Report of activities 2004–2007



Swiss Confederation

Federal Ethics Committee on Non-Human Biotechnology ECNH

1 Mandate of the Federal Ethics Committee on Non-Human Biotechnology (ECNH)

Acting on behalf of the Federal Council, the ECNH monitors and evaluates developments in and applications of non-human biotechnology and gene technology. Its mandate thus covers all applications of biotechnology and gene technology in animals, plants and other organisms, and their impacts on humans and the environment. It comments from an ethical perspective on the questions arising in this connection, and specifically on compliance with the principles of respect for the dignity of living beings, preservation of the safety of humans and the environment, protection of the genetic diversity of animal and plant species, and their sustainable use.

The mandate of the ECNH comprises three main responsibilities:

- It advises the Federal Council and subsidiary authorities from an ethical perspective on the preparation of legislation in the non-human biotechnology area and submits proposals for future law-making.
- It advises the federal and cantonal authorities on the enforcement of federal regulations.
- It informs the public about the questions and issues with which it is concerned and promotes a dialogue on the benefits and risks of biotechnology.

In each of the years under review, the members of the ECNH convened for approx. 10 full-day meetings, including at least one 2-day meeting per year. In addition, public meetings were held for the presentation of Opinions. At the request of the committee members, the meetings generally took place in Bern. Two 2-day meetings were held elsewhere – in Zurich (March 2005) and in Lugano (September 2006).

Legal foundations for the ECNH

The Federal Council established the ECNH by decree in April 1998, on the basis of Article 57 of the Government and Administration Organization Act and Article 11 of the Committees Ordinance. The Gene Technology Act of 21 March 2003, which came into effect on 1 January 2004, created a new legal basis (in Article 23) for the mandate of the ECNH.

Art. 23 Federal Ethics Committee on Non-Human Biotechnology

1 The Federal Council shall appoint a Federal Ethics Committee on Non-Human Biotechnology. It is to be composed of independent experts on ethics and persons from other disciplines who have an academic or practical knowledge of ethics. A variety of ethical approaches are to be represented in the Committee.

- 2 The Committee shall monitor and evaluate from an ethical perspective developments in and applications of biotechnology and shall comment on associated scientific and social questions from an ethical viewpoint.
- 3 It shall advise:
- a the Federal Council on the introduction of regulations;
- b the federal and cantonal authorities on matters of enforcement. In particular, it shall comment on licence applications or research projects of fundamental or exemplary importance; for this purpose, it may inspect documents, request information and consult other experts.
- 4 It shall collaborate with other federal and cantonal committees concerned with questions of biotechnology.
- 5 It shall engage in a dialogue with the public on ethical issues associated with biotechnology. It shall report to the Federal Council periodically on its activities.

2 Members

2.1 Composition

As a discipline, ethics encompasses a variety of approaches, which may lead to different types of justification and/or different conclusions regarding our dealings with various forms of life. To ensure that the various positions, arguments, criteria and standards can be addressed within the ECNH, these ethical approaches need to be represented in a balanced manner. The ECNH consists of 12 members from a range of disciplines. At least half are required to be specialists in philosophical or theological ethics. The members are selected ad personam rather than as representatives of specific interests.

2.2 Chair

With effect from 1 January 2004, Klaus Peter Rippe was appointed by the Federal Council as Chair of the ECNH for the term of office from 2004 to 2007. Klaus Peter Rippe has been a member of the ECNH since it was established in April 1998. He had already taken over the Chair on an ad interim basis in November 2003 following the resignation of the then-Chair Andrea Arz de Falco.

Klaus Peter Rippe studied Philosophy, History and Ethnology. He was a scientific associate at the Universities of Saarbrücken and Mainz and served as Senior Assistant at the Zurich University Centre for Ethics from 1995 to 2002. He is a Privatdozent in Practical Philosophy at Zurich University and lectures at the University of Applied Sciences Northwestern Switzerland (business ethics) and at the Veterinary Medicine (Vetsuisse) Faculty of the Universities of Bern and Zurich (animal ethics). In 2006, he became Director of the IPE Institute for Philosophy and Ethics, Fritz Allemann Foundation, Zurich. He is Director of the "ethik im diskurs" consultancy and currently holds a temporary professorship at the University of Education, Karlsruhe (Germany).

2.3 Members during the period 2004–2007

from the field of philosophical and theological ethics:

Klaus Peter Rippe

ECNH Chair, PhD in philosophy, Privatdozent at the University of Zurich and Lecturer at the University of Applied Sciences Northwestern Switzerland, Director of the "ethik im diskurs" office, Zurich, Professor of Philosophy at the University of Education, Karlsruhe (Germany)

Bernard Baertschi

PhD in philosophy, Senior Lecturer in the Department of Philosophy at Geneva University

Hans Halter

PhD in theology, Emeritus Professor of Theological Ethics and Social Ethics, Lucerne University (resigned on 30 June 2006)

Beat Sitter-Liver

PhD in philosophy, Professor of Practical Philosophy at Fribourg University and Lecturer at the Federal Institute of Technology (ETH) Zurich, former Secretary General of the Swiss Academy of Humanities and Social Sciences (SAGW)

Christoph Stückelberger

PhD in theology, Reverend Professor, Director of the Institute for Theology and Ethics of the Federation of Swiss Protestant Churches (SEK), Professor in Ethics at the Theological Faculty of Basel University

Urs Thurnherr

PhD in philosophy, Professor of Philosophy at the University of Education, Karlsruhe (Germany)

Véronique Zanetti

PhD in philosophy, Professor of Ethics and Political Philosophy at Bielefeld University (Germany)

from the field of natural science:

Kurt Bürki

Professor, Director of the Institute of Laboratory Animal Science, Zurich University

Martine Jotterand

PhD, Associate Professor of Cytogenetics, University Hospital (CHUV), Lausanne

Florianne Koechlin

Biologist, Swiss Working Group on Gene Technology SAG, Blueridge Institute

from the field of medicine:

Cornelia Klauser-Reucker

MD, general practitioner, Caslano (Canton Ticino)

from the field of law:

Markus Schefer

PhD in law, LLM, Professor of Constitutional Law and Administrative Law, Basel University

2.4 Resignations and new appointments

After being awarded emeritus status by Lucerne University, Hans Halter remained a member of the ECNH until the middle of 2006. Christoph Stückelberger resigned from the Committee at the end of 2007, having taken up a new position at Globethics.net in Geneva. In December 2007, the Federal Council announced the appointment of two new members of the Committee for the period 2008-2011: Hans Jürgen Münk, Professor of Theological Ethics and Director of the Institute for Social Ethics at Lucerne University, and Georg Pfleiderer, Professor of Systematic Theology/Ethics at Basel University.

3 Secretariat

The Secretariat reports to the Chair of the Committee and is administratively attached to the Federal Office for the Environment (FOEN). It prepares Committee meetings, supports the Chair and members in carrying out their duties, and produces the Committee's Opinions. It organizes the public relations activities of the ECNH, maintains contacts with Swiss and international authorities and committees that share an interest in non-human biotechnology and gene technology, and is responsible for administrative tasks.

The Secretariat in Bern is run by **Ariane Willemsen**. From August to December 2007, **Andreas Bachmann** (philosopher, Zurich) shared responsibility (50% position) for the Secretariat, while the post holder reduced her working time to 30% for purposes of further education.

