

Report of activities 2000–2003



Swiss Ethics Committee

on Non-human

Gene Technology

1 Mandate of the Swiss Ethics Committee on Non-human Gene Technology (ECNH)

The ECNH is commissioned by the Federal Council to monitor and evaluate developments and applications in the field of non-human biotechnology and gene technology. As such, its mandate covers all applications of biotechnology and gene technology on animals, plants and other organisms and the effects of such applications on human beings and the environment. It issues statements of position on the ethical aspects of related issues, particularly in terms of adherence to the principles of respect for the dignity of creation as well as the safety of human beings and the environment, the protection of genetic diversity in animal and plant species, and their sustainable use.

The ECNH mandate comprises three main tasks:

- 1 It advises the Federal Council and the offices which report to it on ethical matters in the preparation of laws on non-human biotechnology, and makes recommendations on 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 topics it addresses, and promotes dialogue on the benefits and risks of biotechnology.

Pursuant to Art. 57 of the law on government and administrative organisation and Art. 11 of the commission ordinance, the Federal Council set up the Ethics Committee by decree. With the introduction of new gene technology law on 21 March 2003, the ECNH was enshrined under law as a permanent external administrative committee, and the decree is to be replaced by an ordinance.

The ECNH regularly convened on 7 – 8 occasions in each of the years under review for full-day regular meetings. In addition, four annual public meetings were held. At the request of Committee members and with the exception of the public meeting held in Fribourg in May 2001, the venue for these meetings was Berne.

2 Members

2.1 Composition of the Committee

The ECNH comprises a maximum of 12 members representing different professions and disciplines. At least half of these members must be professionals in the fields of ethics, philosophy or theology. Scientific ethics is not tied to any single approach. Rather, it covers a multiplicity of different approaches which produce a wide variety of ways of addressing the manipulation of Nature. Hence, not only interest groups but also these disparate ethical approaches must be equally represented within the Committee in order to ensure a balanced analysis of the various standpoints, criteria and standards.

2.2 Chairmanship

At the end of October 2002 the Chair, Andrea Arz de Falco, stood down. On 1 November 2002 she moved from the University of Fribourg to the Federal Office of Public Health in order to take charge of the new Ethics Section. To the general regret of the Committee, this career move from academia to the federal administration necessitated her departure from the ECNH, since members of extra-parliamentary committees are not permitted to work for the federal administration. Andrea Arz de Falco was appointed by the Federal Council as the first Chair of the ECNH in April 1998 and, in this capacity, was instrumental in setting up and establishing the Committee. On 1 November 2002 Klaus Peter Rippe, Deputy Chair of the ECNH and also a member since April 1998, took over the chair ad interim. In December 2003 the Federal Council appointed him as Chair for the forthcoming term of office (2004–2007).

2.3 Members in 2000–2003

Representing the fields of philosophical and theological ethics:

Andrea Arz de Falco

Dr. theol., Interdisciplinary Institute for Ethics and Human Rights, University of Fribourg, ENCH Chair (until 31 October 2002)

Hans Halter

Prof. Dr. theol., Professor of Theological Ethics and Social Ethics, University of Lucerne

Alex Mauron

Professor, Doctor of Science, Ordinary Professor in Bioethics, University Medical Centre of Geneva (until 31 December 2001)

Succeeded by:

Bernard Baertschi

Doctor of Philosophy, Senior lecturer and research fellow at the Department of Philosophy, University of Geneva (since 16 August 2002)

Denis Müller

Professor, Doctor of Theology, Professor of Ethics at the Faculty of Theology, University of Lausanne (until 31 December 2003)

Klaus Peter Rippe

PD Dr. phil. I, Lecturer at the University of Zurich and the Aargau University of Applied Sciences, Head of the "ethik im diskurs" office, Zurich, ad interim Chair since 1 November 2002

Beat Sitter-Liver

Prof. Dr. phil. I, Professor of Applied Philosophy at the University of Fribourg and lecturer at the Federal Institute of Technology (ETH Zurich), former General Secretary of the Swiss Academy of Humanities and Social Sciences

