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**SPANISH LAW ON GENETICALLY
MODIFIED ORGANISMS**

Daniel Borrillo

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Spanish Law on Genetically Modified Organisms

The advances in genetic engineering and in molecular biology have permitted the manipulation and modification of the genomes of numerous organisms. Although the ability to modify species is not a recent phenomenon, modern genetic science is opening an, until now, unknown dimension by bequeathing a genetic characteristic to a being that it can transmit to its descendants on which it would be difficult to exercise control. From day to day, the industrial applications appear more promising which implies that modifications could massify. In effect, this foresees the large-scale utilization of genetically modified organisms for pharmaceutical products and insecticides or plant growth stimulators. The complexity of the flow and interactions between different genes, genes and microorganisms, and between genes and ecosystems, etc. makes it almost impossible these days to make any sort of prediction about the future of one gene artificially introduced into an organism and the risks that that implies.(1)

It is necessary to distinguish between two types of gene flow. The vertical flow between predecessors and descendants and the horizontal flow between organisms of the same generation whether or not they come from the same species. If the first is relatively unknown, the second is not. The complexity and unpredictability of its interactions and consequences make it very difficult to establish clearly what the future of an artificially introduced gene would be. In effect it could produce unforeseen recombinations and cause a loss of control of the gene or even of the genetically

modified organism (GMO) itself along with all of the ecological risks that that implies. In this way it would be possible for an entire population of GMOs to develop to the detriment of existing populations. It could also pass an artificially introduced gene to other related species (i.e. the passing of a gene resistant to an herbicide to a wild, related species).

Since the 80's, there has been an effort to regulate biotechnology activities. Risk evaluation agencies and regulatory offices of the above-mentioned technologies have multiplied. Following this trend, the Commission of the European Union wrote a report to establish "a community framework toward regulation of biotechnology.(2)" This report stated the need to control two high risk activities, that is: that related to the confined usage of GMO's for an experimental or industrial process (an activity that would take place within the confines of a laboratory) and those related to the voluntary dissemination(3) of GMO's. On April 23, 1990, these reports were manifested in two European Union Directives(4). Since then, an intense harmonization process has taken place in the different countries of the European Union. Spain, one of the last to adopt the new Directives, has a law written by the Secretary of the Environment within the Ministry of Public Works and Transportation.

For the first time in the history of the law, a technoscientific activity is being formally regulated. Neither atomic energy nor chemical activity, although they produce significant risks to the environment and to health, were legally regulated as potentially dangerous activities.

The fundamentals of the European Union's concern stem from the fact that biotechnological activities carry with them a risk of dispersal and eventual contamination that could cross borders. This is certainly a revolutionary fact as we will see now that, for the first time the sovereignty

of the Member States is limited considerably.

First, I will analyze the principles and the overall characteristics established by the Directives and then move on to a study of the Spanish project within the framework of these Directives and of other current European legislation.

European Union Directives

As a result of the United Nation Conference on the environment which took place in Stockholm in 1972, a political preoccupation has arisen in the European Union in relation to effective control of activities that could be damaging to the environment and to public health. When faced with widely varying opinions and the lack of legislation on this theme (above all in the lesser developed countries) the Commission created a project of Directives which aimed to establish norms for the usage of genetically modified microorganisms contained within physical barriers (confinement) as well as control over the liberation of organizations into the environment (intentional liberation). Fundamentally it tried to avoid the existence of genetic paradises that lacked legislation which would permit the invasion of multi-national corporations attracted by this very lack of control. After many years of negotiations, in 1990 the Ministry of the Council approved the two Directives in question.

It is necessary to pause a moment to discuss the conflict that occurred in the Commission of the European Union, because this will allow us to better understand the dimensions of the problem and the prevailing interests at work. In effect, two antagonistic positions did not take long to appear in Brussels. On the one hand, the Directives were ardously defended by the General Direction (DG) number XI (Civil Protection and the Environment), and on the other

hand, the DG III (Industry), DG VI (Agriculture), and even the DG XII (Science and Technology) showed to a greater or lesser degree, considerable misgivings about these normatives. The conflict was a symptom of the opposing interests between the consumers and the ecological associations, on the one hand, and the industries, agrobusinesses and sciences, on the other. The latter preferred, in general, a less strict regimen -i.e. deregulation -in the matter. Soon we will see which arguments were brandished by each of these parties.

