

SEMINAR REPORT
'BIOSAFETY: A LEGAL FRAMEWORK FOR CHILE'
19-21 March 2002
Law Faculty, University of Chile

Tuesday, 19 March 2002

1. OPENING OF THE SEMINAR

- 1.1 The seminar on *Biosafety: Developing a Legal and Institutional Framework for Chile* was held at the Law Faculty of the University of Chile, on 19-21 March 2002.
- 1.2 The seminar was attended by 68 participants, including representatives from various governmental departments, public services, non-governmental organisations, private sector, researchers and scientists. Annex 2 of this report contains the list of participants.
- 1.3 The seminar was organised by the *Centro de Derecho Ambiental* (Environmental Law Centre) (CDA) of University of Chile, and the Foundation for International Environmental Law and Development (FIELD) with the support of the *Servicio Agrícola y Ganadero* (Agriculture and Livestock Service) (SAG) and Chile's *Comisión Nacional del Medio Ambiente* (National Environmental Commission) (CONAMA).

Official opening

- 1.4 The seminar was officially opened by the Dean of the Law Faculty of the University of Chile, Mr Antonio Bascuñán Valdés, who welcomed the participants and thanked the CDA and FIELD for organising it. The Dean expressed his gratitude to the donor institutions which funded the organisation of the seminar: the 'Darwin Initiative for the Survival of Species' of the UK Department for Environment, Food and Rural Affairs (DEFRA) and the *Departamento de Investigación y Desarrollo* (Department of Research and Development) of the University of Chile.
- 1.5 The Director of the CDA, Mr Sergio Montenegro Arriagada, introduced the two co-ordinators of the project and acted as moderator of the seminar sessions held on Tuesday March 19th.

Welcome and introduction to the seminar

- 1.6 The co-ordinator of the project at the CDA, Ms Dominique Hervé Espejo, introduced the seminar in the context of the research project 'Developing a Legal and Institutional Framework for Chile' funded by the Darwin Initiative, and undertaken in partnership with FIELD. She also explained the different phases of the project and the relevance of the seminar to achieve the project objectives.

1.7 The co-ordinator of the project at FIELD, Ms Carolina Lasén Diaz, emphasised that one of the main objectives of the seminar was to bring together the various sectors and parties interested on biosafety in Chile in order to discuss the draft project research papers and different countries' experiences so as to identify key points which a future Chilean regime on biosafety could take into account. The structure of the seminar was also explained to the participants, i.e. a series of presentations and debates on the first two days followed by working group sessions on the third and last day.

Introduction to the agenda and materials of the seminar

1.8 Carolina Lasén apologised on behalf of Ms Ruth Mackenzie, Director of FIELD's Biodiversity Programme, as she had been unable to travel to Chile. She highlighted the only change to the seminar agenda: Ms Lasén's replacing Ms Mackenzie in the first presentation of the day on the Cartagena Protocol on Biosafety.

1.9 The seminar materials were given to participants in a folder which included copies of the current legal situation on biosafety in Chile, as well as five case studies on comparative law and a summary note on the Cartagena Protocol on Biosafety. These documents were presented as drafts on which the participants were asked to comment. The folder also included copies of the full text of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety.

1.10 In the introduction to the seminar materials, an additional reference was made to a current IUCN/FIELD project preparing an Explanatory Guide to the Cartagena Protocol on Biosafety which is at the drafting stage. A copy of the most recent version of the draft Guide was made available to seminar participants for information.

2. INTERNATIONAL AND CHILE'S CONTEXT ON BIOSAFETY

2.1 Carolina Lasén, staff lawyer at FIELD, presented the international context of Chile's obligations as Party to the Cartagena Protocol on Biosafety. The presentation on the Protocol covered the relationship between this new instrument and the Convention on Biological Diversity, its negotiating process and current status, as well as the main obligations for its Parties after it enters into force. In particular, the presentation focused on the advance informed agreement (AIA) procedure which is required prior to the first movement of living modified organisms (LMOs), and on the procedure covering LMOs destined for direct use as food, feed or for processing (LMOs-FFPs). Ms Lasén also covered the role and functioning of the Biosafety Clearing House Mechanism established by the Cartagena Protocol.