Christoph Stückelberger

Prof. Dr. theol., Lecturer in Ethics at the Theological Faculty of the University of Basle, Central Secretary of the Bread for All

Representatives of the field of natural sciences:**Michel Aguet**

Professor, M.D., Director of the Swiss Institute for Cancer Research (ISREC) (until 31 December 2000)

Succeeded by:

Martine Jotterand

Professor, Doctor of Science, Associate Professor of Cytogenetics, Cytogenetic Cancer Unit, Medical Genetic Service, Centre Hospitalier Universitaire Vaudois (CHUV), Lausanne (since 1 January 2001)

Florianne Koechlin

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

Jakob Nüesch

Prof. Dr. sc. techn., Prof. Em., former President of the Federal Institute of Technology, Zurich (until 31 December 2002)

Representatives from the field of jurisprudence:**Beatrice Wagner Pfeifer**

PD Dr. iur., advocate, lecturer at the Faculty of Law, University of Basle (until 31 December 2000)

Succeeded by:

Kurt Seelmann

Prof. Dr. iur., Professor of Penal Law and Legal Philosophy at the University of Basle (member between 1 January 2001 and 31 December 2003)

Representative from the field of politics:**Chiara Simoneschi-Cortesi**

Politician, President of the Federal Commission for Women's Issues (until 31 January, 2001)

Succeeded by:

Representative from the field of medicine:**Cornelia Klauser-Reucker**

Doctor of General Medicine, member of the Central Ethics Commission of the Swiss Academy of Medical Sciences, Caslano TI (since 16 August 2002)

Kurt Weisshaupt, the Committee's advisor and mentor, died unexpectedly in July 2002. A philosopher at the Swiss Agency for Environment, Forests and Landscape (SAEFL), Kurt Weisshaupt was heavily involved in the creation and establishment of the Committee and, at the request of the ECNH, supported and attended meetings and discussions within the Committee from its inception. His skills as a professional interlocutor and advisor were greatly appreciated by all Committee members, and his support of the ECNH secretariat was equally invaluable. He leaves behind a gaping hole and will be sorely missed by all.

3 Secretariat

The Secretariat is responsible for preparing for Committee meetings, drafting statements of position and supporting the Committee Chair and members in the performance of their tasks. It carries out administrative work, organises ECNH publicity activities and arranges contacts with other authorities and commissions in Switzerland and abroad which are active in fields related to biotechnology and non-human gene technology.

The Secretariat has been managed by Ariane Willemsen since February 1999 and reports to the Committee Chair on technical matters and to SAEFL on administrative matters.

4 Monitoring and evaluation of developments in the field of non-human biotechnology

Advice on legislation and the enforcement of federal regulations

The ECNH monitors and evaluates the ethical aspects of developments in the field of non-human biotechnology. It issues statements regarding forthcoming legal projects and concrete permit applications of exemplary or fundamental relevance. This advice on enforcement covers projects aimed at the creation, release and commercialisation of genetically modified as well as pathogenic organisms. However, the ECNH also independently addresses issues in the field of non-human biotechnology with a view to assessing the ethical aspects of future legislation and drafting recommendations.

Statements issued by the ECNH are of an advisory nature and are drawn up for submission to the federal office responsible for the relevant legislative project or permit application. As a rule, the statements are also communicated to the public, with the exception of approval procedures which are still in progress or advisory statements within the framework of an internal administrative procedure based on confidential documents.

Majority and minority opinions

ECNH statements are not necessarily unanimous, and minority opinions are registered as such. The main focus of statements of position is on the argumentation. The aim of internal Committee discussions is to determine where and, in particular, why opinions differ. Experience has shown that the significance of the arguments is normally undisputed, and that differences generally arise in the evaluation of the various arguments. Despite their different ethical standpoints, however, members often arrive at consensus on concrete issues.

