Hemández-Crespo, P., Ortega, F. and Castañera, P. 2001. Impact of Bt- maize on non-target arthropods in central Spain. XXI IWGO Conference. Legnaro, Italia. 27 de October – 3 November.

De la Poza, M., Farinós, G.P., Hemández-Crespo, P., Ortega, F. and Castañera, P. 2001. Monitoring of corn borers resistance to Bt-maize in Spain: forecast of resistance. XXI IWGO Conference. Legnaro, Italia. 27 de October – 3 November.

Castañera, P., Farinós, G.P., de la Poza, M., Ortega, F. 2002. Bt-maize in Spain: monitoring of corn borers resistance and impact on non-target arthropods. SET AC Europe 12th Annual Meeting. Viena, 12-16 May.

De la Poza, M., Farinós, G.P., Hernández-Crespo, P., Ortega, F., Castañera, P. 2003. Efectos del maíz Bt sobre los enemigos naturales asociados al cultivo. 111 Congreso Nacional de Entomología Aplicada. Avila, 20-23 November.

International meetings

“Expert Group on monitoring for insect resistance to Bt-toxins” European Commission. DG XI. Brussels, 1997-2002

“Introducción de plantas transgénicas en la agricultura: evaluación y criterios de decisión”, IAMZ-CIHEAM. Zaragoza. 1999

“The environmental implications of genetically modified plants with insect resistance genes”. European Science Foundation. Bern 2000.

“Monitoring of Environmental Impacts of Genetically Modified Plants”. EU Workshop. Berlin,. 2000

“Risk assessment methods for genetically modified Plants – current trends and new developments”. ESF Workshop. Ceske Budejovice, Check Republic. 2001

“European Round Table on GMO Safety Research”. European Commission. Research Directorate-General. Brussels,. 2001.

“Ecological Impact of genetically modified organisms”. IOBCIwprs. Praga, Check Republic, 2003.

On-going work

Pérez Mellado, Rafael (2003). ‘Transferencia de material genético de maíces transgénicos a los microorganismos del suelo y donde se cultivan’. Madrid: Centro Nacional de Biotecnología. Internal document.

(B): Summary of the study of the National Centre of Biotechnology on the effects of Bt maize on soil microorganisms (in Spanish)

Rafael Pérez Mellado (2003). ‘Transferencia de material genético de maíces transgénicos a los microorganismos del suelo y donde se cultivan’. Centro Nacional de Biotecnología, Madrid.

Resumen:

Se han explorado procedimientos que permiten evaluar la presencia de material genético de posible riesgo ambiental en suelos donde se cultiven maíces transgénicos como paso previo a la evaluación de la transferencia de ese material genético desde maíces transgénicos a la flora microbio lógica de esos suelos, a la vez que se ha evaluado la posibilidad de implementar la trazabilidad molecular de esos suelos, con el fin de estudiar la utilidad de esos procedimientos para su eventual incorporación en un protocolo específico, en el marco de los acuerdos contraídos por nuestro país en el seno de la Unión Europea.

El gen que determina la resistencia a ampicilina, codificando una beta-lactamasa, ha sido utilizado como marcador en los procesos de ingeniería genética para la creación de las variedades transgénicas de maíz que se cultivan. En el periodo de vigencia del Convenio se ha determinado que los sistemas de detección puestos a punto permiten determinar específicamente la presencia de ese gen en suelos, así como la de secuencias de ADN promotoras de transcripción (promotor 35S del virus del mosaico de la coliflor) que controlan la expresión de los genes que confieren nuevas características a los maíces transgénicos. Los resultados obtenidos hasta ahora, aunque siempre provisionales, se han extendido por un periodo que ha comprendido casi tres ciclos de siembra y cosecha.

De forma preliminar puede concluirse que la presencia de secuencias de ADN codificantes del gen de la beta-lactamasa, que se ha utilizado en la construcción de la variedad transgénica COMPA, se encuentra por debajo de los niveles de detección. La misma conclusión es aplicable a las secuencias de ADN conteniendo el promotor 35S del virus del mosaico de la coliflor. El ADN del suelo empleado en las reacciones de amplificación se encuentra en un exceso aproximado de 259 (beta-lactamasa) y 4000 veces (promotor 35S) sobre los correspondientes niveles de detección, de forma que una secuencia codificante del gen de beta-lactamasa podría detectarse si estuviera presente en 7.7 µg de tierra y una secuencia codificante del promotor S35 del virus del mosaico de la coliflor sería detectable en tan sólo 0.5 µg de tierra.