4 Monitoring and evaluating developments in non-human biotechnology

The ECNH is responsible for monitoring developments in non-human biotechnology and evaluating them from an ethical perspective. Under this mandate, it comments on forthcoming legislative projects and on specific licence applications of exemplary or fundamental importance. Advice on enforcement in the case of licence applications covers projects relating to the production, release and placing on the market of genetically modified or pathogenic organisms, and patent applications in this area. The ECNH also addresses certain topics on its own initiative, evaluating them with future legislation in mind and preparing recommendations for the legislature. In the case of emerging technologies and their possible applications, it is usually first necessary to establish a basis for ethical evaluation. For this purpose, the ECNH may also have recourse to external expertise. Specialists are invited to attend hearings and participate in discussions at Committee meetings or are commissioned to produce expert reports. On this basis, the ECNH discusses and draws up its ethical reviews and presents its recommendations to the authorities. In the period under review, the ECNH focused in particular on groundwork of this kind.

Opinions issued by the ECNH are of an advisory nature. They are drawn up for submission to the federal office that is responsible for the legislative project or licence application in question. The Opinions are also accessible to the public, except in cases where a licensing procedure has not yet been completed. Likewise, the ECNH is not entitled to publish, of its own accord, advice provided in the course of an internal procedure on the basis of confidential documents. Decisions on whether such comments are to be published are taken by the authority responsible for the matter concerned.

Majority and minority views

ECNH Opinions do not necessarily take the form of a consensus. Opinions are centrally concerned with the examination of arguments. For this reason, both majority and minority views are published. It has been shown that the members often agree on the meaning of the arguments. Disagreements generally arise only in the evaluation of these arguments. The aim of the discussions within the Committee is then to establish where and especially why the evaluations diverge. Despite the varying ethical approaches, however, the members are frequently in agreement on specific points.

4.1 Advice on legislation and ethical groundwork

4.1.1 Impacts of biotechnology on developing and transition countries

While the promotion of gene technology to combat hunger in developing and transition countries is welcomed by some, others warn against the adverse consequences of this technology for these countries. Both sides see themselves equally as advocating the cause of people in the "South". The ethical implications of biotechnology for developing and transition countries were first addressed by the ECNH at the end of 2003. The initial priority was to gain an overview of this complex issue. Information was sought from various external experts - from the World Health Organization (WHO), the Swiss Agency for Development and Cooperation (SDC), the State Secretariat for Economic Affairs (seco), and what was then known as the Swiss Agency for the Environment, Forests and Landscape (SAEFL, now the Federal Office for the Environment/FOEN) - on the following topics: food security and food sovereignty, the handling of genetically modified food products in direct aid for famine relief, development projects involving technology transfer, agriculture and trade in developing countries and the regulatory framework of the World Trade Organization (WTO), and the regulation of access to genetic resources and equitable benefit sharing under the Biodiversity Convention. To expand the foundations for its internal discussions, the ECNH commissioned an ethical/normative and an empirical study (J. S. Ach, Ethische Analyse und Auslegeordnung zum Thema "Auswirkungen der Biotechnologie auf Entwicklungsund Schwellenländer", September 2003 und M. Saam et al., Les Impacts des Plantes transgéniques dans les Pays en voie de développement et les Pays en transition, October 2003). In September 2004, the ECNH published its findings in a booklet entitled "Gene technology and developing countries. A contribution to the discussion from an ethical perspective".

In discussing the consequences of gene technology for developing and transition countries, the ECNH aimed to illuminate what it considers to be the key ethical aspects of this complex topic and to help shape Swiss policy from an ethical perspective. The ECNH is aware that its contribution to the debate could not cover the effects in all their complexity. How these effects are to be evaluated largely depends on the specific context in which GM crops are cultivated, which may vary widely from one country to another. The ECNH sees it role as highlighting what it regards as the crucial ethical values according to which the effects should be assessed. These fundamental values are universally applicable - in the countries of the South as well as the North.

Switzerland has undertaken various international commitments, notably vis-à-vis countries of the South. These agreements provide a degree of protection for the population of these countries. From an ethical viewpoint, these commitments are a requirement of equity. All applications of technologies are therefore to be evaluated in terms of equity. Of central importance in this regard are the consequences of

the use of such technologies for the observance of the following four fundamental rights:

- Right to food (food security). The fundamental rights to life and integrity of the person imply a moral right to food, i.e. access to safe and nutritionally adequate food.
- of human dignity entails the right to self-determination (autonomy). This includes food sovereignty, which encompasses the freedom of the individual to decide autonomously on questions of nutrition and also the collective level, i.e. the right of countries to regulate trade in agricultural goods (access to markets) themselves and to feed themselves in accordance with their own traditions and cultures.
- Sustainability. It is a requirement of justice to ensure that future generations enjoy life chances comparable to those of the present. This entails a moral obligation to live in a sustainable manner. An integral part of this responsibility is the protection of biodiversity.
- Social peace. Finally, it is incontestable that the right to social peace is an indispensable prerequisite for food security, food sovereignty and the long-term protection of the natural resource base.

The overwhelming majority of ECNH members concluded that the effects of gene technology on developing countries cannot at present be predicted with an adequate degree of certainty. Consequently, they recommended that efforts to resolve the pressing problems should not rely solely on the biotechnological approach. Other approaches should also be pursued and promoted. The ECNH believes that public sector

research should be intensified internationally and better coordinated than is currently the case. In particular, risk research should be promoted, taking into account the specific health, social and economic conditions prevailing in individual countries. In addition, the ECNH emphasizes the importance of supporting other approaches, some of which have proved more efficient and produced better results to date. For the ECNH, it is not ethically acceptable only to promote a single technological approach. Developing countries should also be supported in strengthening their sovereignty with regard to the assessment and licensing of new technologies (i.e. capacity building). In addition, support should be provided for all efforts to guarantee free access to and exchange of genetic resources for purposes of breeding and research, so as to ensure food security worldwide.

4.1.2 Revision of the Patents Act

At the end of 1999, in preparation for the consultation on the Federal Act on Patents for Inventions (Patents Act), the ECNH started to consider in depth the ethical aspects of patenting in the biotechnology field. The first public consultation on the Patents Act ran from the end of December 2001 to the end of April 2002. During this period, the ECNH focused on patenting in relation to animals and plants, and the effects of such patents. The ethical implications of the patentability of genes and gene sequences were only dealt with at a later stage. In 2002, an external expert report on this question was commissioned (Norbert Anwander et al., Gene patentieren. Eine ethische Analyse [Patenting Genes. An ethical analysis], 2002), which provided the basis for the Committee's subsequent deliberations.

The consultation on the draft Patents Act produced such divergent responses that the Federal Council decided to discuss the most controversial issues in a series of round-table talks with interested parties. In the course of 2003, the topic of "patenting and ethics" was also discussed at several meetings between the Federal Institute of Intellectual Property (IGE) and delegations from the ECNH and the Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE). The results of these discussions were integrated into the Explanatory Report issued by the Federal Council for the second round of consultation on the Patents Act in the summer of 2004. The ECNH had further opportunities to provide its input during the internal consultation procedures.

From the outset, the ECNH has explicitly recognized that intellectual achievements in the field of biotechnology deserve to be protected, since it regards as ethically justified the goal of promoting research in the interests of all members of society, as pursued by the Patents Act. By granting a patent, the state accords monopoly rights to the possible commercial exploitation of an invention for a limited period. This gives inventors an opportunity to recoup their research investments and, in addition, to make a profit. In return, the invention is made accessible to the public for the benefit of society as a whole. This balancing of interests needs to be implemented in an equitable manner. As the system was originally developed for inventions involving inanimate material, the ECNH believes that in the biotechnological and biomedical field - i.e. when dealing with living material - particular attention needs to be paid to a number of ethical considerations and concerns in the development of patent legislation.

