Report of activities 2008–2011

Schweizerische Eidgenossenschaft
Confédération suisse
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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 biotechnology and gene technology applications in animals, plants and other organisms, and their impacts on humans and the environment. It comments from an ethical perspective on the issues 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 ECNH mandate involves three main responsibilities:

1 The ECNH advises the Federal Council and subsidiary authorities on the preparation of legislation in the field of non-human biotechnology from an ethical perspective and submits proposals for future legislation.

2 It advises the federal and cantonal authorities on the enforcement of federal regulations.

3 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 around ten full-day meetings, including generally two two-day meetings per year. In addition, public meetings were held for the presentation of opinions. At the request of the committee members, the meetings took place in Bern, with the exception of one two-day meeting in September 2011, which was held in Lausanne.

On 1 January 2010, the new Government and Administration Organisation Ordinance (GAOO) entered into force. Under the revised GAOO, Committee members must disclose their interests. The list of interests is published by the Department of the Environment, Transport, Energy and Communications (DETEC), which has administrative responsibility for the ECNH. The list can also be viewed on the ECNH website.

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 Organisation 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 ECNH mandate.

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 on 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 issues relating to 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 Committee structure and members

2.1 Committee structure

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 non human living beings. 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 twelve members from a range of disciplines. At least half are required to be specialists in philosophical or theological ethics. The members are selected for their personal qualifications rather than as representatives of specific interests.

2.2 Chair

Professor Klaus Peter Rippe has been Chair of the Committee since 2003. Klaus Peter Rippe has been a member of the ECNH since it was established in April 1998 and was appointed Chair by the Federal Council as of 1 January 2004. He had already taken over the chair on an interim basis in November 2002 following the resignation of his predecessor, Andrea Arz de Falco.

Klaus Peter Rippe studied Philosophy, History and Ethnology. He was a research scientist at the Universities of Saarbrücken and Mainz and, from 1995 to 2002, served as Senior Assistant at the Zurich University Centre for Ethics. He lectures in Practical Philosophy at the University of Education, Karlsruhe, in Business Ethics at the University of Applied Sciences Northwestern Switzerland and in Animal Ethics at Vetsuisse, the veterinary medicine faculties of the Universities of Bern and Zurich. In addition, he is director of the "ethik im diskurs" consultancy in Zurich.

2.3 Members from 2008–2011

From the field of philosophical and theological ethics:

Klaus Peter Rippe
Prof. Dr. phil. I, Professor of Practical Philosophy at the University of Education, Karlsruhe (German), lecturer at the University of Applied Sciences Northwestern Switzerland and at VetSuisse, Director of the "ethik im diskurs" office, Zurich

Bernard Baertschi
PhD in Philosophy, Senior Lecturer at the Department of Philosophy and at the Institute of Biomedical Ethics CMU at the University of Geneva

Hans Jürgen Münk
PhD in Theology, Professor of Theological Ethics and Director of the Institute for Social Ethics, University of Lucerne until the end of July 2009; summer semester 2011 and winter semester 2011/12 substitute lecturer in Social Ethics at the Ludwig-Maximilians University, Munich

Georg Pfleiderer
Prof. Dr. theol., Professor of Systematic Theology/Ethics, University of Basel

Beat Sitter-Liver
Prof. Dr. phil. I, Professor of Practical Philosophy at the University of Fribourg and lecturer at the Swiss Federal Institute of Technology (ETH Zurich), former Secretary General of the Swiss Academy of Humanities and Social Sciences and of the Council of the Swiss Academies of Arts and Sciences CASS

Urs Thurnherr
Prof. Dr., Professor of Philosophy at the University of Education in Karlsruhe (Germany)

Véronique Zanetti
Prof. Dr., Professor of Ethics and Political Philosophy at the University of Bielefeld (Germany)

from the field of natural sciences:

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

Martine Jotterand
Prof. Dr.sc., until the end of 2009 Director of the cancer cytogenetics unit and Professor of Genetics, Medical Genetics Service, Centre Hospitalier Universitaire Vaudois and University of Lausanne (CHUV-UNIL), since 2010 visiting Professor of Genetics at the Faculty of Biology and Medicine and since 1 August 2011 Honorary Professor at the UNIL.

Florianne Koechlin
Biologist, Switzerland. Swiss Working Group on Gene Technology SAG, Blueridge Institute, Münchenstein

from the field of medicine:

Cornelia Klauser-Reucker
Dr. med., general practitioner FMH, doctor in Psychosomatics and Psychosocial Medicine and medical hypnosis in Caslano (Canton Ticino)

and legal science:

Markus Schefer
Prof. Dr. LL.M., Professor of Constitutional and Administrative Law, University of Basel

Secretariat

The Secretariat reports to the Chair of the Committee and is administratively attached to the Federal Office for the Environment (FOEN); due to the thematic similarities, it is affiliated to the Waste Management, Chemicals and Biotechnology Division (formerly Substances, Soil Biotechnology until the end of 2009).

The Secretariat aids the Chair of the Committee and its members in the fulfilment of their tasks. It prepares statements and reports for the Committee, prepares committee meetings and organises the public relations activities of the ECNH. It maintains contacts with Swiss and international authorities and committees whose work involves aspects of non-human biotechnology and gene technology, and is responsible for administrative tasks. The Secretariat is run by Ariane Willemsen, lic. iur. M.A.

3 Implementing the mandate

The ECNH has the statutory task to monitor developments in the field of non-human biotechnology and evaluate them from an ethical perspective. The ECNH addresses certain topics on its own initiative with a view to future legislation, and makes recommendations to the legislators. It also comments on forthcoming legislative projects and on specific licence applications which are of exemplary or fundamental importance. In the case of licence applications, this advice includes projects for the manufacture, release and placing on the market of genetically modified and pathogenic organisms as well as patent applications in the non-human field.

The ECNH submits its statements to the federal office responsible for the subject area, a concrete legislative project or the licence application in question. The ECNH's statements are of an *advisory nature.*

ECNH statements are not necessarily based on consensus. They are essentially concerned with an examination of the arguments. In its reports and statements, the ECNH therefore expresses not only the lines of argument which have been discussed, but also the majority and minority views. It has been shown that the members often agree on the significance of the arguments. Disagreements generally arise only in the evaluation of these arguments. The aim of the discussions within the Committee is to establish where and especially why the evaluations diverge and to explain this to the authorities in a comprehensible manner, so that the latter has a sufficient ethical decision-making basis.

3.1 Advice on legislation

The ECNH advises the Federal Council and the federal administration not only on current legislative projects, but also on possible future legislation that may become necessary from an ethical perspective due to new technologies or their applications. In order to make an ethical assessment of emerging technologies and their possible applications, in most cases it is first necessary to establish assessment criteria. In such cases, the ECNH is able to refer to external experts for additional specialist knowledge as required. The latter are invited to attend hearings and take part in discussions at committee meetings. The Committee also has the possibility of commissioning an external expert opinion. On the basis of these principles, the ECNH discusses and draws up its ethical reviews and presents its recommendations to the authorities. As in the previous 2004–2007 period, the ECNH once again focused in particular on groundwork of this kind.

3.1.1 The Moral status of plants

The report "The dignity of living beings with regard to plants – Moral consideration of plants for their own sake" attempts to specify the constitutional and legal understanding of the dignity of living beings in terms of our treatment of plants. Published in April 2008, it aroused controversial reactions. The constitutional obligation to respect the dignity of living beings with regard to animals, plants and other organisms formed the background to the report. An article to this affect was included in the Constitution following a referendum in 1992: Article 24^{novies} paragraph 3 of the old Federal Constitution, which corresponds to Article 120 of the Federal Constitution revised in 1999. At a statutory level, in the Gene Technology Act, which entered into force on 1 January 2004, the term "dignity of living beings" was restricted to relating to animals and plants.

