



Bern, 11 February 2000

REPORT OF ACTIVITIES 1998 / 1999

1. Legal bases

Article 120 of the Federal Constitution (Art. 24^{novies} Federal Constitution) requires the dignity of creation to be respected. For consultation in the implementation and concretisation of this constitutional mandate, the Federal Council appointed the Federal Ethics Committee for Non-human Gene Technology (ECNH) in a decree of 27 April 1998. As part of the draft gene technology bill (Gen-Lex) it is planned to anchor the ECNH as a standing Committee, independent of the administration, in the Law relating to the Protection of the Environment (LPE), and to replace the Federal Council decree with an Ordinance.

2. Mandate

In accordance with the Federal Council mandate, the ECNH observes and evaluates the developments and applications of biotechnology and gene technology in the non-human sector. It issues statements on the questions associated with this from an ethical point of view, particularly in terms of adherence to the basis of respecting the dignity of creation and preserving the safety of humans and the environment, and protecting the genetic diversity of animal and plant species and their sustainable use.

Under its mandate the committee has three tasks. It advises the Federal Council and the subordinate offices from an ethical point of view on the preparation of legislation on non-human biotechnology and may provide the Council with suggestions for future legislation. Furthermore the ECNH advises the federal and cantonal authorities on the enforcement of federal regulations. The ECNH was involved in this procedure according to the new biotechnology ordinances¹, which came into force on 1 November 1999 and which regulate the handling of genetically modified organisms. And finally it informs the public about the questions and topics it addresses, and promotes dialogue about the uses and risks of biotechnology. It may inform the public about its position on individual permit applications, if the permission of the permit authorities has been obtained and the applicant is in agreement.

¹ Ordinance on the release of organisms into the environment (Release Ordinance, RO), Ordinance on the contained use of organisms (Containment Ordinance, CO).

3. Composition of the Committee

At the same time as the Committee was established, the Federal Council selected its members and Chair. According to the decree, the ECNH has a maximum of 12 members, who belong to different professional areas and at least half of whom must be professional ethicists.

The Federal Council has named the following Committee members for the first period of office up to 31 December 2000:

Chair	
Arz de Falco Andrea	Dr. theol., doctor assistant at the Interdisciplinary Institute for Ethics and Human Rights of the University of Fribourg
Members	
Aguet Michel	Prof., M.D., Director, Swiss Institute for Experimental Cancer Research (ISREC)
Halter Hans	Prof. Dr. theol., Professor of Social Ethics at the Institute of Social Ethics at the School of Theology, University of Lucerne
Koechlin Florianne	Biologist, Swiss Working Group on Genetic Engineering SAG, Blueridge Institute (member of the Ethics Committee since 15 March 1999)
Mauron Alex	professeur, docteur en science, Molecular biologist and ethicist, associate professor of bioethics, University of Geneva Medical School
Müller Denis	professeur, docteur en théologie, Professor of Ethics in the Faculty of Theology at the University of Lausanne
Nüesch Jakob	Prof. Dr. sc. techn., prof. em., former President of the Federal Institute of Technology Zurich (ETH)
Rippe Klaus Peter	Dr. phil. I, Philosopher, Management director of the Ethics Centre of the University of Zurich
Simoneschi-Cortesi Chiara	Politician, chair of the Federal Commission for Women's Issues
Sitter-Liver Beat	Prof. Dr. phil. I, Professor of Applied Philosophy at the University of Fribourg, General Secretary of the Swiss Academy of Humanities and Social Sciences (SAHS)
Stückelberger Christoph	PD Dr. theol., Lecturer for Ethics at the Theological Faculty of the University of Basel, Director of the Swiss Aid Agency "Bread for All"
Wagner Pfeifer Beatrice	PD Dr. iur., Lawyer, Lecturer in the Law Faculty of the University of Basel

The Ethics Committee in this form is composed of 7 professional ethicists and 5 representatives from other subject areas (biology, medicine, politics and law). Overall there are 4 women and 8 men.

Scientific ethics is not tied to any single approach. There is a multiplicity of different approaches, which lead to very different accounts of what should be considered ethical, particularly in the field of the manipulation of nature. Therefore a critical look must be brought to the various standpoints, criteria and standards so that decisions can be reached through rational discussion. For this reason, different ethical approaches rather than different interests should be represented in the Committee.