In its discussion, the ECNH focused in particular on the patenting of genes and gene sequences. The ECNH unanimously rejects the patenting of unmodified genes in their natural environment or in an isolated form. The ECNH takes the view that, even when they are isolated, genes are not inventions but discoveries. The distinction between discovery and invention is of regulatory significance and of ethical relevance. Patent law is a system designed to offer rewards and incentives for inventive achievements. Discoveries should not be patentable since the element of inventive achievement is lacking. For the overwhelming majority of the Committee, genes and genetic resources are part of the human heritage and therefore not subject to any kind of exclusive rights. Even if they are classified as inventions under patent law, they should be deemed non-patentable on the basis of other criteria (lack of novelty, insufficient level of inventiveness, lack of commercial applicability).

Despite these considerations, the political climate was in favour of allowing patents on genes. This being so, the ECNH was concerned at least to restrict the scope of patent claims to a precisely defined function of a gene, since absolute protection of genes or gene sequences cannot be justified from an ethical perspective. The ECNH therefore supported utility-based substance protection, as proposed in the draft revision. Utility-based substance protection for gene sequences - as opposed to absolute substance protection in the case of chemical substances - does not amount to technological discrimination, since genes and chemical substances differ in essential respects. What are comparable to chemical substances are not genes, but the proteins coded for by gene sequences and isolated. While for synthetically produced chemical substances all applications are covered by absolute substance protection, patent protection for gene sequences should be restricted to clearly defined applications of proteins. This is justifiable insofar as proteins - unlike chemical substances, which can be produced synthetically – are finite in number. On consequentialist grounds, the ECNH is therefore opposed to broad patent claims relating to proteins. Allowing such patents would soon unduly restrict research, with all the attendant adverse consequences.

Another key goal of the Patents Act is to promote research. In the past, however, patent regulations have sometimes been perceived as obstructive by researchers in the field of biotechnology, especially at public-sector research institutions. This perception was partly due to inadequate awareness of the researchers' own rights. The ECNH therefore supported the adoption in the Act of an explicit research privilege, which should be as broad as possible.

Other important concerns for the ECNH are to secure the farmers' and breeders' privilege. The farmers' privilege allows farmers to reuse material harvested from protected varieties for propagation on their own farm. The diversity of existing crops and farm animals, which makes today's breeding efforts possible, was created by farmers and is based on exchanges of propagating material among farmers. The farmers' privilege is also designed to protect farmers from dependency on suppliers. For the ECNH, enshrining the farmers' privilege in patent legislation - also covering the sharing of small amounts of materials and not excluding any plant species - is an ethical requirement, so as to ensure the maintenance of diversity, despite the fact that in Switzerland today this privilege is not of major importance economically. Free access to and exchange of biological material among breeders (breeders' privilege) has also made a vital contribution to the existing diversity of livestock and crop plants. Preserving and promoting the greatest possible diversity is an important ethical objective.

Benefit sharing is a fundamental ethical concern that extends beyond patent legislation. If - in spite of ethical reservations - patents are granted on genes, then compensation should be provided in the form of benefit sharing. However, benefit sharing should apply not only to the utilization of genetic resources, but also to the application of traditional knowledge. Here, too, compensation is required for earlier efforts contributing to the development of crops, farm animals and medicines. Indication of geographical origin is the only instrument permitting benefit sharing which is mentioned in the relevant European Directive 98/44/EC on the legal protection of biotechnological inventions. The ECNH is aware of the enforcement problems arising in connection with the indication of geographical origin and the benefit sharing requirement, given the difficulties of tracing the origin of genetic resources and traditional knowledge in practice. However, the problems of legal implementation should not lead to the rejection of compensation as an ethical concern. In the elaboration of benefit sharing arrangements, special attention should be given to the equity aspect of "North-South" relations.

4.1.3 Ordinances relating to the Gene Technology Act

Release Ordinance and Containment Ordinance. On 1 January 2004, the Gene Technology Act – approved by Parliament in March 2003 after several years of deliberation – came into effect. It then became necessary to revise the Ordinance on the Use of Genetically Modified Organisms in the Environment (Release Ordinance) and the Ordinance on the Contained Use of Genetically Modified Organisms (Containment Ordinance), both of which had come into effect in 1999. The ECNH is involved in the revision of both of these Ordinances and has had several opportunities to

comment on the drafts in the course of hearings and internal consultations. Work on these Ordinances is ongoing as of the end of the review period.

4.1.4 Popular initiative "For food from GM-free agriculture"

In November 2005, the popular initiative "For food from GM-free agriculture" was approved by a majority of voters and all cantons. This initiative called for an interim provision under Article 120 of the Federal Constitution, prohibiting the use of gene technology in agriculture for a period of five years. In particular, the moratorium covered the import and placing on the market of genetically modified, propagable plants, plant parts and seeds for agricultural, horticultural or forestry applications, but not the use of imported genetically modified food.

Before issuing an Opinion on the initiative, the ECNH consulted external experts: Stephan Häsler (Deputy Director of the Federal Veterinary Office/FVO, the lead agency responsible for drafting the Federal Council's report on the initiative). Herbert Karch (President of the Swiss Association for the Protection of Small and Medium-Sized Farms/VKMB. one of the sponsors of the initiative) and Arthur Einsele (Public Affairs Officer of Internutrition, the Swiss industry association for research and nutrition, a representative of the opponents of the initiative). The Opinion sought to evaluate the arguments from an ethical perspective and to present majority and minority views in support of the deliberative process.

The discussion initially considered the question of when moratoriums are advisable in principle and whether the requirements for a moratorium were met in this specific case. Also discussed and evaluated was the argument advanced by the opponents to the effect that the

initiative would send out negative signals: What psychological consequences could a moratorium have for Switzerland as a research and business centre, particularly with regard to the separation of research from commercial application? Another question raised was whether the initiative should not logically also have called for the promotion of research - given that its supporters argued that the knowledge needed to assess the risks of commercial application was not yet available – and whether and to what extent a moratorium would in practice lead to restriction of the freedom of research. Two other questions were discussed: to what extent the initiative could affect consumers' freedom of choice, and how it could affect farmers' economic freedom. Having weighed up all the arguments put forward, the majority of Committee members concluded that the initiative should be rejected. A minority considered that the initiative should be supported on ethical grounds.

4.1.5 Primate research

In May 2006, a report on the ethical evaluation of primate research was jointly issued by the ECNH and the Federal Committee on Animal Experiments (SCAE). The report was occasioned by an enquiry received by the SCAE from a cantonal animal experiments committee. This committee had been asked to review an application to conduct a study in marmosets, investigating the long-term effects of social deprivation in young animals. The researchers hoped that this study would be useful in developing a primate model for depression research. The cantonal committee's concerns focused on three points. (1) The experimental animals were primates. (2) It was considered that the experiments would be particularly distressing for the animals on account of the long-term effects. (3) Should a primate model of this kind prove successful, it could in future be used routinely for pharmaceutical tests, leading to a sharp rise in the number of animal experiments - especially those involving primates. Although the cantonal animal experiments committee approved the specific application, it requested the Cantonal Veterinary Office to consult the SCAE, so that its concerns could be evaluated as a precautionary measure in anticipation of future applications. The fundamental question, initially, was to what extent the use of primate models should be permissible in depression research. As this essentially involved the clarification of an ethical issue, the SCAE in turn asked the ECNH to collaborate.