The analysis of the directives, and particularly of the second one (90/220), will inform us of the dimensions of the situation analyzed. In effect, the norms affect the process as much as the material regulated. We do not come across, in effect, the regulation of one product in particular (as occurs with pharmaceutical products and foods) but rather the regulation of a specific technique in the service of one type of industry. It attempts to guard, in absolute, a new mode of production founded in biotechnology. This implies the modification of a "culture of risk" that always considers risk after the fact. The classic notion of risk, dealt more with "dangerous products" than with "dangerous techniques or processes".

If we start from a classic conception of risk, there is no reason that genetic engineering should be submitted to regulation as a dangerous activity in itself. As a matter of fact, the principle scientific and industrial objections to the directives are based in this argument, in that, according to these groups there are no legitimate motives to stigmatize an activity that has not yet shown any particular danger.

The Directives invert this logic. They do not attempt to prove whether a product is dangerous (or could be dangerous) before limiting its production and circulation but rather regulate before the danger emerges. This attitude

could, legally speaking, be expressed as the articulation of "the prudence principle"(5). The prudence principle would permit biotechnology advances to occur at a much slower rate. In other words, scientific and technological advances could, thanks to this principle, be accompanied by what we call an ethical, philosophical advance (with its eventual translation into the judicial sphere). The classic culture of risk starts from the assumption of the free business and commercialization of products as long as the danger has not yet been proven. The new culture of risk, based on the principle of prudence, inverts the proposition. It considers that prudence should be imposed whenever harmlessness has not yet been proven. In summary then it could be said that "prudence" does not have to prove risk in order to regulate and is not applied to dangerous products so much as to offensive techniques. But this mode of production is not limited to genetic modification. Other activities exist that could be considered as dangerous, such as cloning. The Directives, however, only refer to the first. To limit the control of genetic engineering instead of extending regulation to all bioproduction is, as M.-A. Hermitte says, perfectly irrational. It is a pity that they did not take advantage of the conflict to include within the regulation classic biological methods of genetic selection that the legislation does not address.

The Directives opted for horizontal treatment: independent of the product, that which is regulated is the technique of creation and production. On the contrary, the United States has opted for a type of vertical treatment, that is, only the dangerous product is taken into account, independent of its production technique. In this way, the Pharmaceutical authorities control the medicines, the Food and Drug administration controls food products, etc. This is known as "one door, one key." Every door has its key, and every product has its particular system of regulation. This perspective continues to gain supporters in the Commission

of the European Union (in spite of the spirit of the Directives and the position of the Parliament). The return to vertical treatment implies returning to the classical notion of risk and probably it would be necessary to confront traumatic experiences again before perceiving the need for a preventative policy.

The principle obstacle for the effective application of the Directives comes from, as we said before, the actual interior of the Commission. The DG XI finds itself isolated in spite of the existence of texts with a clear environmental orientation. Remember that the powerful SAGB (Senior Advisory Group on Biotechnology) supported by the CUBE (Concertation Unit on Biotechnology in Europe) and the DG's III, VI and XII continue to demonstrate their disagreement with the Directives. In the name of industrial competitiveness the DG III (in a communiqué dated January 17, 1992) insists on models that are more flexible and less regulated like those of the United States and Japan(6). Reclaiming the application of the method "one door, one key" implies avoiding the process of authorization and control established by the Directives and moving towards a less rigorous mechanism. Let us take as an example the European Union's regulations of new food products; under a vertical application of regulation, those food products that result from GMO's would not be submitted to the control of the Directives. The same would occur with medicines and other substances derived from GMO's. In this way treating the products and not the process would betray the spirit of the Directives and sacrifice the sharp control of the inevitable and irreversible risks.

Another culminating aspect of the debate was related to the theme of "the right of information." At first, and in spite of the pressure from DG XI, the question was not considered by the Commission. In a reform to the Directives, the Parliament introduced the question but it was transformed

by the Commission into a simple recommendation left to the decision of the Member States. The Spanish project makes no mention of this right.

