

## SPAIN

# COMMERCIALISATION DRIVES PUBLIC DEBATE AND PRECAUTION

January 1999

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### **‘Safety Regulation of Transgenic Crops: Completing the Internal Market?’**

**A study of the implementation of EC Directive 90/220**

**Main contractor: The Open University  
contract no. BIO4-CT97-2215, 1997-1999**

This report forms part of the overall final report for the DGXII/RTD biotechnology programme on the Ethical, Legal and Socio-economic Aspects (ELSA)

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## OVERVIEW

### Enhanced co-ordination and precautionary measures

The beginning of the commercialisation of food products derived from genetically modified organisms (GMOs) has had impacts on several levels in Spain. It has spurred public debate, prompted changes in GMO regulation, and encouraged closer co-operation among administrative bodies. Overall, it has led to some redefinition of the concept of precaution in regulatory practice. To some extent, it has reopened questions that the regulators considered to be resolved, such as whether or not authorisation of a genetically modified (GM) product means that it can be treated like a conventional product.

The social dispute in Spain over GMOs erupted in late 1996, when imports of GM soya and maize from the USA began. Before, there had been virtually no public debate on the topic. Since 1996, a large number of public events (such as conferences, workshops, and organised public debates with participation of all the involved actors) have covered the topic, even though no generalised public debate, such as has occurred in some northern European countries, has taken place. Critics of genetic engineering have acquired a more prominent position. The public dispute has made weak spots in the regulatory process apparent and has also prompted some redefinition of the regulatory framework for GMOs. The issue has been debated in Parliament (in particular, in relation to questions of GM food safety), and this prompted the final approval of a GMO regulation which had been stalled for several years.

Commercialisation has also been behind the adoption of a more precautionary approach to GMO risk assessment by the public administration. The Spanish National Biosafety Commission (CNB) has treated dossiers for commercialisation in more detail than authorisations of similar GMOs for field trials, assessing a number of questions that have come up in the public debate (for example, concerning herbicide use and insect resistance).

The CNB and the competent authority (CA) have responded to public concerns despite the scant social conflict about GMOs in Spain. For instance, the CA told applicants to try to avoid the use of marker genes resistant to antibiotics, after a public dispute erupted over possible antibiotic resistance in relation to the imported Ciba/Novartis maize at the end of 1996. The CA also decided in 1997 not to accept any more dossiers from Spanish applicants for commercialisation if they featured antibiotic-resistant marker genes. The reason for this decision was not concerns over health effects, which the CNB saw as unlikely. Rather, it was a response to the public debate, and the 'unnecessary' (because technical alternatives existed) negative impact on public perception of GMOs: 'If people are really that worried about [antibiotic markers], then it is better to eliminate them, as there is no necessity to use them' (CA interview, 7/5/1997). However, the CA did not try to block any dossiers sent in by other competent authorities because of this issue.

Commercialisation has encouraged closer co-ordination among administrators. For example, in the case of variety registration the administrative body responsible discusses all its decisions with the Directive 90/220 regulators, and invites comments on its planned registrations from the CA. Another example of co-ordination is the effort made by the novel food regulators to ensure that all products submitted to the Directive 90/220 procedure in

Spain are also evaluated under the Novel Food Regulation (NFR), or carry an explicit statement that prohibits their use as food. Before the NFR came into effect, several applications for commercialisation presented to the Spanish CA were stalled because of this question. The regulators from the Ministry of Health responsible for novel foods did not want these products to receive the go-ahead under 90/220 because they feared the products might be sold for food uses without appropriate evaluation.

Another effect of commercialisation was a change in the position of regulators on market stage monitoring. When imports of GM maize from the USA began in late-1996, specific market stage monitoring of GM plants was seen more as an interesting idea rather than an absolute necessity, to be conducted in order to calm down public debate, 'just in case', or to conduct scientific studies about ecological interactions. The evaluation of the product itself was considered basically closed at the moment of its authorisation. The Spanish CA had not previously demanded monitoring for any product authorisation in the EU.

This position changed because of the public debate about the issue. Now, some Ministry of the Environment (MIMA) officials consider market stage monitoring should be a general policy for all future GM crops. They consider it to be an integral part of the risk assessment in specific cases and a means of evaluating long-term risks which cannot be evaluated in field trials. Not only do MIMA officials emphasise the need for monitoring (for insect-resistance to Bt crops) and possible limits to the areas planted, but they also point to the implications of problems after commercial planting starts (such as prohibition of the crop). Apart from the monitoring programme under way for the Ciba/Novartis maize (as part of a European effort), future monitoring of other Bt plants is foreseen.

The Ministry of Agriculture (MAPA), too, has recently required wide-ranging monitoring as a condition for commercialisation, thereby reversing their earlier position. At the beginning of 1997, MAPA tried to register the Ciba/Novartis maize without imposing any specific conditions. A campaign organised by Spanish and other European NGOs (non-governmental organisations) led to a suspension of the registration process. Apart from environmental NGOs (such as Greenpeace, Aedenat and Adena), the public opposition of some agricultural organisations played an important role in the protest. At least one of them voiced opposition to the planned registration in the MAPA committee on new varieties.

MAPA declared in April 1997 that it would not register the maize for the time being, because other countries (like France and Italy) had refused to do so. France had originally proposed the authorisation of the maize EU-wide but then refused to register it at the national level.

The regulation for National List registration of transgenic seeds published in March 1998 then established a general requirement for monitoring programmes for GM crops, as a Spanish national initiative (Spanish Ministry of Agriculture, 1998a). When authorising the inclusion of the Ciba/Novartis maize in the national varieties register in March 1998, MAPA made the authorisation conditional on (among other things) monitoring for insect resistance, effects on soil micro-organisms and effects on animals fed with the product. In the case of the appearance of resistant insects, the Ministry has reserved the right to revoke the registration (Spanish Ministry of Agriculture, 1998b). This specific monitoring programme, as well as the general requirements stated in the plant varieties regulation, is one of the few instances of the Spanish authorities imposing more stringent conditions on a

GMO than have been considered at the EU-level. With the imposition of monitoring conditions, the pre-marketing risk evaluation has in fact been extended beyond product authorisation. MAPA's monitoring demands for the Bt maize go well beyond the original conditions for trial releases under Directive 90/220.

Both Ministries, MIMA and MAPA, changed their position on monitoring because of the public debate over the long-term effects of GM crops in Spain (which frustrated MAPA's planned registration of the Ciba/Novartis maize in early 1997) and in other European countries. MAPA's decision to require monitoring was also influenced by the French precedent (the conditions imposed are the same as those imposed in France just a few weeks earlier) and by MIMA, which since the end of 1997 had been asking for monitoring.

Public debate has also had some influence on the biotechnology industry in general. The industry has started to prepare for the monitoring of specific effects in Spain, as it is already doing in other countries. At least one company is financing research to check that the data from the field trials for their Bt crops are correct, especially under the local conditions in Spain. They see this research (as well as the recent hiring of an entomologist) as part of a resistance control strategy.

Commercialisation has also created pressures for more rapid market authorisation. The case of the maize imports from the USA shows that trade issues can become an important consideration, especially since Spain is one of the biggest EU customers. The Spanish Ministry of Commerce repeatedly tried to influence European and other Spanish authorities to allow maize imports from the USA when these were threatened by delays in European authorisations for certain GM maize varieties.

### **Commercialisation and acceptability of products**

The commercialisation of GM food products has opened up the question of the conditions for the acceptability of these products in the market. However, in Spain the issue of labelling has not been as prominent as in some other countries.

An NGO coalition critical of genetic engineering has been demanding a moratorium on GMO releases to the environment since 1996. While they accept labelling as a necessary condition for free consumer choice, most of the NGOs refuse to become publicly involved in the labelling debate because of their opposition to GMO releases in the first place (Todt and Luján, 1997). The only demands so far from consumer organisations have been for clear labelling. None of these organisations has adopted a position opposing novel foods. In practice, the monitoring requirements for crop cultivation have played a more important role than labelling in defining the overall acceptability of GM products.

The question of consumer acceptance has come up in a rather diffuse way. Spanish consumers and consumer organisations have so far not exerted any direct pressure on retailers or the food industry. However, there exists a general social unease which is reflected in studies on public perception (see Atienza and Luján, 1997). The uncertainty about consumers' attitudes and behaviours with respect to GM food is having some impact (however limited) on the market. Spanish retailers have started to take some 'precautionary' measures of their own, for instance, by trying to avoid GM ingredients in their own brand products or by demanding certified non-GM products from their suppliers. At least one

supermarket chain is considering the possibility of creating a line of non-GM products. However, in taking these measures, retailers are not responding to any direct public criticism or conflict but rather to a general uncertainty. All of them state that they are being cautious and trying to pre-empt any possible conflict, especially in view of the conflicts that have developed in other EU member states.

This illustrates how the social resistance to GM foods in one national market can spill over to influence another. Some of the biggest Spanish retailing chains are owned by French companies. To some extent, these are translating their precautionary reaction to the French debate on novel food into the Spanish market, despite the absence of any direct pressures. This may create an obstacle to GM foods in the Spanish market, regardless of any administrative efforts to create consumer confidence (for instance, by labelling).

### **Ambivalence about precaution**

The regulatory process is not guided by a clearly predefined definition of precaution. Rather, the meaning of precaution is established by regulatory practice, partly in response to public pressures. The overall approach to precaution which underlies the regulatory process is ambivalent.

For example, the CNB's risk evaluations take into account a relatively wide range of health and environmental issues. The CNB has on many occasions suggested further studies of the possible environmental implications of GM crops. Regulators have been sensitive, up to a point, to social demands for wider criteria for precaution. They have tried to influence the design of GMOs or have adapted the regulatory process in response to public concerns. However, the CA's authorisations have been based on establishing that there exists no evidence of any immediate risk. The CA does not usually make authorisation of a field trial or product conditional on additional studies. The studies that the CA requests are more to enhance knowledge of GMO behaviour. Some effects are either excluded from the evaluations, or not studied in the detail that the NGOs demand.