Between January and June 2005, a joint ECNH-SCAE Working Group was charged with studying this fundamental question and reporting to the two full Committees. The Working Group chose to invite external experts from various disciplines to attend hearings, so that specific points could be discussed from different perspectives. It also invited the study director whose application had given rise to the discussions. The minutes of these meetings were submitted to the external experts for review and approval before being passed by the Working Group. The members of the two full Committees were also in possession of all the meeting documentation and were able to follow the Working Group's deliberations step by step via the minutes, which facilitated their discussion of the Working Group's findings and their approval of the final report.

After a brief examination of the issue, it became clear that what needed to be discussed was not only the question of primate models for depression research but the general question of the ethical acceptability of experiments involving primates. The discussion proceeded in three steps.

The first step involved an examination of whether it is even ethically acceptable to weigh up interests in the case of primate experiments. This depends on the question of who counts morally, i.e. who is to be included for their own sake in the circle of moral consideration. For some people, the distinction between great apes and other primates is of crucial importance in the discussion of moral status. The second fundamental question was: how much do those receiving moral consideration for their own sake count? Two possible views were distinguished - the egalitarian and the hierarchical. The egalitarian position assumes that other living beings actually have the same interests as humans and are therefore to be accorded equal status. On the hierarchical view, while other living beings deserve moral respect, they are not all of equal status. In both committees, the majority adopted a hierarchical position, thus attaching greater value to human interests than to comparable interests of apes, and greater value to apes' interests than to those of other primates.

On the basis of their fundamental positions, a clear majority of the members of both committees considered the weighing of interests to be ethically *unacceptable* for experiments involving *great apes*. This entails an absolute prohibition on experiments with great apes. For all other primates, however, the majority held the weighing of interests to be permissible.

The second step was concerned with the criteria to be adopted for the weighing of interests. Under the Swiss approval procedure, every animal experiment has to be justified on the basis of a weighing of interests. In a process of this kind, the interests of humans in primate research are to be weighed up against the animals' distress, or their interest in freedom from distress. The greater the

stresses imposed on the animals, the more stringent is the evaluation of the justifications supposed to offset the animals' suffering. Even if a scientific need has been demonstrated for an animal experiment, this does not mean that a weighing of interests becomes redundant, or that the interests of an animal in not being subjected to an experiment are automatically outweighed by the human interest in the experiment. Such a conclusion can only be the result of a careful weighing of interests.

The study that gave rise to the discussion used the method of deprivation to induce changes in the brain of young marmosets, leading to symptoms comparable to those seen in people with depression. Although no immediately life-threatening effects or organic damage can be observed, deprivation has severe, lifelong effects on the brain and thus on the animals' behaviour, learning ability and reactions. These changes are irreversible; indeed, the aim of the experiment is precisely to overtax the adaptability of the brain so as to investigate the short- and longterm effects of deprivation.

To evaluate the stresses imposed on the marmosets, one needs to tackle the question of whether self-awareness should be ascribed to primates. Self-awareness is defined as the ability to generate a synthesis (an "image" or "idea") of oneself from the stream of conscious experience. Depression impairs, among other things, the social bonding abilities that are of crucial importance to marmosets. However, it is difficult to conceive of social ties in the absence of some kind of selfawareness. The existence of such a self-conception in primates is controversial and remains an open question. It should, however, be borne in mind that marmosets are used in depression research because, as primates, they are very close to humans, on account of their social-familial structure, certain behaviour patterns and neurophysiological similarities. The question thus arises whether, epistemologically, such research does not de facto presuppose the existence of self-awareness in primates without making this explicit. This would mean, however, justifying the research in scientific terms without exposing its ethical unacceptability.

On the basis of the severity levels currently used to classify experimental procedures, both committees concluded unanimously that deprivation in young marmosets and its consequences for the animals should in future be classified under the highest severity level (3). For the great majority, the marmoset study is among those severity level 3 experiments that inflict the highest degree of suffering on animals and are hence unacceptable. Thus, on this view, the experiments are not permissible because they fail to meet the criterion of acceptability. For a minority, the permissibility even of such distressing animal experiments remains a question of proportionality. On this view - and under current legislation, which does not recognize the criterion of acceptability - the permissibility of an experiment can only be determined by a weighing of interests.

In case the arguments of the majority of members of both committees should be rejected, the third step dealt with the weighing up of human interests in primate experiments against the animals' suffering. As regards the human interests, the following aspects were considered and evaluated: (1) the aim of the research, (2) possible resultant problems, (3) the scientific quality of the research project, (4) the prospects of success and (5) the existence of alternative approaches in depression research. In the weighing of interests - which in itself was only regarded as acceptable by a minority - the majority took the view that work with the marmoset model and its applications contributes to the achievement of an important good, namely a better knowledge of depression. However, the likelihood of such an animal model being successfully developed was rated as low by the majority. The majority felt unable to say whether or not alternative approaches equivalent or comparable to the marmoset model are available. However, the level of stress to which the animals would be subjected was unanimously rated as high. The members were also unanimous in the view that the benefit aimed for was not sufficient to outweigh the high level of stress and justify the marmoset study. Both committees thus unanimously concluded that the stress imposed on the primates by the experiment in question is disproportionate, and that this method of research should therefore not be used. In addition, if a question can only usefully be answered in an interdisciplinary manner, then, scientifically speaking, not only is a monodisciplinary research approach inadequate, but also a monodisciplinary evaluation of a research application.

These deliberations and the resulting recommendations were summarized in a booklet, which was presented at a press conference in Bern on 22 May 2006. The content aroused widespread interest and controversy. The Swiss National Science Foundation (SNF), one of the institutions to which the recommendations were addressed, and which had co-funded the primate studies that gave rise to the debate, received an advance copy of the report. The SNF was also given the opportunity to distribute its own press release at the press conference held by the two committees. The joint report was subsequently featured in the 14 December 2006 issue of the scientific journal Nature, leading to further comment in Swiss newspapers. In February 2007, the National Council Committee for Science, Education and Culture (WBK) rejected a motion by Maya Graf (Green Party, Canton Basel-Land), which - alluding to the primate report – sought to introduce a ban on experiments involving primates. In its demands, the motion went beyond the recommendations of the two committees. The publication also had an effect on the evaluation of applications relating to primate experiments. Thus, on the basis of the general considerations in the ECNH-SCAE report, the Animal Experiments Committee of Canton Zurich appealed against an approval granted by the Zurich Cantonal Veterinary Office. The appeal was initially upheld by the Cantonal Council. At the end of 2007, the case was pending at Zurich Administrative Court.

4.1.6 Dignity of living beings with regard to plants

Three forms of protection for plants are enshrined in the Federal Constitution: the protection of biodiversity, species protection and the obligation to take into account the dignity of living beings in dealing with plants. The requirement to respect the dignity of living beings was included in the Constitution following a referendum in 1992 (Art. 24^{novies} Para. 3 of the old Federal Constitution, corresponding to Art. 120 of the Federal Constitution as revised in 1999). With regard to legislation, the scope of the dignity of living beings was restricted to animals and plants in the Gene Technology Act.