Hasta el presente, no se han detectado bacterias Gram-positivas resistentes a ampicilina en las muestras de suelos estudiadas, y cuando se han detectado lo han sido en bajo número y sin diferencias significativas entre suelos no cultivados y suelos cultivados con maíz convencional o con maíz transgénico.

Experimentos preliminares han permitido el diseño de sondas de ADN específicas de bacterias Gram positivas que han mostrado ser útiles para la amplificación específica de fragmentos de ADN directamente de muestras del suelo. Nuevas sondas están en proceso de diseño y comprobación así como el desarrollo de protocolos de análisis

que permitan avanzar en la caracterización molecular de suelos donde se cultiven variedades de plantas genéticamente modificadas.

Annex III: A farmer case study²³

Antonio is a small/medium farmer who grows fields of his own in Aragon and, among several crops, he used to sow maize. Antonio is an associate of an agrarian cooperative, which provides him with the inputs he needs and then markets his produce. This cooperative works within a broader association of cooperatives, embracing about thirty agrarian cooperatives from Catalonia and Aragon.

In 1998, when Antonio was going to buy seeds to sow maize, he was advised by the cooperative to try a new variety: the Bt COMPA maize from Novartis (now Syngenta). He was told that it was more resistant to the corn borer, and that it could be sprayed with glyphosate (a wide-spectrum herbicide that is cheaper than other herbicides used for maize). He was also told that these seeds were more expensive, though he would get a larger yield and he would save money on herbicides. That year, Bt maize was fully recommended by the cooperative (which was advised by the inputs division of ACTEL), though 'conventional' maize was also available to any farmer who asked for it.

Antonio understood the Bt maize to be an improved version of conventional maize, as did most of the cooperative associates, so he bought it. Nobody told him how it should be grown, or about any precautions he should take, or about its characteristics or potential for environmental harm. Thus, for instance, nobody told him to establish any safety barriers of conventional maize around fields growing this Bt maize.

The maize crop yielded a satisfactory output. However, Antonio didn't sow Bt maize in the following years because, according to him, its productivity wasn't very different from that of conventional maize. He thought that the return wasn't worth the additional costs of the seed. It must be said that Antonio is likely to grow Bt maize again, but first he wants to be able to see more clearly the worth of the Bt maize, something he hasn't seen yet. The maize output is still dependent on the weather (in 1998 the weather conditions were unfavourable for maize and caused lower than expected yields), on pests (other than the corn borer), on international markets, and on public grants (when outputs are high, the market collapses and prices fall). Altogether that means that, for the time being, Antonio doesn't perceive any great advantage in growing Bt maize.

Other associates of this cooperative have continued to grow Bt maize. They say that it isn't that bad, although they too don't see much difference from conventional maize. However, now they definitely know that they are required to establish a safety perimeter (which is a disincentive, especially for those who have small fields). These farmers think of Bt maize as some kind of complementary insurance. All the farmers are aware of the need to avoid yield decreases in any way they can, and this technology allows them to work in a preventive way. Antonio thinks that there is also a psychological component involved due to the uncertainties faced by farmers in growing any crop, so he suspects that it is the youngest and the most professional farmers who are growing the most Bt maize. Furthermore, government institutions and the agricultural firms that advise farmers are encouraging this trend.

Extracts from the farmer's interview (16 January 2004)

Interviewer: I have been told that you grew transgenic maize. When did you grow it?

Antonio: Five or six years ago [this means around 1998-9, the first harvests].

Interviewer: How did you get this variety of maize?

²³ We would like to thank an anonymous colleague for help in finding this source and also in his contribution to the case study. To complement the information we interviewed the farmer (by telephone) on 16 January 2004. All the quotes in this section are from this interview. The real name of the farmer has been concealed as well as the name of the cooperative.

Antonio: I am a member of an agrarian cooperative which provided us with it, so I grew it. They brought us those seeds and we planted them, there isn't any other reason. We were told that it was effective against the corn borer and that it was resistant to herbicides.

Interviewer: But in the following years you didn't plant it anymore, did you?

Antonio: Correct, I didn't.

Interviewer: Why?

Antonio: Because I didn't find it to be more profitable than the other varieties. Nowadays it is not grown much at all here. I know one farmer who still has planted it in some seasons, but only because the seeds were given to him by the seed company without him having asked for them. They said: 'Have it, plant this one because it will work fine'. But he hasn't found any real improvements with it by comparison with other varieties.

Interviewer: But then, was it the seed company itself that provided you with this maize?