The CNB's definition of GMO risks has focused on health problems and, specifically, on environmental interactions. The studies required by the CA concern a relatively wide range of possible effects, though these have not led the CA to object to many consent applications. Most (but not all) of the possible effects on health and the environment that have come up in the public debate are discussed during the risk assessments. Risk assessments routinely include the evaluation of genetic stability, gene transfer, pathogenicity, capacity for survival and dissemination, and negative effects on other organisms. In addition, in a number of cases, the CBN has discussed other issues such as insect resistance, effects of long-term use, and also some 'secondary' effects, such as herbicide use. In all these cases, the burden of evidence lies with the applicant to show that there is no current evidence of any clear risk.

The CNB has not so far promoted any separate scientific studies on risk, mainly because it lacks the funds. However, it has made explicit to a number of field trial applicants the need for more studies on environmental risks and the interactions of the GMO with the environment, especially concerning gene transfer. The CNB considers it important that more studies on ecological interactions should be done by companies in their field trials in Spain. According to CNB members from MIMA, most companies in Spain are not

sufficiently aware of the possible environmental implications (for example, of gene transfer) and they usually design their trials only for agronomic evaluations. Part of the CA's approach is to encourage the design of trials which allow environmental effects to happen, in order to improve their assessment of GMO behaviour.

However, in the majority of cases the additional studies requested by the CNB risk evaluations have not been binding conditions but suggestions. So far, few authorisations for field trials or products have been denied. In all the authorisations, the level of overall risk has been defined as 'not significant' or 'effectively zero'. However, the CA has objected to a dossier in at least one case (AgrEvo oilseed rape). The company had made claims in its dossier which in principle were only applicable to environmental conditions in northern Europe. The Spanish CA considered this to be a serious fault in the risk assessment and demanded trials to study the interaction of the crop with its environment (and especially with wild relatives) under Mediterranean conditions.

While the general effects of herbicide use have been discussed in the CNB, no specific assessment of herbicide implications (herbicide use or residues) forms part of the risk assessment for herbicide-tolerant crops. These issues are deferred for consideration under other legislation.

The obligation for the consent-holder to monitor commercial GM crop cultivation in Spain is an element of a wider definition of precaution, especially since the varieties registration regulation explicitly states that the crop's registration will be revoked if any environmental or health problems show up during monitoring. A general monitoring requirement might lead to risks becoming implicitly more acceptable during authorisation (because they would be tested during monitoring). In practice, however, MAPA's monitoring programme (at least for the Ciba/Novartis maize) means a definite strengthening of the definition of precaution because it will involve the study of a number of effects that were not studied in field trial releases.

MAPA introduced monitoring when this issue was already being discussed at the European level. Before that, neither MAPA nor MIMA had seen monitoring as decisive for commercialisation. As in the case of the antibiotic-resistant marker genes, the change in policy on monitoring is a reaction to public debate and pressure from NGOs, not necessarily an expression of a previously-stated wider definition of precaution. In the case of the antibiotic-resistant marker genes, for instance, CA members consider any health problem to be negligible. However, in practice, regulators are accepting a broader definition of precaution.

### **Limits to risk assessment**

Indirectly, the regulators acknowledge the limits of their risk assessments. The view of Ministry of the Environment officials is that the CNB's risk assessment can limit potential risks and identify 'evident' or 'imminent' risks, and that remaining risks will be controlled through market-stage monitoring programmes now that varieties registration demands monitoring.

Indirectly, the value-laden nature of the assessments is also acknowledged, while at the same time the argument of sound science is invoked to justify regulatory decisions (as it is

in other contexts). For instance, one member of the CNB defines the classification of GMOs according to their level of risk (as well as the establishment of the criteria of acceptability) as 'totally subjective' but possible as long as the experts involved are sufficiently competent (CNB interview, 30/1/1998). The prevailing view is that the evaluations have to be conducted exclusively by scientific experts, because of their knowledge about genetic modification.

This definition of risk used by the CNB also acknowledges, implicitly, the role of uncertainty. Uncertainty, even though never mentioned explicitly, also comes up in the evaluations. The fact that on several occasions the CNB has suggested studies on, for instance, the long-term effects of transgenic crops, shows a recognition of the scientific uncertainty with respect to GMO effects. CNB members also point out the limits of extrapolating from the results of field trials, and acknowledge that risk evaluation cannot be based exclusively on information gained through such trials.

Neither socio-economic effects nor concepts like sustainability are used as explicit criteria for risk assessment, although they do play an indirect role. Some CNB members see sustainability, especially with respect to agriculture, as one overall goal of the assessments. And CNB members see some of the products authorised, such as herbicide-tolerant or Bt crops, as contributing to that goal (for instance, because of their potential to reduce pesticide use).

### **Decision making and democracy**

The formal structure of the regulation excludes participation, and in practice only limited ways of participation are opening up. It is not clear if this is considered a serious limitation to the process by all those relevant actors who might ask for more participation. The dominant view in the CNB and the CA is that membership should be limited to recognised scientific experts. The Spanish GMO regulation defines the National Biosafety Commission as having a 'strictly technical character'. Participants from outside the public administration must be experts from institutions active 'in the subject matter covered by the... [Spanish biotechnology] law'.

The CA's strict interpretation of this part of the regulation led in 1998 to the decision to reject the demands for participation of a few NGOs, such as CODA. However, in response to a proposal from the trade union *Comisiones Obreras* (CCOO), a university scientist has now been accepted as a permanent member of the CNB. Before the establishment of the permanent CNB, the possibility of wider public participation was discussed, at least within MIMA. MIMA members of the preliminary CA tried to introduce social participation in the CNB, to the point that the preliminary CA encouraged NGOs to start preparing a representative, even before those NGOs had considered this possibility.

The level of interest, or involvement, of public interest groups and individual citizens in GMO regulation has been limited. Only the CCOO has pursued a demand for participation with any effort. Not only has social participation remained a side issue in the public debate and among NGOs, it is not even clear if participation in the CNB would satisfy most of the critics of genetic engineering. Most Spanish environmental organisations are reticent on the issue of participation in administrative bodies, and often prefer a strategy of open confrontation (López *et al.*, 1998).

## **An expert committee as de-facto policy maker**

The Spanish regulation of genetically modified organisms (GMOs) centres on the idea of shared responsibility between different administrative bodies and among different levels of the public administration. Both the National Biosafety Commission (CNB) and the Competent Authority (CA) are collective bodies with representation from various ministries. The CNB and CA have formed a tight mutual relationship. In practice, the CNB expert committee is the key actor and has implicitly adopted a policy making role.

This active role of the CNB in defining the practice of regulation has been helped by the fact that the formal legislative framework for GMOs has been slow in developing in Spain. The regulation (Kingdom of Spain, 1997) which set out the detailed administrative framework for the execution of the Spanish GMO legislation (Kingdom of Spain, 1994), a simple transposition of Directives 90/219 and 90/220, was only approved by the government in June 1997.

The CNB (because of its central role in the entire process) has also become an informal body of inter-ministerial co-ordination through which the represented ministerial departments exchange information. In fact, the CNB deals with issues which in theory are the responsibility of other administrative bodies. This also means that boundary issues are debated (and decided on) in the CNB. In practice, an informal link is made among the different aspects of GMO regulation through the CNB, since this is the only place where all the aspects are discussed.

A number of the health and environmental issues raised by critics are considered during risk assessment (as well as, informally and on a case by case basis, other concerns). Various reasons have favoured this. First, from the start the Ministries of the Environment and Health were given a key role. Second, members of the CNB come from a range of disciplines (including microbiology, biotechnology, agronomy, general biology, pharmacy and chemistry, but no specialised ecologists). Third, at least in some cases, there is co-ordination of all the ministries and discussion of boundary issues in the CNB. For instance, co-ordination between MIMA and MAPA played an important role in the introduction of monitoring for variety registration.

In this sense, the mixed composition of the CNB and its institutional location seem to have contributed to some sensitivity to public concerns. In this way, the social debate is reflected up to a point in the CNB, despite the absence of representatives of NGOs. However, the demands of some critics for wider social criteria to be included in the risk assessment are still far from being met.

## **Conclusions**

Genetic engineering and transgenic products have so far not turned into an important issue of public debate in Spain. The country is not in a situation where the public could have a direct influence on regulation, let alone in the design of products (Todt, 1997). On the other hand, the limited public controversy that exists is exerting an indirect influence on sectors of the market for transgenic products. In the same manner, while the regulatory process has not been as directly influenced by public debate as in some other EU member states, it is responding to some of the public concerns. Especially significant in this sense are the

precautionary measures that have been introduced in the last two years, both in response to some public demand and to pre-empt future protest.

## SIX ASPECTS

### 1 REGULATORY BOUNDARIES

#### 1.1 General boundary issues

The boundaries between the administrative bodies responsible for crops, foods, feeds, seeds and pesticides are informal. No formal regulatory boundaries were established, either because of the lack of specific legislation or the lack of practical regulatory experience. The only exceptions are novel foods and transgenic seeds. Especially the lack of experience explains why until now only very few boundary issues have cropped up. Most of these could be solved in the National Biosafety Commission (Comisión Nacional de Bioseguridad, CNB), which has informally become a body of interministerial co-ordination. There is in general no organised inter-ministerial contact among administrations concerning GMO-regulation outside of the CNB, nor between the CNB and other administrations not (yet) represented. The fact that the CNB and the competent authority (CA) are closely interconnected has contributed to a fairly informal working of the entire regulatory process, without formal policy statements or formal contacts between ministries. Most regulatory decisions in Spain in relation to GMOs are prepared in the CNB and then signed without change by the CA.

For the regulatory process under Directives 90/219 and 90/220, the Ministries of the Environment and of Public Health have been established as the prime responsables. The Competent Authority (*Autoridad Competente*, CA) and the CNB are both located in the Environment Ministry (see Appendix III). In practice, the representatives of the MIMA and the MSC have always collaborated very closely in the authorisation process. The provisional Competent Authority has always established its final decisions jointly with the representatives from MSC by consensus.