We indicated at the beginning of this analysis the revolutionary nature of the Directives in the sense that they imply curtailment of the sovereignty of the States. We will examine how this regime of inter- and intrastate control functions. Conforming with the Articles XI-XVI of the second Directive the States should authorize the fabricator or the importer before the commercialization of the GMO. Within a maximum of ninety days after being notified, the authorizing agent, if it authorizes the commercialization, should send a record to the Commission. Upon receipt of the record, the Commission will immediately send the record to the competent authorities of all of the Member States (Article XIII). If within a period of sixty days no Member States object, the competent authority concedes the authorization so that the product can be commercialized anywhere within the European Union. But in case a competent authority from another Member State formulates an objection, he will send the record back to the original authorizing agent in order to reassess the situation. If an agreement cannot be reached the final decision will be made in Brussels which can even prohibit an authorized product in a Member State of the Union. In addition, Article XVI establishes that a State can restrict or provisionally prohibit the use and/or the sale of the product (that has been duly notified and authorized) within its territory. Although the majority of the national legislatures reserve this prerogative as stated by the Directives, the Spanish legislature has renounced it.

Now that the overall characteristics of the Union model have been presented we turn to the Spanish case attempting at all moments to refer to the Union's standard and to the legislation of other member countries.

The Situation in Spain

The preliminary project for the law that adopts the European Union's Directives was written by the DG of environmental policy within the Secretary of the State of Water and Environmental policies (Ministry of Public Works and Transportation). This preliminary project was supposed to have been dealt with by the second week in April of 1993. Owing to the dissolution of the *Cortes* (Spanish Parliament) and the advancement of the electoral calendar by the head of government on the 12th of April, the preliminary project was approved by the Council of Ministry five months later on the 29th of September.

In spite of the fact that Spanish authorities played with the possibility of implementing the Directives as regulations, it was not possible because there was no general law for the protection of the environment on the Peninsula to refer to; in agreement with Article 149.1 of the Constitution all creation of norms relating to the environment should emanate from legislative power. In addition, the project foresaw the possibility of infractions and penal sanctions that could only be established by law (Article 25 of the Constitution). Consequently, they followed the legislative path.

The project was finally approved and converted into law on the day of June 3, 1994(7).

I will first present the Articles of the law. I will then briefly expound on the context in which the project was created and pass, finally, to the analysis of its most controversial elements.

The law implemented by the European Union Directives

The law is composed of 31 Articles divided into 7 chapters, two additional provisions and 7 final provisions. The first chapter (general provisions) refers to the objective and the range of application of the law. It deals with "the establishment of a legal system of rules applicable to confined usage activities, voluntary liberation of GMOs, and commercialization of these organisms and the products they could produce for the purpose of avoiding the eventual risk or reducing the possible danger that these activities could produce for human health or the environment" (Article 1). The second paragraph excludes from the range of the law "the activities mentioned in the previous article when the genetic modification of the organism is obtained by techniques of mutagenesis or by cellular fusion, including that of plant cell protoplasts, in which the resulting organisms could also be produced by traditional methods of multiplication or by culture, given that these techniques do not suppose the utilization of GMO's as receptor or parent organisms. In the same way, the usage of the techniques of in vitro fertilization, combination, transduction, transformation or whatever other natural process and polyploidic induction, are excluded from this law as long as DNA recombination molecules are not used and the organisms are not genetically modified" (Article 1).

The second, third, and fourth chapters create the legal framework for regulation of the activities contemplated by law; principally the obligations of those qualified to perform authorization procedures. The fifth chapter (information and control/checking) deals with the confidentiality of certain information as well as emergency situations and vigilance. The sixth chapter is dedicated to the system of infractions and sanctions classifying the former as light, serious, and very serious. The administrative powers are contemplated in the seventh chapter. The law establishes the creation of a collective body whose mission is to carry out the authorizations. Finally, the law obliges

the government to create a national Commission of Biosecurity within a span of three months after its full participation.