Antonio: No, it was provided by our cooperative in association with 40 more cooperatives, which provides us with seeds and markets our cereals too. [Our cooperative] brought these seeds and I planted them, though I haven't planted them again.

Interviewer: So you didn't find much difference...

Antonio: No, I didn't find any at all and the seeds were a bit more expensive. I don't remember how much more expensive they were, but it could be around 5000-6000 ptas (about 25-30 euro) more expensive per hectare.

Interviewer: When you were provided with those seeds, were you told to implement any particular measure?

Antonio: No, we were told nothing about this. They gave it to us and said that we should do the same as we do with the other varieties. The only thing they added was that it was effective against the corn borer and that it was more resistant to a herbicide. And that's all. They didn't tell us about any possible problem in harvesting it or anything else.

Interviewer: Were you told to set a safety perimeter?

Antonio: No, they didn't say that either. We grew it in the same way as we do with any other variety.

Interviewer: In your region, are the few farmers who are still growing transgenic maize satisfied with it or do you think that everybody has had the same reactions as you have had to this maize?

Antonio: I only know one person who is still growing it, and he does so because he is the one who was given the seeds by the company. But he hasn't been told anything either.

Interviewer: Do you know if this transgenic maize has been marketed in a different way than the others?

Antonio: The cooperative collected it and I don't know what they did with it.

Interviewer: But do you think that selling this maize has been profitable?

Antonio: I think that they had trouble selling it, though I don't know that too well. Had anyone analysed the maize, then maybe some problem could have arisen, but from what I see, transgenic maize is mixed with the rest of maize.

Interviewer: So going back to the previous question, this transgenic maize was more expensive to you and it didn't provide you with any advantage?

Antonio: No, and I haven't grown it any more. I have grown two other crops of maize since then, but not transgenic. I can't find in it any advantage with respect to the conventional varieties.

Interviewer: Do you have a lot of trouble with the corn borer in your region?

Antonio: In some years we have had some problems with it. But it doesn't happen very often, although it is a problem in some years.

Interviewer: Did you find any difference in the [reduction of] vulnerability of the maize to the corn borer when you grew the transgenic maize?

Antonio: No, I didn't find any difference. With regard to kilos of production per hectare it was not more profitable either.

Interviewer: Thank you; this is all I wanted to ask you. Do you want to add anything else, or to make any comment on the current situation?

Antonio: I think that farmers tend to grow less transgenic crops in my region. I have asked if anyone has planted transgenic seeds, and the answer was negative.

Interviewer: Ah,... [At this point, the interviewer wanted to confirm some of the previous assertions again, so some questions were repeated, with some slight variations] by the way, do you know what happens with these transgenic crops when they have been harvested...

Antonio: No, I don't. Well, here there is a dealer who buys maize, but I don't know what he does with it. I don't think that he asks whether the maize he buys is transgenic or not either. When people bring the maize to him, he takes it and that's all; he doesn't ask whether it is transgenic or not.

Interviewer: So, when you got the seeds, you didn't get any indication about what things you should do.

Antonio: No, no. They gave it to me as they do with any other kind of maize. I planted and harvested that crop as I do with any other one. They told me that it would have a better yield though I didn't get it.

Interviewer: Was the consumption of water and the time of labour different?

Antonio: No, they were the same. Well, I grew it in the same way I had always done. They gave it to us in the way they do with any other variety. The only things they told us was that it was transgenic, as well as more resistant to the corn borer and herbicides. They also told us that it had a better yield, though this didn't happen. This doesn't mean that any other farmer didn't get a better yield, but that wasn't my case.

Interviewer: Thank you very much.

Annex IV: Additional information

GM crops trials in Spain

With regard to GM trials, four sources provide different figures of the evolution of GM varieties trials in Spain:

- 1 According to an official report from the Spanish Minister of the Environment *The Environment in Spain, 2000* (Ministry of the Environment, 2001) the number of field trials with GMOs were progressively reduced after having reached a maximum in 1998. From 3 trials carried out in 1993, they reached a peak of 146 in 1998, while in the year 2000 they went down to 39.
- 2 According to Garcia Olmedo (2001), the number of trials until 2001 in Spain were 128. He states that the Autonomous Communities of the Balearic Islands and Cantabria are the only ones that have not carried out trials, and Andalusia is the one with the most trials, with a total of 67. The largest number of these trials have involved maize (27), tomato (14), sugar beet (11), cotton (7), melon (6), and tobacco (5). The main applications have been herbicide-tolerance (32), insect-resistance (26), biological modifications (22), virus resistance (13), and genetic expression (10).
- 3 According to the environmentalist group *Ecologistas en Acción* (figures for the end of 2001), Spain has done/is doing 181 transgenic trials, maize being the most important (62), then sugar beet ('remolacha', 22), cotton (16), and potato (10). However, according to other figures shown at the Feria de Zaragoza 1999, the main type of trials from 1992 to 1999, of 130 in Spain, were: maize herbicide-tolerant 27%; maize insect-resistant 14%; maize both herbicide-tolerant and insect-resistant 7%; tomato 18%; sugar beet: 11%; tobacco: 7%.
- 4 According to Marin Palma (2001:247) Andalucía has carried out 154 trials, and Castilla y León 84.