No general division of responsibilities for authorisations under Directive 90/220 is planned, the CNB will continue to work on the basis that each member comments on the aspect of the GMO-application that falls into their area of work. This mode of functioning establishes informal boundaries along the lines of the long-established sectoral responsibilities of the different ministries. At the same time it allows the open discussion of any inter-ministerial issue with representatives of all of the ministries involved.

The CA wants to include several more representatives from the Agriculture Ministry in the National Biosafety Commission, either as permanent members or for giving expert advice on specific questions (like pesticides or feeds). As a permanent member for questions relating to herbicide resistant crops they want to include an expert from the MAPA office which regulates pesticides. There has been a permanent representatives from the seeds regulators for several years.

The GMO regulatory process is still heavily concentrated around the CNB and CA under Directive 90/220, for the lack of activity in other sections of the administration. Only relatively recently have other administrative bodies assumed some responsibilities for a few

of the GMO-related aspects: the Ministry of Health and Consumption (MSC) for the regulation of novel foods, and the Ministry of Agriculture, Fisheries and Food (MAPA) for the regulation of seeds. The administrative bodies which hold responsibilities for other aspects related to GMO (like pesticides or feeds) have not yet become involved in the process nor have they assumed any formal responsibilities.

For transgenic *seeds*, there has existed a specific regulation for variety registration since March 1998. The authorisation for cultivation of a transgenic crop variety is responsibility of the Direction for Seeds at the Ministry of Agriculture. They are preparing to adapt the Spanish legislation further, but only by incorporating the changes made necessary by the future European directive. No other modifications or pieces of legislation are planned.

The seeds-crops interface has been well established. Two experts in plant varieties are permanent members of the CNB, one of them being the current head of MAPA's Seeds Direction, the other his predecessor. The seeds regulators consult all the steps they take with the CNB and seek the backing of that body for all their decisions, even though these are their exclusive responsibility. In addition, all of the authorisations for variety registration are discussed by the CA, in order to give all of the Ministries represented a chance for comment. For instance, the authorisation for cultivation of the Novartis maize, before MAPA's final decision, was submitted to this Competent Authority for comment (which played an important role in the subsequent introduction of a monitoring requirement, see Section 3.2).

Inter-ministerial issues have not been a topic in public debate, nor has any NGOs or industry asked the administration to clarify or take into account any of these issues.

For transgenic *feed*, no Spanish legislation exists. The responsible administration (the Direction for Animal Health of the Agriculture Ministry) has not treated the issue, and is awaiting its European regulation. Only once the CNB called upon an expert in feeding stuff from MAPA for a question related to feeding uses. The CNB has been trying to include that person as a permanent member of the CNB (no decision had been taken by April 1998) because it considers important that feeding products are checked in the absence of a specific regulation for transgenic feeding stuff.

The entire regulatory process has so far experienced few major internal conflicts nor did it have to cope with strong pressure exerted on it by other actors. Conflicts between administrative bodies have been limited mostly to questions of interpreting the relation between Directive 90/220 and the Novel Food Regulation (NFR) (which stalled product authorisation for a while, see below). The same goes for relations with most non-administrative actors. Specifically the CNB and the CA, on the one hand, and the biotechnology industry as well as a number of NGOs, on the other hand, have maintained a fairly co-operative relationship. Only few NGOs have had any contact with CNB or CA. And only in few cases did they ask for information about the CNB's or CA's work or decisions, or made public any critical comments or demands.

## **1.2 Crop/food boundary**

The legal framework is exclusively provided by European law, especially the European Novel Food Regulation (NFR) (EC, 1997a). Spain never tried to enact any specific national

regulation regarding novel foods or their labelling. The administration responsible for novel food authorisation are the Direction of Public Health at the Health Ministry and the Direction for Food Policy at the Ministry of Agriculture.

Both of the bodies conduct the processing of applications jointly. Each has delegated the scientific evaluations to a corresponding public research centre (the Carlos III Institute of Health for the MSC, and the Agriculture Research Institute for the MAPA). No specific commission or other institution for the evaluation of novel foods has been established, nor will there be experts assigned to the matter. Expertise will be requested on a case by case basis according to needs, either from the designated centres or from other public research centres. EC recommendations, like Recommendation 97/618 (EC, 1997b), form the basis for these evaluations. Decisions are taken by consensus between those two bodies, based on the evaluations from the corresponding centres. However, the details of the process have not been established yet since until now only one evaluation has been conducted (all the other cases were simple notifications under the NFR).

In the written regulation, as well as in regulatory practice, the regulatory processes of crops and foods are completely separate. Both the MIMA and the Novel Food regulators agree that the definition of environmental and health effects is sufficiently clear for segregating them (and that no “environmental” effects are to be evaluated under the novel food procedure). The evaluations of foods are strictly for health effects, since any environmental effects are already covered by the evaluation under 90/220 by the CNB, which all products must complete before entering the procedure according to the Novel Foods Regulation. In consequence, the MIMA is not considered to play any role in the novel foods evaluations.

An administrative boundary question arose between the novel food regulators and the CNB on the relation between the Novel Foods Regulation and the Directive 90/220. The novel food regulators insist that all applications submitted for commercialisation under 90/220 in Spain also pass through the novel food authorisation process (in case the products will or could be used at some point for human foods), to make sure that no GMO-product authorised under 90/220 is sold for food purposes without the novel food authorisation. For products in principle not destined for food processing, the authorisation under 90/220 must state specifically that no food uses are permitted (on request from the novel food regulators). Before the NFR went into effect, several products submitted to the Spanish CA were stalled in the CNB because the novel food regulators demanded that those products enter the NFR process before receiving authorisation under 90/220. Only when the NFR entered into force in 1997, did the novel food regulators agree to proceed with the authorisation procedures for these products. On dossiers sent to the Spanish CA for comment by other competent authorities (including the Novartis maize and Monsanto soya) the novel food regulators made the same demands.

### **1.3 Crop/pesticide boundary**

The issues in relation to the use of herbicide resistant crops (HRCs) and their effects have so far only be treated by the National Biosafety Commission. Administrative bodies, like the ones responsible for pesticide regulation, have not become involved with those issues. No organised relationship has been established between the CNB and the pesticide regulators, except for some sporadic informal contacts; no collaboration exists with respect

to authorisation of herbicide use. While the CNB considers necessary better contacts with the pesticide regulators these have not yet materialised.

Authorisation of herbicides and pesticides is a joint responsibility of the Ministry of Agriculture (MAPA) and the Health Ministry (MSC), while the control of the utilisation of these products is exclusive responsibility of MAPA. For the lack of any practical experience with herbicide resistant crops, no administrative procedure has been established so far. According to the MAPA office responsible for herbicide authorisation, the herbicide's authorisation (and questions related to herbicide use) should be treated separately from the authorisation of the herbicide resistant crop itself.

The question of impact of herbicide resistant crops on the amount of herbicides used was discussed in the CNB, but only in a very general way. According to CNB members interviewed, the authorisations for herbicide resistant crops were given with the CNB members personal understanding that these plants will reduce herbicide use. However, no detailed consultations were made on this issue, nor was this presumed reduction in herbicide use stated in writing as a reason for authorising the product. There is no policy of reduction of herbicide use (as in the Netherlands) or anything similar. The possible development of insect resistance was treated in a similar way by the CNB during the authorisation process.

In relation to some of the possible risks the CNB makes a distinction between environmental and agronomic effects (see Section 2.2). In others, however, the risks are seen as an overall agricultural and environmental problem at the same time, as in the case of possible development of resistance to Bt in (harmful and beneficial) kinds of insects.

#### **1.4 Spanish-European dynamics**

In general, the Spanish CA and the Ministries involved have closely followed all developments on the European level, generally applying the European regulations and decisions without change. They have never tried to directly influence European policy, e.g. by banning products. One of the few exceptions was when the Spanish CA asked for clarification on the boundary between Directive 90/220 and the Novel Food Regulation on the European level (for the question raised by the novel food regulators on the relation between the two provisions, see above). Another exception are the Spanish varieties registration procedure's monitoring demands.

Up to now there has generally been no conflict between the conclusions reached by the CNB on products (as stated in the written evaluations) and the ones reached by the European Commission committees (like the former DG VI based ones). (for example, the CNB never saw any serious health or environmental problem with the Novartis maize). The Spanish CA did play an active role, however, in raising objections to dossiers submitted to other competent authorities. Objections to some products included comments about unsolved questions concerning metabolites and residues. In another case, the CA objected to a herbicide resistant oilseed rape by AgrEvo because the company had not done any field trials on the behaviour of the crop in the Mediterranean environment. The objection was based on this general fault in the risk assessment procedure, not on any more specific reasons like development of herbicide-resistance weeds (however, the CA argued that

studies on gene transfer to wild relatives in all environments were necessary, precisely to be able to decide if this could constitute any problem or not).

This European centred approach can also be found in other actors. The official positions of a number of Spanish industry association (for instance, the Federation of the Food and Drink Industry, FIAB, or the association of maize processors Humaize) and of NGO actors (especially environmental NGOs) are the positions agreed on (if there are) by the respective European associations these actors are linked to.

## **2 NORMATIVE JUDGEMENTS**

### **2.1 Predictive/normative links**

The expertise present in the National Biosafety Commission is varied. Of its 13 current members, three have a professional background in biology, three in plant genetics or biotechnology, two in agronomy. Other areas represented include chemistry, toxicology, and pharmacy. However, the CNB does not include any specialised ecologist. The CNB's relatively mixed composition and its localisation in the Ministry of the Environment as well as the important role of the Health Ministry (based on the explicit goal stated in the Spanish Law of minimising risks for human health and the environment) seem to have favoured a risk assessment focus which goes beyond a risk assessment based solely on molecular biology. For instance, possible effects on ecosystems like gene transfer are evaluated (see next section).