The requirement to respect the dignity of living beings in the case of plants as well as animals is thus unequivocally stated both in the Federal Constitution and in the Gene Technology Act. What is not clear, however, is what this dignity consists in and what it entails for our dealings with plants. Since the ECNH was first established by the Fed-

eral Council in April 1998, it has been expected to make suggestions as to how the vague notion of "dignity of living beings" used in the Constitution can be fleshed out from an ethical perspective in relation to plants. Previous discussion has been shaped by legal interpretation of the Constitution, with the concept of the dignity of living beings being taken to refer to the value of the individual organism in its own right. For the ECNH, however, the initial goal was to pursue the ethical discussion independently of the legal debate, so that none of the fundamental ethical positions implicit in the legal discourse would be adopted uncritically.

In 2004, in preparation for this ethical discussion, the ECNH commissioned a literature review from Jürg Stöcklin, Professor of Botany and a research group leader at the Institute of Botany, Basel University. In 2007, this study was published as "Die Pflanze. Moderne Konzepte der Biologie" in the series of volumes devoted to ethics and biotechnology. In parallel with this study, Florianne Koechlin, a member of the Committee, interviewed a number of experts. In addition, between 2003 and 2006, the ECNH consulted several other external experts from a variety of disciplines.

The general ethical question is whether and why plants should be protected. Either they are to be protected for their own sake, or they are to be protected for the sake of others. It is indisputable that, in certain cases, plants should be protected for the sake of others, e.g. because they are useful to humans. Independently of the idea of the dignity of living beings, the central question thus remains whether plants have an inherent worth and should therefore also be protected for their own sake. For some people, however, the mere question whether our treatment of plants requires moral justification offends common sense. Moral consideration for plants is regarded as nonsensical. In some people's view, our dealings with plants are on morally neutral ground and consequently actions involving plants do not require any justification. Others, however, offer different reasons for wishing to exclude plants from the circle of organisms deserving moral consideration for their own sake: if this area of human behaviour also called for justification, human life would become too complicated and morally demanding. In addition, there would be a risk that ethical positions considering plants for their own sake could undermine higher-priority moral responsibilities to humans (and animals).

In the first phase of the discussion, the members of the ECNH hoped to be able to derive general criteria for our treatment of plants from specific, paradigmatic examples. However, it transpired that in the case of plants - unlike animals - it is scarcely possible to appeal to moral intuitions. Society largely lacks a common sense of how plants should be treated. Within the ECNH, too, there were highly heterogeneous intuitions as to the extent and justification of moral responsibilities to plants. The only criterion on which all the members could agree, despite their widely differing intuitions, was that plants must not be damaged or destroyed arbitrarily. However, it remained unclear whether - and if so what - specific rules of conduct can be derived from this prohibition.

As the intuitive approach was not helpful – quite apart from the fact that the authority of intuitions in ethical discourse is a controversial issue – a theoretical procedure was subsequently adopted. Fundamental ethical positions were assessed with regard to the treatment of plants: which ethical positions assume that plants have an inherent value and therefore permit moral consideration of plants for their own sake? Although it became apparent that no fundamental ethical positions were shared by all members, a number of conclusions were drawn concerning the treatment of plants which commanded unanimity or majority support.

The report was published in April 2008 and is also available on the website (www.ekah.admin.ch)

4.1.7 Nano(bio)technology

Applications of nanotechnological developments in the life sciences and the use of biological materials and designs to produce technical nanosystems are believed to hold out enormous potential, not only in medicine but also in agriculture and nutrition. New technical possibilities may also give rise to new ethical questions or changes in the emphasis placed on existing questions. In 2005, this topic was addressed by the ECNH. It consulted external experts to find out about the possibilities of the nanotechnology/biotechnology interface and also commissioned an ethical review. This study was published as the first volume in a new series devoted to ethics and biotechnology.

In 2006, the Federal Office for the Environment and the Federal Office of Public Health began working on the action plan "Risk assessment and risk management for synthetic nanomaterials 2006-2009". In collaboration with experts from academia, industry and other federal agencies, they prepared a report providing a basis for the formulation of recommendations on measures to protect human health, the environment and employees against possible risks associated with nanotechnology. In addition, an accompanying group representing a variety of stakeholders was consulted, so as to ensure that the evaluation took into account as many different perspectives as possible. The two Federal Offices' basic report was

issued in July 2007. In April 2008 the Federal Council approved the Action plan "Synthetic Nanomaterials".

The ECNH was represented in the accompanying group by the Executive Secretary and had several opportunities to comment on draft versions of the report and to contribute ethical considerations. Against this background, the decision was taken to set aside the topic of nanotechnology for the time being and focus instead on the ethical issues raised by a new technological development, synthetic biology.

4.1.8 Synthetic biology

The field of synthetic biology, which is still in its infancy, is dominated by an engineering-type approach. It is based on the idea that life can be systematically rebuilt or redesigned for specific purposes. However, no consistent definition of synthetic biology has yet emerged.

Currently, research is focusing on the deconstruction and reduction of organisms: the genomes of existing bacteria and viruses are first to be reduced to the minimum set of genes required to support basic metabolism. Subsequently, synthetic components are to be incorporated into this minimal genome, so that these biological systems can perform new functions. Up to this point, synthetic biology is widely considered to involve an extreme form of genetic engineering. However, a further goal of synthetic biology is, in a third step, to assemble DNA sequences (known as BioBricks) to create new kinds of biological systems. Whether this goal is achievable in principle is still questioned by some. What is certain is that this step would go beyond genetic engineering. The computer-aided design of DNA sequences is also classified as synthetic biology. Here, one must distinguish between the synthesis of DNA sequences from existing organisms, and the computer-aided design and subsequent synthesis of new, non-pre-existent, DNA sequences. *Existing* DNA sequences are already being synthesized commercially today.

In the longer term, researchers envisage possible applications in medicine, power generation, environmental protection, the production of new pharmaceuticals or the military sphere. There are even dreams of synthetic biology as a universal technology. However, a gulf remains between vision and practice. The notion of working with biological components in different contexts depends on the components functioning in the same way in each case. This is particularly problematic in biology, as the context plays a key role in how biological components function.

In synthetic biology, researchers work with systems that have the functions or at least some of the functions - of life forms. If the new possibilities opened up by synthetic biology are to be evaluated from an ethical perspective, it is essential to address the question of what life is. This question has previously arisen in connection with other technologies, but never as urgently as with certain goals of synthetic biology. In order to gain an overview of the concept of life as applied to date in philosophy, the ECNH commissioned a study from Andreas Brenner, which was published in the autumn of 2007 as part of the series of volumes devoted to ethics and biotechnology. The ECNH subsequently held a number of hearings to discuss various aspects of the question with experts. At the end of 2007, two further expert reports were commissioned: the first (by Giovanni Maio) is to provide an ethical map of synthetic biology, and the second (by Anne Eckhardt) is to compile information on the organization and goals of this new technology. These reports, which are to be completed in the first half of 2008, will serve as a basis for further discussion and the elaboration of recommendations by the Committee.

4.2 Advice on implementation

Mandate and role of the ECNH in the approval procedure for GMO release applications

In the Federal Council's decree of appointment of 28 April 1998, the ECNH was charged with advising the Federal Council and subsidiary authorities from an ethical perspective both on the preparation of legislation and on enforcement in the non-human gene technology and biotechnology area. These responsibilities were enshrined in Art. 23 Para. 3 of the Gene Technology Act. The Committee's mandate also includes, for example, commenting on applications for the experimental release of genetically modified organisms in cases of exemplary significance from an ethical perspective. Under Art. 18 Para. 4 item b of the Ordinance on the Use of Genetically Modified Organisms in the Environment (Release Ordinance, FrSV), applications are therefore also submitted by the regulatory authority to the ECNH for comment. The ECNH is responsible for deciding whether to comment on an application from an ethical perspective. At present, given the relative lack of empirical data, the ECNH considers all GMO release applications to be exemplary in principle.