The Federal Constitution and Gene Technology Act are both explicit in stating that account should also be taken of the dignity of living beings in relation to plants. However, it is unclear what constitutes this dignity and what it implies for the way in which plants are consequently treated. Since the ECNH was established by the Federal Council in April 1998, the Committee has been expected to suggest ways in which this vague constitutional concept, "the dignity of living beings" in relation to plants, could be made more specific at ordinance level. Having been in existence for ten years, during which time it looked closely at the concept in relation to animals in general and primates in particular, the Committee broached this complex topic. In particular it was urged to do so by the Federal Office for the Environment, which is responsible for specifying the concept at ordinance level. In the preceding years it had prepared by hearing a range of experts and commissioning an expert report from Prof. Jürg Stöcklin, from the Botanical Institute at the University of Basel. This report was published in 2007 in the ECNH "Beiträge zur Ethik und Biotechnologie" *(Contributions to Ethics and Biotechnology)* book series, appearing under the title "Die Pflanze – Moderne Konzepte der Biologie" *(The Plant – Modern Concepts in Biology).*

The meaning of the German term "Würde" – "dignity" – is based on two different traditions: the *bonitas* and the *dignitas* tradition. Whereas the *dignitas* tradition is characterised by both the philosophical and the theological, the *bonitas* tradition is predominantly linked with Christian theological concepts. According to this tradition, all living beings created by God have bonitas, whereas only human beings, who were created in God's image, are accorded *dignitas*. The French version of the Federal Constitution refers to the *intégrité des organismes vivants* in the context of the dignity of living beings in clear contrast to *dignité humaine*. In the Italian version *dignità della creatura,* as in the German version, this distinction is lost.

The concept of living beings includes animals, plants and other organisms. The current discussion on the dignity of living beings has been influenced by the constitutional interpretation, in which the concept of dignity relates to the worth of the individual living being for its own sake. The legal concept of the dignity of living beings differs from that of human dignity. The obligation to take account of the dignity of living beings with regard to animals and plants is met when their interests are considered and it is determined that these have less worth than the human interest in damaging them. The ECNH's task, however, has been to conduct the ethical discussion for the time being irrespective of the legal debate, so as not to accept ethical premises implied in the legal discussion without subjecting them to a critical review.

The general ethical question facing the ECNH is whether and why plants should be protected. Either they are worthy of protection in themselves or they should be protected for some other reason or reasons. It is undisputed that circumstances exist under which plants should be protected for other reasons, e.g. because they are of use to human beings. Independent of the term "the dignity of living beings", the key question therefore remains of whether plants have inherent worth and therefore whether or not they are worthy of protection for their own sake.

For some, merely the question of whether it is justified to treat plants morally is an affront to "common sense". A moral consideration of plants is thought to be nonsense. In many people's opinion, the way we treat plants is a neutral issue and our treatment of plants consequently requires no justification. But there are also those who believe that plants should not be included in a moral consideration of living things for their own sake for other reasons. If humans were required to justify their treatment of plants, human life would become too complicated and morally too demanding. There is also the danger that more highly ranked moral obligations towards people (and animals) could be relativised as a result of ethical positions that take account of plants for their own sake.

In an initial phase of the discussion, the Committee hoped to be able to establish general criteria for the treatment of plants on the basis of concrete, paradigmatic examples. However, it

became evident that in the case of plants – in contrast to animals – it is not possible to have recourse to moral intuition. There is no general societal understanding of common sense when it comes to the treatment of plants. The ECNH members also showed very diverse intuition in relation to the extent and legal justification of moral obligations towards plants. The only criterion on which all members could agree, despite the very diverse directions of their intuition, was that plants should not be treated in an arbitrary manner. The intuitive approach did not, however, lead any further; furthermore, it is debatable whether intuition should play a role in ethical discussions. In a second attempt, it was therefore decided to take a theoretical approach. Fundamental ethical positions regarding the treatment of plants were established: Which ethical positions assume that plants have inherent worth, and therefore permit a moral consideration of plants for their own sake? It became evident that no fundamental ethical position was shared by the members.

Nevertheless, some conclusions could be drawn, which were either unanimous or supported by the majority:

- The concept of the dignity of living beings does not provide them absolute protection, but requires their interests to be considered. The ECNH's position thus supports the legally prevailing interpretation of the concept.
- The majority of committee members support a hierarchical position, according to which either human interests are ranked highest and those of animals higher than those of plants, or one which assigns human characteristics a privileged status and classes other living beings according to their similarity to these human characteristics. In both cases people always take precedence and plants are ranked lowest. No example could be found in which a consideration of interests would result in plants being prejudiced in a morally impermissible manner, unless in the case of *arbitrary* damage to a plant. From the point of view of the ECNH, all prejudice or damage to plants may consequently be justified, apart from arbitrary damage, i. e. damage *without reasonable* grounds. By definition, this may not be justified and is therefore morally impermissible. When it comes to plants, the concept of the dignity of living beings is therefore essentially a moral appeal to be conscious of the fact that we are dealing with living things.

The publication of the report in April 2008 aroused considerable attention not only in Switzerland, but also internationally. In particular in plant science circles, there were objections to the very fact that the issue had been raised and considered, despite the constitutional and statutory terms of reference within Switzerland. Media attention reached a peak in October 2008 when the IG Nobel Prize was awarded to the ECNH for the report and to the people of Switzerland for including in the Constitution a legal concept of the dignity of living beings for animals and plants. The IG Nobel Prize is awarded each year at Harvard University in Cambridge, USA, for academic work which initially provokes mirth and then gives pause for thought. Committee member Urs Thurnherr represented the ECNH at the award ceremony in Boston. The originally purely satirical prize is nowadays an award of considerable renown in academic circles. Some of the laureates have gone on to receive a Nobel Prize.

In June 2009 the ECNH organised a workshop in Bern on this topic. A group of about 40 representatives from the worlds of academia and politics discussed in detail the results of the Committee's report and the legal concept in terms of its applicability to plants as well. It is hoped that the ECNH will be able to work with universities on a closer academic analysis of the topic.

3.1.2 Synthetic biology

Synthetic biology is still a relatively recent field of research, and is shaped predominantly by engineering sciences. At its core lies the idea that life can be designed and reconstructed in a systematic manner. However, so far no uniform definition of synthetic biology has emerged. At present the main focus of research is the deconstruction and reduction of organisms: the genomes of existing bacteria and viruses are reduced to a minimum so that only metabolic functions are maintained. In a second step, artificial modules are integrated into this minimal genome so that these biological systems can perform new functions. Until now, synthetic biology has been widely considered to be a form of extreme gene technology. However, one of the aims of synthetic biology is, in a next step, to reconstruct sections of DNA (so-called *biobricks*) in such a way that new types of biological system are formed. Whether this objective can actually be achieved is debated by some. What is clear, however, is that this step would go beyond the realms of gene technology. Synthetic biology also encompasses the computer-controlled creation of DNA codes. It must be decided whether DNA codes of existing organisms should be synthesised or whether new DNA codes which do not yet exist should be created on a computer and then synthesised. *Existing* DNA

sequences are already synthesised on a commercial basis.

Longer term, research scientists hope to find applications in the fields of medicine, energy generation, environmental protection, the manufacture of new pharmaceuticals and the military; some even dream of synthetic biology becoming a universal technology. However, in practice we are still far removed from this vision. In order to be able to work with biological components in a range of contexts, the components need to function uniformly. As environment plays an important role in the functioning of biological components, it is very difficult to achieve the required degree of uniformity.