The only factor that played a role in the selection of several of the representatives of the different ministries for the preliminary CNB was the overall knowledge of (or general professional involvement with) molecular biology. No conscious effort was made to cover a number of specific scientific fields. In the subsequent selection of the two scientific experts from outside the administration (a biotechnologist and a plant geneticist) did this idea play a role. With the recent official creation of the CNB, efforts are being made to include other members for their specific expertise of which there currently exists a perceived lack in the CNB.

Individual CNB members mention in interviews the preservation of biodiversity as well as sustainability (especially in agriculture) as goals of the CNB's work. And they state that these concepts are implicitly taken into account during deliberations. Biodiversity is defined by the CNB's MIMA-members as natural biodiversity which must be protected from possible effects that GMOs could have. GMOs are not seen to contribute to improving biodiversity (through the possibility of creating a large variety of new plants). Sustainability in agriculture is defined as an improvement over the current environmental situation. In this sense, for instance, herbicide resistant crops are seen as contributing to sustainability. In the case of the Novartis maize, the concept of sustainability arose in the discussions in the CNB: the GM plant was seen as a contribution to sustainability because of its perceived potential of reduced use of insecticide.

However, neither sustainability nor any other related concept is being used as an explicit guide for risk assessment, nor are they stated in the legislation nor are they mentioned in the written risk assessments. Nor do the evaluations mention socio-economic effects.

In relation with the markers resistant to antibiotics, especially ampicilline, the CNB has been questioning their use after a public debate started on their possible effects on human health in 1996. Unofficially, CNB members and the Competent Authority even told companies, that the CNB would not accept any marketing applications in the future of products containing these kind of markers. They urged applicants to substitute antibiotics resistant markers with other kind of markers in products already under development. However, this position of the National Biosafety Commission is not so much based on concerns about health effects of antibiotics markers (which they consider extremely unlikely) as on concerns about public acceptability of GMOs (especially after Austria raised this issue in its rejection of the authorisation of the Novartis maize).

## **2.2 Risk assessment**

The evaluations in the National Biosafety Commission are based on the establishment of the absence of evidence of a clear risk, according to explanations given by CNB members. The CNB and MIMA work on the basis of the understanding that “zero risk does not exist” and that authorisations for GMOs should not be withheld if there is no evidence of a “clear and evident risk” (which would be deemed unacceptable). Again, this means for an authorisation the establishment of the absence of evidence of risk, and not the collection of evidence for the absence of risk. Future, still unknown effects should not condition GMO approval, even though they cannot be excluded: “if current knowledge does not show an unacceptable risk for health or the environment, we cannot conclude there does not exist any risk, only that current knowledge does not show an unacceptable risk” (interview, 6/2/1998).

The terminology used in the written risk assessments, however, is confusing. Authorisations are justified with the stated conclusion that the GMO or field test in question “does not represent any risk” (or any “significant risk”, or presents a risk of “effectively zero”, all of these terms are used) for human health and/or the environment. These terms would indicate that the risk evaluation has established the absence of risk.

The specific issues routinely evaluated (as stated in CNB’s written risk evaluations) are the following: potential for gene-transfer (especially, in the case of crops, to non modified plants of the same kind or to wild relatives); genetic and phenotypic stability; pathogenicity to other organisms, especially humans; capacity to survive, reproduce and disseminate of the modified organism; negative effects on other organisms; control and treatment of residues (in the case of field trials). These evaluations are done based on CNB members’ knowledge and secondary source data, in no case has the CNB obliged any applicant of conducting additional trials in order to proceed with the authorisation. It did, however, suggest further study in a number of cases (see below).

Overall, the concerns discussed informally by the CNB and sometimes stated in the official risk assessment documents include a number of health and environmental issues raised in the public debate by NGOs. These are, apart from gene transfer, the long term effects of the use of genetically modified crops, the use of markers resistant to antibiotics, the

development of resistance of target insects to Bt crops as well as the effects of these crops on non-target populations, as well as issues related to the use or characteristics of herbicides (in relation to the authorisation of herbicide resistant crops). While some of these issues are stated only occasionally in the written risk assessments, the antibiotics marker issue, the potential for gene transfer, and the health implications of herbicide use (residues) were mentioned with certain frequency in the evaluations.

If there are well defined concerns over long-term effects (like possible insect resistance) but no evidence of an imminent risk, these concerns should be treated by post marketing monitoring and special working groups (which means in practice extending the evaluation beyond product authorisation). If monitoring shows that the crops create a problem they would have to be eliminated.

An acceptable level of risk, then, is defined as a “controllable” risk. In the case of a field trial that means that all the possible interactions of the GMO with the environment are under control, and cannot propagate beyond the field. Unacceptable would be the introduction of a GMO into the environment without any such control. Even though this classification is seen as a “totally subjective concept”, usually there is unanimity in the CNB on what is considered acceptable (interview, 30/1/1998). Acceptability has to be decided case-by-case, and cannot be decided by a general rule. Generally not acceptable would be any “general impact on an ecosystem” (interview, 30/1/1998). As specific non-acceptable effects are mentioned: some effects resulting from the transfer of introduced characteristics from one field of GM plants to another of non-GMO plants (while possible transfer of herbicide resistance was accepted in authorisations, transfer of virus resistance from future virus resistant plants is seen by several CNB members as probably non-acceptable because of higher risks), transfer of multiple resistance in plants and multiply resistant weeds, and effects on animal populations.

The CNB defines risks stemming from GMOs primarily as environmental risks with respect to natural ecosystems. The definition of risk as mostly relating to problems on the molecular level of GMOs (as, for instance, used in the French biosafety committee) is seen as secondary, especially because genetic engineering allows very precise and controlled modifications (as compared to traditional methods which were less precise, and never questioned for their genetic imprecision). Even though information on the molecular level is important, key are the environmental interactions. Measures to control possible risks have to be taken on the ecological level.

Several authorisations for field experiments (especially of herbicide resistant crops) included a statement urging (but not obliging) the applicant to plant non modified plants of the same kind around the GM plants to force favourable conditions for gene transfer in order to be able to study its likelihood. In the case of modified micro-organisms, studies were asked for on gene transfer to micro-organisms in the soil. Even though these environmental risk assessment studies were asked for (usually as suggestions) in several field trials, only in a very few cases has the applicant handed in results of these tests after the completion of the field study, according to the CNB.

Most of the other issues raised in risk assessment concerned the handling of the GMOs. These included, for instance, avoiding accidental spillage during transport or guaranteeing the complete destruction of the GMO after the end of a field test.

CNB-members consider as important future possible environmental problems the transfer of resistance to virus and questions in relation with GM micro-organisms (especially the transfer of their characteristics to other micro-organisms) because both virus and micro-organisms are very difficult to control. This is why reliable suicide mechanisms are considered very important.

According to CNB members, risk cannot be quantified, at most certain levels (like 0-5) can be established. But the level of risk assigned to a GMO, again, is “totally subjective” (interview, 30/1/1998). The quality of the evaluation depends then on the quality (knowledge) of the experts involved. The CNB is using the risk assessment procedure from the UK as a guideline, even though it is difficult to apply because of the subjectivity of the classification.

### **2.3 Familiarity**

Even though the term *familiarity* is basically not used in official statements, it is informally applied in regulatory practice, especially in defining non-GMO baselines.

The CNB uses the comparison of GMOs to their non-modified counterparts (as a “familiar baseline”). The comparison of GMOs with similar non-modified plants during the evaluations is considered a valid concept because there exists more than sufficient information on the behaviour of most of these plants in different environments (and all of them are cultivated crops, not wild species, and normally these are not being cultivated near natural areas). And the only difference to a non modified counterpart would be the characteristic introduced by the genetic modification. However, authorising, for instance, GM soya (as a hypothetical example) for plantation in Spain would be difficult because there is not sufficient information on the behaviour of that crop (in its non-modified version) in the local environment. On the other hand, allergenic effects of GMO soya (if they are shown to be more or less the same as in non-GMO soya) cannot be attributed to the genetic modification of the plant, since they are also present in its non-modified baseline. In this sense, an acceptability of known effects of familiar plants is established.

In relation with novel foods, familiarity is being used in two ways. The regulators at MSC have decided to base their safety evaluations for the moment on the concept of substantial equivalence. Substantial equivalence is established through a comparison of a novel food’s nutritional and toxicological characteristics with those of a non-GM counterpart. The NFR regulators would like evaluations to continue to be based on this interpretation of substantial equivalence because they consider it a reasonable concept. The other meaning of familiarity is related to the concept of “non negligible consumption” of a product.

### **2.4 Specific cases**

#### *Insect resistance*

MIMA officials see possible effects (like the development of resistance in target insects) as an environmental and agronomic problem at the same time, even though the delimitation is seen to be unclear. That is why both the Ministry of the Environment and the Ministry of Agriculture will be involved in the monitoring programme for Novartis’s Bt maize.

Development of resistance in target-insects is considered more an agronomic problem than an environmental one (which means that from the point of view of MIMA it cannot be considered an adverse effect). Harmful effects to non-target insect populations (the latter of which are regarded as beneficial, not as pests like the target species) are defined as a clear and important environmental problem. From the regulatory point of view, this means that the commercialisation of Bt maize could not be rejected from the environmental point of view (because of the lack of scientific evidence of effects on beneficial insects).

In relation with Bt crops, none of the risk assessments considers resistance as a serious problem, with the argument that there is no scientific evidence so far. However, in some authorisations of field trials with Bt crops, the CNB suggested studies on the impact on non-target species. In one marketing authorisation for a Bt crop (Monsanto Bt cotton), the issue of development of resistance by target insects was considered. Here, after consulting with university scientists who were doing studies on this and other issues for the applicant company, it was decided that there was not sufficient evidence to decide against the crop for this reason.

#### *Herbicide use*

The CNB stated in one decision in relation with a field trial that the implications of herbicide use were not relevant for the authorisations under Directive 90/220. This position has been informally reiterated in several occasions (see part 6). However, CNB members also state in interviews that authorisation for a herbicide resistant crop should be denied if it can be expected that overall herbicide use could increase.