When the ECNH evaluates a specific application, it often offers comments on two different levels. Firstly, it makes recommendations in the form of *advice on enforcement*, which can be directly implemented on the basis of existing law. In such cases, if the enforcement authority follows the reasoning underlying the positions of the ECNH, it can directly invoke the Committee's advisory opinion in issuing its decision. Secondly, the ECNH can formulate rec-

ommendations in the form of advice on legislation, looking ahead to future law-making. It is not always possible, on the basis of existing regulations, for recommendations from an ethical perspective to be taken into account in a decision on a specific individual case. It may be that it only becomes clear from the specific individual case that the existing regulations lead to a regulatory decision that is not ethically acceptable. In such a case, the recommendations made by the ECNH are addressed not to the enforcement authority but to the legislature, pointing out the need for action as perceived by the ECNH and calling for legislative efforts to prevent ethically unacceptable decisions in the future.

4.2.1 Releases of genetically modified organisms

In January 2007, three applications for the release of genetically modified organisms were submitted to the Federal Office for the Environment by the ETH and Zurich University. When the documentation was complete, it was submitted for comment to the other federal bodies involved in the review procedure, including the ECNH.

One of the applications, submitted by the Zurich University Institute of Plant Biology, concerned a study designed to investigate how various transgenic wheat lines with enhanced specific resistance to mildew (a fungal disease) perform in a field trial and to what extent these plants are resistant to fungal diseases. At the time when the application was reviewed, some of the plant lines were still in development.

The second application from Zurich University concerned a field trial of greenhouse-grown hybrids of transgenic wheat and jointed goatgrass (*Aegilops cylindrica*), a species of wild grass found in Switzerland. These ex-

periments are designed to provide information on how modified genes are propagated and whether they can become established in the genome of a wild species over several generations. The site for both of these trials is the Agroscope Reckenholz-Tänikon Research Station ART in Zurich.

The third application, from the ETH Zurich Institute of Plant Science, involved the experimental cultivation of transgenic wheat plants with enhanced (non-specific) fungal resistance. In these plants, the modification relates to genes with a broad spectrum of activity. The plants are therefore resistant to various fungal pathogens. The trial is to be carried out at the Reckenholz-Tänikon site and at the Centre viticole du Caudoz in Pully (Canton Vaud).

As well as studying whether transgenic wheat plants also show greater resistance to fungal diseases in the field and how this functions under natural conditions, the trials are also designed to investigate biosafety aspects – e.g. whether transgenic wheat plants have any detectable impact on other forms of life, such as soil organisms or insects, or the consequences of outcrossing (transfer of transgenic traits to wild plants). The trials are to take place from 2008 to 2010.

At its meeting on 22 June 2007, the ECNH concluded that most of the open questions arising in the discussion were of a legal nature or related to biosafety issues that remained to be clarified. It is not within the remit of the ECNH to establish whether the legal requirements have been met with regard to a step-bystep procedure or the admissibility of approvals for plants on which no data are available at the time when the application is submitted. Likewise, other bodies are responsible for investigating whether biosafety is assured. It is true that these areas also involve judg-

ments, the effects of which could be evaluated from an ethical perspective. However, when its discussions took place, the ECNH had no knowledge of the evaluation of this matter made by the Federal Expert Commission for Biosafety (FECB), which also advises the Federal Council and the authorities. Under these circumstances, the ECNH merely reported the points which had been discussed and noted that it expected the competent authorities to take account of these considerations in their evaluation. One of the important responsibilities of the ECNH is certainly to continuously monitor the entire enforcement process and its effects. Should the need arise from an ethical viewpoint, the ECNH always has the option of drawing up recommendations for future legislation without reference to a specific application.

4.2.2 Placing of genetically modified organisms on the market

Food and feed products

In the period under review, no applications to place genetically modified food or feed products on the market were submitted to the ECNH for ethical evaluation, and no new approvals were granted either by the Federal Office of Public Health or by the Federal Veterinary Office.

Live vaccines

In 2006, the application for authorization of the live vaccine ProteqFlu-Te (for protection against equine influenza) was submitted to the ECNH for evaluation. The ECNH declined to issue any comments, taking the view that this application was not of paradigmatic significance. Instead, in its letter to the regulatory authority, it referred to the animal ethics considerations it had already formulated in connection with the authorization procedure for EURIFEL FeLV in the autumn of 2003. The ProtegFlu-Te and Eurifel FeLV vaccines were both approved at the same time by the Federal Veterinary Office in the spring of 2007.

In accordance with Art. 35 Para. 2 of the Release Ordinance, the FOEN maintains a public registry of all genetically modified organisms for which marketing authorization has been granted. This registry is available (in English) at: http://www.bafu.admin.ch/biotechnologie/01760/01761/index.html?lang=en

5 Publications

The ECNH publishes its Opinions on its website (www.ekah.admin.ch). Opinions on fundamental questions are also published in booklet form. In addition, selected external reports on non-human biotechnology topics which are commissioned by the ECNH in support of its own work and may also be of interest to a wider audience are published in a series of volumes launched in 2006 entitled "Beiträge zur Ethik und Biotechnologie".

5.1 Booklets



Gene technology and developing countries. A contribution to the discussion from an ethical perspective (September 2004) For a brief description of the content, see Section 4.1.1.



Research on primates
– an ethical evaluation
(May 2006)
For a brief description
of the content,
see Section 4.1.5

ECNH booklets are available in print format in English, French and German, and electronic versions (also including Italian) can be downloaded from the ECNH website (www.ekah.admin.ch). In addition, in response to significant demand, an English translation of the 2001 publication on the dignity of animals was produced in 2005 for classroom use and as a contribution to the international debate.

5.2 "Beiträge zur Ethik und Biotechnologie" series

Expert reports commissioned by the ECNH which are of interest to a wider audience are published (in the original language) in a series of contributions to ethics and biotechnology. These reports provide a basis for consideration of the ethical aspects of biotechnology and serve as working papers for the ECNH

The volumes in this series can be ordered from the BBL Publication Distribution Office, CH-3003 Bern (www. bundespublikationen.admin.ch; please quote order no.), or from bookshops. The books are sold at cost (around CHF 12). The entire content can also be downloaded free of charge in PDF format from the ECNH website (www. ekah.admin.ch).



Andreas Bachmann, Nanobiotechnologie. Eine ethische Auslegeordnung (Nanobiotechnology. An ethical review), 2006 (BBL order no. 810.001; ISBN 978-3-905782-00-4)



Jürg Stöcklin, Die Pflanze. Moderne Konzepte der Biologie (The plant. Modern biological concepts), 2007 (BBL order no. 810.002; ISBN 978-3-905782-01-1)



Andreas Brenner, Leben. Eine philosophische Untersuchung (Life. A philosophical investigation), 2007 (BBL order no. 810.003; ISBN 978-3-905782-02-8)

Andreas Bachmann focuses on a particularly promising area of nanotechnology - nanobiotechnology. The aims of this discipline are twofold: to apply nanotechnological developments in the life sciences ("Nano2Bio") and to use biological materials and designs to produce technical nanosystems ("Bio2Nano"). After some preliminary remarks on nanotechnology in general, the first part of the review highlights the enormous potential of nanobiotechnology with reference to (possible) applications in biomimicry, medicine, agriculture and nutrition ("nanofood"). The second part gives an account of the ethical aspects of nanobiotechnology discussed in the literature, namely risks for humans and the environment, equity ("nano-divide"), military applications, data protection, nanomedicine and enhancement. The ethical problems specific to each aspect are explained - without offering answers - in such a way as to promote a more structured debate as to the ethically appropriate management of nanobiotechnology.