One of the most interesting points is the time that the Spanish state has taken to translate the Directive into National Law, more than four years. The law is not so complete nor so innovative that it deserves almost four years of discussion.

The points of the law are faithful to the Directives and put in motion the need to create a system of observation and control of the investigation activities and the industrial processes that are implied by the utilization of GMO's in order to guarantee the safety of the environment and of public health. The faithfulness is diluted as we advance in the analysis of the text of the law.

In spite of the declaration of good intentions from the beginning, the problem of risk to the environment and to public health was perceived in a disparate manner by different authorities. In this way, the Ministries of Agriculture, Education, and Industry tried to modify the title of the preliminary project considering that the word "risk" could be badly perceived by public opinion. The title was maintained thanks to the intervention of the Spanish DG of Environmental Policy that stated at all times that the Directives intended precisely to reduce the eventual damage and in consequence the word "risk" should be maintained in the title of the project.

In the Project of the law the general administration of the State was responsible for conferring the authorizations for the voluntary liberation of GMO's and for their commercialization (Directive 220). The Autonomous Communities were responsible for the authorization of confined use of GMO's (Directive 219). In the parliamentary debate the

Catalan group (Convergència i Unió) proposed an Amendment, stating that the responsibility of the Autonomous Communities be extended to include the right to authorize voluntary liberation, except in particular cases foreseen by the law(8).

On a national level the competent authority is composed of a "collective body of representatives of the Ministries of Health and Consumption, Public Works, Transportation and Environment, Agriculture, Fish and Food Products, Industry and Energy, and Education and Science" (Articles 30-33). It is important to note that the preliminary project foresaw the participation of only the Ministries of Health and of Public Works. The other Ministries were introduced in the project owing to an explicit request of the authorities of the aforementioned budgets. The introduction of Agriculture, Industry, and Education in this collective organization is not, to my understanding, a decision devoid of consequences. Very much on the contrary, these Ministries had manifested their hostility toward the Directives considering that they could engender negative reactions on the part of public opinion. The multiplication of representatives of the Administration could itself provoke diversity not only in the authorization criteria but also in how those rules are put into effect given that, as we have indicated earlier, every sector is going to claim a specific system for the distinct types of products (that is, industry for industrial products, agriculture for plants and animals, education for scientific experiences...) reducing in this way the range of the environmental secretary with regard to those products that could have contaminating characteristics (i.e. pesticides). Only the Administration is qualified to confer authorization. This implies that the collective body (Central Administration) will evaluate the risks that GMO's could produce, instrument petitions for utilizations, counsel, and decide the authorization.

Other European legislations have opted for a system of authorization closer to the spirit of the Directives. For example, the French law of July 13, 1992 establishes that the body responsible to authorize confined usage is the Commission de génie génétique(9) composed of experts in genetics, the environment, and public health where at least one third of the Commission is composed of specialists in protecting the environment and public health and also includes a representative of the Office parlementaire d'évaluation des choix scientifiques et technologiques. The responsible body for authorizing voluntary dissemination (Commission d'étude de la dissémination des produits issus du génie biomoléculaire(10)) is composed of the persons ideally suited for the matter; a member of the Office of Parliament, representatives of Environmental Protection agencies, Consumer Groups, Unions, and concerned professional associations.

In contrast to the Spanish Commission, the function and organization of the French Commission is extensively regulated by French Legislation(11). The most surprising thing of the Iberian project is its marked technical and centralist character(12). In effect, in contrast to other legislations, the authorizations are given by administrators. Only the creation of a national Commission of Biosecurity whose character is merely consultive and is composed of representatives of the previously mentioned Ministries (is this double representation?) allows the participation of experts in the matter (final third provision). No participation is foreseen for Environmental Protection groups, for Consumer groups, for professional associations, for Unions, nor for concerned groups. Not only are they not included at the level of the responsible authority to grant the entitlement (as in the case of the majority of the Member States) but they are also denied participation at the level of a consultive Biosecurity Commission that is not linked in any way to the administration. It is surprising in this

sense the statement of the Socialist Party representative in the parliamentary debate who, in front of the opposition's request to create a Biosecurity Commission more representative of the distinct sectors, responded by saying, "any attempt to plan that Unions, professional ecologists, and citizen associations be represented could provoke a series of differences, in principle already begun by trying to know who the citizen associations are to a sufficient degree and by trying to agree on who is going to determine this fact knowing that there are hundreds of groups in our country."

