Avosetta Meeting on GMOs (Siena, 29-30 September 2006)
Spain

Agustín GARCÍA URETA,
University of the Basque Country

1) Which is the national regulatory approach to GMO in the Member States? Is there a horizontal act on GMO or just sectoral regulations apply in the Member States?

- State rules

The basic rules are enshrined in two pieces of legislation. Spain initially transposed Directives 90/219 and 90/220 by Law 15/1994, of 3 June. It also adopted Royal Decree 951/1997, of 20 June, which incorporated Directives 94/51 and 94/15. Nowadays, Directives 98/81 and 2001/18 have been transposed by Law 9/2003, of 25 April, which sets up basic rules on the contained use, deliberate release and placing on the market of GMOs (and repeals Law 15/1994, of 3 June). The Law is supplemented by Royal Decree 178/2004, of 20 January, to which the Law refers in various provisions. This Royal Decree repealed Royal Decree 951/1997, of 20 June). According to its preamble, it has taken into account further developments in EU law, i.e., Regulations 1829/2003 and 1830/2003.

Law 9/2003 covers the contained use, deliberate release, and the placing on the market of GMOs.

It should be noted that the ECJ (Second Chamber) declared that Spain had failed to adopt the laws, regulations and administrative provisions to comply with Directive 98/81. Although the Spanish Government sought the dismissal of the Commission's action under Article 226 EEC, it did not dispute that it had not transposed the Directive within the prescribed period (Case C-333/01, *Commission v. Spain*, judgment of the ECJ of 13 March 2003).

Two other pieces of legislation adopted by the Spanish Parliament should be mentioned:

- Law 29/2006, of 26 July, on safeguards and rational use of medicines and sanitary products. It indicates that activities on the contained use or deliberate release of GMOs used or to be used in medicines for human or veterinary consumption are subject to Law 9/2003.
- Law 30/2006, of 26 July, on seeds, nursery plants and phytogenetic resources.

- Autonomous Communities rules

The Autonomous Communities have adopted certain measures regarding GMOs. They mainly concern organisational matters, save certain Communities (e.g., Aragón, Cataluña and Castilla-León) that have enacted substantive provisions dealing with administrative procedures, either for the authorisation and management of GMOs or for the imposition of fines.

- Andalucía: Decree 178/1999, of 7 September, regarding the competent bodies on contained use and deliberate release of GMOs.
- Aragón: Decree 65/2006, of 7 March, on competent bodies and rules regarding contained use, deliberate release and placing on the market of GMOs.
- Asturias: Decree 55/2004, of June 18, on the organisation and competences for the carrying out of activities for contained use and deliberate release of GMOs.
- Castilla-La Mancha: Decree 1/2000, of 11 January, conferring competences concerning GMOs or products containing them.
- Castilla y León: Decree 42/1999, of 8 March, approving the procedure for the imposition of fines regarding contained use, deliberate release and placing on the market of GMOs, in order to prevent risks for human health and for the environment.
- Cataluña: Decree 152/2003, of June 23, establishing rules regarding the contained use and deliberate release of genetically modified vegetables.
- Madrid: Decree 109/2000, of 1 June, on the creation of a regional office for the control of GMOs and the Regional Biosafety Commission.
- Navarra: Decree 204/1998, of 22 June, transferring competences to the Department for the environment regarding the contained use and deliberate release of GMOs, Order 6/2000, of 12 January, on the Regional Biosafety Commission.
- Valencia: Decree 69/2006, of 24 May, on the creation of the Committee for the control of GMOs.

In addition, the Autonomous Communities have adopted measures within the context of fauna and flora protection that may affect GMOs. They refer to the control of GMOs in broad terms, e.g., by labelling, or to the protection of local species.

2) Executive competencies in the Member States: which national authority is responsible for the area of Dir. 98/81 and Dir. 2001/18 and for the area of Reg. 1829/2003 and Reg. 1830/2003?

Law 9/2003 has three legal bases: Article 149.1.6 of the Spanish Constitution, empowering the State to adopt general measures on the coordination of public health; Article 149.1.23 (basic environmental measures); Article 149.1.14 (exclusive competence on the Treasury). This means that the Autonomous Communities are also entitled to adopt further measures on GMOs, provided they do not contradict the basic rules adopted by the Spanish Parliament.