4. Secretariat

The Secretariat is technically subordinate to the Chair of the Committee and administratively to the Swiss Agency for the Environment, Forests and Landscape (SAEFL). Initially the Secretariat was run by Dr Kurt Weisshaupt, SAEFL, in an interim capacity. Since 1 February 1999 it has been run full-time by Ariane Willemsen, lic. iur., MA. The Secretariat supports the Committee Chair and the members in the fulfilment of their tasks, carries out the administrative work of the Committee and arranges contact with other domestic and foreign authorities and Commissions whose areas of interest include biotechnology and gene technology in the non-human sector.

5. Meetings

The Committee commenced its activity on 29 May 1998. In 1998 it met five times, and in 1999 ten times, in Bern. This frequency was necessary because of the many legislative projects in progress in the field of gene technology, but proved to be a great burden in terms of time and work for a part-time Committee.²

6. Statements

Immediately after taking up its work the Ethics Committee concerned itself with putting the Federal Constitution term "dignity of creation" (Art. 120 BV) into concrete form. This constitutional term plays a central role in non-human gene technology.³ The concretisation of the term at the level of laws and ordinances is a substantial task for the ECNH; the term also provides an important foundation for the ethical evaluation of gene technology projects.

Since its appointment the ECNH has delivered six Statements. Five of these concerned draft laws, and one an application for a field trial using genetically modified maize. The Statements of the ECNH do not have to be unanimous. Minority opinions are registered as such. It has however been found that despite different ethical approaches towards concrete questions, a consensus could often be found.

² The meetings took place on 29 May, 19 June, 25 August, 4 November and 15 December. In 1999 the meetings were held on 27 January, 10 February, 17 March, 6 May, 25 June, 13 August, 24 August, 25 September, 4 November and 9 December.

³ In the French version of the new Federal Constitution, the term "la dignité de la créature" has been replaced by "l'intégrité des organismes vivants". The Ethics Committee has expressed in a Statement for the Federal Office of Justice, that it is not in agreement with the change of the term, either for formal, or for substantial reasons.

In addition to answering the questions of private individuals and institutions, the Committee has delivered the following Statements since its inception:

1998

- Statement on the consultation document on the draft gene technology bill of 5 September 1998

1999

Advice on legislation:

- Statement on the draft gene technology bill, federal agency consultation, of 1 March 1999
- Statement on the Biotechnology Ordinances, federal agency consultation, of 1 March 1999
- Statement on the draft gene technology bill, 2nd federal agency consultation, of 19 August 1999
- Statement on the dignity of creation in animals, concretisation as part of the revision of the Animal Protection Law, of 17 November 1999

Enforcement advice:

- Statement on the application for a field trial using genetically modified maize by Plüss-Staufer AG, Oftringen, of 17 March 1999

6.1. Statements on the draft gene technology bill

The draft gene technology bill aims to regulate existing gaps in the legislative regulation of non-human gene technology in Switzerland. A range of laws is affected by the modifications. The Law relating to the Protection of the Environment (LPE) however forms the framework for gene technology. The ECNH supported the legislative process through several steps, both during the public consultation procedure and also as part of the internal consultation of the authorities .

Despite having been in existence for only a short time, the Committee was able to issue a Statement on the Consultation Document. The Statement covers a range of opinion in this controversial area and certain questions have not yet been adequately discussed.

The central point in its Statement was a consideration of the area of validity of the "dignity of creation". The majority were of the opinion that the duty to respect the dignity of creation was limited to animals and plants, omitting other organisms. The Committee was unanimous in the conviction that gene technology must not be discriminated against in comparison with other technologies. There was also unanimity that the genetic modification of an animal or a plant did not per se injure its dignity. Additional criteria would be needed to determine whether such damage had occurred. However if a planned genetic intervention injures the dignity of an animal or a plant, according to the criteria which are still to be defined, there would be an urgent need for a special justification of the intervention.

The discussion of possible justifications for interventions that would injure dignity has only just begun. The handling and application of the various justifications should be done on a case by case basis, assessing the severity of the intervention in the "dignity of creation" and the importance of the justifiable interests.

In a second Statement for the Swiss Agency for the Environment, Forests and Landscape (SAEFL), the ECNH commented on its tasks and anchoring at the legislative level. The basic discussion about the implementation of the Constitutional definition of the dignity of creation was also continued at the legislative level. The complexity of the term "dignity of creation" at the state of current discussions can only offer a rough guideline. The discussion about concretising the term has become a process. It will show the importance of tackling concrete projects to determine principles and criteria establishing when the dignity of an animal or plant should be considered to have been injured.

On the basis of the preceding discussion of basics, and also because of its engagement with a concrete application⁴, the Committee has been able to formulate specific recommendations as part of a third Statement. The Committee also made extensive comments from an ethical viewpoint on the reasons for and against a moratorium on the release of genetically modified organisms, without however giving a final position.