In the field of synthetic biology we are dealing with systems which possess the functions – or at least some of the functions – of living beings. In order to be able to assess the opportunities that synthetic biology opens up, we need to answer the question as to what life is. This question has already been asked in connection with other technologies, but in view of some of the targets which synthetic biology sets itself, answering this question has obtained a degree of urgency. In order to obtain an initial overview of the current philosophical use of the concept of life, in autumn 2007 the ECNH commissioned Andreas Brenner (Basel) to carry out a study entitled "Leben – Eine philosophische Untersuchung" *(Life – A philosophical investigation),* which was published in the "Beiträge zur Ethik und Biotechnologie" *(Contributions to Ethics and Biotechnology)* series. The ECNH subsequently conducted hearings with experts on various aspects of this subject. At the end of 2007, two further expert reports were commissioned. The first was from the Institute for Ethics and History of Medicine at the University of Freiburg (Germany), which was asked to construct an ethical map of synthetic biology. This was published in 2009 under the title "Synthetische Biologie – Eine ethisch-philosophische Analyse" *(Synthetic Biology – An ethical and philosophical analysis).* In another study, Anne Eckhardt (risicare GmbH, Zurich) collated for the ECNH information about how this technology is organised and what its objectives are. ECNH member Bernard Baertschi (Institute of Biomedical Ethics CMU at the University of Geneva) was asked to address the issue of the moral status of artificial living beings. His considerations were also published in 2009 under the title "La vie artificielle – Le statut moral des êtres vivants artificiels" *(Artificial life – the moral status of artificial living beings).*

In its report, the ECNH assesses the various goals and methods of synthetic biology, in particular looking at the ethical justification for its aspiration to create living beings in a controlled manner. In the first part of the report, the ECNH concentrates on the issue of what the products of synthetic biology actually are and whether and to what extent there are any ethical obligations towards these products which stand in the way of synthetic biology applications. The second part of the report is devoted to issues of ethical responsibility.

The report suggests that, in order to answer the question as to what extent it is, in principle, possible or otherwise to produce living things under controlled conditions, we must first establish what constitutes the concept of life upon which the assessment is based. There is a range of fundamental ontological positions. The majority of Committee members have a monistic understanding of life, i. e. what we conceive of as life relates to the purely physical and chemical characteristics of living things. The minority of Committee members hold other views – the vitalist and dualistic position, and also the sceptical view. All ontological positions, however, allow for the possibility that the vision of synthetic biology may be successful and that living beings may result from its methods.

Even if certain long-term visions of synthetic biology envisage the manufacture of all types of living things, at present the main focus is on microorganisms, which are being worked with or which are to be manufactured as products. In the context of Article 120 of the Swiss Federal Constitution, which requires that the dignity of living beings be taken into account in dealing with animals, plants and other organisms, it must be established whether or not microorganisms have inherent worth. From the point of view of the ECNH, the way in which living things are created, whether artificially or naturally, does not have any impact on their moral status. Whether microorganisms have something which can be termed "inherent worth" or "dignity", and whether they should therefore be considered from a moral viewpoint, depends on the ethical approach which is applied. The majority of the Committee members take a biocentric approach: microorganisms have inherent worth, because they are alive. One minority group takes a pathocentric approach: as there is no indication that microorganisms perceive damage to their beings as such in any way, according to this minority group, microorganisms are not living beings which are to be taken account of in moral terms. A second minority takes an anthropo-relational approach. Microorganisms are to be considered in moral terms as a result of their relation to people. However, in a consideration of interests, for the members who allow that microorganisms have inherent worth, this inherent worth is

ascribed only minimal importance as a result of their hierarchical position. In practical terms, therefore, none of the members have objections to a project involving microorganisms.

The differences in the ontological positions held within the ECNH are expressed in the different views regarding the degree of control which can be exercised over processes in and products of synthetic biology. These differences influenced the discussion regarding ethical responsibility. In the public debate the ,"slippery slope" argument is also raised, that developments in synthetic biology will inevitably have negative consequences. The members agree that these arguments are useful in raising the issue of the possible negative consequences of synthetic biology, so that attention is paid to its development in this field. However, in their view, the doubts raised to date do not at present justify vetoing synthetic biology projects.

Just as with all technologies and their applications, synthetic biology needs to be assessed and judged from all the various aspects of justice. Issues relating to risk ethics should also be addressed. The ECNH acknowledges that synthetic biology opens up a broad field of research and application. However, despite rapid developments, it is unclear what the actual applications might be. The field is dominated by visions and uncertainties, i. e. a typical risk situation exists. In the ECNH's view, there are a number of plausible risk scenarios but too little empirical data to carry out a risk assessment. In this report, the ECNH therefore restricts itself to referring to the ethically required course of action in the case of risk situations – a process which is already legally established in other areas of technology. The precautionary principle is applied and in accordance with the step-by-step principle, work may only be carried out under special safety conditions which are appropriate to the organism. The ECNH is of the opinion that there is as yet insufficient data upon which to base a statement on whether the current legal regulations for dealing with genetically modified organisms are sufficient in the case of synthetically manufactured organisms.

In May 2010 the ECNH was the first national ethics committee to publish a report on the ethical aspects of synthetic biology. The German language version of the report was already published in electronic form in December 2009 in order to reflect the topicality of the subject. At the invitation of the European Commission's Directorate-General for Research and Innovation, in the summer of 2010 committee member Martine Jotterand presented the report on behalf of the ECNH at the 8th Global Summit of National Ethics Committees organised by the World Health Organisation (WHO) in Singapore.

3.1.3 Research on primates

In May 2006, a report on the ethical evaluation of primate research was jointly issued by the ECNH and the Swiss 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 research into depression among humans. 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 become involved. It soon became clear that the issue under discussion was not simply whether it was permissible to use primate models in depression research, but about the acceptability of experiments on primates in general.

In their report, the two committees discussed the criteria according to which each animal experiment must be justified following a consideration of interests, in accordance with Swiss law. In such a consideration of interests, the human interest in primate research and the distress suffered by the animals, that is to say, their interest in being free from distress, should be weighed against each other. The greater the weighting given to the stress caused to the animals, the stronger the justification given for the distress caused to the animals must be. Even if it can be shown that a particular animal experiment is scientifically necessary, this does not mean that a consideration of interests is no longer required or that the interest of an experimental animal in remaining

free from distress can be given less weight than the human interest in the animal experiment. Such a conclusion can only result from a careful consideration of interests. In this situation, it is essential to assess the extent to which the research project is likely to prove successful. From an ethical viewpoint, it should be possible to gauge the prospects of success in order to be able to weigh them against the distress caused to the primates. Even though there is a certain degree of uncertainty regarding potential success in any research, the fact alone that knowledge will be gained is not enough to assess the ethical relevance of a project.

The considerations of both committees evoked considerable interest and there was much debate following their publication. The opinion of both committees was confirmed by the Swiss Federal Supreme Court in two judgments issued on 7th October 2009 (2C_421/2008 and 2C_422/2008). The Swiss Federal Supreme Court was required to decide on two other applications to carry out experiments on primates, as an appeal had been made against the decision of the cantonal authority concerned. As the court of last instance, the Swiss Federal Supreme Court ruled that knowledge acquisition must also be weighted, irrespective of whether "pure" or "basic applied research" is being carried out. Freedom of research and protection of animals are given equal status in the Constitution. In the opinion of the Federal Supreme Court, it is unconstitutional to weight freedom of research higher per se than the interest of animals to remain free of suffering.

The ECNH is also attentively following developments in the field of primate research. In order to establish an up-to-date basis for the discussion, in 2009 the Committee asked Prof. Peter Kunzmann, Professor of Applied Ethics at the University of Jena (Germany), to draw up an expert report on the moral status of primates, which he did in collaboration with Prof. Nikolaus Knoepffler. This report was published in 2011 under the title "Primaten – Ihr moralischer Status" *(Primates – their Moral Status),* volume 8 of the "Beiträge zur Ethik und Biotechnologie"*(Contributions to Ethics and Biotechnology)* series.

3.1.4 Risk Ethics

New technology creates new opportunities and new risks. In all areas of biotechnology and its applications we are confronted with uncertainties regarding the consequences of our actions, i.e. with typical risk situations. The concept of risk is characterised by the variables "extent of damage" and "probability". A risk exists if there is a certain degree of probability that damage will occur. In assessing a risk, it is therefore its expected value which is significant. The aim of risk analysis is to determine the *expected value* in a particular case, i.e. to determine the risk as a product of probability and extent of damage. The hope that nothing terrible will occur should not influence the course of action, and nor should fear of the consequences prevent action.

Across a whole range of issues, the ECNH was required both to look at risk analysis and assessment in specific cases, and also to establish the ethical principles for the course of action in risk situations in general. Because very few publications exist on Risk Ethics in the German-speaking world, in 2008 the ECNH published a study by Benjamin Rath entitled "Ethik des Risikos – Begriffe, Situationen, Entscheidungstheorien und Aspekte" *(Risk Ethics – concepts, situations, decision theories and aspects)* as a contribution to the discussion on risk ethics. The study appeared as volume 4 of the "Beiträge zur Ethik und Biotechnologie" *(Contributions to Ethics and Biotechnology)* series.