Law 9/2003 sets out the basic competences of the Central Administration of the State (CAS):

- to grant authorisations on the placing on the market of GMOs or products containing GMOs.
- to authorise additional evaluations of deliberate releases that may be requested during the procedure for the placing on the market of GMOs.
- to grant authorisations regarding the import or export of GMOs and of products containing GMOs, including their supervision and the imposition of fines;

– to authorise the contained use or the deliberate release of GMOs for any other purpose in the following cases: i) if they are going to be used in medical substances for human use and for veterinary purposes, and also in other products, including sanitary ones, and others that may represent a risk for human health.

The above mentioned authorisations are to be granted by the Interministerial Council on GMOs, which includes representatives from all CAS Departments having competences affected by Law 9/2003.

The CAS is also empowered to carry out inspections and impose fines regarding activities on the contained use and deliberate release of GMOs within the context of Law 13/1986, on the coordination of scientific and technical research. Likewise, the CAS carries out similar activities within the framework of Law 3/2000, on the legal status of seeds and plants.

As indicated before, the Autonomous Communities also enjoy certain competences since both Articles 149.1.16 and 149.1.23 only empower the State to adopt framework measures that consequently cannot carry out a complete harmonisation. Without prejudice to the competences of the CAS, they are empowered to carry out the activities regulated by Law 9/2003 regarding the contained use of GMOs, and to grant authorisations for the deliberate release of GMOs provided they do not concern the placing on the market. They may submit representations regarding applications for deliberate release or the placing on the market to be authorised by CAS. The Autonomous Communities are also empowered to carry out inspections and to impose fines save in those fields belonging to the competence of the CAS.

3) Implementation and enforcement of Directive 2001/18/CE on the deliberate release into environment of GMO:

a) What about risk assessment, management and the concept of precaution?

Although it is not expressly mentioned in Article 45 of the Constitution, the precautionary principle is part of Spanish Law since it is enshrined in EU and international law. In fact, Law 9/2003 recalls in its preamble both international and EU law regarding the application of the precautionary principle. However, it is not explicitly mentioned in any of the provisions of the Law or of Royal Decree 718/2004. Unlike the ECJ, the Spanish courts have mainly referred to this principle in general terms without adopting a more advanced standpoint on this matter, as reflected by certain cases regarding food safety. Nevertheless, the Law implements the safeguard clause set out in Article 23, albeit the procedural clauses are lacking, save the duty to inform to the Commission and the other Member States on actions adopted in this field.

Article 3.4 of the Law empowers the CAS to adopt, in urgent and serious cases, any necessary measures to protect human health or avoid irreparable damages to the environment.

As regards risk assessment, Law 9/2003 follows what is required by Directive 2001/18 (e.g., Article 4, regarding the deliberate release of GMOs)

b) Which is the impact of the complex, multi-level EC law procedure for the release of GMO in domestic administrative systems and organizations? In particular, which are the procedures of authorization? Are the scientific bodies involved in such a process, and what is their influence on the competent authority' decisions?

In order to answer to some of the abovementioned questions it is important to distinguish the different procedures set out in Directive 2001/18 and how they have been transposed in Law 9/2003. Broadly speaking, Spanish law follows the wording of the Directive regarding the data to be submitted by applicants, the role of public authorities, their coordination, particularly in the case of EU procedures, and the submission of information to the Commission. However, there are certain differences:

- Deliberate GMO release for any other purpose than for placing on the market

  Law 9/2003 merely lays down some of the requirements of Directive 2001/18. Certain aspects, such as the technical information to submitted by applicants, e.g., data on personnel and training; the interaction between the GMOs and the environment, information relating to the conditions of release and the potential receiving environment are set out in Royal Decree 178/2004. The preamble to Law 9/2003 justifies this standpoint by saying that technical matters, subject to future amendments, should not be included in the Law. It is for this reason that the Law (Article 12) does not specify in detail the procedure of Article 6 of the Directive and leaves this matter to Royal Decree 178/2004:

  - paragraph 5 (acknowledgement of the date of receipt of notification, and of the decision, 90 days);
  - 6 (periods that cannot be taken into account for the purpose of calculating the 90 day period);
  - 7 (duty to give reasons if further information is requested by the competent authority);
  - 8 (duty to give a *written* consent either authorising or rejecting the application for release). However, the Law indicates that if an express decision is not given within the period prescribed, it must be assumed that the application has been rejected. According to Royal Decree 178/2004, express decisions are to be taken only if they grant an authorisation for the deliberate release of GMOs. This contradicts the wording of the Directive and of the ECJ's case law (e.g., Case C-230/00, *Commission v. Belgium*).