#### *Herbicide resistance*

The CNB is in accord with the view of the majority of the competent authorities that development of resistance in weeds is acceptable as long as there exist means of control (as in the case of the OSR authorisation). In decisions concerning the authorisation of herbicide resistant crops, the CNB basically followed the European Commission's normative argument given in relation with the Plant Genetic Systems (PGS) oilseed rape in 1996: The transfer of the herbicide tolerance gene to non HR plants of the same kind, considered unlikely, could not be considered a problem since there was always the possibility of using herbicides other than the one the HR plant had been made tolerant to.

If crops or wild plant species become resistant to herbicides, that would in principle be only an agronomic problem (because herbicides are not use outside of agricultural fields), which in turn is in principle not considered an adverse effect from the environmental point of view. However, the overall delimitation between agronomic and environmental effects is considered unclear.

#### *Antibiotic resistance*

The issue has been discussed by the CNB for several years, but in no instance did the CNB see any possibility that antibiotic markers could lead to a health problem. However, according to the personal view of the head of the CNB, the loss of this antibiotic (as unlikely as it is judged) would be an unacceptable effect.

### **3 RISK ASSESSMENT RESEARCH**

#### **3.1 Risk assessment research and regulation**

The risk evaluations conducted by the CNB when deciding on a dossier are based on the data provided by the applicants. No separate data collection (e.g. based on specific risk assessment projects) exists. The Ministry of the Environment has not sponsored nor financed any GMO risk assessment research, neither in general nor regarding any specific issue that came up during the processing of the applications. (The only projects in preparation are the maize monitoring programme, see below, and a planned financial aid for a research project on GMO detection methods.) However, they do not exclude this possibility (nor the possibility of demanding specific additional field tests from an applicant) for the future, at least in the case of an authorisation for commercialisation. But this would be in specific cases only, because in general the information provided by the applicants is adequate, according to several CNB members.

There are no risk assessment research projects being financed by any Spanish public R&D (research and development) programme. The reasons are that there are few researchers in universities or research institutions working in this area, and that interest in the scientific community (which in practice heavily influences funding priorities) is almost non-existent. The only exception is a subprogramme of the National Biotechnology Plan which finances projects on environmental effects and applications of GM micro-organisms. The main area of work has been biological containment systems for GM micro-organisms, and their interactions with other soil micro-organisms. Spanish researchers are participating in some EC-financed projects, as for instance the Valencian Institute for Agronomic Research (IVIA), which participates in a study on virus resistance.

No risk assessment research has ever been considered in relation with GM products being commercialised right now. Nor has there ever been any intent to use such research for regulatory purposes. The secondary source research data used by the CNB in their evaluations comes from publications concerning experiences and risk assessment research in relation with GM cultivation's in the USA. (for instance on Bt resistance); European data is used to a lesser degree.

According to the CNB, testing safety safely can only be done by trying to design field trials so gene transfer or other possible effects are allowed to take place. Since field trials constitute very controlled situations, running certain risks is acceptable because that way data on the possible effects of large-scale use of the GMO in question can be collected. Trials which by their own design exclude environmental effects from happening are not considered useful. The CNB has asked applicants in repeated occasions to plant, for instance, non-GMO plants next to the modified crop under trial to create conditions for studying gene transfer: "it its more important to almost experiment, and to gain experience" than to control trials too much (interview, 29/1/1998).

#### **3.2 Market stage monitoring**

The only monitoring programmes in preparation in Spain are the ones in relation with the Novartis maize: one is based on the monitoring programme discussed in the DG XI expert

committee, and the second one is a national requirement in relation with the authorisation of Bt maize seeds. The first one will investigate exclusively the development of resistance to Bt in insects harmful to maize. The programme, developed in conjunction with the Spanish National Research Council (CSIC), is organised by MIMA, which also puts up part of the financing. The remainder of the resources comes from the CSIC (personnel and equipment). The scientific work is responsibility of researchers from an institute of the CSIC, the Centre for Biological Research (CIB).

The researchers involved in the Bt monitoring programme see their work as a sectoral one which could be enlarged into a multidisciplinary project to monitor effects on other (less important harmful as well as beneficial) insects, as well as other possible long-term effects. In fact, while the DGXI committee in principle only discussed studies on the European corn borer, the agreement between MIMA and CIB covers also the study of *Sesamia* (because of its importance as a pest in Spain).

The execution of the programme is still in its first stage, the establishment of a baseline for the susceptibility of pests to Bt toxin in Spain (December 1998). After identifying four representative zones for maize cultivation in Spain (Andalucia, Central Plains, Zaragoza, Galicia), a collection of larvae in the field (in areas where no Bt maize was planted in 1998) was conducted. Six populations (4 for *Sesamia*, 2 for the European corn borer) are being tested (only 2 samples are available for the European corn borer because in half of the 4 zones no or very few European corn borer larvae were found, which reiterates the importance of testing for the more important pest, *Sesamia*). In the next step (to be finished in January of 1999) the following generation of insects is being tested in the laboratory for Bt resistance. The baseline established by this method is to be compared to insects collected in Bt maize fields in 1999. The frequency of the testing is higher for *Sesamia*, because it produces more generations in a year in Spain (3 to 4) than the European corn borer (1-2).

Right now Bt monitoring is only foreseen for maize but MIMA officials believe the same programme might be applied to other Bt plants, once approved. According to the president of the CNB, the Ministry of the Environment will demand that all new transgenic varieties up for registration be accompanied by an insect resistance control programme.

When authorising the inclusion of the Novartis maize in the national varieties register in March 1998, the Agriculture Ministry stated as condition the conduction of a far reaching five year monitoring programme, which will investigate several issues, well beyond the study of insect resistance (Spanish Ministry of Agriculture, 1998b). Apart from evaluating the insecticidal effectiveness of the crop and monitoring for Bt resistance in insects, it demanded monitoring for effects on soil micro-organisms as well as bacteria in the digestive tract of animals fed with the maize. The company has also to pass on to MAPA detailed data on cultivated areas and subsequent sales of the seeds. These conditions respond to public pressure, after the dispute over variety registration of the product in 1997 (see next section). MIMA influenced MAPAs decisions through the co-ordination in the CA. For instance, MIMA insisted that the monitoring include requirements for tracing the cultivation and commercialisation of the maize. MAPA also took into account the French precedent of demanding monitoring (as well as the USA Environmental Protection Agency requirements). In fact, the specific conditions imposed in Spain are the same which were imposed in France just a few weeks earlier.

This national Spanish monitoring programme based on the MAPA requirement is for the most part still under preparation. So far, only the collection of data about the cultivated areas has been completed. For the monitoring of the environmental effects mentioned, the Spanish regulation gives the company two years after seeds registration to present a detailed monitoring plan to MAPA. However, MAPA expects Novartis to present this plan shortly. Then, if the plan is considered satisfactory, MAPA and Novartis will decide on the organisational and scientific details of its execution. The scientific work is expected to be done in collaboration of MAPA's own National Institute for Agronomic Research (INIA) on the one hand, and the CSIC and the Spanish National Centre for Biotechnology, on the other hand. Co-ordination with MIMA's monitoring effort is expected, but the MAPA programme will be executed independently. According to the company, Novartis will finance the execution of the monitoring activities, at least in the beginning (the Spanish regulation makes any company that sells a registered GM variety responsible for conducting monitoring).

### **3.3 Plant variety registration procedure**

The testing procedure that has been established by the seeds regulators (from the Ministry of Agriculture) for the registration of transgenic seeds is basically identical to the one used for conventional varieties. The tests to be completed before registration are exactly the same as for non-GM seeds, aiming at establishing the stability, distinctiveness, uniformity and agronomic value of the variety. However, according to MAPA's modified varieties registration regulation from March of 1998 (Spanish Ministry of Agriculture, 1998a), GM varieties registration will be conditioned to monitoring which may include monitoring for health or environmental effects. In case monitoring shows that "there exist risks for human health or the environment" (as stated in the regulation), the variety's registration will be cancelled. I.e., in practice, registration of transgenic seeds implies continuation of risk assessment to evaluate uncertainties which could not be sufficiently evaluated during the 90/220 product authorisation. It is interesting to note that Spain has actually modified its legislation for varieties registration to cover all future GM varieties. In all cases a monitoring plan will be obligatory.

MAPA has decided to conduct tests for GM varieties on the same sites where the applicants conduct the trials with those plants for authorisation under Directive 90/220 (instead of doing separate tests on sites where non transgenic seeds are usually being tested). Also, a specific regime of scientific observation was established (in conjunction with the Biosafety Committee). Both measures were adopted to try to pre-empt public debate about the trials. However, in no case were specific GM risk issues (like Bt resistance) investigated during those trials.

Novartis applied at the beginning of 1996 for the registration of the same variety of GM maize seed in Spain for which they had also asked registration in France. While all the tests necessary for the authorisation of the variety convinced MAPA that the seeds could be registered (and that they would not create any ecological nor agronomic problems), a final political decision had been pending since March 1997. Part of the reason for that was a campaign conducted by Spanish and European NGOs urging the Ministry not to register the variety. The representative of one of the national farmers unions, the Small Farmers' Union (UPA), argued against the authorisation in the Varieties Committee. UPA cited as arguments, apart from the possible impacts on non-target insects, increased herbicide use,

and ampicilline resistance, the socio-economic effects of increased industrialisation of agriculture (UPA, 1997). While the associations of maize farmers urged MAPA to authorise the product, the official response (in April of 1997) to the debate was that the maize would not be registered in Spain until France (which originally proposed its authorisation under 90/220) registered the maize. MAPA argued that while there were no technical reasons against the maize, registration would not be convenient because of the lack of consensus on the European level. Only in March of 1998 (after France authorised cultivation) the variety was registered in Spain, but under the condition that a monitoring programme be conducted (see Section 3.2).

According to MAPA officials, the public controversy on registration has discouraged some companies to submit transgenic seeds for registration in Spain. Right now, about 20 studies for registration with three kinds of different plants are being conducted.

