



## **The report of a delegation of the committee on scientific and technological assessment of Italy's chamber of deputies (vast)**

### **Legislation and research issues at stake in the Italian parliament**

Berne, October 27-28, 2003

*Over 2002 the Chamber of Deputies carried out some important lawmaking processes particularly focussing on the relations between scientific and technologic decisions and humans. On such occasions, in accordance with the rules governing the admittance of qualified civilian experts, discussions bringing together experts from the scientific and academic worlds, leading figures of the civil society, of associationism, non governmental organisations and alike have been experimented in order to reach a fully informed decision and to promote forms of discussions aided by "specialists". Such discussions developed through parliamentary fact-finding activities and hearings in the Committee stage and brought to a number of amendments that individual Members or the same Committees submitted for consideration by the House and that were then passed, so changing the original text written by the Government.*

*The communication focuses on two specific cases concerning the bills on the legal protection of biotechnologies and in vitro fertilisation.*

*The general outline of the method followed a parliamentary trend to develop relations between the Chamber and the scientific world on topics calling for assessment of scientific and technologic decisions; over and above the cases regarding biotechnologies and their relations with humans, it must be kept in mind that the VAST Committee periodically organised Seminars on important scientific topics of current parliamentary importance (five dedicated seminars as from October 2002 to date on technologic innovations and transport, scientific research, aerospace policy, industrial policy for information technology, industrial districts). The results were used, for example, to represent the Chamber at the discussions on the Green Paper on space policy launched by the European Union.*

#### **1. Introduction**

During the current Parliament the Chamber of Deputies has frequently addressed topics related to the relations between humans and the ethical, social, and individual freedom issues concerning people and arising from the utilisation of new technologies or scientific processes.

The most important topics indubitably include the two bills on the legal protection of biotechnologic inventions and medically assisted in vitro fertilisation.

These occasions were an excellent opportunity to assess the inadequacy of the parliamentary fact-finding activities performed on issues where political decisions, more than in any other field, must be taken after thorough, analytical consideration of the questions in hand.

During the law-making process related to these bills, new forms of discussions bringing together experts from the scientific and academic community, leading members of the civil society, of associationism, of non governmental and organisations and trade associations were experimented to acquire the opinions of the scientific world and "civil society" and hence reach a fully informed parliamentary decision.

External contributions were acquired by Parliament by conducting fact-finding activities and hearings in the Committee stage.

These activities are regularly foreseen by the Rules of Procedure of the Chamber and played a crucial role in detailed inquiries on issues where parliamentary discussions and decisions hinged on in-depth knowledge of the scientific matters and of cultural, ethical and social implications.

Some of these contributions and the ideas they triggered off at the end of the fact-finding activities led to a series of amendments that individual Members and the same Committees then submitted for consideration by House; these amendments were passed by the House and so changed the original text of the bill.

All the contributions were made public as all the interventions had been recorded in shorthand: these records are available on the Chamber website in e-format. This reveals the Chamber's commitment to two-way relations with the citizens informing on how parliamentary decisions are reached during the lawmaking process, and on the contributions of "outside" experts.

The method adopted on such occasion follows a parliamentary trend to advance relations between the Chamber and the scientific community on topics calling for the assessment of scientific and technologic processes. In addition to the specific cases that will be described briefly herein, the driving role of the VAST Committee in acquiring the contributions and findings of the scientific community and the worlds of research and production on important political matters related to scientific and technologic issues must be underlined. In the period between October 2002 and October 2003 the VAST Committee periodically organised Seminars on scientific topics of major parliamentary interest, such as technologic innovations and transport, the state of the art of scientific research in Italy, the future of aerospace policy in Italy and Europe, industrial policy for information technology, technologic innovation in industrial districts. All the results provided were entered in the parliamentary records and used on different occasions. For example, thanks to the experts' contribution, the Chamber produced a document on the topics of the Green Paper on space policy set by European Research Commissioner Busquin, and this document was sent to the European Union as the Chamber's contribution to the discussions on European Union space policy.

The two specific cases are described hereinunder.

### **3.2. The bill on the legal protection of biotechnology inventions**

During the consideration of the bill to confer to the Government delegated powers on the legal protection of biotechnologic inventions, which was passed and sent to the Senate where it is currently being considered (A.S. 1745-B), the technical observations made by the scientific community blended efficiently with the lawmaking process at the Chamber.

The bill that enables the Government to acknowledge directive 98/44/EC of June 6, 1998 of the European Parliament and Council on the legal protection of biotechnologic inventions, in conformity with the Court of Justice's decision of October 9th 2001, permits patentability of biologic material, and of production process methods and use of biologic material, provided that it meets with the requirements of the invention.

The main Committees (X Comm. Productive Activities and XII Comm. Social Affairs) conducted fact-finding activities on the legal protection of biotechnologic inventions in order to acquire the necessary information to investigate the bill when reported to the Chamber. On this occasion, leading members of the scientific and academic world, of the institutions involved and of civil and religious associations were heard in order to have a pluralistic representation of the current positions on a topic that is directly related to humans, such as biotechnologies.

The following persons were heard: the representatives of the national Committee for biosecurity and biotechnologies, an advisory body to the Government composed of experts and representatives of the competent Ministries; representatives of the National Research Committee (CNR) (*Consiglio nazionale delle ricerche*); representatives of the industrial and research communities, such as the national Association for development of biotechnologies (Assobiotec) (*Associazione nazionale per lo sviluppo delle biotecnologie*) and the Association of Pharmaceutical Companies (*Farindustria*); representatives of the Italian Society of human genetics (SIGU); leading members of the religious community (CEI) (Italian Episcopal Conference); university professors and experts in the fields of law, economics and legal theory.