    In addition, Royal Decree sets out a time-period of 3 months for the adoption of a decision whilst Directive 2001/18 refers to a 90 days period. Its should be noted that the time-periods of Directive 2001/18 are subject to the rules of Regulation 1182/1971, determining the rules applicable to periods, dates and time limits, not to those set out in the Common Procedure Law 30/1992.

According to data from the EU and various other sources, the number of authorisations for deliberate GMO release in Spain between 1993-2005 has been as follows:

1993: 3
1994: 12
1995: 9
1996: 19
1997: 41
1998: 47
1999: 42
2000: 11
2001: 18
2002: 18
2003: 41
2004: 21
2005: 24
Total: 306

- Placing on the market of GMOs as or in products

Law 9/2003 follows the rules set out in Directive 2001/18, particularly regarding the items of information to included within the application for authorisation and the measures to be taken by the applicant in order to protect human health and the environment if new information becomes available with regard to the risks of GMOs to human health or the environment. The basic rules concerning the standard procedure are also included in the Law. However, neither the time-periods laid down in Article 15 of the Directive, save the period of validity of the consent, nor the procedure for the renewal of consents is laid down in the Law. They are included in Royal Decree 178/2004.

As in the case of the deliberate release of GMOs, there are certain differences between Directive 2001/18 and Spanish Law, particularly regarding the time-periods, 3 months instead of 90 days for the preparation of an assessment report.

Neither Law 9/2003 nor Royal Decree 718/2004 regulates the procedure if objections are submitted (Article 18 of Directive 2001/18). Although it is an EU procedure, elemental rules on the transposition of Directives would require proper transposition of that provision.

It should be noted that both Law 9/2003 and Royal Decree 718/2004 indicate that if the competent authority does not take an express decision, it must be understood that the application has been rejected. This provision affects any of the authorisations envisaged in Law 9/2003 and Royal Decree 718/2004. As indicated before in respect of the deliberate release of GMOs (Article 6(6)), Directive 2001/18 requires the public authority to either indicate that it is satisfied that the notification complies with the Directive and that the release may proceed, or that the release does not fulfil the conditions of the Directive and that the notification is therefore rejected. The Directive also requires an express decision if the assessment report referred to in Article 14(3)(b) indicates

that the GMOs should not be placed on the market (Article 15(2)). Even the renewal of consents is subject to an express decision on the part of the competent authority (Article 18(1)).

- Administrative and scientific bodies participating in relevant procedures

  Law 9/2003 refers to two different bodies:

  The Interministerial Council on GMOs (*Consejo interministerial de organismos modificados genéticamente*). This body is empowered to grant authorisations for the contained use, deliberate release and placing on the market of GMOs. All CAS Departments having competences within the scope of the Law are represented in this body. Its decisions may be subject to appeal before administrative courts. It participates in EU authorisation procedures.

  The National Biosafety Commission (*Comisión Nacional de Bioseguridad*). This is a consultative body of the CAS. Its main competences are as follows:
  - It must inform on any applications for authorisation (within 10 days).
  - It verifies whether the information included in the application complies with the requirements of Law 9/2003, if measures concerning the management of wastes, safety and response in case of an emergency are adequate
  - It also informs on applications submitted to the Autonomous Communities for authorisation.

  The Commission includes members from CAS Departments (19 members), from the Autonomous Communities, and from expert institutions (including individuals, up to 6 members). Experts may also be requested to submit their opinions in particular cases.

  The reports delivered by the Commission lack binding effects.

  Both the Interministerial Council on GMOs and the National Biosafety Commission are attached to the Spanish Ministry for the Environment.

  Other bodies created under different Laws cannot interfere with the powers attributed to those created by Law 9/2003 if the latter are acting within their competences (e.g., second additional provision to Law 30/2006, of 26 July, on seeds, nursery plants and phytogenetic resources).