This study provided a basis for analysing the risk aspects of synthetic biology. Risk ethics also played a role in the Committee's statements on the ongoing revision of the Ordinance on the Contained Use of Organisms; (Containment Ordinance, ContainO); on several occasions in the course of 2011, it examined various risk analysis and assessment models. Risk ethics also influenced the discussion on the report on the ethical requirements with regard to the release of genetically modified plants, which was published at the end of 2011.

3.1.5 Ethical requirements with regard to the release of genetically modified plants

In November 2005 the Swiss electorate voted in favour of the popular initiative "For foodstuffs from GM-free agriculture". This meant a five-year general moratorium on growing and selling genetically modified (GM) plants and GM seeds, until the end of November 2010. In December 2005 the Federal Council decided to mandate the Swiss National Science Foundation with conducting the national research programme "Uses and risks associated with the release of genetically modified plants". The final report of this research programme is due 2012. In 2009 the Federal Council decided to extend the moratorium on the commercial release of GM plants by a further three years until November 2013, so that a decision can be made about the further course of action based on the results of the national research programme. If it is decided not to extend the moratorium further, from the end of November 2013 it will

again become possible to grow and sell GM plants commercially. In view of these circumstances, the ECNH has produced a report on the ethical requirements on the experimental and commercial release of genetically modified plants.

The ECNH has shown that the assessment of experimental or commercial releases depends to a large extent on the models used to describe the nature of genetically modified plants. The Committee identifies two explanatory models and shows why the model which takes the concept of substantial equivalence as a basis is inadequate for making an assessment. This explanatory model assumes that a GM plant is essentially the sum of the original plant which served as a basis for the GM plant and the genetically engineered additional characteristics. It is assumed that the properties of the original plant are known. Of the genetic products which are expressed from the GM plant as a result of the new characteristics (e. g. toxins or proteins), only the effects of those for which no other empirical values are available must be tested. The ECNH explains that, as a result of the complex regulatory and physical links within cells and organisms, GM plants may have both intended and unexpected effects. Besides these pleiotropic effects, epigenetic effects also lead to changes in the plant. These changes may be triggered by the environment and often explain why plants grown outdoors react differently to those grown in the laboratory. Because there is always the possibility that there may be unintended and unexpected effects, GM plants should not be assessed on a causal basis, but must be based on a risk model.

This has practical consequences. The majority of the ECNH members are of the opinion that GM plants may be released on an experimental and commercial basis provided the required knowledge is available to assess their risks and these risks are reasonable for the third parties who are exposed to them. It therefore follows that, in the case of experimental and commercial releases, the precautionary principle must be applied. In addition, a step-by-step approach must be adopted, when and so far as sufficient knowledge is available to permit an assessment as to whether the risks associated with the next step are reasonable for third parties. This step-by-step course of action must also apply to commercial releases. In order to generate the required knowledge to conduct a risk assessment, there is a need for context-related and independent research. If it is found that intellectual property rights restrict such independent risk research, a corresponding privilege to conduct research should be established in law. If releases were continuously monitored, unintentional undesirable and unexpected effects could be determined as early as possible and risk assessment kept up to date.

3.1.6 Ethical approach to fish

Another major theme addressed by the Committee was the ethical treatment of fish. As wild stocks are increasingly overfished and the breeding and farming of both saltwater and freshwater fish shifts to aquacultures, the question as to how fish should be treated from an ethical viewpoint becomes more and more urgent. During the period covered by this report, the Committee carried out preparatory work with a view to producing a later report.

The term "fish" includes an enormous bandwidth of very different living beings. Until now there has been a serious scientific controversy over whether fish are sentient beings. Against this background, the issue of moral status arises in relation to the treatment of fish. The *scala naturae*, which reflects many commonsensical opinions on the moral status of living beings, places fish above plants but below other animals in the hierarchical order of things. This finds expression in the fact that applications in biotechnology and other modern techniques are more advanced in the case of fish than in the case of other (vertebrate) animals.

The ECNH invited several external speakers from the federal administration, NGOs, wholesale distributors and research scientists to investigate the problem of overfishing, the scientific requirements for aquaculture and its potential economic importance for Switzerland, the economic importance of fish for consumption and nutrition in Switzerland and the current legal framework. In order to form an overview of the scientific question as to whether fish are sentient beings, the ECNH also commissioned an expert opinion from Prof. Helmut Segner, Head of the Centre for Fish and Wildlife Health (FIWI) at the University of Bern. The Committee also asked Dr. Markus Wild, research scientist in Theoretical Philosophy at the Humboldt University in Berlin, to provide an expert report on these questions from the perspective of the philosophy of animals. Both reports will be published in 2012.

3.1.7 Consultation on ongoing revision of acts and ordinances

During the reporting period, the ECNH commented on the revision of the following acts and ordinances:

– **FVO Ordinance on the Treatment of Experimental Animals and the Production of Genetically Modified Animals as well**

as on the Procedure for Animal Experiments (Animal Experiments Ordinance). In February 2009 simultaneous hearings were held on the Animal Experiments Ordinance and the Ordinance on the Electronic Information System for the Administration of Animal Experiments (AAEO). The ECNH decided not to issue a report on the AAEO, as the latter does not touch on any issues that are within the ECNH's remit. In its statement on the Animal Experiments Ordinance, the Committee commented in particular on the new criteria which, as a result of statutory requirements to take account of the dignity of living beings in the case of animals, must form part of a consideration of interests when a decision is being made regarding licence applications to perform animal experiments (alteration of appearance, excessive instrumentalisation and humiliation). In particular the Committee indicated that these new criteria must be taken into consideration independently of animals' perceptions, unlike the pre-existing criteria regarding stress levels. These criteria should therefore be removed from the degree of severity list and be separately regulated.

– **Spatial Planning Act.** In April 2009 the ECNH touched on the consultative bill for the Spatial Planning Act. It pointed out that regulations on the coexistence of GM and conventional agriculture have yet to be finalised and would need to be addressed in relation to spatial planning.

– **Ordinance on the Contained Use of Organisms (Containment Ordinance, ContainO).** After the Gene Technology Act came into force in January 2004, a revision was begun of the Ordinance on the Handling of Organisms in the Environment (Release Ordinance, RO), in force since 1999, and of the Ordinance on the Contained Use of Organisms (Containment Ordinance, ContainO). The revised Release Ordinance came into force in September 2008. The ECNH has issued statements on the complete revision of the Containment Ordinance on several occasions. In particular it made comments on the proposed regulation of risk analysis and assessment in Annex 4 of the Containment Ordinance. The revision of the Containment Ordinance was still pending during the reporting period.

– **Changes to the Gene Technology Act on the Extension of the GMO Moratorium in Agriculture.** In November 2005 the Swiss electorate and cantons accepted the popular initiative on food from GM-free agriculture. This meant the addition of a transitional provision to Article 120 of the Federal Constitution, where by no GMOs may be used in agriculture for a period of five years. In particular the introduction and placing on the market of reproducible genetically modified plants, plant parts and seed intended for environmental use in agriculture, gardens or forests was prohibited, but not the use of imported genetically modified foodstuffs. In 2009 the Federal Council presented the results of a consultation on changes to the Gene Technology Act, whereby the existing moratorium would continue to form part of the Act, essentially remaining unchanged for a further three years until the end of November 2013. Having already made a statement on the ethical aspects of the popular initiative, the ECNH dispensed with a renewed discussion of the moratorium, as no new ethical issues were raised by this amendment to the law. However, it issued a critical statement on the limitation of the objection and appeal proceedings, which were handled in the same bill.