### **3.4 Familiarity**

The CNB sees non-GM crops used as baseline in evaluations as familiar because sufficient information on their behaviour exists (see Section 2.4).

### **3.5 Ecological models**

The written risk evaluations show that some of the GMO's direct interactions with its environment are routinely evaluated. However, from the available material, it is difficult to judge the real importance of any ecological models in the assessments. The CNB itself qualifies their evaluations for authorisation as an equilibrium between studying environmental and microbiological effects. Ecological imbalance is defined as a notable effect on any element of an ecosystem which influences other elements.

## **4 LABELLING PRACTICES**

### **4.1 General**

Labelling has been demanded for a number of reasons in Spain (Todt and Luján, 1997). The one given most often is based on the right to know, and to choose, and demands labelling even in the absence of any scientific evidence of the transgenic product being different. This position is being defended by the consumer organisations, trade unions, a number of environmental organisations, some scientists and administration officials. Other, less frequently given arguments are that labelling would improve the social climate for a more rational debate by avoiding the impression that industry wants to hide something, and that labelling would basically fulfil an existing social demand. However, there is an important subgroup of environmentalist NGOs which see labelling as a secondary concern because what they demand is a moratorium on GMO releases and products. Labelling, even though important, "does not solve anything", according to one environmentalist (interview, 7/5/1997). On the other hand, there was a group (made up mostly of scientists and public administration officials) who had a favourable position on labelling but only if this was accompanied by more public information on genetic engineering. Some even wanted to delay the introduction of labelling until the public had acquired sufficient knowledge on the issue so they could interpret the labels "correctly" (interview, 7/3/1997).

However, the public debate on the issue has remained relatively low-key. Even though some environmentalist NGOs demanded clear labelling from the novel food regulators at MSC, at no point did they gain any influence on the process. Nor did the public, its concerns and its somewhat unclear perception of the regulatory process (Atienza and Luján, 1997) play any direct role in the decisions taken so far on labelling of foods, crops or seeds.

It seems unlikely that labelling will accommodate the ecologists' demands which centre on a moratorium for GMO release. Consumer organisation also have demanded clear labelling, the absence of which has been their main point of critique of transgenic foods. Their concerns could be accommodated by clear labelling. However, the issue of GMO-products has not been among their primary concerns. One NGO (VidaSana) which is working for the promotion of organic agriculture presented a "non-GMO" label already in 1997. However,

this label has not acquired any widespread use (even though some organic farmers are using it, based on tracing the origin of feeds etc.).

Nor has labelling been an important issue for the food industry or retailers. A group noticeably absent from the public debate are the supermarkets and their industry associations. Most of the big supermarket chains have not made public comments on the issue. None has received any public pressure (be it from clients or NGOs) to take a position. Only one chain (the biggest Spanish company in the sector, and a consumers co-operative) made public a position on GMOs and demanded mandatory labelling, motivated by concerns of their co-operative members. Some retailers even see labelling as a problem because it might create consumer distrust in a market like the Spanish one where most consumers are not directly aware of the specific issues in relation with transgenic foods. The retailers do, however, detect a generalised social uneasiness on the issue which is corroborated by studies that show a clear negative public perception of genetic modification for food products (Atienza and Luján, 1997). Retailers are responding to this situation while avoiding any public statements: the issue has so far only had effect on the internal decision making of retailers.

Several of them are trying to avoid the use of transgenic ingredients in products sold under their own brand name. The reasons given for this are to counteract any possible future public debate over their products, even though none of the retailers sees any specific health or environmental concerns. Another reason is that three of the biggest retailing chains in Spain are owned or co-owned by French retailers who are extending their own policy of avoiding transgenic products into the Spanish market. At least one of the Spanish retailers has conducted a broad survey to trace the origin of the ingredients of all of their brand products. In some cases, they even demanded from their suppliers certificates guaranteeing the non-GM origin of a product. However, the company has not taken a firm decision on whether to go GM-free on their entire line of brand products. One of the reasons they cite for such a move would be taking advantage of a possible new market of organic (and non-GM) foods.

In general, the food industry does not consider future labelling to have a decisive long-term impact on the market. One industry representative suggests that at the most some food companies would change the ingredients of their products to avoid the use of transgenic base materials, but only temporarily, until the consumer had gotten used to the labels (in fact some companies started doing this after Regulation 1139/98 came in force, to avoid being among the first companies to market labelled GM foods). On the other hand, this position has not lead the industry to promote voluntary or national labelling efforts because of uneasiness about a possible short-term negative consumer reaction.

The “may contain” label is being rejected by almost all the actors involved, except the biotechnology industry and its direct customers (like the maize or soya processors). The Spanish Federation of the Food and Drink Industry (FIAB) follows the position of the corresponding European association (CIAA), rejecting the “may contain” label because it might create confusion. On the other hand, the implications of selling foods made from mixtures of GM and non-GM raw materials are not considered serious. So far, none of the big food companies has definite plans of trying to capitalise on a possible future market for non-GM foods. The only (weak) pressure for segregation so far has come from a few food

processor and retailers (see above) who have demanded certificates of non-GMO origin of raw materials from their suppliers.

Neither the Ministry of the Environment nor the Health Ministry have tried to promote segregation, nor are they planning to demand it. But they would like to see it happen because it would facilitate unequivocal labelling. The MIMA has always been in favour of clear labelling (which is one reason why they are planning to finance research on detection methods). Members of the CNB have discussed this issue with representatives from industry, to inform themselves about the possible problems of segregation.

## **4.2 Labelling under Directive 90/220**

Directive 97/35 (which amended Directive 90/220 on the issue GMO labelling) was incorporated without any significant change into Spanish law (see appendix A). Seeds will be labelled as genetically modified, based on a label proposed by the company, even though the seeds regulators are hoping for a future common standardised European labelling format.

All of the marketing applications processed by the Spanish CA include proposals by the applicants on labelling of GMOs. So far, decision making processes on labelling of crops/seeds and foods have been independent of each other. More co-ordination between labelling under Directive 90/220 and under the NFR is being proposed to make it easier to track GMOs along the entire production and processing chain. Being able to positively trace those products is seen as a fundamental prerequisite for efficient labelling which the current labelling provisions make difficult. According to a member of the CNB, labelling is not being used (nor necessary) for other precautionary reasons.

## **4.3 Labelling under the Novel Food Regulation**

As in most other EU countries, there is no Spanish legislation on labelling. General labelling requirements for food are derived directly from the Novel Foods Directive. Future labelling provision will be based exclusively on EC decisions, once the detailed implementation of the NFR has been decided on. No national interim regulation is foreseen: So far no labelling guidelines have been issued from the novel food regulators at MSC.

In practice, until now very few of the authorised GMO products (especially soya and maize) or any derivatives are being labelled. Nor has voluntary labelling been put into practice by food companies. As far as labelling under 1139/89 is concerned, quite a number of food companies are still selling products made from non-GM ingredients in stock; they will switch to GM supplies only after their non-GM stock runs out. Others have changed the ingredients of their products to avoid soya or maize (to escape labelling for the time being). The current practice in labelling (as well as testing for DNA or protein) depends entirely on the individual company, no general industry-wide rule has been put into practice. Some companies are labelling on the basis of certified origin of the raw-material, others on the basis of tests. Still others simply apply labels when in doubt. Only few companies are trying to find non-GM sources, and currently there are almost no “GM free”-labelled products on the market. The industry expects to take decisions on labelling for the most part basing itself on the EU-wide list of labelling-exempted ingredients, once this list

has been compiled. The beginning of labelling of some food products has so far not caused any negative reaction from retailers (with only a few exceptions).

Before Regulation 1139/98 fixed the presence of DNA or protein resulting from the genetic modification as the labelling criterion, the novel food regulators' own interpretation of equivalence was based on the idea that GM-products with the same nutritional, metabolic or toxicological characteristics as their non-GM counterparts were to be considered equivalent. The presence of DNA or protein was not considered to affect equivalence. The MSC officials stated they would prefer the labelling decision being based on this criterion (rather than basing labelling on the mere fact that a product is genetically modified, or on the presence of a protein or DNA)

The MSC has not embarked on any programme to develop or adapt detection methods. However, the ministry has started to design a common strategy with the Spanish Autonomous Regions, which will be in charge of controlling and enforcing labelling.

#### **4.4 Feed labelling**

No labelling provision exists for feeds. The issue of segregation and labelling of feeding stuffs (or other GM products) has come up in some agricultural co-operatives, but has yet to become an important issue for the farmers associations. Only one of them (the UPA) has made public a position on transgenic products, rejecting them.

## **5 A EUROPEAN MARKET?**

### **5.1 Market implications and Spanish-European conflicts**

The social debate in Spain over transgenic products and their effects had for the most part remained confined to a fairly limited circle of actors. No large social debate, as in some other EU member states, has taken place (Muñoz, 1997). However, the introduction of GM foods was responsible for creating a certain level of public debate. A newly-formed NGO-coalition opposed to the current way of management of genetic engineering was established in 1996. Among its members are a number of the most important Spanish environmental, agricultural, "third world" and animal rights NGOs. Consumer organisations, on the other hand, have been virtually absent from the debate. Some agricultural organisations (especially the ones representing small farmers on the national and regional level), have campaigned against genetically modified crops. And one of the two biggest Spanish trade unions has adopted an official position critical of genetic engineering and has been urging detailed changes in the approach to regulation (among them: more public control and participation, application of the precautionary principle, and socio-economic evaluation of products; see: CCOO./Fundación 1. de Mayo, 1997). Despite of the absence of a wide-ranging social debate, the concerns defended by the critics have gained a certain influence in regulation and marketing. And studies show a clear negative public perception of genetic modification for food products (Atienza and Luján, 1997).

The only GM products being marketed in quantity in Spain are maize and soy beans imported from the USA. Both products are used as raw materials for the food and feed

industries. So far the overall markets for both products have not been affected by the debate. No restriction of any kind has so far been imposed in Spain on any GM product (the only exception being the monitoring requirements in relation with the variety registration of the Novartis maize, see Section 3.2.). All the imports are un-segregated, and are processed by the companies receiving the raw material like any non-GM material. It is, however, important to note the influence that developments in other national markets have on the Spanish one; a good example is how French retailers are implicitly translating some of their reactions to the French GM food debate to Spain (Section 4.1).