4.1 Advice on legislation

4.1.1 “La dignité de la créature” in the federal constitution

As a result of a people’s initiative held in 1992, Art. 24novies Para. 3 of the old federal constitution (OFC) was amended to the effect that animals, plants and other organisms must be handled with due consideration to the dignity of creation (French: la dignité de la créature; Italian: la dignità della creatura). When the federal constitution was updated in 1999, Art. 120 of the French version replaced the term “dignité de la créature” with “intégrité des organismes vivants”.

In March 2000, for a variety of reasons, the ECNH lodged an objection to this amendment in the French version. The original term is germane to the Switzerland-wide discussion and has already influenced several draft laws. Moreover, the concept of “intégrité” is not synonymous with the concept of “dignité”, nor is the term “être vivants” equivalent to “créature”. In particular, the concept of integrity is distinct from the concept of dignity. The concept of dignity implies a call to exercise moral care and respect, whereas the concept of integrity relates to the protection of an entity (e.g. a person or a gene). Moreover, the provision of Art. 24novies OFC was undisputed. Hence the ECNH members were at even greater pains to understand why the French version of the new federal constitution (NFC) was amended without explicitly tabling the amendment for debate and informing the electorate.

4.1.2 From gene technology bill (Gen-Lex) to gene technology law

In March 2000 the Federal Council approved the gene technology bill (Gen-Lex) for submission to parliament. The aim of this bill was to close existing gaps in regulations, and in particular to implement the constitutional directive governing “Respect for the dignity of creation”. To date the ECNH has provided assistance and advice at various stages of the legislative process, both during the official public consultation procedure and at official internal consultations within the federal administration. ECNH statements were primarily concerned with the debate on the scope of validity of the “dignity of creation”, the inclusion of ethical criteria at the legal level, and the regulations governing its own mandate since the ECNH is to be raised to legal status as part of the revision.

The Federal Council’s bill had a three-year passage through parliament. The pre-consultation work fell within the remit of the Parliamentary Committees for Science, Education and Culture (SEC) of the Council of States and National Council. Following submission by the Federal Council of a legal reform package based on the environmental law, in line with the original aim of the motion “Non-human gene technology, legislation” (the “Gen-Lex motion”), the Council of States SEC decided on a special law. Various ECNH members were invited to hearings held by the two parliamentary advisory committees, and presented their views on specific issues. At the behest of Prof. R. J. Schweizer, the advisor to the two SECs (Council of States SEC and National Council SEC), the ECNH examined concrete proposals regarding the formulation of the Article of the gene technology law which governs the dignity of creation, since the existing formulation was regarded as

unsatisfactory. On the basis of previous discussions within the ECNH, a recommendation was submitted to the parliamentary committee.

Following the conciliation procedure to resolve any differences, parliament adopted the gene technology law in March 2003. On 19 November 2003 the Federal Council enacted the law, which came into force on 1 January 2004 following expiry of the deadline for the optional referendum (which was not taken up).

4.1.3 Moratorium on commercial release

On 2 May 2000 the ECNH held its first public meeting on the topic “Should genetically modified organisms (GMOs) be released into the environment? The options: approval – moratorium – ban”. The aim was to discuss the ethical aspects of the arguments already put forward in political debates. Following the public discussion, the ECNH meeting on 9 May 2000 unanimously approved a statement expressing the ECNH’s opposition to a legal ban on the release of GMOs. On the other hand, the majority of members voted in favour of a moratorium on commercial releases and in favour of experiments conducted for the specific purpose of approval for the commercialisation of GMOs. It also recommended a strict approval procedure for research-related projects.

The ECNH recommendation was based on the ethical evaluation of pro and contra arguments. The aim of the moratorium was not to call a halt to reflection, but to examine international experience acquired in the release of GMOs and to promote the opportunity for open public debate. The ECNH stated its opinion that research into solution approaches other than those related to gene technology was also important.