– **"Risk assessment and risk management of synthetic nanomaterials 2006–2009" Action Plan.** Applications of developments in the field of nanotechnology in life sciences and the use of biological materials and construction plans to manufacture technical nanosystems are considered to have enormous potential, not only in medicine, but also in agriculture and nutrition. On the other hand, new technical opportunities also bring new risks. The ECNH addressed this issue early on, conducting hearings with external experts and commissioning an ethical study which opened the 2006 "Beiträge zur Ethik and Biotechnologie" book series (Andreas Bachmann, *Nanobiotechnologie. Eine ethische Auslegeordnung (Nanobiotechnology. An ethical appraisal),* 2006). When, in 2006, the Federal Office for the Environment and the Federal Office of Public Health launched the action plan entitled "Risk assessment and risk management of synthetic nanomaterials 2006–2009", the ECNH decided to suspend its work on the topic and instead concentrate on the ethical assessment of another new technology, synthetic biology, that had not yet been widely discussed in political circles. The ECNH was also represented by its secretariat in the support group set up by the Confederation to implement the action plan.

3.2 Advice on enforcement

Under Article 23 paragraph 3 of the Gene Technology Act, the ECNH has the mandate to advise the Federal Council and subsidiary authorities on ethical issues related to on non-human gene technology and biotechnology not only when preparing legislation, but, in exemplary cases or those which are of particular significance, on enforcing this legislation. The mandate includes dealing with genetically modified organisms (GMOs) in contained systems (e. g. in the laboratory or in greenhouses), and the experimental (and, if ever allowed at some stage, commercial) release of GMOs. It also encompasses the placing on the market of genetically modified food for human consumption and animal feedstuffs as well as the assessment of patent applications which aim to ensure the protection of objects or procedures which may infringe on the dignity of living beings. The regulatory authority concerned in each case submits the application to the ECNH for comment. The ECNH decides whether a case is exemplary or of particular significance from an ethical viewpoint, and provides comments accordingly.

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 make recommendations 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 when a decision on a specific individual case is made. It is possible 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 mechanisms to prevent ethically unjustifiable decisions in the future.

3.2.1 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. Having been considered by all the offices involved, the applications were approved. The ECNH also submitted its considerations to the licensing authority. The trials were carried out during the reporting period 2008–2010; the results are still being assessed.

One of the applications, submitted by the Zurich University Institute of Plant Biology, concerned a study designed to investigate how various genetically modified wheat lines with enhanced specific resistance to the fungal disease mildew 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 being developed.

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 experiments 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 was 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 was 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 show greater resistance to fungal diseases in the field and how this functions under natural conditions, the trials were 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).

When the applications for trials due to take place in 2009 and 2010 were approved, the applicant had not yet provided all the trial details. The applicant therefore submitted the additional information required by the licensing authority at the end of 2008 and at the end of 2009/beginning of 2010, and this was passed on to the ECNH for comment. The ECNH chose not to issue a statement on this additional information. Instead it decided

to address the issue of the ethical requirements on releases of genetically modified organisms irrespective of specific applications.

In accordance with Article 56, paragraph 2 of the Release Ordinance, the FOEN maintains a public registry of all genetically modified organisms for which marketing authorisation has been granted. This registry is available (in English) at www.bafu.admin.ch/biotechnologie/index.html?lang=en.

3.2.2 Tolerance level authorisation for traces of GMO in foodstuffs

Under Article 23 of the Foodstuffs and Utility Articles Ordinance (LGV) and Article 6a of the FDHA Ordinance on Genetically Modified Foodstuffs (GMFO), traces of genetically modified organisms in foodstuffs are tolerated without the need for authorisation, provided it can be proven that food safety is guaranteed and there is no threat to the environment according to current scientific knowledge.

– **Maize NK603.** In October 2008 the Federal Office of Public Health invited the ECNH to provide a statement on the authorisation of tolerance levels for traces of maize NK603. The genetically modified maize produced by the Monsanto company expresses a protein which makes the maize plant resistant to glyphosate, an active substance in herbicides (e.g. in the herbicide "Roundup Ready"). An application for authorisation in foodstuffs is pending.
  The ECNH declined to comment on the specific case, but did draw attention to the difficulties involved in assessing safety aspects. It recommended that the effects of the tolerance level authorisation procedure should be carefully observed and if necessary adapted in agreement with the authorities concerned.

– **Maize 1507.** In January 2011 the Federal Office of Public Health (FOPH) submitted a further application for tolerance level authorisation for traces of the genetically modified maize line 1507 produced by the companies Pioneer Hi-Bred and Mycogen Seeds. Genetic information which produces an insecticide and herbicide has been introduced into this maize line.
  The ECNH referred to the ECNH Considerations on tolerance level authorisation, with which the FOPH was already familiar, and to its 2003 report "Gentechnik fürs Essen" (Gene Technology for Food), in which the ECNH discussed in detail the various ethical aspects which should be considered in connection with the authorisation of genetically modified foodstuffs.

The Federal Office of Public Health maintains a list of pending applications, GM foodstuffs and tolerance level authorisations under the following link: www.bag.admin.ch/themen/lebensmittel/04858/04863/index.html?lang=de. (not available in English)

3.2.3 Placing genetically modified animal feedstuffs on the market

– **Maize 1507.** In May 2011 the Federal Office for Agriculture, the regulatory office responsible for authorising genetically modified animal feedstuffs, reconsidered an application from the Pioneer Hi-Bred and Mycogen Seeds companies for authorisation of the maize line 1507. The application had been pending since 2001. In 2003 and 2006 the applicants had submitted further documents required by the authorities in order to make an assessment. The ECNH had already commented on this matter in 2002. In 2011 it again expressed its opinion on this renewed application. The procedure had not yet been completed at the time of writing.

The Federal Office for Agriculture provides information about permitted and tolerated GMOs in animal feedstuffs in Switzerland at: www.blw.admin.ch/themen/00011/00074/index.html?lang=de. (not available in English)

4 Publications

The ECNH publishes its statements on its website at www.ekah.admin.ch. Reports on fundamental issues are also published in brochure form. Selected external expert reports which are of interest and importance to a wider public are published in the "Beiträge zur Ethik und Biotechnologie" *(Contributions to Ethics and Biotechnology)* book series, which first appeared in 2006. All other external studies and expert reports whose content has a particular bearing on current discussions are only available in electronic form on the ECNH website.

4.1 ECNH brochures

The dignity of living beings with regard to plants – Moral consideration of plants for their own sake (April 2008)
For a short description of the contents see Sec. 3.1.1

Synthetic biology – Ethical considerations (May 2010)
For a short description of the contents see Sec. 3.1.2

The ECNH brochures are available in printed form in German, French and English, and also in Italian in electronic form on the ECNH website www.ekah.admin.ch.

The ECNH main reports are also used by various higher education institutions as teaching materials.

4.2 Beiträge zur "Ethik und Biotechnologie" book series

In the "Beiträge zur Ethik und Biotechnologie" (Contributions to Ethics and Biotechnology) book series, the ECNH publishes expert reports which it has commissioned and which are of interest to a broad public. These expert reports contain principles for addressing the ethical aspects of biotechnology and serve as working papers for the ECNH.

The books in the "Beiträge zur Ethik und Biotechnologie" series can be purchased from the Federal Office for Buildings and Logistics FBL, Verkauf Bundespublikationen, CH-3003 Bern (www.www.bundes-publikationen.admin.ch; provide article number) or from bookshops. The books are sold at a cost price of about Fr. 12.–. The texts can also be downloaded free of charge in PDF from the ECNH website www.ekah.admin.ch.

Benjamin Rath, Ethik des Risikos. Begriffe, Situationen, Entscheidungstheorien und Aspekte (Risk Ethics. Definitions, situations, decision theories and aspects), 2008 (Volume 4 in the book series) FBL article number 810.005.d; ISBN 978-3-905782-03-5

Risk Ethics is concerned with the ethical valuation of decisions on how to act in risk situations; that is to say, decisions which involve an element of risk when put into practice. To what risks may a person expose themselves or others? In order to be able to answer this question, in the first section of the book, essential terms relating to risk ethics are defined and various different risk situations identified. In the second part, three different decision theories in Risk Ethics are described (Bayesian Decision Theory, Maximin Principle, Precautionary Principle) and the implications of each discussed. The decision theories in risk ethics include a range of positions, from those characterised by a rational approach through to one which attempts to avoid the worst case scenario. Finally, the third part deals with aspects which are of considerable importance in the debate on risk ethics. Some of these are described in more detail, for example the function of consent and compensation, individual rights, property rights to risks and how these are distributed.