  By Royal Decree 1697/2003, the Ministry for Agriculture created a consultative body GMOs to be used in agriculture (*Comisión Nacional de Biovigilancia*).

  It is difficult to assess the real impact of consultative bodies within the decision-making process. However, bearing in mind their composition, particularly in the case of the National Biosafety Commission, in which the Spanish Food Safety Agency participates, their opinions are followed by the Interministerial Council mentioned above.

c) What about self-monitoring and supervision by administrative bodies and public entities (NGOs, etc.)? How the safeguard clause is applied?

Supervision of the execution of any laws in Spain is always foreseen in any piece of legislation. However, the carrying out of such activities is a different story since public authorities either lack the manpower or the willingness to implement an effective supervisory policy. As in other cases regarding the protection of the environment, most of the complaints are brought forward by NGOs, as it happens with GMOs. However, access to reliable data is difficult despite the growing awareness among certain (still minor) sectors of the population. From a legal viewpoint, Law 9/2003 empowers the CAS to carry out controls within the context of imports and exports of GMOs. The Autonomous Communities are empowered to carry out controls in the fields attributed to them. Unlike other sectors, e.g., waste, where private individuals, duly authorised, may be empowered to carry out inspections, in principle, only civil servants are entitled to inspect and monitor activities subject to GMO regulations. Article 32 of Law 9/2003 declares that the holders of activities subject to the Law must collaborate with the public authorities, allowing them to carry out controls, take samples and collect any information necessary for the accomplishment of their missions. Those officials are also entitled to adopt precautionary measures that may include the closure of an installation, the seizure of GMOs or of products containing GMOs.

However, Law 9/2003 does not expressly require the ACS or the Autonomous Communities to draw up plans for the carrying out of inspections following European Parliament and Council Recommendation 2001/331, on minimum criteria for inspections in the Member States. In fact, the National Biosafety Commission has indicated that monitoring of GMOs is difficult.[1] Information regarding the number of inspections already carried out is not available. By judgment of 17 February 2004, the Spanish Supreme Court held that inspection reports can be distinguished from other subsequent decisions to be adopted by public authorities, e.g., in a procedure for the imposition on a fine, and therefore they are subject to the regulation on the access to information.

One of the activities that has been heavily criticised is the carrying out of fields experiments. According to NGOs, approximately more than 300 tests have been reported between 1993 and 2005. Most of those tests have been undertaken by private companies. NGOs have claimed that

- information regarding those tests is unavailable;
- they have been carried out without any type of isolation from the environment;
- the recommended distances are not respected;
- there have cases of unauthorised experiments;
- in a number of cases unauthorised varieties have been mixed with permitted varieties in the same experiment field;
- experiments are also camouflaged under the term “demonstration fields”.[2]

Nevertheless, as is nowadays acknowledged, the requirements for the carrying out of those tests have been tightened up.

[1] Minutes of the 43th meeting of the National Biosafety Commission, at paragraph 11.
[2] Source: Greenpeace, *Impossible Coexistence*, available on the Internet at: www.greenpeace.org/international/press/reports/impossible-coexistence.

d) How are transparency and participation dealt with? What about the access to information on GMOs?

Transparency and participation are dealt with by Law 9/2003 in broad terms. Whilst the rules on transparency basically follow what Directive 2001/18 indicates, those regarding public participation merely rely on standard regulations set out in the Common Administrative Procedure Law 30/1992.

- Deliberate release for any other purpose than for placing on the market

Unlike Directive 2001/18, Law 9/2003 does not contain a provision relating to public participation. It merely refers to this matter by indicating that the results derived from that procedural stage will be taken into account by the public authority. Therefore, the Law indirectly foresees the existence of a public participation stage. By contrast, Royal Decree 178/2004 sets out a period of 30 days. However, it is doubtful whether this provision really complies with Article 9 of Directive 2001/18, which expressly requires the Member States to lay down arrangements for public consultation, including a "reasonable" time-period in order to give the public or groups the opportunity to express an opinion. Depending on the complexities of the information to be analysed that period of 30 days may not be adequate for the submission of an opinion by the public.

