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SPAIN

TRANSPOSING AN EC REGULATION THROUGH NEGOTIATION

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'GMO Releases: Managing Uncertainty about Biosafety'

A study of the implementation of EC Directive 90/220

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**Assessment of the Ethical and Socio-economic Effects and
Technological Risks from Biotechnology**

OVERVIEW

The law enacted by Spanish parliament on the use and release of GMOs barely does more than transpose the content of the EC Directives 90/219 and 90/220. The Spanish Competent Authority has not yet succeeded in getting a decree enacted to authorise the establishment of an official National Biosafety Commission. There is a provisional Commission that acts as if it were official and that is pressing for a legal framework and a budget to make it easier for its members to perform their work. So far the members of the provisional Commission have proved to be more concerned with avoiding dissent than with encouraging debate, whether scientific or social. They have concentrated their efforts on meeting their internationally-agreed obligations without provoking disputes rather than on striving to position Spain at the centre of the debate on the uncertainties arising from biotechnology development. Technical experts and scientists have worked steadily towards reaching an agreement in an area which still lacks the economic influence to be considered a valuable contribution to scientific and economic matters in Spain.

Scientific awareness of the risks

Among the international scientific community, concern had been expressed about the uncertainties raised by biotechnology research since the Asilomar Conference in 1975. Spanish scientists began to share this concern in the 1980s, a period of economic recovery when government initiatives and much-needed subsidies revived scientific activity and allowed at least some progress to be made, albeit limited by the modest human resources then available. At that time, the fields of biomedicine and general biology had a relatively influential scientific community compared with other areas (Camí *et al.*, 1993), mainly because good relations with the most important international centres for scientific development had led to the emergence in Spain of a strong community of biochemists and later to the introduction of molecular biology (Santesmases and Muñoz, 1995).

The awareness shown by this small but influential group of scientists (biochemists and molecular biologists), in the forefront of their fields, and with close connections to the political and scientific authorities, together with the ambitions of successive governments from the transition to democracy to the present day, succeeded in forging a place for biotechnology among the priorities of the newly-established Spanish science policy. Biotechnology was included as a priority in the Science and Technical Research Mobilising Programmes (*Programas Movilizadores de Investigación Científica y Técnica*), promoted by the Science and Technical Research Advisory Commission (*Comisión Asesora de Investigación Científica y Técnica* - CAICYT), and in the special programmes which were established prior to the implementation of the Science Law.

The Science Law, passed in 1986, deals with the setting up of the National Science Research and Technological Development Plan (*Plan Nacional de Investigación Científica y Desarrollo Tecnológico*). This plan, which was established in 1988 with the public intervention of the President of the Government (Mr Felipe González), includes a National Biotechnology Plan (*Plan Nacional de Biotecnología*) that has been implemented over the last decade.

Priority was also given to research in areas closely related to biotechnology, such as the public perception of biotechnology (Moreno *et al.* 1990, 1992; Luján and Moreno, 1994)

and the analysis of uncertainties about biotechnological research. An informal group was set up within the administrative and management structure established to implement the National Science Research and Development Plan to discuss and explore such issues. The group was composed of a small number of interested scientists, capable of generating data and ideas and of following the Brussels discussions about biotechnology which gave rise to Directives 90/219 and 90/220 (Borrillo, 1994a, 1994c).

This group of scientists was responsible for drawing attention to the risks posed by biotechnological research, amid a political context of Spain's entry to the EC (1985), which had increased the interest of Spanish people in all the EC's activities. However, the group's view about the risks was not generally held among scientists specialised in biotechnology. One reason is that these were still early days for biotechnology in Spain; the Spanish Biotechnology Society (*Sociedad Española de Biotecnología* - SEBIOT) was not founded until 1989. Another is that Spanish scientists were neither accustomed to using their influence as a group nor to expressing their interests or concerns in public.

Thus a few key scientists, together with the science policy authorities, took a lead in making Spain aware of biosafety issues. The report on biotechnology published by the OECD (1996) had an important influence on their thinking. In 1985, planning began for a research centre devoted to biotechnology, the National Biotechnology Centre (*Centro Nacional de Biotecnología*). This centre was initially housed in accommodation borrowed from the Institute of the Soil Science of CSIC, until the completion of a purpose-built installation (with P-3 laboratories) was completed on the campus of the Autonomous University of Madrid in 1992 after delays of a bureaucratic, political and scientific nature.

In 1993, an ambitious Animal Health Research Centre (*Centro de Investigación en Sanidad Animal*), under the auspices of the Ministry of Agriculture, Fishing and Food (*Ministerio de Agricultura, Pesca y Alimentación*) was inaugurated in Valdeolmos, also in Madrid. This is a high security biological centre (with P-4 laboratories), carrying out research on molecular virology and biology, immunology, pathology and the diagnosis of exotic diseases, as well as environmental toxicology. This research interest on the part of the Ministry of Agriculture developed from a research tradition in agrarian and cattle science. So far, this centre has not been involved in research on GMOs for deliberate release.