Benjamin Rath, lic. phil., studied Philosophy, Economics and modern German literature at the universities of Hagen, Helsinki and Zurich. He is currently writing a thesis on Risk Ethics.

Joachim Boldt, Oliver Müller, Giovanni Maio, Synthetische Biologie. Eine ethisch-philosophische Analyse (Synthetic Biology. An ethical-philosophical Analysis), 2009 (Volume 5 in the book series) FBL article number 810.006.d; ISBN 978-3-905782-04-2

Similar to physics and chemistry, the aim of synthetic biology is not only to analyse but also to create and recreate the objects it deals with. In this newly established field of research, the vision of creating new single-cell life forms opens up the technical possibilities of producing living things.

This book investigates the possible consequences of our understanding of life and our relationship to life. Metaphors such as "living machine" show how unclear the ontological status of newly formed life forms may be. Furthermore, the step from gene manipulation to creating new life forms will have consequences for humans' understanding of themselves. The dangers of misuse, e.g. in the case of pathogenic synthetic organisms, are discussed from an ethical point of view and the risk of uncontrolled dissemination of synthetic organisms examined. Rules which are already well known from the field of gene technology are being put to practical test in synthetic biology. In order to attempt to understand the specific ethical problems of synthetic biology, a difference is made between research and areas of application and a systematic approach taken to the central ethical issues.

Dr. Joachim Boldt is a research scientist at the Institute for Ethics and History of Medicine at the University of Freiburg (Germany). He works within the "Biological Signalling Studies" excellence cluster, examining the ethical issues of synthetic biology. Further areas of his work include clinical ethics and fundamentals of philosophical ethics. Dr. Oliver Müller heads the group of young researchers "Zur Natur des Menschen als Orientierungsnorm in der Bioethik" *(On the nature of humans as a standard for orientation in bioethics)* at the Institute for Ethics and History of Medicine at the University of Freiburg (Germany). He works on issues relating to philosophical ethics, philosophical anthropology, and technological and cultural philosophy. Prof. Giovanni Maio is Director of the Institute for Ethics and History of Medicine and heads the Interdisciplinary Ethics Centre at the University of Freiburg (Germany).

Bernard Baertschi, La vie artificielle. Le statut moral des êtres vivants artificiels (Artificial Life. The moral status of living beings), 2009 (Volume 6 in the book series) FBL-Article-number 810.007.f; ISBN 978-3-905782-05-9

What moral status do artificial living beings have? The question of the moral status of each individual living organism is of central importance, as this gives us a basis for determining how we should treat that particular living organism and what moral boundaries we are set in relation to its use.

Up until now, only naturally occurring living beings have been known to humankind. However, we will most likely be able to produce artificial living beings in the near future. This, at least, is the declared aim of synthetic biology. This raises the question as to whether the artificial nature of these living beings has an effect on their moral status.

In an attempt to answer this question, this volume first of all identifies what it means to accord a living being moral status. Taking this understanding of life, which is in harmony with that of the biological sciences, the various meanings of the dichotomy between "natural" and "artificial" are then explained. The investigation comes to the conclusion that moral status is independent of whether we are dealing with a natural or an artificial living organism.

Dr. Bernard Baertschi, lecturer and research scientist at the Interfaculty Centre for Medical Bioethics and Human Sciences at the University of Geneva, works in the fields of normative and practical ethics. He is the author of *Enquête philosophique sur la dignité. Anthropologie et éthique des biotechnologies (Philosophical Study of Dignity. Anthropology and the Ethics of Biotechnology),* Geneva, Labor & Fides, 2005, as well as of *La Neuroéthique. Ce que les neurosciences font à nos conceptions morales (Neuroethics. What neurosciences do to our moral conceptions),* Paris, La Découverte, 2009. Bernard Baertschi is also a member of the ECNH.

Arianna Ferrari, Christopher Coenen, Armin Grunwald, Arnold Sauter, Animal Enhancement. Neue technische Möglichkeiten und ethische Fragen. (Animal Enhancement. New technical opportunities and ethical issues), 2010 (Volume 7 in the book series) FBL article number 810.008.d; ISBN 978-3-905782-06-6

The current intense debate on the ethical aspects of "human enhancement" also throws new light on the scientific and technical "enhancement" of animals. Admittedly, "animal enhancement" is in many respects a well-known phenomenon. In agriculture in particular, animals have long been intentionally improved through breeding, and some experiments on animals can also be understood in these terms. However, whereas a key issue in the debate on human enhancement is the fundamental differentiation between healing and improvement, in the debate regarding animals this distinction is largely irrelevant. As a result of current scientific and technical developments, the level of intervention and potentially its ethical significance too are changing. This book is probably one of the first studies to provide a broad overview of developments in the field of the converging technologies and sciences which play a role in animal enhancement and examines the key ethical issues involved.

Dr. Arianna Ferrari is a research scientist at the Institute for Technology Assessment and System Analysis (ITAS) at the Karlsruhe Institute of Technology (KIT). Her work there involves looking at the ethical and

political issues surrounding human enhancement. Further areas of her work are animal philosophy, philosophy of technology, philosophy of biology and issues in the field of applied ethics. Christopher Coenen is also a research scientist at the ITAS and is at present working in the fields of human enhancement, synthetic biology and nanotechnology. Prof. Dr. Armin Grunwald is head of ITAS and of the Office for Technology Assessment (TAB) in the German Bundestag, which is run by ITAS. He is also Professor of Philosophy of Technology and Technical Ethics at the KIT. His fields are the theory and practice of sustainable development, ethical issues in nanotechnology and synthetic biology, as well as the theory and methods of technology assessment. Dr. Arnold Sauter has been a research scientist at the TAB since 1995. Since obtaining a doctorate in zoology and genetics he has been involved in interdisciplinary investigations into a wide range of biotechnologies and medical technologies, focusing on the results of genome research and applications in gene technology.

Peter Kunzmann, Nikolaus Knoepffler, Primaten. Ihr moralischer Status (Primates. Their moral status), 2011 (Volume 8 in the book series)
FBL article number 810.009.d; ISBN 978-3-905782-07-3

The legal and moral status of primates has considerably improved in recent years. What is the reason for this new assessment? What contribution is made by the ethical arguments on which it is based? Is it their similarity to people which makes primates so special in the animal world? Or should we no longer treat them as animals from an ethical point of view, but as people? The study's arguments are based on the unique skills and characteristics which make primates so special. According to the study, this justifies their moral status and dignity, which must prove its worth in view of the new possibilities of technical interventions.

Prof. Peter Kunzmann is Professor of Philosophy and research scientist in science ethics at the Friedrich Schiller University in Jena. His work focuses on animal and nature ethics in the field of applied ethics and he is active in the "Dignity in Gene Technology" research group. He is a member of the "Science and Values" commission at the Sachsen Academy of Sciences and of the "Dignity of Animals" working group at the Swiss Federal Veterinary Office (FVO). Prof. Nikolaus Knoepffler is Professor of Applied Ethics at the University of Jena and head of the university's Ethics Centre. He is a member of the German federal government's Central Ethics Commission for Stem Cell Research and of the Bavarian state government's Bioethics Commission. He is also Vice President of the German Academy for Transplant Medicine.

4.3 Further external expert reports

Further external expert reports published on the ECNH website:

- Anne Eckhardt, Synthetische Biologie. Organisation und Ziele (Synthetic biology. Organisation and objectives), March 2008: This brief report looks at how the field of synthetic biology research is organised and which objectives are pursued by the various players.
- Anne Eckhardt, Michèle Marti (co-author Valentin Küng), Lebensmittel – Neue bio- und nanotechnische Entwicklungen (Foodstuffs – New developments in biotechnology and nanotechnology), April 2010: This report gives an up-to-date overview of the wide-ranging new developments in the field of non-human biotechnology.
- Samuel Camenzind, Das Klonen von Tieren. Eine ethische Auslegeordnung (Animal Cloning. An ethical appraisal), May 2010: This expert report provides an appraisal of the arguments in answer to the question of whether it is ethically acceptable to clone animals and if so, under which conditions.