2.2 Following this presentation a debate took place between the participants and a panel formed by Carolina Lasén and the two foreign experts invited

to the seminar, Ms Amanda Gálvez Ph.D., lecturer at the Faculty of Chemistry at the *Universidad Nacional Autónoma* of Mexico, and Ingrid Noeh, Director of the Department on Biosafety and Risk Assessment of the Federal Environmental Agency in Germany, both of whom were members of the Mexican and German delegations, respectively, to the negotiations of the Cartagena Protocol. The debate with the seminar participants revolved around the negotiations of the Protocol and Chile's role in them as member of the so-called 'Miami Group'.

- 2.3 Ms Dominique Hervé, lawyer and researcher at CDA, explained the current legal and institutional situation in Chile regarding biosafety, stressing the existing fragmentation between the different government departments (agriculture, fisheries, economy, foreign affairs, health), the private sector, the academic and scientific community, and civil society. The conclusions reached by Ms Hervé demonstrated the need to establish a policy on this issue in Chile, with appropriate principles and objectives to facilitate co-ordination and ensure the coherence of the work of the different institutions. A clear and well co-ordinated policy would set the basis for the legislative framework needed in its implementation. Dominique Hervé also stressed the need to address biosafety in a holistic manner and not from a sectorial or fragmented point of view, which is the current situation in Chile, both at the legal and institutional level.
- 2.4 After this presentation, the discussion focused on the lack of co-ordination and the contradictions of the current situation in Chile, in the absence of a clear biosafety policy. The participants welcomed the project's research and framework as being an area where there is little information in Chile on policy developments both at the national and international level.
- 2.5 The seminar participants gave their views on the different aspects related to biosafety and biotechnology in Chile, such as the role of consumer organisations and recent lawsuits related to risks to human health posed by GMOs; Chilean research on GMOs; the consequences of the use of GMOs in agriculture; the context of Chile's biodiversity; and problems resulting from GMO contamination.

Wednesday, 20 March 2002

3. REGIONAL LEGAL FRAMEWORKS

- 3.1 This session was chaired by Professor Raul Brañes, founding president of the *Asociación Latinoamericana de Derecho Ambiental* (Latin American Association of Environmental Law), legal consultant and regional expert.
- 3.2 Carolina Lasén Díaz (FIELD) introduced the European Union's (EU) legal framework on biosafety, covering its overarching principles, scope of application of existing legislation and relevant biosafety institutional framework. Ms Lasén focused her presentation on the regulated activities

and the authorisation procedures for the different GMOs. Moreover, reference was made to the new EU legislative proposals pertaining to labelling and traceability of GMOs. The presentation finished with the issue of the current 'de facto' moratorium on new authorisations for the commercialisation of GMOs in the EU.

- 3.3 Manuel Ruiz Muller, Director of the Programme on International Affairs and Biodiversity of the *Sociedad Peruana de Derecho Ambiental* (Peruvian Society of Environmental Law), presented the Regional Biodiversity Strategy of the Andean Community and the programmes addressed in its Action Plan on biosafety. Mr Ruiz also summarised the current legal developments on biosafety in the five countries of the Andean Community (Bolivia, Colombia, Ecuador, Peru and Venezuela), which have incipient biotechnological capacities but do not make commercial use of GMOs.
- 3.4 After the presentations on regional biosafety frameworks addressed, amongst other issues, the implementation of the precautionary principle, the entry of GMOs as food aid in the Andean Community countries and the possibility of contamination of centres of origin, the level of participation of civil society in the drafting of the Regional Biodiversity Framework in the Andean Community and the relationship between biosafety and access to genetic resources as a result of germplasm being sent from developing to developed countries for its improvement.