- Placing on the market

Law 9/2003 does not lay down any rules regarding public participation. Royal Decree does not implement Article 24 of Directive 2001/18, which requires the Commission to make available to the public the summary of the dossier submitted by the applicant and the assessment report indicating that the GMO(s) in question should be place on the market. Although these two obligations have to be satisfied by the Commission, it is questionable the standpoint adopted by the Spanish legislature since it hardly complies with basic requirements regarding the implementation of EC Directives.

- General transparency provisions

Article 20 of Law 9/2003 somewhat follows Article 25(2) of Directive 2001/18. Accordingly, prospective applicants are entitled to declare that certain items of information and of data should be regarded as confidential by the public authorities. However, unlike the Directive, Law 9/2003 does not refer to information "the disclosure of which might harm [the applicant's] *competitive position*", which seems to restrict reliance on the confidentiality clause.[3] In any case the applicant must provide the public authority with verifiable justification. The competent authority must adopt a decision on this matter (no time-period is specified). Information protected under the confidentiality clause will not be divulged.

[3] However, Article 25(1) of the Directive indicates that the Commission and the competent authorities shall not divulge to third parties any confidential information notified or exchanged under this Directive and shall protect intellectual property rights relating to the date received."

Law 9/2003 declares that in any case certain items of information will be kept confidential: i) general description of the GMO or GMOs, ii) name and address of the notifier, iii) purpose of the release, location of release and intended uses; iv) methods and plans for monitoring of the GMO or GMOs and for emergency response; v) environmental risk assessment; vi) confinement measures; vii) assessment of effects on the environment and on human health. Following Article 25 of Directive 2001/18, the Law declares that for all GMOs which have received written consent for placing on the market or whose placing on the market was rejected as or in products under the Directive, the assessment reports carried out for these GMOs and the opinions of the scientific committees consulted shall also be made available to the public. Releases of GMOs and authorisations for the placing on the market are also included.

According to Article 49 of Royal Decree 718/2004, the competent authorities must make available to the public the information on authorisations regarding contained use, deliberate release for any other purposes than for placing on the market, and the placing on the market of GMOs. Likewise, they must make available the GMOs which have received written consent for placing on the market or whose placing on the market was rejected as or in products, the assessment reports, the results concerning controls on the placing on the market and the reports from the National Biosafety Commission (albeit the Directive employs a broader term, "the opinion(s) of the Scientific Committees consulted").

By Law 27/2006, the Spanish Parliament implemented Directive 2003/4, on access to environmental information. This Law includes within the concept of environmental information, that referring to biodiversity, including GMOs. It also proclaims the right to participate, in an effective and real manner and according to applicable rules, on administrative procedures for the grant of authorisations regarding, *inter alia*, GMOs.

The Spanish Ministry for the Environment publishes on the Internet several items of information:[4]

- The latest minutes of the National Biosafety Commission. They mainly refer to the examination of notifications, inspections of installations subject to authorisation and also to developments at EU and national level.
- Notifications and authorisations on the contained use, deliberate release and placing on the market. It also includes risk assessments.

NGOs are consulted during the drafting of new regulations. They also participate in the Advisory Council for the Environment a body attached to the department for the Environment. This Council consists of different member of the Spanish Government and also of NGOs. It must deliver a report on drafts laws and regulation that may affect the environment.

- Other transparency provisions

In the case of very serious offenses, the competent authorities are entitled to publish the names of offenders plus the fines imposed.

[4] Available on the Internet at: www.mma.es/portal/secciones/calidad_contaminacion/omg.

Competent authorities must set up registers including the location of: i) GMOs released for any other purpose than the placing on the market; and ii) GMOs grown following the prescriptions of the Law to be placed on the market. The Department of the Environment (of the ACS) must also create a register with data flowing from the Autonomous Communities plus its own data.

e) How is the court review? Is the legal standing of third parties and associations allowed?

Court review is to be carried out within the context of Law 29/1998, regarding Administrative Law courts. So far, there are no judicial decisions on GMOs in Spain. Previous judgments regarding the application of the precautionary principle mainly dealt with food safety and the courts merely referred to it in broad terms. Therefore, it is not easy to deduce future outcomes. Judges will mainly rely on the reasons provided by the competent authorities to support or, less likely, quash their decisions. Procedural matters will also have an important role to play. The key question would be which of the breaches of EC Law may lead to the overturning of an authorisation.