5 Cooperation and networking

Since it was set up in 1998, the ECNH has established numerous contacts both in Switzerland and abroad, in particular within Europe. The Chair, members and secretariat take part in selected discussion groups and conferences in the field of non-human biotechnology and related subjects. The Committee also benefits from the many contacts maintained by the committee members as part of their professional activities; these are of great advantage to the ECNH and its work.

5.1 Cooperation with other federal committees

The ECNH works with other federal committees whose area of work overlaps with the field of non-human biotechnology and gene technology. In particular it has close contacts with the Federal Committee on Animal Experiments (SCAE), the National Advisory Commission on Biomedical Ethics and the Swiss Expert Committee for Biosafety (SECB). Cooperation is mainly topic- and situation-based. There is an exchange of information between the chairpersons and secretariats, and the committees exchange the minutes of their meetings; this allows all parties to keep up to date with the issues under discussion.

In November 2009 the heads of the Federal Commission for NBC Protection (ComNBC), the Swiss Federal Nuclear Safety Commission (NSC), the Commission for Protection against Radiation and Radioactivity Monitoring, the SECB and the ECNH met for a discussion which was held on the initiative of the heads of ComABC and the SECB. The commission secretariats exchanged information about their respective mandates and work and on their position in the organisation of the federal administration.

5.2 Cooperation with other Federal Administration offices

The intensity of the ECNH's contact with the federal offices whose work is in some way concerned with non-human biotechnology varies according to the main focus of its current work. The most important contact partners for the Committee are always 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), Federal Office for Agriculture (FOAG) and the Institute of Intellectual Property (IPI). On a thematic level, the Swiss Agency for Development and Cooperation (SDC) and the State Secretariat for Economic Affairs (SECO) are also contact partners. In addition, the ECNH maintains contact with the Swiss Unesco Commission (Focal point) at the Federal Department of Foreign Affairs.

The FOEN has an Ethics Office which has maintained close contact with the ECNH since it was established in 1998. The ethicist employed in this office is a permanent guest at each ECNH committee meeting. Until the end of 2009, this position was held by Gérald Hess, and since August 2010 by Andreas Bachmann.

Also of importance to the ECNH is the exchange with the Centre for Technology Assessment, TA-Swiss. In December 2007, the Swiss parliament decided to affiliate TA-Swiss (formerly affiliated to the Swiss Science and Technology Council SSTC) to the Swiss Academies of Arts and Sciences. TA-Swiss' mandate and internal organisation has, however, remained the same. The Executive Secretary of the ECNH is a permanent guest at the TA-Swiss steering committee meetings. ECNH members or the Secretary also collaborate in TA project support groups on an individual basis.

5.3 International networking

European Society for Agricultural and Food Ethics. Internationally, the European Society for Agricultural and Food Ethics (EurSafe) is the ECNH's most important networking and communication platform. This organisation was established in 1999 on the initiative of Dutch and Danish ethicists. During the reporting period, the 8th EurSafe Congress, entitled "Ethical Futures. Bioscience and Food Horizons", took place in July 2009 at the University of Nottingham (UK). In 2010 the Executive Secretary of the ECNH again served on the scientific committee for the 9th EurSafe Congress, having previously served in 2005. This was held in September 2010 at the universities of Deusto and the Basque Country in Bilbao. The title of this congress was "Global Food Security: Ethical and Legal Challenges".

8th Global Summit of National Bioethics Advisory Bodies. On 26 and 27 July 2010, immediately prior to the 10th World Congress of Bioethics, the 8th Global Summit of National Bioethics Advisory Bodies took place in Singapore. At this summit, the EU Directorate-General for Research and Innovation organised an event on synthetic biology, at which the ECNH was invited to present its report on this subject. Committee member Martine Jotterand represented the ECNH at this summit and presented the Committee's considerations.

Meeting of Experts: "Fish Welfare: the interplay between science and ethics". On 29 and 30 November 2010 the Ethics Institute at the University of Utrecht organised an international conference at which experts from various scientific fields (marine biology, physiology, philosophy and ethics) came together to discuss the scientific requirements for a moral consideration of fish. The secretariat of the ECNH attended this conference.

British Nuffield Council on Bioethics. In May 2011 the Chair of the ECNH attended a Nuffield Council workshop on the subject of "Solidarity in Bioethics". Likewise in summer 2011, the ECNH took part in a Nuffield Council consultation on the subject of emerging biotechnologies. Furthermore, the Secretaries of the ECNH and of the National Advisory Commission on Biomedical Ethics (NEK) as well as the Director of the Centre for Technology Assessment (TA-Swiss) were invited in May to a discussion with the *Science & Innovation Section at the British Embassy in Bern,* which was also involved in this consultation.

6 Events

In April 2008 at a public event in Bern, the ECNH presented its report "The dignity of living beings with regard to plants – Moral consideration of plants for their own sake". At the Federal Administration's request, the Committee laid out in this report its considerations on how the concept of the dignity of living beings with regard to plants can be more closely defined. Both the Constitution and the law require that the dignity of living beings should also be considered with regard to plants. Following an introduction to the subject and short presentations on individual aspects of the report, the audience then engaged in an active discussion of the topic.

Following the controversy launched by the publication of the report, in June 2009 the ECNH invited around 40 persons from the fields of ethics, plant research, research policy and business to a one-day workshop on the subject. The workshop was organised into three thematic modules (ethics and culture/moral-historical perspective, plant research perspective and research policy/research ethics), which were introduced by keynote speakers.

In May 2010 the ECNH presented its report "Synthetic biology – Ethical considerations" to the general public. This report also aroused considerable interest, as the first reports on synthetically produced bacteria appeared in the science media only 10 days after its publication.

In December 2011 the ECNH presented its report "Ethische Anforderungen an die versuchsweise und kommerzielle Freisetzung gentechnisch veränderter Pflanzen" *(Ethical requirements on the experimental and commercial release of genetically modified plants).* The report was also presented and discussed at a public event.

7 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 statements and publications issued and expert reports commissioned by the ECNH. Volumes in the series "Beiträge zur Ethik und Biotechnologie" *(Contributions to Ethics and Biotechnology)* can also be downloaded free of charge in PDF format.

8 Committee budget and remuneration of committee members

The ECNH is an extra-parliamentary administrative committee which reports to the Federal Council. The Committee is administratively attached to the Federal Office for the Environment (FOEN); due to the thematic proximity, it is affiliated to the Waste Management, Chemicals and Biotechnology Division (formerly Substances, Soil, Biotechnology until the end of 2009).

The FOEN provides the ECNH with an annual budget of around CHF 150 000 to fulfil its mandate. These funds are used for public relations activities, external research, studies and expert reports, and publications. The ECNH is independent with regard to the content of its work. It is accountable to the FOEN for using its funds appropriately.

Until the end of 2009, the members of the ECNH were remunerated in accordance with the Ordinance on Daily Allowances and Remuneration for Extraparliamentary Committee Members. For meetings, employees received a daily fee of maximum CHF 200, while self-employed members received twice this amount. Since the new Government and Administration Organisation Ordinance (GAOO) came into force on 1 January 2010, all members receive a maximum of CHF 400 per day.

December 2011

For the Federal Ethics Committee on Non-Human Biotechnology

Prof. Dr. Klaus Peter Rippe
Chair

Ariane Willemsen, lic. iur., M.A.
Secretariat

External experts attending ECNH meetings during the period 2008–2011

Andreas Bachmann
ethik in diskurs, Zurich
Meeting on 18/19 June 2010; lecture on the subject of "Ethical evaluation of accumulated risks".

Heinrich Binder
Federal Veterinary Office FVO
Meeting on 24/25 September 2010; lecture on "Handlungsbedarf und Handlungsmöglichkeiten aus Sicht des BVET" (The need for action and opportunities to act; view of the FVO) as part of the focus topic "Ethical treatment of fish".