4. EXAMPLES OF NATIONAL LEGAL FRAMEWORKS ON BIOSAFETY

- 4.1 Brazil - The first study of national comparative law was presented by CDA's researcher Valentina Durán, who introduced Brazil's regulation on biosafety, being the richest country in biodiversity and the second largest world producer of conventional soya. Ms Durán, a lawyer at CDA, underlined the different positions of the public sector and the debate in Brazilian society, concluding that Brazil has abundant legislation on the matter compared to its surrounding countries, although the recent legal actions brought to courts and the conflicts between the various interested sectors remain unresolved.
- 4.2 Cuba – Ms Marcela Main, lawyer at Chile's National Commission on the Environment (CONAMA), introduced the case study on Cuba's legal and institutional biosafety framework. Ms Main's presentation started with the objective of the country's National Biodiversity Strategy in relation to the development of an ethical and environmental biotechnology in Cuba. The presentation went on to address the Legislative Decree 190/99 on biosafety and the licensing mechanism to develop GMO activities in contained use as well as their release into the environment, including the import and export of these organisms and their derivatives.
- 4.3 Argentina - Dominique Hervé (CDA) focused on the scope of the Argentinean system on biosafety and its institutional framework, given

that this country is one of the major world producers of GM crops. The regulatory system in Argentina on this issue only applies to the farming sector and there is no general regime on the safety of biotechnology or biosafety. Ms Hervé summarised the different authorisation procedures pertaining to GMOs, covering the testing of GMOs, their release, the flexibility of the conditions of permits for research and release already obtained, and the permit for commercialisation. The latter requires the need to analyse whether it is appropriate or not to introduce the product in the market, and not just to examine its environmental impacts. Ms Hervé stressed the aim of the Argentinean regulatory framework, which is to allow for the implementation of the country's option to promote modern biotechnology in the agricultural sector.

- 4.4 New Zealand - Carolina Lasén (FIELD) continued the session on comparative law and presented New Zealand's biosafety regime. The legislative framework of this country, a law from 1996, is currently under review in light of the report issued by an independent Royal Commission set up by the New Zealand government. In this context, a voluntary moratorium was agreed with the industry for new authorisations during the work of the Royal Commission. While the government is implementing most of the legislative and institutional reforms recommended by the Royal Commission, the moratorium has subsequently been extended until October 2003. A crucial feature of the biosafety policy of this country is the wide consultations undertaken in its review and the high level of public participation in the decision making on issues related to GMOs.
- 4.5 Professor Raul Brañes closed the session by giving examples of national frameworks while putting forward a number of proposals and recommendations for the national biosafety laws of Latin American countries. Mr Brañes stressed the importance of the need to regulate the uncertainties surrounding biosafety and the opportunities given by biotechnology taking into account the rich biodiversity of the region and the importance of its farming practices, in particular in the context of the Chilean case. Furthermore, he noted that the existing national legislative systems in the region can be divided into two types: those with a 'traditional' legislation on the introduction of exotic species and traditional biotechnology focusing mainly in the agriculture sector, and those with specific legislation on the safety of modern biotechnology, which is the case of Brazil, Cuba and Peru. Mr Brañes finally made a number of recommendations on policy, legislation and administration as regards biosafety, as well as on other related areas such as regional biosafety systems, international co-operation and public participation.
- 4.6 The round of questions and debate touched upon the issues of national regimes on labelling and traceability and the existing differences between countries and its consequences on international trade. Seminar participants made remarks on the labelling of nutritional aspects of certain food products and the implementation of the criteria on 'substantial equivalence'. The issue of traceability and product

differentiation was also addressed in the debate in relation to good agricultural practices and the monitoring of these products. Furthermore, questions on the practice and cost of the segregation between GMOs and non-GMOs and their derivatives, as well as questions on producers liability, in relation with the marketing of their products, were raised.