The legal standing of third parties and associations is set out in Law 29/1998. According to this provision, affected parties are entitled to challenge decisions adopted by public authorities before the courts. Unlike general environmental laws adopted by the Autonomous Communities, Spanish Law implementing EC legislation on GMOs does not grant an *actio popularis*. Associations may also challenge decisions either if they are affected by a decision or if they are entitled to do so for the protection of legitimate collective interests.

f) Which is the nature of the penalties fixed according to art. 33 (criminal, administrative, civil sanctions)?

Law 9/2003 sets out only administrative fines. Following a standard distinction employed in administrative laws, it refers to minor, serious and very serious offenses. Fines range as follows:

- minor offenses: up to 6.000 €;
- serious offenses range from 6.001 to 300.000 €;
- very serious offenses: from 300.001 to 1.200.00 €.

In the case of serious and very serious offenses the competent authority may also decide the provisional of definitive closure of the activities. Provisional closure may be adopted in the case of minor offenses. The suspension of the activity may also be taken before the commencement of the procedure leading to the imposition of a fine. In any case those found guilty must restore the environment to the state prior to the carrying out of the offense. If the amount due is inferior to the benefit obtained by committing the offense the fine will be increased twice the benefit derived from the offense. The Autonomous Communities are entitled to set out further offenses and also to increase the amounts of the fines. Needless to say, they cannot reduce them (judgment of the Spanish Constitutional Court 196/1996).

There are no available data on fines. As mentioned before, in the case of very serious offenses the public authorities may publish the amount of the fine plus the names of the offenders and the nature of the offense.

Apart from the abovementioned measures the Criminal Code also lays down certain provisions for the protection of the environment that may be invoked in the case of GMOs although they are not expressly mentioned (Article 325).

Overall, the provisions included in Law 9/2003 comply with the criteria set out in Article 33 of Directive 2001/18 (penalties shall be effective, proportionate and dissuasive).

4) Authorisation of the placing on the market of GMOs

1. Authorisations for GMOs other than food and feed: what about risk assessment, management and the concept of precaution? Is the benefit resulting from GMO use considered as a factor to be balanced against the expected risk? Does the risk assessment take into account that the GMO may be released under very different climatic and geographical conditions? Is the public involved? Do the authorities issue general authorisations, or do they restrict authorisations to specific climatic and geographical conditions? Are there third party rights of standing to challenge an authorisation?

Some of the questions have been answered in the preceding paragraphs. Local conditions are taken into account, albeit it is difficult to assess up to what extent.

2. Authorisations for GM Food and Feed under Regulation 1829/03:

aa) What is the national practice in relation to the EC authorisation procedure? Are there national risk cultures expressed in the consultation procedure? How are transparency and participation dealt with?

It is difficult to verify whether national risk cultures are duly expressed in the authorisation procedure. The minutes of the Biosafety Commission do not provide information on this particular point. Developments at EU level are regularly discussed by the Biosafety Commission, e.g., the preparation of an interpretative guide on Regulation 1829/2003, matters discussed in the Committee under that Regulation. As regards transparency and participation, the legal background has already been referred to above.

5) Coexistence:

1. what have MS done in order to protect non-GM agriculture/processing/trade/consumption? Focus on GM free zones, coordination of agricultural practices, liability, and implementation of art. 31(3) of Dir. 2001/18

Coexistence has been a matter largely discussed among NGOs, bearing in mind that Spain has authorised around 31 varieties of GM maize, the first one in 1998. According to data obtained from various sources, including Greenpeace, the surface of GM maize in Spain (in hectares) is as follows:

1998: 22.468
1999: 25.72
2001: 11.598
2002: 20.992
2003: 32.248
2004: 58.200 to 60.000
2005: 50.000 to 57.000

A Greenpeace report titled 'Impossible Coexistence',[5] based on research including laboratory tests of samples taken from maize fields of 40 Spanish organic and conventional farmers, indicates that in almost a quarter of the investigated cases in Aragón and Cataluña unintended and unwanted presence of GE maize was found in the maize fields of non GE farmers. The GE contamination was as high as 12.6%. Aragón is the Spanish Autonomous Community that has the largest number of hectares of GM maize (30.000 to 40.000 hectares of a total of 67.753 hectares of maize cultivation), whilst Cataluña is the second one (17.170 hectares of a total of 40.913 hectares).