6.2. Statement on the Biotechnology Ordinances

The ECNH has made a Statement on its role in the assessment procedures for applications to handle genetically modified organisms. The Ordinances came into force on 1 November 1999.

6.3. Statement on the dignity of animals as part of the planned total revision of the Animal Protection Law

The Constitutional term "dignity of creation" demands a modification of the Animal Protection Law. The ECNH was therefore asked by the Federal Veterinary Office (FVO) to put in concrete terms what respecting the dignity of animals would signify for the Animal Protection Law.

The Animal Protection Law protects animals from unjustifiable suffering, pain and harm, and fear. In the opinion of the ECNH, however, the Constitutional term "dignity of creation" provides more comprehensive protection. The Committee confirmed its opinion that intervention in animals does not per se represent injury to their dignity. If however dignity is injured, a comparative assessment of the interests of human exploitation and the interests of animal protection is necessary. Only if the injury to dignity can be justified by overwhelming human interest is the dignity of the animal nevertheless considered to be respected, despite the intervention. The interests of animal usage are differentiated according to type of use, which is why the ECNH has distinguished between the individual areas of use in carrying out the evaluation of interests. The ECNH also confirmed its opinion that genetically modified animals and non-genetically modified animals should be treated identically by the law. The evaluation of interests for the breeding, keeping and use of animals should thus be extended to non-genetically modified animals.

⁴ See Statement on the application by Plüss-Staufner AG, Oftringen, for a field trial using T25 maize, of 17 March 1999

6.4. Statement on an application for a field trial using genetically modified maize

The ECNH received an application for a field trial of genetically modified maize. It drew up ethical criteria for the assessment of the project and made the assessment using these criteria. Ethical criteria must take the form of principles, so that they are applicable to all comparable applications. The ECNH therefore also states its position according to its mandate only on exemplary cases. The ECNH in its assessment was unanimous (with three abstentions) in recommending the rejection of the application.

Since one of the central tasks of ethics is to analyse the goals and effects of human actions, the ECNH took into consideration the goals of the application and its justification. It finds fault with the fact that the application documents and the publication in the official journal were inadequate to the task of informing the affected public on the goals and possible effects of the experiment. It therefore requested both the applicant and the competent authority to provide a complete, clear and understandable announcement and documentation. The concerns of the public and their need for information should be included in planning, and care should be taken to ensure a socially acceptable experimental design. The economic, ecological and social impacts of the planned experiment should be presented openly, evaluated and weighed up against each other. The evaluation of the ECNH led to the conclusion that in this concrete application, the possible economic advantages did not outweigh the negative social consequences and possible harm to the environment.

7. Public information work

The Committee discussed various ways to implement its public information mandate, and also concerned itself with the task of promoting public dialogue. In the initial phase of the Committee's work however, the basic discussions of content and the preparation of Statements as part of legislative consultation were foremost. In the field of biotechnology, several large-scale legal adaptations are currently taking place.

On 19/20 May 1999 a conference on human dignity and the dignity of animals took place at the University of Lausanne. The Committee was one of the organisers of this event. A publication is in preparation. Further public appearances were limited to participation in events by invitation. Approaches to the Committee to lecture on its work were taken up by the Chair, individual members and the Secretariat.

8. Contacts and collaboration

According to the specific task, the ECNH works together with other Federal Committees. Thus a direct information exchange takes place with the Federal Committee for Biosafety and a specific collaboration with the Federal Committee on Animal Experimentation in animal protection bills.

First contacts with other Committees with similar mandates were made at the international conference "On ethical issues arising from the application of biotechnology" from 16 to 19 May 1999 in Oviedo, Spain.

9. Perspectives

In the first half of 2000, a Statement on the Consultation Document of the Transplantation Law, in particular on xenotransplantation, is planned. Statements on the Consultation

Document of the Patent Law and on Terminator-Technology are on the agenda. The use of gene technology in agriculture will be a further subject with which the ECNH will concern itself.

The entry into force of the Biotechnology Ordinances has reinforced the inclusion of the ECNH in the permit procedures. The ECNH will therefore, in addition to its legislative consultation, also consult on enforcement from an ethical point of view using exemplary cases.

A further priority will be to make the ECNH and its work more visible to the public. Using concrete subjects, the working methods of the Committee should be made transparent to a broad public. The opening of a Website is planned for spring 2000. A Newsletter will also report periodically on the activities of the Committee.

For the Federal Ethics Committee on Non-human Gene Technology

Chair

Dr Andrea Arz de Falco

Secretariat

Ariane Willemsen