5. TECHNICAL AND SCIENTIFIC ASPECTS RELATED TO BIOSAFETY

5.1 Ms Amanda Gálvez Ph.D, from Mexico's *Universidad Nacional Autónoma*, talked about the division between the legal and the scientific regime on biosafety in Mexico (a megadiverse country where 25% of the population work in agriculture and which has the highest diversity of corn in the world). Dr Gálvez pointed out the advantages of environmentally friendly biotechnologies for the increase of agricultural production and the need not to halt the advancements of science. After outlining the Mexican biosafety legal framework, she concluded that it is necessary to undertake multidisciplinary assessments with independent funding within a framework of transparency and participation in the decision-making. Moreover, Dr Gálvez emphasised the need to do assessments that take into consideration the impacts of GMOs in global biodiversity and socio-economic factors, which would require broader assessments than the usual and take account of the possible long term effects.

5.2 Following this, Ingrid Noeh, Director of the Biosafety and Risk Assessment Department of the German Federal Environmental Agency, presented the German experience on risk evaluation, including that on GMOs and biosafety. Mrs. Noeh explained the German case within the regulatory framework of the EU and focused in the evaluation of environmental risks regarding biosafety and the role of the precautionary principle. The German procedure of risk assessment is currently under review due to the new EC Directive on GMOs which will be soon entering into force. To conclude, Mrs. Noeh complemented her presentation with the example of the risk evaluation of the Bt corn in Germany which resulted, in line with the precautionary principle, in not granting authorisation for commercialisation of a specific GM corn variety due to the possible adverse effects in non-targeted organisms and antibiotic resistance.

5.3 The debate after the presentations revolved around the problem of illegal traffic of GMOs which can reach very high volumes of seeds being traded. Some participants noted the challenges which organic farmers are currently facing and the need to conduct case studies for certain types of products, such as those claiming to have homeopathic, nutritional or environmental properties. While the need to take into account socio-economic factors was also stressed by some participants, others mentioned the importance of the right to health and the necessary protection of consumers, in particular as regards allergies as many effects

are still unknown, which, in turn, is related to the labelling of products derived from GMOs.

6. THE CASE OF CHILE'S BIODIVERSITY AND USE OF MODERN BIOTECHNOLOGY

- 6.1 Ms Mary Kalin Ph.D, Director of the Millennium Centre for Advanced Studies in Ecology and Research in Biodiversity of the University of Chile, presented the situation in Chile where there is a very high level of endemism, higher than in Brazil, and is especially so in the central regions where less than 5% of the territory is protected. In addition to this, Dr Kalin showed the high number of exotic species introduced in Chile and the problems they cause, weeds in particular, as well as the direct and indirect effects of their spread.
- 6.2 Mary Kalin indicated several elements that need to be taken into account in a future national strategy on GMOs, including the need to accept the existence of unknown environmental risks and establish an acceptable level of risk taking into account scientific, economic, social and environmental factors, as well as the necessary endorsement of the precautionary principle. She also stressed the importance of conducting and monitoring field tests of GMOs in accordance with the life cycle of the plants or organisms. Moreover, the possible problems resulting from GM trees and related Chilean industry, for which long term field tests should be undertaken before commercialisation, was also addressed. Dr Kalin finished her presentation by referring to the need to consider, at national level, the option of not having GMOs or, at a global level, not having GMOs in those regions rich in biodiversity such as Chile's region XI.
- 6.3 Romilio Espejo, from the *Instituto de Nutrición y Tecnología de los Alimentos* (INTA) (Institute of Nutrition and Food Technology), University of Chile, presented the situation related to the use of GMOs in research and commercialisation in Chile. The former, consists mainly of genetically modified micro-organisms used and contained in laboratories under the commitment of following a series of non binding good practices based on international standards. However, there is no control over the elements of risk containment. About 300 laboratories in Chile systematically produce genetically modified bacteria and yeast, but in the case of transgenic plants less than 10 laboratories have the necessary technology. Regarding the capacity of Chilean laboratories to detect GMOs, very few of them have the necessary technology which proves that there is a real lack of resources for the eventual compulsory labelling of GM products. On the other hand, there has not been any official release of GMOs in Chile, although it is neighbour to the second largest producer of GM crop varieties, Argentina.
- 6.4 The seminar participants were very interested in the information given in this session and the related the lack of knowledge in the country about the use of modern biotechnology. The debate reflected a number of