Some food processors (like producers of organic products, or multinational companies which had to sustain much more pronounced reactions in other countries) have tried to avoid GM raw materials, at least until labelling provisions are in place. Also, there are some cases of food companies deciding to withdraw from research and development efforts for transgenic foodstuffs. As in the case of retailers, a perception of consumer uneasiness more than direct consumer actions was the basis for these decisions.

In the case of maize, the issue of international trade came up. Spain is one of the biggest importers of maize from the USA., and has signed long-term contracts. In the dispute over the import of GM maize at the end of 1996, and again at the beginning of 1998, government officials stressed the importance of not restricting imports to ensure the maize supply. The Ministry of Commerce did contact the MIMA in mid 1998 to ask them for help in unblocking the USA maize imports through a rapid EU authorisation for the maize varieties in question. As far as variety registration of the Novartis maize in Spain was concerned, the public dispute led to holding up the process for about a year (see Section 3.3).

A number of important biotechnology and food companies consider that the social debate will disappear after a few years, when people get used to the products. In that sense, their overall long-term strategy in relation to the sale and use of GMOs does not seem to have been decisively influenced by the debate. Nor do they see new market opportunities (like a market for non-GMO products, or improved opportunities for organic food) as a result of the debate. However, a few seeds companies do consider necessary a different approach to their markets in the future (like considering the final consumer instead of only their direct clients in market analyses). Representatives from one company even consider that it was a strategic error to start sale of GM products with Bt maize or herbicide resistant soy beans, because of their not having any clearly visible advantage for the final consumer, which contributed to consumers' receptiveness to the arguments of the environmentalists.

## **5.2 Ciba/Novartis Bt maize**

In the case of the maize from Novartis, limited public and political controversy erupted in several instances. Spain changed several times its position on the authorisation of the maize on the European level. While in mid 1996, the minister for the environment voted against the product, at the end of the same year she favoured authorisation. Spain voted in favour of maize because CNB considered that there were no health or environmental problems. Negative opinions by other CAs were studied, but did not have any influence. In November of 1997, Spain did not want to vote against Austria in the Art. 21 committee meeting, and manifested (like other countries) their disagreement with the present system of decision making. CNB members point out that the solution for avoiding such a conflict in the future would have to pass through a standardised format for risk assessment. Only if there are

guidelines accepted by all of the member states would the other EU members accepted the risk assessments made by one country.

Until now, the market for maize and maize products in Spain has not been significantly influenced by the import of mixtures of transgenic and non-transgenic maize from the U.S. According to the associations of maize processors (Humaiz), there have been only a few requests by food companies for certificates of non-GM origin of the maize. But neither this association nor companies processing the maize have responded to these demands. As far as the seeds market is concerned, Novartis has encountered concerns among farmers about the commercial prospects of genetically modified maize. While this forced the company to conduct a wide-ranging information campaign, it is unclear if those concerns really have had any effect on the sale of Bt maize seeds (which is sold since April 1998).

### **5.3 Monsanto soybean**

In relation with Monsanto's herbicide tolerant soya, there has been no significant social debate in Spain. The administration never adopted any restrictive measures nor raised objections. The only exception were protests of environmentalists (and an ensuing, short-lived but widespread public controversy) when the first ships from the USA arrived in Spanish ports carrying soya in 1996. Apart from general references made to this GMO by critics, no specific actions or debates have taken place featuring soya.

Nor has there been any significant effect so far on the Spanish market for soya and products derived from it. One of the multinational food companies operating in Spain asked the soya processors to guarantee that their soya oil was GM-free. The food company decided to change their production line to other oils when the soya processors told them that that was impossible because all the soya imports were mixtures. However, this has not affected the food market because only 10% of the soya is destined for food uses (most of the remainder is destined for animal feed).

## **6 LINKS TO PESTICIDE REGULATION**

### **6.1 Herbicide resistance**

The issue of transfer of herbicide resistance genes has not been treated in any piece of legislation. No administrative body has prepared any regulation to try to prevent this possible problem. Nor has pesticide regulation taken account of herbicide resistant crop-related issues in any way, for instance by introducing new criteria for herbicide use.

Questions related to herbicide use are generally considered by the GMO regulators to formally fall under Directive 91/414. However, transfer of resistance is seen as a joint problem. Approval under Directive 90/220 should not be given if it can be suspected that a herbicide resistant crop might lead to the creation of herbicide resistant weeds. That is why co-ordination among ministries is considered vital (even though this has not materialised yet). The CNB for its part has assumed the responsibility of trying to evaluate possible effects on herbicide use when discussing product authorisation under 90/220. In the case of one recently studied herbicide resistant crop for instance, the CNB informally evaluated

data from Spanish field tests that showed that herbicide use decreased. And that, even though in 1995 the CNB had stated that questions in relation to herbicide use were not to be evaluated during the 90/220 procedure.

## 6.2 Secondary metabolites and residue limits

No special administrative procedure has been set up so far for treating secondary metabolites and residue limits in relation with herbicide resistant crops. Formally, the procedures for non-GM crops apply. Up to now, the consultations in relation with herbicide resistant crops have been informal: The designated president of the CNB is also member of the Spanish Commission for the Evaluation of Plant Protection Products, where she raised questions that had come up in the CNB in relation with herbicides (like, for instance, the question of secondary metabolites as a result of the use of herbicides on herbicide resistant crops) The CNB also consulted with the responsible person from Agriculture. These purely informative consultations helped the CNB in their decision making on herbicide resistant crops.

However, none of the ministries represented in the CNB nor the pesticide regulators have so far taken on these issues (beyond the collection of information).

In their favourable advice on marketing for herbicide resistant cotton, the CNB did not try to take any technical decision in relation with herbicide use (like establishment of residue limits, which would be necessary for an eventual food use of this crop), which normally would be taken by MAPA. The CNB regards these as questions of pesticide regulation irrelevant to crop authorisation and a responsibility of MAPA and the above mentioned Pesticide Commission (which would have to authorise the herbicide's use on the herbicide resistant crop and set limits *after* the authorisation of the crop under 90/220).

However, the *general* health and environmental implications of new metabolites or residues resulting from the application of a herbicide on a herbicide resistant crop are considered relevant. In fact, they are studied by the CNB (by its MSC member who also shares responsibilities in pesticide authorisation) before giving authorisation of that herbicide resistant crop, based on data provided by the applicant. Once a herbicide expert from MAPA becomes a member of the CNB, it is hoped that that person will check questions in relation with herbicide use during product authorisation.

The issues of herbicides discussed during deliberations on herbicide resistant crops were several: In a number of authorisations of field tests with herbicide resistant crops, the CNB urged studies on herbicide residues on the plants. In the case of several applications for field trials with a herbicide resistant crop, the issue of the relatively high toxicity of the herbicide to be used was discussed and more data requested (even though in the end the trials were authorised). In one case, the herbicide resistant crop's impact on herbicide use was studied. This way, apart from residues and metabolites, several of the secondary issues of herbicide resistant crops were treated in the 90/220 procedure, if only informally and only with respect to their general implications.

The Ministries of Agriculture and Health operate a special Joint Residues Commission which sets the residue limits for herbicides and pesticides, based on the product's toxicology and on "good agricultural practice".

## 6.3 Herbicide extension

Up to now (September 1998), according to the administrations responsible for the regulation of herbicides, no application has been officially received for the authorisation of a herbicide for use on a herbicide resistant crop nor for an increase in residue limits on an already authorised herbicide. So far no herbicide is authorised to be used on a GMO. No efforts have been made to standardise herbicide-tolerance genes.

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## APPENDICES

### Appendix I Abbreviations

Bt	<i>Bacillus thuringiensis</i>
CA	Competent Authority for Directive 90/220 ( <i>Autoridad Competente</i> )
CBR	Centre for Biological Research
CIAA	<i>Confederation de l'Industries Agro-Alimentaires</i>
CNB	National Biosafety Commission ( <i>Comisión Nacional de Bioseguridad</i> )
CODA	<i>Coordinadora de Organizaciones de Defensa Ambiental</i>
CCOO	<i>Comisiones Obreras</i> (Trade Union)
CSIC	Spanish National Research Council
DNA	deoxyribonucleic acid
EC	European Commission
EU	European Union
FIAB	(Spanish) Federation of the Food and Drink Industry ( <i>Federación de la Industria de Alimentos y Bebidas</i> )
GM	Genetically modified
GMO	Genetically modified organism
Humaize	Association of maize processors
INIA	National Insitute for Agronomic Research
IVIA	Valencian Insitute for Agronomic Research
MIMA	Ministry of the Environment ( <i>Ministerio de Medio Ambiente</i> )
MAPA	Ministry of Agriculture, Fishery and Food ( <i>Ministerio de Agricultura, Pesca y Alimentación</i> )
MSC	Ministry of Health and Consumption ( <i>Ministerio de Sanidad y Consumo</i> )
NFR	Novel Food Regulation
NGO	Non-governmental organisation
PGS	Plant Genetic Systems
R&D	Research and development
UPA	Small Farmers' Union ( <i>Unión de Pequeños Agricultores</i> )
US(A)	United States (of America)