The focus of the ECNH deliberations was not the duration of any moratorium, but rather the conditions which must be fulfilled from an ethical standpoint in order to ensure a democratic decision-making process. The ECNH emphasised the time-consuming nature of a democratic decision-making process that pursues research and agricultural objectives in Switzerland. However, ECNH members agreed that social problems should not be tackled from the outset by outright bans. Concern was expressed that a long-term moratorium could impede research in Switzerland.

4.1.4 Revision of the Animal Protection Law

In September 2001 the Federal Veterinary Office (FVO) submitted the draft of the revised Animal Protection Law for public consultation. The ECNH was primarily involved in the definition of the "dignity of creation" in the APL. The ECNH, in conjunction with the Federal Committee on Animal Experiments had already examined the issue ahead of the consultation process and drawn up a joint brochure on the dignity of animals (cf Section 5.1).

Under the terms of Art. 120 Para 2 of the federal constitution, the dignity of creation must be respected. In the opinion of the ECNH, such dignity is respected provided it is not abused. In the opinion of the overwhelming majority of ECNH members, a violation of the dignity of animals is always manifested if animals are unjustifiably exposed to pain, suffering or injury, or if they are unjustifiably exposed to fear and distress. Such unjustifiable exposure to all these forms of stress is already prohibited under the terms of the Animal Protection Law. However, the ECNH believes that stress can cover additional aspects such as manipulations of appearance, humiliation, and

the excessive instrumentalisation of animals. These forms of stress also require justification.

The majority of Committee members distinguishes between the violation and the abuse of the dignity of animals. If a gene technology project affects the dignity of an animal, the human benefits must be balanced against animal protection interests. Violations of dignity are permissible provided such a balancing of interests has determined that these violations of dignity are justifiable. If a violation of dignity is deemed unjustifiable or if no such balancing of interests has been performed, this constitutes impermissible abuse of the dignity of the animal.

In the summer of 2002, at the request of the FVO, the ECNH examined the thirty or so proposals which had been submitted for public consultation with a view to defining the dignity of creation under the terms of the Animal Protection Law. The responses to the consultation process mainly focused on the wellbeing and intrinsic value of animals, the criteria governing the dignity of animals which the ECNH had already submitted, and the necessity for a balancing of human benefits versus animal protection interests. While the formulations focused on different aspects depending on the interests represented, they were regarded as consistent in terms of their objectives.

The ECNH determined that two specific formulation proposals were more or less equivalent: the first was based on the concept of wellbeing (in the sense of a positive form of protection against violation of dignity), and the second was predicated on the concept of stress (in the sense of a regulation against negative abuse). Accordingly, the ECNH recommended two definition variants to the FVO which incorporate these two formulations. For systematic

reasons, however, the ECNH favours the formulation predicated on a regulation governing abuse.

4.1.5 Killing of animals in experiments on animals

In the spring of 2003, at the request of the Committee on Animal Experiments, the ECNH discussed ways of assessing the ethical aspects of killing animals as part of experiments on animals. According to the wording of the Animal Protection Law, the painless killing of an animal – even in the case of high-level animal use – is regarded as "not severely stressful". However, this viewpoint runs counter to the intuitions and convictions of the Committee members.

The Committee expressed the unanimous opinion that killing an animal as part of an experiment as well as other forms of animal use must be morally justified after balancing the human benefits against animal protection aspects. As explicitly stated in the German animal protection law, however, it is morally wrong to kill animals "on no reasonable grounds". Hence the painless killing of animals also requires sufficient justification. And the more animals which are killed, the more relevant the reasons for justifying this killing must be. One of the difficulties of balancing human benefits against animal protection interests lies in the fact that we know little about the significance of death and suffering for animals. Another problem is that we do not know how to compare this type of stress rationally and balance it against other relevant benefits.

The ECNH unanimously regarded the death of an animal as at least more serious than "slight pain". However, the view that death constitutes the "greatest damage" to an animal was not represented by the Committee. The

Committee also disagreed that the life of animals constitutes an absolute value, but that the killing of animals should be subject to a balancing of interests. In the opinion of the ECNH, the ethically relevant differences between animal species must be given due consideration in the balancing of interests.