So far, the Spanish Government has not adopted a regulation on coexistence. There is a draft version (last issue of 20 April 2006), which has the subject of several comments by NGOs.[6] They argue that the draft does not longer support the GMO industry; however, the Decree does not tackle certain key questions:

- In the case of GM maize the safety distance is 200 metres but, in their opinion, this is insufficient since pollen travels longer distances (up to 800 metres and beyond). In addition, the draft indicates that that distance may be waived if owners of adjacent fields reach an agreement provided this does not affect third parties. According to Annex II, a different distance may be authorised by the Autonomous Communities depending on the planning of the sowing season so as to avoid the coincidence of flowering periods. Article 8 of the draft indicates that any agreements between farmers belonging to the same geographical region regarding coexistence will take priority over specific measures set out in Annex II to the Decree. Those agreements may also reject the growing of GMOs. The Decree does not indicate who is to comply with the abovementioned distance of 200 metres, e.g., those growing GMOs or adjacent owners.
  Article 9 of the Decree includes a further exception according to which, safety distances are not applicable if adjacent fields grow GMOs belonging to different species, or if all crops of the same area are GMOs.

- The draft takes as a reference for coexistence rules the thresholds of adventitious presence of GMOs below which food does not require a label indicating that it is genetically modified (0.9% in the case of authorised GMOs; 0.5% in the case of non-authorised GMOs).

- The draft includes certain obligations to be complied with by farmers planning to grow GMOs: i) prior notification (1 month before the sowing) to adjacent farmers, to those within the safety distance mentioned above, and to the Autonomous Community; ii) farmers sowing GMOs must employ seeds

[5] *Supra* note 1.
[6] Available on the Internet at: www.tierra.org/transgenicos.

officially monitored in order to "guarantee the purity and quality of the harvest"; iii) farmers must keep the labels that appear in seeds containers for five years; and iv) they must also inform any person to which the harvest is sold or transferred about the species and the genetic modification to which it has been subject.

- The Ministry of Agriculture with the support of the Ministry for the Environment and taking into account the plans adopted by the Autonomous Communities, is to enact a monitoring plan every year. The Autonomous Communities will inspect the percentage of crops set out in the plan both during farming and also during harvest.
- A register of fields with GMOs is to be created with information supplied by farmers.

Overall, NGOs have criticised the draft because, in their opinion, it does reduce the risks of GMO pollution. In particular, they have highlighted the following problems:

- The draft minimizes the problem of genetic pollution and avoids the obligation to respect a cero threshold of pollution in ecological agriculture.
- It gives equal rights to traditional and GMOs farmers.
- It does not tackle the question of liability (Spain has not yet transposed Directive 2004/35).

NGOs (Friends of the Earth, COAG, Greenpeace, Intereco, Red de Semillas, and SEAE) have requested the Spanish Government to withdraw the current draft and to submit a new (improved) version alongside the comments made by those organisations.

The obligation to set up registers (Article 31(1) of Directive 2001/18) has been considered under question 3) (d) (above).

2. Have MS established a scheme ensuring GM free zones? How does the special impact assessment based on Art. 6(3) Habitats Dir. work?

- GM free zones

Spain has not established a scheme ensuring GM free zones. However, some Autonomous Communities have declared themselves GMO-free, joining the European Network of GMO-free Regions. This is the case of Asturias that has also adopted a Parliament Resolution of 20 May 2004, declaring its intention to invoke before the National Biosafety Commission the criterion that the authorisation of GMOs in Asturias will have a negative impact on agricultural production strategies. The Parliament of the Autonomous Community of the Balearic Islands also passed a Resolution on GMO-free and expressed its intention to join the European Network of GMO-free Regions. So far, more than 30 municipalities have also passed GMO declarations. However, it is difficult to track the number of local authorities that have approved similar declarations bearing in mind that there are more than 8.000 municipalities in Spain. According to information obtained from the European Network of GMO-free Regions, the distribution of municipalities per Autonomous Community would be as follows:

Andalucía:	Almonte, Pozoblanco.
Asturias:	Aller, Cangas de Narcea, Castropol, Penamellera Baja, Carreno, Riosa.
	Baleares: Esporles, Manacor, Perreres.
Cataluña:	Rubí, Ripoll, Valls.
Castilla-La Mancha:	Albacete
Murcia:	Bullas
País Vasco:	Arama, Itsasondo, Elgeta, Zaldibia, Abanto, Amoroto, Arratzu, Aulesti, Balmaseda, Izurtza, Muskiz, Otxandio, Turtzioz, Amurrio.