In contrast to other European legislatures, the Spanish one has not assured "the right to information" to its citizens(13). On the contrary, it clearly establishes in Article 23 the confidentiality of information. It is foreseeable that industrial secrets will be systematically invoked by the Ministry of Industry in order to limit information. We know about the debates that have occurred in other Parliamentary discussions, about the conflict between the "right to information" and "industrial secrets." We find there is a germ of conflict between two distinct interests (the protection of the environment and health, on the one hand, and industrial protection on the other). The lack of agreement between Spain's position and that of the other Member States in this regard is considerable. In Germany, they call for a public referendum every time a voluntary liberation is to be authorized. Holland places a notice in a local newspaper every time a party wants to disseminate GMOs. The public is therefore informed about the characteristics of the GMO and the place that the dissemination will take place before the Administration makes a decision. Every person in Holland can object and, if the Ministry of Environment considers it necessary, they can turn the decision over to a public referendum. The United Kingdom is also marked by the availability of information to the public and also demands a detailed report and various

publications in local newspapers. In the United Kingdom parliamentary debate took place about the issue in which 122 Non-Governmental Organizations (NGO) participated (Greenpeace, World Wide Fund for Nature, Soil Association, Friends of the Earth, Pesticides Trust, Women's Environmental Network, Farm and Food Society, Green Alliance, Parents for Safe Food, etc.). In Article 6 II, French legislation provides for the publication of the petition to liberate GMOs in the region where the dissemination will take place.

The Danish case is quite significant. It was the first country in the world to legislate on this question. Since 1986, a law has established the prohibition(14) of dissemination and complete availability of information to the public in the cases of confined usage. Before the Danish Ministry of Environment confers authorization, it sends information not only to the authorities but also to 20 NGOs (Consumer associations, Unions, religious groups, and ecologists(15)). In this way we see different handlings of the same question.

Two items deserve special attention; firstly, the system for responsibility and secondly, the system of sanctions established by the normative. Considering that liberating GMOs could endanger people, goods, environment, and public health it is a fundamental interest to establish a system of responsibility and sanctions that are in harmony with the values defended by the norm. With regard to penal responsibility, Spanish law is much less coercive than other legislations. If we look at French legislation, chapter IV of title III calls for penal sanctions of up to one year in prison for those who perform GMO dissemination without the proper authorization. Spanish law calls for the closing of the installations where the infraction was committed and the prohibition of the commercialization of the product (Article 27,C). The French legislation also authorizes the court to demand the publication of the judicial decision in order to

inform the public. Everything indicates that the treatment of this type of product will be submitted to "objective responsibility or responsibility without guilt." It would have been more prudent to establish a system of obligatory safeguards in order to guarantee the compensation of any eventual damage. Spanish legislation does not contemplate this hypothesis and everything leads us to believe that the debate does not touch on the subject.

If the Spanish law appears to preoccupy itself particularly with the protagonism of the administrators when it comes to establishing the system of responsibility of the administration, silence is absolute. There is not a single provision regarding administrative responsibility in the entire project. In the case of authorizations that produce damage, legal provisions remain to be drawn up.

In this way Spain seems to have opted for a vague legislation and, in the end, it is not very protective of the environment or of public health. The role played by the Secretary of Environment was diminished upon the introduction of various Ministries into the authorization committee. The law regularly defers to the regulatory power. This activity of the executive could produce a diversification of the authorizations attributing authority to Agriculture for food organisms, to Industry for industrial markets, etc., diminishing in this way the possibility of control.

The mandate of the Directives is clear. It tries to make the States responsible for safeguarding and adopting all adequate measures in order to avoid negative consequences on human health and the environment that could be derived from the utilization, liberation, and commercialization of GMOs. It is less clear how to deal with determining levels of acceptable risk, the way to evaluate risk, or the specifications of the analyses of the social impact of these techniques. These elements come more from the interaction

between different national and international social agents than from the text of the Directive.