4.1.6 Xenotransplantation

In February 2000 the ECNH stated its position on the draft law on the transplantation of organs, tissues and cells (Transplantation Bill, TxG) submitted for public consultation. The TxG governs the treatment of human and animal organs, tissues and cells which are destined for transplantation in humans. In accordance with its mandate, the ECNH focused in particular on the ethical aspects of xenotransplantation, i.e. the transfer of animal organ or cell transplants to humans, and especially on aspects related to animal ethics. Xenotransplantation necessitates major intervention in a large number of animals, i.e. a high level of animal use. Nevertheless, the explanatory report on the TxG failed entirely to take animal ethics into account.

The ECNH based its assessment of xenotransplantation on the considerations it had already expressed on the move to provide a more concrete definition of the constitutional term "dignity of creation" in the Animal Protection Law. In the case of xenotransplantation, human ethical interests such as life sustenance, quality of life, individual health, safety, and socio-ethical as well as economic interests must be balanced against animal ethics interests such as protection against injury and other violations of dignity. After balancing interests in the abstract, a clear majority of ECNH members voted in favour of a moratorium on Xenotransplantation, recommending

that clinical research on human beings should not be permitted in this field at present. The ECNH also unanimously voted in favour of a moratorium on pre-clinical research on primates. Moreover, it recommended that the Federal Council formulate a mandate to promote public discussion on the opportunities and risks, perspectives and problems of transplantation in general and xenotransplantation in particular. An initial minority regarded organ xenotransplantation as ethically permissible, but not research on primates. In the view of this minority, only clinical research should be permitted on human beings. A second minority also wanted to exclude primates from research. A third minority favoured a general moratorium banning any form of research on animals for the purposes of xenotransplantation.

4.1.7 Amendment to the ordinance on the control of blood, blood products and transplants

In October 1999 both houses of parliament approved an amendment to the federal decree on the control of blood, blood products and transplants, with a view to tightening the regulations governing transplants of animal origin (xenotransplantation). This also necessitated an amendment to the ordinance. As part of an informal hearing in the summer of 2000, the ECNH referred to its statement on xenotransplantation. In the opinion of the ECNH, the handling of animals should be regulated not only with due regard to human safety but also with due regard to animals and their welfare. From an ethical standpoint, human health should not be the only consideration.

4.1.8 Creation of chimeras

A company approached the ECNH and asked for an ethical opinion on the creation of chimera mice and an evaluation of public reaction to such a project. The aim was to inject adult human liver stem cells into mouse blastocytes and implant these in pseudo pregnant mice. The intention of this project was to produce animal models in which drugs for the treatment of liver disease in humans could be developed. However, before such a project could be attempted in Switzerland, the company wanted to determine public opinion and the ethical issues involved.

In legal terms, the only law which mentions the creation of chimeras is the law on reproduction medicine. However, this law does not govern issues related to human-animal chimeras. The ECNH therefore examined the more general aspects of these issues, based on developments in, for example, the field of cellular xenotransplantation, and consulted various experts. Based on experience to date, reputable experts have expressed doubts as to whether it is possible, at this point in time, to create stable chimeras. Regrettably, the company which had approached the ECNH declined at short notice an invitation from the ECNH. No statement was drafted, but developments continue to be monitored.

4.1.9 Revision of the Patent Law

The ECNH has been examining the ethical aspects of patenting in the field of biotechnology since as early as the end of 1999, with a view to the consultation process on the law on patents. The first stage of this examination focused on patents on animals and plants and the implications of such patents. The patentability of genes, gene sequences, cells and micro organisms was not addressed at this stage. In addition to providing a basis for the consultation process, the aim of the initial statement was to summarise the arguments discussed in public and bring the Committee's own deliberations into the discussion, as a contribution to the public debate.