According to Sanz Magallón (2001:82), the first GM crops trials in Spain were carried out in the following years: 1992 tomato; 1993 rape, maize; 1994 sunflower, sugar beet, lucerne, eucalyptus trees, several bacteria; 1995 melon; 1996 potatoes, cotton, cherries, oranges, wheat; 1997 fungi, tobacco, cucumber; 1998 soyabean, birch trees, several viruses; 1999 rice. Furthermore, and according to E. Torres Manzano (2002:3), of the 124 trials that were notified to the European Commission in 1999, only 17 were notified by public research institutions while the rest (86%) were notified by the private sector, mainly multinationals. Andalusia is the Autonomous Community that has carried out the largest number of trials, in particular of the following crops: cotton, maize, sunflower, alfalfa, melon, potato, sugar beet, soyabean, tobacco, poplar trees, tomato and rape. In Asturias, there have been trials of eucalyptus and pine trees; in Castile La Mancha of tomato, sugar beet and maize; in Castile-León of rape, sugar beet and maize; in Catalonia, of tomato and maize; in Extremadura on tomato, maize and soyabean; in Galicia of vine and maize; in Madrid of maize; in La Rioja of tomato and sugar beet; in Valencia of melon, citrus fruits, plum trees, maize, sugar beet and tobacco. According to Greenpeace (2001, personal communication), Monsanto has experiments in the town of Los Palacios in Andalusia, one of its two work stations in Spain; up to 2001, Monsanto had done a total of 124 trials with transgenic seeds in Spain, mostly in Andalusia. Transgenic cotton research attracts great interest in Andalusia as 95% of Spanish cotton and 80% of the EU's cotton is produced in this Autonomous Community. According to an analysis of the SNIF database for the 1991-2002 period presented in Lheureux *et al.* (2003), of 1,687 notifications of GM field trials presented in the EU as of February 2002, Spain submitted 180.

Some related background economic information

Much of the maize demand in Spain is used for livestock feed. Figures of the evolution of meat production in Spain show that pork has increased from 1.703.490

tons in 1989 to 2.892.255 in 1999, that is 69.8 per cent. With regard to cattle the augment has been from 459.258 to 677.573 respectively or 47,5 per cent. In particular meat and meat related product exports raised only in five years between 1995 and 1999 149 per cent and this increase was of 174.7 in the case of pork. However, the degree of self-provision of cereals for meat production is only of 60 per cent. In particular, 70 per cent of its imports come from the EU and the other 30 from other countries such USA and Argentina (Sanz-Magallón, 2001:100-104). In relation to soyabeans, crucial for the Spanish livestock production, Spain is only able to produce 1 per cent of its demand, much of it transgenic, although it is not possible to know exactly to which extent as it comes together with the non-transgenic one. However, Spain has partly reduced its dependence on maize imports in the last few years. From only covering 47 per cent of its internal demand now it is able to cover up to 56 per cent in 1999 being most its imports from France (63 per cent). One of the "aims" being implicitly cited as desirable is to reach "self-sufficiency" in livestock feed production.

Nevertheless, as it is widely known, maize crops demand large quantities of water and usually have an important effect on soil erosion. Being Spain a country with suffers both problems, -serious water scarcity and acute erosion, specially along its Mediterranean basin- is it to be expected that intensification of its agriculture due to further introduction of (Bt) maize crops could aggravate this situation. The highly contested National Hydrologic Plan includes plans to expand such water-intensive crops and it is likely that social pressures will also come up as these projects come into being. Furthermore, pig production in areas such Catalonia, with as many pigs than people (6 million of each) is creating huge problems of nitric water contamination, a situation that may act as a stopper for a further development of this sector.

Expectations that European subsidies from Common Agriculture Policies (CAP) will be drastically reduced in Spain also introduce further pressures on farmer to join and to create a highly competitive agro-industrial structure in which GMOs are presented as to have an inevitable role.