Thomas Binz
Federal Office for Public Health FOPH, Biological safety and human genetics Division
Meeting on 26 August 2011 presenting the revision of the Ordinance on the Contained Use of Organisms (ContainO).

Joachim Boldt
nstitute for Ethics and History of Medicine, University of Freiburg (Germany)
Meeting on 13 June 2008, joint presentation with co-authors Oliver Müller and Giovanni Maio of the ethical analysis of synthetic biology commissioned by the ECNH. Title of presentation: "Von der Manipulation zur Kreation. Ethische und ontologische Aspekte der synthetischen Biologie" (From Manipulation to Creation. Ethical and ontological aspects of synthetic biology). (The expert opinion was published as volume 5 in the ECNH book series.)

Mariann Breu
Consumption and Economy project manager, WWF Switzerland
Meeting on 24/25 September 2010; lecture entitled "Überfischung und Kriterien für Wildfang: Erfahrungen im Zusammenhang mit Labels und der Zusammenarbeit mit der Lebensmittelbranche und anderen Unternehmen im Fischsektor" (Overfishing and criteria for wild stocks: experiences in connection with labels and cooperation with the food industry and other companies in the fish sector) as part of the focus topic "Ethical treatment of fish".

Doris Bühler
Federal Office for Agriculture FOAG, Technical field: Fertilisers
Meeting on 26 August 2011, Discussion on EKAH's statement on the consultation regarding the authorisation as animal feed of the genetically modified maize line 1507.

Samuel Camenzind
Meeting on 16/17 October 2009, presentation of the report commissioned by the ECNH on "Klonen von Tieren – eine ethische Bewertung" (Animal Cloning – an ethical assessment).

Christopher Coenen
Institute for Technology Assessment and System Analysis (ITAS) at the Karlsruhe Institute of Technology (KIT)
Meeting on 30 April 2010, joint presentation with Arianna Ferrari and Armin Grunwald of the report on Animal Enhancement commissioned by the ECNH. The expert report appeared as volume 7 of the ECNH book series.

Anne Eckhardt
risicare GmbH, Zurich
Meeting on 3 March 2010, presentation of the study on "Neue Entwicklungen im Bereich Lebensmittel" (New developments in the field of foodstuffs) commissioned by the ECNH.

Arianna Ferrari
Institute for Technology Assessment and System Analysis (ITAS) at the Karlsruhe Institute of Technology (KIT)
Meeting on 30 April 2010, joint presentation with Christopher Coenen and Armin Grunwald of the report on animal enhancement commissioned by the ECNH. The expert report appeared as volume 7 of the ECNH book series.

Joachim Frey
Institute for Veterinary Biology, University of Bern and member of the Swiss Expert Committee for Biosafety SECB

Meeting of 5 December 2008 on "Mikroorganismen: Modelle und Versuchsanordnungen der synthetischen Biologie" (Microorganisms: models and experimental arrangements in synthetic biology) and speaker at the ECNH press conference on synthetic biology on 10 May 2010.

Basil Gerber
Federal Office for the Environment FOEN, Biotechnology Division
Meeting on 26 August 2011 presenting the revision of the Ordinance on the Contained Use of Organisms (ContainO)

Andreas Graber
Zurich University of Applied Sciences ZHAW
Meeting on 10 December 2010, lecture entitled "Einführung in Fischzucht und Aquakultur: Anforderungen aus naturwissenschaftlicher Sicht, Techniktrends in der Schweiz und weltweit (Import)" (Introduction to fish farming and aquaculture: Requirements from a scientific perspective, technical trends in Switzerland and worldwide (import)) as part of the focus topic "Ethical treatment of fish".

Armin Grunwald
Institute for Technology Assessment and System Analysis (ITAS) at the Karlsruhe Institute of Technology (KIT)
Meeting on 30 April 2010, presentation of the report commissioned by the ECNH entitled "Animal Enhancement" with Arianna Ferrari and Christopher Coenen. The expert report was published as volume 7 in the ECNH book series.

Kurt Hanselmann
i-research & training, Zurich
Meeting on 5 December 2008 on the role of microorganisms in the ecosystem (part of the discussion on synthetic biology)

Markus Hardegger
Federal Office for Agriculture FOAG, Technical field: Fertilisers
Meeting on 26 August 2011, Discussion on EKAH's statement on the consultation regarding the authorisation as animal feed of the genetically modified maize line 1507.

Bruno Heinzer
Oceans campaign coordinator, Greenpeace Switzerland
Meeting on 13 August 2010; lecture as part of the focus topic "Ethical treatment of fish": Overview and introduction to the topic of overfishing, aquacultures and transgenic fish.

Hans Hosbach
Federal Office for the Environment FOEN, Waste, Substances, Biotechnology Division
Meeting on 31 October 2010; exchange of information with the head of the FOEN division with administrative responsibility for the ECNH.

Peter Kunzmann
Ethics Centre at the Friedrich Schiller University, Jena (Germany)
Meeting on 13 August 2010; presentation of the opinion commissioned by the ECNH entitled "The moral status of primates". The report was published as volume 8 of the ECNH book series.

Giovanni Maio
Institute for Ethics and History of Medicine, University of Freiburg (Germany)
Meeting on 13 June 2008, joint presentation with co-authors Oliver Müller and Joachim Boldt of the ethical analysis of synthetic biology commissioned by the ECNH. Title of presentation: "Von der Manipulation zur Kreation. Ethische und ontologische Aspekte der synthetischen Biologie" (From Manipulation to Creation. Ethical and ontological aspects of synthetic biology). The expert opinion was published as volume 5 in the ECNH book series.

Oliver Müller
Institute for Ethics and History of Medicine, University of Freiburg (Germany)
Meeting of 13 June 2008, joint presentation with co-authors Joachim Boldt and Giovanni Maio of the ethical analysis of synthetic biology commissioned by the ECNH. Title of presentation: "Von der Manipulation zur Kreation. Ethische und ontologische Aspekte der synthetischen Biologie" (From Manipulation to Creation. Ethical and ontological aspects of synthetic biology). The expert opinion was published as volume 5 in the ECNH book series.

Sven Panke
Federal Institute of Technology ETH Zurich
Speaker at the ECNH press conference on 10 May 2010 on synthetic biology.

Samuel Roulin
Federal Office of Public Health FOPH, Biological Safety and Human Genetics Division
Meeting on 26 August 2011 presenting the revision of the Ordinance on the Contained Use of Organisms (ContainO).

Rainer J. Schweizer
Professor emeritus at the University of St Gallen
Speaker at the meeting on 17 June 2011 on the factors leading to the regulation of gene technology in a separate law.

Helmut Segner
Centre for Fish and Wildlife Health FIWI, University of Bern
Meeting on 24 September 2011, presentation of the report commissioned by the ECNH entitled "Kognition und Empfindungsfähigkeit von Fischen – eine Bestandesaufnahme aus biologischer Sicht" (Cognition and sentience of fish – an appraisal from a biological perspective).

Salome Sidler
Legal Affairs Division 2, Federal Office for the Environment FOEN
Speaker at the meeting on 17 June 2011 Freedom of Information Act; Information on the Act and its implications for the work of the ECNH.

Urs Weingartner
Label meat and fish purchasing department, Coop supermarket
Meeting on 10 December 2010; lecture on wholesalers' criteria and requirements in fish production, purchasing and consumption as part of the focus topic "Ethical treatment of fish".

Florian Wild
Federal Office for the Environment FOEN, Legal Affairs Division
Meeting on 10 December 2010; exchange of information with the head of the Legal Affairs Division of the FOEN.

Markus Wild
University of Berlin
Meeting on 24 September 2011, presentation of the expert opinion commissioned by the ECNH entitled "Kognition und Empfindungsfähigkeit von Fischen – eine Bestandesaufnahme aus tierphilosophischer Sicht" (Cognition and sentience of fish – an appraisal from the perspective of animal philosophy).

Anne-Gabrielle Wust Saucy
Federal Office for the Environment FOEN, Biotechnology Division
Meeting on 4 March 2011, presentation of the work of the Biotechnology Division;
Meeting on 26 August 2011 presenting the revision of the Ordinance on the Contained Use of Organisms (ContainO).

Impressum

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