As is the habit in legislative practice, the Directives tend to be written in a general way leaving the different Member States considerable margin for maneuvering in the national implementation. The Spanish law maintains practically the same degree of generality as do the Directives; the specifics in many cases are postponed to future regulation (Article 6.4, 7.1, 20.1, for example). If we consider the hegemonic presence of the administration, not only in the authorization process but also in that of information and control we could affirm that the risks related to the GMOs are perceived not as purely scientific but as "administrative" in the sense that the administration presents itself as being self-sufficient in the evaluation of those risks. The Spanish law does not call for participation of civil society, and experts and scientists have only a secondary role of counseling the administration.

There are no strict sanctions as are established by the French legislation; nor is there public participation as there is in Germany; nor maximum transparency of information as called for by Danish legislation; nor debate over the responsibility for ecological damage as took place in the United Kingdom; nor does the Spanish law include the scientific excellence included by the Dutch Commission. The Spanish text subtly avoids these themes.

As Hermitte says, "On a political level the arbitration has been very clear. Brussels created the initial obligation. Denmark, Germany, and Holland have opted for great prudence; the United Kingdom for transparency; and France for the science of the elites and for illustrative despotism.(16)" Spain for its part is left with a taste in its mouth of not having known how to or of not being able to elaborate an original doctrine.

NOTES

1. About the general theme of the complexity of the interdependence between live organisms and the ecosystems see: Nazli Choucri (Ed.), *Global Accord: Environmental Challenges and International Responses*, MIT Press, 1993.
2. COM (86) 573 in fine.
3. The terms dissemination and voluntary liberation are used interchangeably in the text to mean any situation where GMOs are exposed or are circulated freely without physical or chemical barriers that limit their actions.
4. 90/219/CEE, Directive of the Council of the 23rd of April of 1990, related to the confined usage of genetically modified microorganisms.
90/220/CEE, Directive of the Council of the 23rd of April of 1990, on the intentional liberation into the environment of GMOs.
both are published in the Official Journal of the European Union on the 8th of May of 1990 (L 117).
5. Recall that the "principle of prudence or of precaution" arose at the Stockholm Conference and was applied for the first time at the Vienna Convention on the protection of the ozone layer (1985). The Maastricht Treaty incorporated it in Article 130 and the International Conference of Rio de Janeiro made a central issue of it.
6. The flexibility and at times the deregulation proffered by the successive Reagan and Bush governments (nothing indicates that Clinton will change perspective) is officially legitimated by the concept of "previously gained experience." This implies that one obtains a certain familiarity with an organism and that familiarity permits examinations that are

progressively less rigorous. The North American system is based on vertical control and the decentralization of vigilance appears as a principle.

7. The law 15/1994 that establishes the judicial system for confined usage, voluntary liberation and commercialization of GMOs in order to prevent risks to human health and to the environment, official Bulletin of the State no. 133, 4th of June of 1994 pages 17781-17788.

8. It is exclusively the responsibility of the State to confer authorization for commercialization of the GMO as well as the authorization for confined usage and voluntary liberation when the objective is the possible incorporation into human or veterinary medications (Article 30, 2 a) or in those assumed to be derived from the law of Fomento y Coordinación de la Investigación Científica y Técnica.

9. Whose secretariate is insured by the Ministry of Environment together with that of Investigation.

10. The secretariate responsibility to the Ministry of Environment and to the Ministry of Agriculture.

11. Article 3.

12. If we look at the German law we will see that it is not possible to authorize a dissemination without consulting the authorities of the Lander in which the dissemination will take place.

13. French legislation specifically considers this right in Article 12.

14. Evidently this law was revised in 1991 in order to adapt it to the European Union Directives.

15. Recall that the first notification of dissemination was carried out by the Ministry of Environment to the Parliament in order to "assist the debate and assure a visible public scrutiny and testify the good will of the industries and public powers."

16. M.-A., et Noiville, Ch., "la dissémination volontaire d'organismes génétiquement modifiés dans l'environnement: une première application du principe de prudence", Revue Juridique de l'Environnement, n° 3, Limoges, 1993, p 401.