Philosopher and ethicist Andreas Bachmann is Operations Director of the "ethik im diskurs" consultancy (Zurich). His main interests are general ethics, risk ethics, care ethics and dementia ethics, and philosophy of the good life.

This volume deals with plants, and how they differ from animals, from the perspective of modern biology. Swiss legislation calls for the dignity of living beings to be respected in the case of plants as well as animals. While there are certain indications as to what the dignity of animals consists in, the question arises: in virtue of what properties could dignity be ascribed to plants? In contrast to animals, there is a greater tendency to perceive plants as mere objects rather than as forms of life that are to be respected and protected for their own sake.

It is first shown that plants and animals share a long evolutionary history. Even though they differ fundamentally in their organization, there are strong similarities with regard to their cellular structures and degree of complexity. There follows a description of the capacity of plants to pick up, store and react to information from their environment. On this basis, it is argued that the differences between plants and animals are only of degree. From a biological perspective, animals cannot be claimed to be more highly developed than plants.

Jürg Stöcklin is Professor of Botany and a research group leader at the Institute of Botany, Basel University. He works on plant ecology and population genetics and on questions of evolutionary biology.

Andreas Brenner considers the question "What is life?" from a philosophical perspective. To set the framework for a response, it is first shown why this question is so difficult to answer, and why the so-called life sciences contribute little to its elucidation.

In philosophy, by contrast, the question of life has been explored in depth from the earliest days. Twentieth-century biophilosophical theories revisit these positions in an original manner and, adopting a wide variety of approaches, reveal the reflexivity of life. The concept of life thus arrived at is tested against "artificial life" designs, i.e. computer science models and synthetic biology projects. It is examined whether and to what extent the concept of life is applicable in such cases. Finally, the study returns to the question of the reflexivity of living entities. On this view, recent scientific observations can be interpreted to the effect that life is articulated in the generation of meaning (signification). This conception is studied in biosemiotics.

Andreas Brenner teaches philosophy at Basel University. His most recent publication is "Bioethik und Biophänomen. Den Leib zur Sprache bringen" (Bioethics and biophenomenon. Expressing the lived-body.), Würzburg 2006.

6 Contacts

In its almost 10-year history, the ECNH has established a wide range of contacts in Switzerland and especially also within Europe. The Chair and the Executive Secretary take part in selected discussion groups and conferences dealing with non-human biotechnology and related areas. However, the ECNH also benefits from the numerous contacts maintained by Committee members in the course of their professional activities.

6.1 Collaboration with other federal committees

The ECNH collaborates with other Swiss federal committees that are responsible for areas overlapping with non-human biotechnology and gene technology. Such collaboration is specified in its mandate, in particular with the Federal Committee on Animal Experiments (SCAE), the Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE) and the Federal Expert Commission for Biosafety (FECB). Collaboration is primarily topic- and situation-specific. The - to some extent institutionalized - exchange of information between the various Chairs and Secretariats, and especially the sharing of minutes, makes it possible for the committees to follow each other's internal discussions.

6.2 Collaboration with other federal bodies

Interactions with the various federal authorities dealing with non-human biotechnology vary in intensity depending on the priority topics of the ECNH. The Committee's most important partners on an ongoing basis are the Federal Office for the Environment (FOEN), which also has administrative responsibility for the ECNH, the Federal Veterinary Office (FVO), the Federal Office of Public Health (FOPH), the Federal Office for Agriculture (FOAG) and the Federal Institute of Intellectual Property (IGE). Certain topics also call for liaison with the Swiss Agency for Development and Cooperation (SDC) and the State Secretariat for Economic Affairs (seco).

Also important for the ECNH are its exchanges with the Centre for Technology Assessment (TA-SWISS), which was until the end of 2007 attached to the Swiss Science and Technology Council (SSTC) and is now a Centre of Competence of the Swiss Academies of Arts and Sciences. To ensure the exchange of information, the Executive Secretary attends meetings of the TA-SWISS Steering Committee as a guest. In certain case, members of the ECNH also participate in supporting groups for TA projects.

In connection with the publication on primate research, discussions were also held with or under the auspices of the Swiss National Science Foundation. At these discussions, the ECNH was also represented by the Chair and the Executive Secretary.

During the period under review, contacts were also newly established with the Swiss UNESCO Commission at the Federal Department of Foreign Affairs. This "focal point", which represents Switzerland's interests vis-à-vis UNESCO, approached the Secretariat in connection with the negotiations concerning the UNESCO Universal Declaration on Bioethics and Human Rights. Together with a delegate from the FOEN, the Secretariat represented Switzerland at the negotiations for this Declaration, which was adopted by the Member States in Paris in October 2005. In the spring of 2006, Switzerland also hosted, on behalf of UNESCO, a regional consultation on science ethics. This meeting, held at UN Headquarters in Geneva, was jointly sponsored by the ECNH, which was represented by the Chair and the Executive Secretary.

6.3 International contacts

Platform for European Bioethics Committees

The platform for discussions between European bioethics committees in the non-human biotechnology field was initiated by the Netherlands Commission on Genetic Modification (COGEM) in 2002. It organized a workshop to promote dialogue on ethical topics among national ethics committees concerned with non-human biotechnology. The second meeting was held in Bern in September 2003. In October 2005, the ECNH once again acted as host, after a meeting due to be held in Belgium was cancelled for financial reasons. This event was attended by representatives of bioethics committees from 12 European countries. Partners from the various federal offices and from other federal committees were also invited. The fourth meeting was scheduled to take place in May 2007 in Ålesund (Norway) but had to be postponed due to clashing dates.

European Society for Agricultural and Food Ethics

Internationally, the European Society for Agricultural and Food Ethics (EurSafe) continues to serve as an important platform for contacts and communication. This organization was established in 1999 on the initiative of Dutch and Danish ethicists. Between 2000 and 2002, the ECNH was also represented on the Executive Committee of EurSafe. At the 5th Congress, held in Leuven (Belgium) in September 2004, the Executive Secretary of the ECNH served on the scientific committee selecting workshop presentations. The 6th Congress took place in Oslo in June 2006 and the 7th in Vienna in September 2007.

7 Public events

In September 2004, the ECNH hosted a public debate in Bern on "developing countries and gene technology", at which it also presented its booklet on this subject. In May 2006 – also in Bern – a press conference was held at which the booklet on primate research was jointly presented by representatives of the ECNH and the SCAE.

8 Website

Content on the ECNH website (www. ekah.admin.ch) is available in English, French, German and Italian. Users can find information on the Committee's mandate and current membership, as well as the Opinions and publications issued and expert reports commissioned by the ECNH. Volumes appearing in the series "Beiträge zur Ethik und Biotechnologie" can also be downloaded free of charge in PDF format.