The results of the hearings were accompanied by memos, studies and written reports, and led to the presentation of parliamentary amendments (by individual Members or the main Committees), thereafter passed by the House, with changes to the original text presented by the Government.

In particular, some of the amendments passed and directly related to observations made during the hearings concerned some relevant and innovative issues with respect to the contents of EC directive, such as:

- the inclusion in the body of the law of the provision that safeguards previous commitments and international Agreements;
- the necessity to obtain the consent of the person from whom the biologic matter protected by patent has been removed, or on whom it will be used, for removal and for each utilisation;
- the absolute ban of patentability of the human body from conception through the various stages of development, comprising the genic sequence. This is to guarantee that the patent law fully respects the dignity, integrity and basic rights of human beings and the environment. On the contrary, patentability is permitted for elements isolated from the human body and a DNA sequence for protein production;
- exclusion from patent protection of inventions whose commercial use is hazardous for public order, the health and lives of human beings and animals, the conservation of plants and the environment;
- exclusion from the patent protection of cloning technology processes for humans; ban of any use of human embryos, human embryonic stem cells;
- non patentability of inventions regarding genic analysis protocols, the use of which would lead to “discrimination” of humans.

### **3.2 The bill on intravenous medically assisted fertilisation**

The same process was applied to the inquiry regarding the bill on medically assisted in vitro fertilisation (A.C. 47 and annex), the text of which was passed by the Chamber on June 18th, 2002 and is currently being considered by the Senate (A.S 1514).

It is a very significant measure because to date there are no laws regulating this matter and the contents of the bill gave rise to a strong political debate crossing the borders of the majority parties and the opposition and involving the personal positions of individual Members based on cross-party ideals.

The topic of medically assisted in vitro fertilisation was the fruit of an in depth parliamentary debate that took place during the last two governments (1996 – 2001; 2001 to date) and engaged numerous parliamentary activities (oversight and policy-setting guidelines, fact-finding inquiries, hearings, etc.). The main Committees were able to analyse thoroughly the positions of the scientific community, the results of the national Committee for Biosecurity and the different ministerial commissions set up as from 1994, as well as the advances in the law on the matter. During the previous Parliament, within the framework of the inquiry on the numerous bills on the subject, the Committee on Social

Affairs of the Chamber had conducted a fact-finding inquiry to investigate fully the different aspects of the issue, including the ethical, medical scientific and juridical (legal) ones. This inquiry consisted of hearing the opinions of experts, representatives of professional associations, and bodies and organisations with different ethical and religious ideas and the inquiry results were put forward in the report on the unified text of the bill for the Assembly. The text was passed by the Chamber on May 26th, 1999 and sent to the Senate that did not complete its examination. During this Parliament, the XII Committee on Social Affairs of the Chamber started consideration of the new bill and decided to acquire the results of the previous fact-finding inquiry, and to carry out informal hearings aimed at updating the general outline of the subject matter.

Also in this case, in depth scientific investigations were conducted on the areas of interest, and the difficult, and at times controversial, nature of the topic in hand did not gain enough support to smooth out all the political snags, and hence so far the bill has not been passed. In fact, a sufficient majority has not been reached on some of the points and consequently a broad, homogeneous text has not been approved.

The provision passed by the Chamber regulates the activities of in vitro fertilisation and protect the rights of all persons involved “including the unborn child”. Heterosexual married couples or cohabitees, who have reached majority age, are fertile and alive, can be granted access to in vitro fertilisation for problems of sterility or infertility and difficulties in having children that cannot be successfully treated by medical science. So called “heterologous fertilisation” (using male or female gametes not originating from the couple) is forbidden. In vitro fertilisation can only be performed in authorised centres (public and private), after informed written consent is given by both applicants. Each of the two applicants can revoke consent at any time, unless a child has been conceived.

A child born by in vitro fertilisation has the status of a legitimate child, i.e. a recognized natural child. In order to protect children born after heterologous fertilisation – not permitted – the spouse or cohabitee cannot disclaim paternity of the child, if findings reveal his/her consent to the heterologous fertilisation, while the third donor of the gametes is not granted any legal parental relationship with the child and has no rights, nor obligations towards him/her.

Specific regulations protect the embryo and human dignity, therefore the following are prohibited: cloning of humans; commercialisation of gametes; surrogate mothers (rented wombs); production of human embryos for any other reasons than permitted by law; eugenic selection of embryos and gametes; early splitting of the embryo or ectogenesis (development of the embryo outside the body); fertilisation of a human gamete with a gamete of a different species and the production of hybrids or chimeras; experiments using human embryos (their use for clinical research for diagnostic and therapeutic purposes is permitted); cryoconservation (except for the case specified later) or elimination of embryos, whereas cryoconservation of both male and female gametes is permitted.

Depending on the case in question, administrative sanctions and fines can be enforced. It is to be clarified that the parents applying for in vitro fertilisation can be punished only if they provide untruthful declarations to obtain the right to use to in vitro fertilisation.

Sanitary operators are allowed to refuse on grounds of conscientious objection.

## **Conclusions**

The above-mentioned examples show that these topics were addresses by the Chamber by means of lawmaking processes using the contributions of external experts. Moreover, the in depth scientific and cultural investigations on the issues in question were specific to the ordinary lawmaking process, even if the activities engaged (hearings, fact-finding inquiries etc.) are generally at the disposal of the Committees.

This parliamentary approach has become more common for issues of major scientific importance and it also exercise the workings of the VAST Committee. Alongside the normal activities at the disposal of parliamentary Committees, the VAST Committee stimulates and solicits in depth study of scientific issues of political relevance, not only limited to the consideration of specific bills, but at times anticipates or calls for their promulgation and acquires, in any case, relevant investigative contributions.