## Appendix II Interviews

Albert, Armando	Information and Documentation Center (CINDOC) of the Spanish National Research Council (CSIC)
Albert, Luis Felipe	Spanish Association of Maize Transformers (HUMAIZ)
Alcalde, Esteban	Novartis Seeds España, S.A.
Alvaro, Gregorio	Complutense University (Madrid)
Arriola, Antonio	Quality Department, CONTINENTE supermarkets
Arranz, José Ignacio	Dept. of Food Hygiene, Spanish Ministry of Health (MSC)
Avilar, Ricardo	Greenpeace
Barahona, Elisa	General Technical Secretariat, Spanish Ministry of the Environment (MIMA)
Bermejo, Isabel	European Natural Heritage Fund — <i>Fondo Patrimonio Natural Europeo</i>
Caballo, Covadonga	Environmental Health Department, Spanish Ministry of Health (MSC)
Cabasés, Jesús	Ecological Association for the Defense of Nature — <i>Asociación Ecologista de Defensa de la Naturaleza</i> (AEDENAT)
Candela, Milagros	Department of Genetics, Complutense University (Madrid)
Castañeda, Pedro	Center for Biological Research (CIB)
Costa, Jaime	Technical Director, Monsanto España, S.A.
Delgado, José Manuel	Environmental Department, Union of Small Farmers — <i>Unión de Pequeños Agricultores</i> (UPA)
Diaz, Francisco	Department of Ecology, Complutense University (Madrid)
Escribano, Enrique	Brand Products Dept., PRYCA Supermarkets
Esteban, Mariano	Director, Spanish National Biotechnology Research Center
Fernández, Yolanda	Dpto. Calidad, Hipermercados ALCAMPO
Fernández de Gorostiza, M.	Department of Seeds, Spanish Agriculture Ministry (MAPA)
Fresno, Ana	Dept. of Environmental Quality and Evaluation, Spanish Ministry of the Environment (MIMA)
González, Felipe	CEASA Agroforestal

Granda, Maria Luisa Institute for Agricultural Technical Research (INIA), MAPA

Groome, Helen Bask Farmers' Organization— *Agricultores y Ganaderos de Euskal Herria* (EHNE)

López de Haro, Ricardo Department of Seeds, Spanish Agriculture Ministry (MAPA)

Martínez, José Miguel Manager, Spanish National Biotechnology Research Programme

Moas, Jorge Association of Farmers Organisations — *Coordinadora de Organizaciones de Agricultores y Ganaderos* (COAG)

Ortego, Felix Center for Biological Research (CIB)

Pérez, Rafael Spanish National Biotechnology Research Center

Pino, Federico National Association of Soya Extractors (ANES)

Riechmann, Jorge First of May Foundation (*Comisiones Obreras* Trade Union)

Roda, Lucia General Technical Secretariat, Spanish Ministry of the Environment (MIMA)

Ruiz, José Asociación VidaSana

Sánchez, Ana Dept. of Technological Programmes, Spanish Ministry of Industry

Tirado, Cristina National Confederation of Consumers — *Confederación Estatal de Consumidores y Usuarios* (CECU)

Urrialde, Rafael Spanish Consumer's Union — *Unión de Consumidores de España* (UCE)

Vela, Carmen Executive Director, INGENASA

Velázquez, Pilar Federation of the Food and Drink Industry (FIAB)

In addition, representatives from several agrofood companies were interviewed.

## Appendix III Spanish GMO regulation

### 1. Spanish regulatory structure for GMOs

The European Directives 90/219 (on contained use) and 90/220 (on deliberate release) were transposed into Spanish law in 1994 (Law 15/94). However, the Regulation (Royal Decree 951/97) which describes the detailed framework for the law's application in regulatory practice was published only in 1997, six years after the given deadline for the transposition. The regulation of GMOs in Spain was therefore a provisional one up until the end of 1997, when at least one of the official bodies foreseen by the Law (the Competent Authority) was finally established. This delay reflects the low importance given to this issue by successive governments, but was also influenced by a change in government after the 1995 elections, and ensuing administrative changes (like the creation of the new Ministry of the Environment). The most important practical effect of this delay has been the restriction of GMO regulation to a limited number of administrative actors. It has also reinforced the positions of MIMA and MSC in controlling the process. On the other hand, it also was responsible for restricting the means of control available to the CA.

The Spanish Law 15/94 (Kingdom of Spain, 1994) is a simple, almost literal adoption of the Directives, which does not introduce any elements beyond the ones required by the Directives (Borrillo, 1997). The Regulation 951/97 (Kingdom of Spain, 1997), apart from developing the Law in detail, incorporates several changes to the original Directives adopted by the European Union in the meantime. These are the Directives 94/51 and 94/15 (adaptations of Directives 90/219 and 90/220), and the Directive from May 1997 which introduces labelling provisions for GMOs. The Regulation also incorporates several Decisions by the European Commission on criteria for risk assessment, forms for information interchange between the Competent Authorities, and simplified procedures for deliberate release of plants.

With the publication of this Regulation, the Spanish Competent Authority (CA) as well as the National Biosafety Commission (CNB) could be officially constituted. Both were operating up to that time in a provisional mode, with the CA's functions being performed basically by two civil servants in the Ministry of the Environment. Even after the official creation of the regulatory bodies, the clear domination of the entire process (including CNB and CA) by persons from the public administration will continue (Luján *et al.*, 1996). For instance, the number of scientists from organisations (like universities) not directly linked to any of the ministries involved remains very low (6 out of a total of at least 21 members).

The Competent Authority is a collective body. For its official designation both *Autoridad Competente* and *Organo colegiado* (Colleged Body) are used. It is co-ordinated by the Environmental Ministry (MIMA) whose members are representatives of five different Spanish ministries, all of them having the administrative rank of *Director general*. The president of the CA is the Director general for Environmental Quality and Evaluation of the Ministry of the Environment. The other four member are from the Ministry of Health and Consumption (MSC), the Ministry of Agriculture (MAPA), the Ministry of Industry, and the Ministry of Education. This Competent Authority, which held its first session in November of 1997, has the decision authority mainly for commercialisation and research projects financed by the central government. The Law also foresees the creation of regional Competent Authorities at the level of the Spanish *Comunidades Autónomas* (Autonomous

Regions) which would assume the responsibility of decision in all other cases (especially non-commercial release, confined use, and control). Up to now, only a few of the regional governments have partly assumed these responsibilities, the remainder of which have been taken on by the Competent Authority on the national level for the time being.

This distribution of co-responsibility is characteristic of the entire Spanish approach to GMO regulation. The National Biosafety Commission (CNB), again co-ordinated by the Ministry of the Environment, is composed of representatives of the same ministries that have a voice in the CA (the CNB president being from the same MIMA Directorate General as the head of the CA). In addition, there are representatives from the Ministry of Economics and Finance (for questions of international trade) and the Ministry of the Interior (in relation to accident prevention under 90/219). Furthermore, up to six experts and representatives of all of the 16 Autonomous Regions can participate as permanent members. The CNB can call on external expert bodies on a case-by-case basis during the deliberation of the dossiers.

The CNB is an advisory body, on whose reports the CA bases their decisions (especially in relation with the authorisation of field trials or products). Despite this formal advisory function, the provisional Competent Authority has up to now always followed the recommendations of the CNB. Here it has to be taken into account the close interrelation between the 2 bodies. This situation can be expected to continue: the two permanent bodies will remain connected by administrative decisions. For instance, the members of the CA will nominate their own representatives to the permanent CNB. And the head of the CNB is at the same time the secretary of the CA.

However, the formal constituting session of the CNB had still not taken place by September of 1998 because some Ministries, which were not represented in the provisional CNB have still to designate their representatives.

The dossiers are discussed in the CNB, the result being the publication of a written risk evaluation which reflects the collective view of the CNB members. According to members, these decisions are reached by consensus. The risk evaluation document usually includes a short discussion of the aspects falling under the six areas as given in Section 2.2. Suggestions to the applicant for further studies (if any) are stated under each of these area headings. The final decision is given as stated in Section 2.2. The risk evaluations are forwarded to the CA which up to now has accepted them without change.

Apart from the law and regulation based on the Directives 90/219 and 90/220 as well as a specific regulation for the variety registration of transgenic seeds (from March 1998) there are no other pieces of Spanish legislation *specifically* dealing with GMOs, not in relation to food, feed, nor pesticides (apart from the general pesticide legislation derived from Directive 91/414).

## 2 *Status of authorisations*

Until the beginning of 1998, more than 80 authorisations for field trials have been granted by the provisional CNB, only 5 of them for micro-organisms, the rest for crops. The number of trials has increased dramatically, from 9 application received in 1995 and 18 in 1996, up to 37 applications in 1997. All the petitions have been granted so far. Most

prominent in the tests have been maize, tomato, beet, tobacco, cotton, and melon. Three products (tomato, Bt cotton, HR cotton) had been forwarded with a favourable opinion by the Spanish CA to the European authorisation process as of April 1998.

### 3 *Social participation*

The definition of the CNB by the Regulation as having a “strictly technical character” and the condition of experts for the participants from outside of the public administration precludes the participation of representatives of non-governmental organisations (NGOs). Despite the declared wish of the civil servant who acted as the provisional CA and head of the provisional CNB before 1997 to allow the participation of (knowledgeable) NGO-representatives in the Biosafety Commission, all the other members of the CNB were in favour of a formulation of the Regulation which would exclude wider social participation. Membership in the CNB was conditioned to having an academic relationship with biotechnology, and being linked professionally to a public (preferably research) institution. The predominant reason given for this was that to be a CNB member a high level of specialised technical knowledge was prerequisite. Some NGOs, as well as a major trade union (*Comisiones Obreras*), had asked the Ministry of the Environment to be represented in the Biosafety Commission. After the Regulation stipulated (the above mentioned) conditions for CNB-members, the trade union proposed a university scientist (not connected to any NGO) to be their representative. The MIMA has not decided yet if to accept this person. Other NGOs, however, declared from the outset that even if possible, participation in such a body would never be for real, and would most likely serve as a public relations facade. Therefore, they did not request participation, while developing a more conflictual strategy in opposing GMOs. However, the NGOs mention the possibility of a national referendum on transgenic foods as a way of public participation.

The Regulation, while specifying which information must be public, does not set more requirements for public information than does the Law, which is extremely limited in this matter (López *et al.*, 1998). Only in the case of contained use operations classified as “high risk” is the information of the public obligatory; in all other cases it is in the power of the administration to decide. However, up to now, the Ministry of the Environment has provided on request all the non-confidential information it obtains in relation with the GMO regulation.