9 Budget and remuneration of **Committee members**

The ECNH was established by the Federal Council, which also appoints the members. Administratively, however, the Committee is attached to the Substances, Soil, Biotechnology Division of the Federal Office for the Environment. The FOEN provides the ECNH with an annual budget of around CHF 200 000 to fulfil its mandate. These funds are used for public relations activities, external research, studies and expert reports, and publications. With regard to the content of its work, the ECNH is independent. For the appropriate use of its funds, the ECNH is accountable to the FOEN.

The members of the ECNH are remunerated in accordance with the Ordinance on Per Diem Payments and Compensation for the Members of Extraparliamentary Commissions (SR 172.311). For meetings, employees receive a daily fee of CHF 200, while self-employed members receive twice this amount.

June 2008

For the Federal Ethics Committee on Non-Human Biotechnology

Klaus Peter Rippe Chair

Ariane Willemsen Executive Secretary

External experts attending ECNH meetings during the period 2004–2007

Felix Addor

Swiss Federal Institute of Intellectual Property (IGE), Member of the Executive Board

Meeting on 26 August 2004 to discuss the public consultation on the revision of the Patents Act (PatG); meeting on 26 August 2005 to discuss the internal consultation.

Daniel Ammann

Swiss Working Group on Gene Technology (SAG)

Meeting on 18 March 2004 to discuss "pharmacrops".

Andreas Bachmann

ethik im diskurs, Zurich
Meeting on 1 June 2006 to discuss
nano(bio)technology, presentation of
the ethical review commissioned by
the ECNH.

Heike Baranzke

Moral Theology Department, Faculty of Catholic Theology, Bonn University Meeting on 20 April 2006 to discuss the dignity of living beings with regard to to plants.

Antony Blanc

Head of Biopharma Business Team, Syngenta

Meeting on 27 January 2004 to discuss biopharmacy: agrochemical industry perspectives.

Heinz Böker

Head of the Affective Disorders Unit at Zurich University Psychiatric Hospital

Meeting of the ECNH-SCAE Working Group on "Primate models" held on 12 May 2005 to discuss the significance of primate research from the perspective of clinical psychiatry.

Andreas Brenner

Basel University
Meeting on 20 April 2007, presentation of his philosophical investigation of the concept of life, commissioned by the ECNH.

Karoline Dorsch-Häsler

Federal Expert Commission for Biosafety (FECB), Executive Secretary Meeting on 22 June 2007 to discuss applications for the release of genetically modified organisms.

Federal Committee on Animal Experiments (SCAE), members

Meeting on 19 January 2006 to approve the joint ECNH-SCAE report on primate research.

Arthur Einsele

Head of Public Affairs, Syngenta/Internutrition Meeting on 27 January 2004 to discuss biopharmacy: agrochemical industry perspectives; meeting on 12 March 2004 to discuss the popular initiative "for GM-free food".

Christoph Errass

Federal Office for the Environment (FOEN), Legal Division

Meeting on 28 January 2005 to discuss the planned ECNH Ordinance; meeting on 22 April 2005 to discuss the revision of the Release Ordinance (FrSV), in particular the procedure for applicants and the regulatory authority in weighing up interests with regard to the dignity of living beings.

Olivier Félix

Federal Office for Agriculture (FOAG), Means of Production Division, Plant Protection Products Section Meeting on 7 December 2006 to discuss the revision of the Plant Protection Products Ordinance (PSMV).

Nikolai Fuchs

Goetheanum, Dornach, Head of Agriculture Section Meeting on 20 April 2006 to discuss the dignity of living beings with regard to plants.

Martin Girsberger

Swiss Federal Institute of Intellectual Property (IGE) Meeting on 26 August 2004 to discuss access and benefit sharing.

Franz P. Gruber

Altex

Meeting of the ECNH-SCAE Working Group on "Primate models" held on 14 April 2005, hearing on research involving primates in general and marmosets in particular.

Stephan Häsler

Federal Veterinary Office (FVO) Meeting on 26 November 2004 to discuss the popular initiative "for GM-free food".

Paul Herrling

Head of Corporate Research, Novartis Meeting of the ECNH-SCAE Working Group on "Primate models" held on 28 February 2005 to discuss the topic: "Indispensability of primate research in general and of primate models of depression in particular".

Hans Hosbach

Federal Office for the Environment (FOEN), Biotechnology and Substance Flows Section

Meeting on 19 March 2004 to discuss the revision of the Ordinances relating to the Gene Technology Act, in particular the Release (FrsV) and the Containment Ordinance (ESV); meeting on 28 January 2005 to discuss the planned ECNH Ordinance; meeting on 22 June 2007 to discuss the concise report by the ECNH on

Hans Werner Ingensiep

Essen University

Meeting on 20 April 2006 to
discuss the dignity of living beings
with regard to plants.

the dignity of living beings with

regard to plants and the draft Release

Ordinance for internal consultation.

Katharina Jenny

Swiss Agency for Development and Cooperation (SDC)

Meeting on 18 March 2004 to discuss the impacts of gene technology on developing and transition countries.

Herbert Karch

Swiss Association for the Protection of Small and Medium-Sized Farms (VKMB)

Meeting on 26 November 2004 to discuss the popular initiative "for GM-free food".

Alain Kaufmann

Lausanne University
Meeting on 26 October 2006:
information on the Grenoble report
"Démocratie locale et maîtrise sociale
des nanotechnologies – Les publics
grenoblois peuvent-ils participer aux
choix scientifiques et techniques?"
(Local democracy and social control
of nanotechnologies – Can the Grenoble public participate in scientific and
technological choices?).

Georg Karlaganis

Federal Office for the Environment (FOEN), Substances, Soil, Biotechnology Division

Meeting on 26 October 2006 to discuss the federal action plan on nanotechnology.

Frederick Meins

Friedrich Miescher Institute (FMI) for Biomedical Research (Epigenetics), Basel

Meeting on 7 December 2007 to discuss the synthetic biology topic: "What is life?"

Matthias Meyer

State Secretariat for Economic Affairs (seco)

Meeting on 18 March 2004 to discuss the impacts of gene technology on developing and transition countries.

Ursula Moser

Federal Veterinary Office (FVO), Executive Secretary of the Federal Committee on Animal Experiments (SCAE)

Meeting on 18 November 2005 to discuss the next steps regarding the ethical evaluation of primate experiments; meeting on 19 January 2006 to approve the joint ECNH-SCAE report on primate research.

Sven Panke

Federal Institute of Technology (ETH) Zurich

Meeting on 24 August 2007, introduction to synthetic biology.

Christopher R. Pryce

Federal Institute of Technology (ETH)
Zurich

Meeting of the ECNH-SCAE Working Group on "Primate models" held on 14 April 2005, hearing on research involving marmosets.

Andrea Raps

Federal Office for the Environment (FOEN), Biotechnology and Substance Flows Section

Meeting on 22 June 2007 to discuss applications for the release of genetically modified organisms.

Beda Stadler

Institute of Immunology, Medical Faculty, Bern University
Meeting on 7 December 2007 to
discuss the synthetic biology topic:
"What is life?"

Jürg Stöcklin

Basel University
Meeting on 26 August 2004 to discuss
the dignity of plants, presentation
of the findings of the study commissioned by the ECNH.

Louis Tiefenauer

Paul Scherrer Institute (PSI) Meeting on 22 April 2005, introduction to nanotechnology.

Federal Ethics Committee on Non-Human Biotechnology (ECNH) c/o Federal Office for the Environment (FOEN) CH-3003 Bern

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