The ECNH unanimously agreed that intellectual efforts in the field of biotechnology are worthy of protection. The rationale behind this standpoint was the ethical and, in the Committee's opinion, justifiable objectives of the patent law to promote research in the interests of all members of society and to achieve a balance of interests. Opinions were, however, divided on the permissibility of patenting living beings. Based on this fundamental consensus, the ECNH drafted a model for an "inventor's privilege", with the aim of developing a system for the protection of intellectual property in biotechnology: one that meets ethical requirements by realising inventors' interests in the exclusive use of their invention, while endeavouring to avoid the problematic effects arising from the patenting of living beings. However, the ECNH expressly declined to rule on whether this model can be implemented within the framework of the existing patent law, or whether a new type of system is required for intellectual property protection. A brochure on this subject, based on the ECNH statement, was published at the end of 2001.

The consultation process took place between the end of December 2001 and the end of April 2002. In its statement the ECNH emphasised that intellectual efforts in the field of biotechnology merited protection. Moreover, the members unanimously agreed that the difference between a discovery and an invention was relevant for normative and ethical reasons and was of major importance. While this distinction is enshrined under law, in practice it appears to be becoming increasingly blurred. The belief that patenting could lead to the increased commercialisation of living creatures was also unanimously shared, but was evaluated differently depending on the context. There was also general consensus on the fact that parts of the human body were not patentable for ethical reasons. However, partly due to differing analyses of the problem and partly due to different assessments of the consequences, opinions differed on whether patents were ethically permissible for modified parts.

Additional important factors for the ECNH were the enshrinement and assurance of farmers' and breeders' privileges. These privileges are founded on ethical grounds and are based on considerations of justice. In the opinion of the ECNH, the traditional right of passing on small quantities of seeds at no charge must also be included in farmers' privileges. An additional key element of the law on patents is the beneficial impact which the patent system has on research. To ensure this positive effect, the ECNH recommended a broader interpretation of the research privilege, particularly in view of the fact that researchers were increasingly criticising the obstacles which the law on patents posed to research.

Due to the wide divergence of opinions reflected in responses to the consultation process, the Federal Council decided to examine the most controversial questions in more detail at a series of round-table discussions with affected groups. In addition, several discussions on "Patenting and Ethics" were held between the Institute for Intellectual Property and a delegation from both the ECNH and the Swiss National Advisory Commission on Biomedical Ethics in the course of 2003, in order to resolve open or controversial questions from an ethical standpoint. The results of these discussions will be incorporated in the report on the proposed second consultation process on the patent law.

4.1.10 "Terminator" or genetic use restriction technology

Genetic use restriction technology (GURT) is a technology that genetically modifies plants such that particular traits can be externally regulated and thereby controlled. There are two ways in which this technology can be applied: to exert an external influence either on plant reproduction (e.g. by inhibiting seed germination) or on the expression of other specific plant traits. When used to prevent the germination of seeds, the term "terminator" technology is now commonly applied.

Seeds constitute the basis of nutrition, and a gene technology procedure which permits the external control of seeds is of vital importance. It involves the fundamental ethical dilemmas facing the international community in the economic, ecological and social areas. An in-depth discussion of the ethical aspects of this technology was prompted by a parliamentary motion. However, after two years without being debated, this motion was eventually shelved by parliament.

With a view to balancing the benefits and risks of this technology (which is still at the laboratory stage), a systematic overview of the pros and cons was compiled. The overview examined the research aspects as well as aspects relating to the dignity of creation and the economic, social and ecological implications. Based on its deliberations, the ECNH drew up a report in October 2000 in which it agreed, with two abstentions, to conduct a comprehensive evaluation of the implications of the technology. A narrow majority recommended that the technology be permitted but only under specific conditions which must be fulfillable. By contrast, a large minority voted against permitting use of the technology at this point in time. A moratorium was proposed in order to collect more extensive data on the implications of this technology.