- Article 6(3) of the Habitats Directive

It is difficult to obtain information on the practical application of Article 6(3) of the Habitats Directive in Spain. This Member State formally transposed the Directive by Royal Decree 1997/1995. However, this regulation does not elaborate on the procedure for the assessment of plans or projects. This is mainly (but not entirely) a matter for the Autonomous Communities. In any case, Royal Decree 1997/1995, Article 6(3) (first sentence), leaves open this matter since it merely refers to an adequate assessment to be carried out according to applicable measures, either from the State or from the Autonomous Communities. The latter have adopted measures on the assessment of plans or programmes requiring the assessment of those affecting, *inter alia*, areas designated under Directive 92/43. However, those measures neither repeal nor amend the obligation set out in Article 6(3) of Royal Decree 1997/1995. Bearing in mind the broad meaning of the term "project" in Article 6(3) of the Habitats Directive, it could be argued that the carrying out if field experiments and the deliberate release of GMOs are both covered by that provision. The case-law regarding Article 6(3) of the Habitats Directive would support this conclusion (Case C-98/03, *Commission v. Germany*; Case C-127/02, *Waddenzee*).

6) How GMO traceability and labelling issues are dealt with in the Member States' legislation (Reg 1829/2003, Dir. 2001/18, reg 1830/03)? Do national systems of verification exist? How do they work? Which are the penalties introduced by national legislators?

- Traceability

Law 9/2003 follows Regulation 1830/2003. It provides that operators that commercialize GMOs or products containing GMOs must keep and transmit data and information, to be specified in ancillary regulations, to facilitate their control and possible withdrawal, at all stages of the placing on the market, so as to obtain the retrospective location of GMOs movements at all stages of production, manufacturing and distribution. The data that must be communicated to the public authorities consists of: i) an indication that the product in question contains or consists of GMOs; and ii) an identifier, according to the corresponding EU procedure. In the case of a product consisting of mixtures of GMOs to be used only and directly as food or feed, or for processing, the abovementioned information may be substituted by a declaration of use by the operator together with a list of the unique for all those GMOs that have been used o constitute the mixture. The information must be kept for a period of 5 years.

The Spanish Food Safety Agency has issued certain guidelines regarding traceability for food processing industries.[7]

- Labeling

The provisions regarding labeling are parallel to those set out in Regulation 1830/2003. Accordingly, for products consisting of or containing GMOs, operators must ensure that: (i) for pre-packaged products consisting of, or containing GMOs, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' appear on a label; and (ii) for non-pre-packaged products offered to the final consumer the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' shall appear on, or in connection with, the display of the product.

Spanish legislation also indicates that the aforementioned rules (traceability and labeling) do not apply to traces of GMOs below thresholds set out in Regulation 1830/2003.

- Penalties

Law 9/2003 sets out certain express penalties in the case of traceability and labelling:

- Serious offenses: the failure to comply with labelling requirements of GMOs and products containing GMOs; the failure to comply with traceability requirements to set out in ancillary regulations. Penalties: fines range from 6.001 up to 300.000 €, including the temporary or permanent closure of the installation, or the seizure of GMOs or products containing GMOs, or the prohibition to place on the market those products.
- The breach of labelling or traceability requirements may also be included within the heading minor or very serious offenses, since they both refer to catch-all clauses, such as the infringement of any requirements of the Law, or of the conditions lay down in the authorisations.

7) How are Member States implementing Directive 2004/35/EC on Environmental Liability with specific reference to GMOs?

Spain has not yet transposed Directive 2004/35. In fact, the Spanish Government has not even submitted a bill to the Spanish Parliament. The Minister for the Environment indicated on 6 September that the Government may submit it by the end of the current year.

[7] Available on the Internet: http://www.aesa.msc.es/aesa/web/AESA.jsp.