Regulating biotechnology

Until this centre was established under the Ministry of Agriculture, it was the Ministry of Education and Science (*Ministerio de Educación y Ciencia*) that had been chiefly responsible for promoting the development of biotechnology in Spain. However, responsibility for Spanish environmental policy is assigned to the Ministry of Public Works, Transport and Environment (*Ministerio de Obras Públicas, Transporte y Medio Ambiente*), hence this ministry became involved in the regulation of biotechnology and represented the Spanish position during the Brussels discussions on the draft Directives 90/219 and 90/220 in the 1980s.

Environmental issues and environmental policy are of far less importance to government than public works and transport policy. Environment's position in the hierarchy is as a directorate general dependent on the Secretary of State (*Secretaría de Estado*), originally for Water and Environmental Policies (*Políticas de Aguas y Medio Ambiente*) and today for Environment and Housing (*Medio Ambiente y Vivienda*). The most pressing environmental

concerns are those related to drought and water. Spanish concern for the environment, unlike that of more developed Northern European countries, gives little attention to the risks of biotechnology. Differences in economic development and in climate help explain the differences in environmental concern between Spain and its geographic neighbours.

There has been little public debate in Spain on the economic, environmental and social impacts of biotechnology research and genetically modified products. There are three factors that might help explain this situation, although they do not offer a complete explanation: (i) GMO releases are a recent phenomenon, (ii) the environmental groups have not yet turned their attention to biotechnology and genetic engineering issues, and (iii) the ecologist community is small and weak compared with other disciplines such as biochemistry and molecular biology.

It is within this framework of political, social and economic priorities that the group of experts tried to bring Spain to terms with the complex issue central to the social debate in other European countries, that is, the uncertainty about the risks of the use and release of GMOs. The contact maintained during the 1980s between the group of experts responsible for Spanish science policy and the environmental policy-makers in charge of implementing Directives 90/219 and 90/220 in Spain meant that administrators and experts specialised in biosafety were available to form a provisional National Biosafety Commission (*Comisión Nacional de Bioseguridad*) and to seek the institutional consensus necessary for Spain's participation in this field.

Contained use of GMOs was already a topic of discussion among the group of key scientists involved with biotechnology policy, in connection with laboratory work in Spain, but concern with deliberate release arose only as a result of the need to implement Directive 220/90. The drafting of the law was seen as merely a technical and administrative task; the political issues which had arisen in other countries were ignored, even by the environmental movement. This context influenced the later evolution of the parliamentary stage of the Spanish law, since there was no advisory agency to inform parliamentarians on matters related to science and technology. As a result, the parliamentary debate had scarcely any public impact.

Two proposed amendments to the introduction of the articles of the law are worth noting here: one on citizens' rights to any information on GMO releases (proposed by *Partido Popular*) and the other on the participation in the National Biosafety Commission of NGOs such as consumer associations and trade unions (proposed by *Izquierda Unida*). Both amendments were rejected, because of political pacts made by the Spanish government rather than because of the content of the amendments. Since the Spanish Socialist Party (*Partido Socialista Obrero Español*, PSOE) lost its absolute majority, it has been obliged to rely on the support (constantly under negotiation) of nationalist parliamentary groups in order to perform its legislative tasks. Consequently an amendment proposed by these groups on extending some of the responsibilities for GMO regulation to regional governments (*Comunidades Autónomas*) was accepted. Although few regional governments had requested authority to regulate GMO releases, this extension could be justified by the constitutional mandate to transfer responsibility for environmental matters to regional governments. Thus in the Spanish law there are now two levels of responsibility for GMO regulation: (i) the General State Administration for the deliberate release and commercialisation of GMOs, and (ii) regional governments for contained use and deliberate releases for research purpose.

Implementing the legislation

It took almost four years for Spain to adopt the Directive. The delay may be a consequence of the low priority given to biosafety in relation to environmental issues, since the Spanish law is not so complex or innovative as to warrant long preparation.

The new law has established that the Competent Authority will take the form of a joint body, including representatives from the following ministries: Health and Consumption (*Sanidad y Consumo*); Public Works, Transport and Environment; Agriculture, Fishing and Food; Industry and Energy (*Industria y Energía*); and Education and Science (*Educación y Ciencia*). The Competent Authority, according to the draft royal decree which should definitively authorise its functioning, will be chaired by the Director General of Environmental Policy (Ministry of Public Works, Transport and Environment) and will have a secretary, who will be a civil servant from the same directorate.

The provisional National Biosafety Commission has been acting as the Competent Authority, by providing reports, resolving conflicts among different bodies of the General State Administration, and supporting the work of the Director General of Environmental Policy.

Between 20 December 1992 and 5 April 1995, the Competent Authority received 23 official applications relating to the deliberate releases of GMOs. Most (18) had been approved by August 1995, and the remaining five were being processed. The applications involved 11 companies and two publicly funded research and development centres. Ten of the companies belong to the agricultural sector (direct production or services) and the other one to the forestry sector. Most of the deliberate releases of GMOs that have taken place involve genetically modified seeds, mainly of tomatoes, maize, sunflower and sugar beet. The predominance of foreign companies among the applicants is noticeable. Examples include Plant Genetic Systems (Belgium), Pioneer and Monsanto (USA) and Van der Have (Netherlands) (see Appendix IV for further information).