issues of interest to the participants which included human health considerations, the high level of malnourishment and tuberculosis in the country, and the potential problem of resistance to antibiotics. Other issues of interest were the need to study the biodiversity of the marine species, as only 10-15% are known, which reflected the lack of taxonomists and how crucial they are to distinguish between native and exotic species. In addition to all this, the lack of information on exotic marine species was reminded as well as that there are about 700 exotic species of terrestrial plants in Chile. Generally, the issues of lack of funding for research, as well as the need to apply the precautionary principle were raised. The current negotiations on a trade agreement between Chile and the EU were also pointed out as this agreement will have the effect on Chile's private sector of having to comply with EU's requirements for the import and commercialisation of products derived from GMOs, including their labelling.

Thursday, 21 March 2002

7. WORKING GROUP SESSIONS

- 7.1 The organisation of the work of the seminar moved on from plenary sessions to two working groups. The first working group focused on the debate on the technical and scientific issues related to the risk assessments of GMOs and capacity building needs in Chile. The second working group discussed the legal and institutional needs to develop a biosafety framework in Chile.
- 7.2 After the discussion in the working groups, the participants that acted as rapporteurs for each group presented their conclusions to the plenary.
- 7.3 The first working group did not have enough time to agree on specific recommendations but their deliberations focused on the identification of possible types of GMOs in Chile and their related potential risks. These risks can derive from: the cultivation of seeds and derived food products; the production of genetically modified trees; genetically modified weeds which could hybridise with other crops; and fish farming of GM shellfish and fish. All these organisms result in risks to biodiversity and human health, risks to the environment in general (water and soil) and socio-economic risks to small breeders, farmers and fishermen. The need for raising awareness among the scientific and the academic communities, as well as the private sector, was brought up by this working group. The UNEP/GEF project to develop a national biosafety framework in Chile, co-ordinated by CONAMA, was also debated.
- 7.4 The second working group discussed the current situation and the legal and institutional needs in Chile for the development of a biosafety framework. The recommendations from this group were presented to and accepted by the plenary and included in Annex 1 to this report.

8. CONCLUSION AND CLOSING OF THE SEMINAR

8.1 The project co-ordinators from CDA and FIELD thanked the participants and foreign experts for their active participation in the seminar. They considered the level of participation and discussion during the seminar very satisfactory, and were positive that the main objective of initiating the debate on biosafety and exchanging information and viewpoints at the national level was achieved. Furthermore, they informed the participants of the next stage of the CDA/FIELD project, which is the distribution of the final report and recommendations of the seminar to all participants and competent authorities on the subject.

8.2 Sergio Montenegro, Director of the CDA, described some of the key activities of the Centre on Environmental Law (CDA) and announced the coming publication of an Environmental Law Journal, highlighting that information about the CDA can be found on their website at www.derecho.uchile.cl/cda. After thanking the funding institutions, invited experts, participants and co-ordinators Mr. Montenegro officially closed the seminar at noon on 21 March 2002.

Annex 1

Seminar recommendations

The ten recommendations resulting from the seminar “*Biosafety: A legal framework for Chile*”, held in Santiago, Chile, on 19-21 March 2002, are as follows:

1. To establish a national policy on biosafety.
2. To legislate on biosafety issues at the national level.
3. To overcome the existing fragmented approach to biosafety with legislation that incorporates a multi-disciplinary approach.
4. To take the debate to the Parliament with a commitment from government, the people of Chile and the necessary allocation of funds.
5. To initiate a legislative debate involving all stakeholders.
6. To establish a national legal framework on biosafety as a ‘Law of the Republic’.
7. To legislate with caution (that is, considering the precautionary approach) in the context of extreme positions worldwide.
8. To motivate politicians to give biosafety a high priority and work on this issue looking at the long term.
9. To legislate following the approach that risk assessments must be done on a case by case basis.
10. To make trade and environment compatible.