4.1.11 The dignity of plants

The discussion on the “terminator” technology increasingly turned the spotlight on the issue of the dignity of plants. Art. 120 of the federal constitution expressly acknowledges the dignity of plants: The dignity of creation must be respected in animals, plants and other organisms. However, it is unclear how this dignity is exhibited in concrete terms. For example, is the dignity of plants affected by, for example, suppressing its reproductive capability or controlling other essential traits of a living thing? To examine these issues in more detail and prepare for future statements, the ECNH invited Dr Angela Kallhoff of the University of Münster, Germany, to present her dissertation on the “Principles of plant ethics: the evaluation of plant life in biology and philosophy” in January 2003. The following key issues were addressed: Why can plants not be handled in any way we wish? What is the rationale behind the obligation to respect something? What is the object

of our respect? What criteria constitute a violation of respect? The discussion threw up various issues regarding GURT: To what extent does GURT affect the dignity of plants? Does it negate the criteria of plant ethics? Does GURT represent an additional step in control over plants compared with terminator technology? Are the effects of GURT acceptable in industrial as well as developing countries?

4.1.12 Substantial equivalence

In the course of 2002, prompted by the ethical evaluation of a permit application for the commercialisation of genetically modified maize, the ECNH examined the concept of substantial equivalence. The concept is applied in assessing the safety of foodstuffs and animal feed obtained from genetically modified organisms (GMOs) as well as components thereof. In the authorisation procedure for genetically modified products, however, the concept is applied to evaluate health risks but not to verify environmental safety. The aim is to determine whether a GM product is just as safe or just as unsafe as the corresponding conventional product.

The original understanding of the concept is predicated on the assumption that a genetically modified food can be compared to a conventional non-GM food and is equivalent to it except for the additional properties inserted using gene technology. Selected properties of a GM product are compared with the corresponding properties of a non-GM food. The question is whether the additional property, inserted using gene technology, substantially changes the character of a GM food compared with the conventional product.

The ECNH, in its discussion of the concept, concentrated on two factors: Firstly, the concept of substantial equivalence relates only to food safety (in

terms of human health), while ignoring other values which are also involved in the commercialisation of GM products. Secondly, the concept permits only a relative risk assessment based on a comparison with normal foods. Yet even conventional foods may contain ingredients that have damaging effects.

The concept is primarily criticised for being a theoretical idea for which only very vague conditions exist for its implementation. In particular, the current view that a foreign gene in the genome of a plant could produce undesirable and sometimes unexpected effects in addition to the intended ones, and that these may not be immediately recognisable, illustrates the difficulties and limitations of the concept and principle of substantial equivalence. The concept of substantial equivalence has undergone certain changes. According to the revised understanding which has been adopted at the international level, substantial equivalence provides only a starting point for risk assessment and hence constitutes only a first step in safety assessment. One of the main difficulties is that there is no evaluation procedure of this type which can also produce reliable statements on the long-term risks of GM products. Therefore, in situations of uncertainty or where there is a lack of knowledge, the precautionary principle must be applied to any ethical evaluation.

4.1.13 Effects of biotechnology on developing and newly industrialised countries

One of the most important topics which the ECNH addressed in 2003 was the "ethical effects of biotechnology on developing and newly industrialised countries". Due to the broad scope of this topic, the first step was to obtain an overview of the various issues before embarking on a systematic ethical analysis. Various external experts from the World Health Organisation (WHO), the Swiss Agency for Development and Cooperation Agency (SDC), the State Secretariat for Economic Affairs (seco) and the Swiss Agency for Environment, Forest and Landscape (SAEFL) advised ECNH members on aspects of food safety and food sovereignty, attitudes to the permissibility of GM foods as direct aid for famine victims, development projects to promote technology transfer, agriculture and trade in developing countries, the boundary conditions of the World Trade Organisation (WTO), regulations governing access to genetic resources, and the fair distribution of benefits ("access and benefit sharing") as defined in the Cartagena Protocol on Biodiversity.

As a basis for further internal discussion, the ECNH commissioned two studies: a survey of ethics and standards, and an empirical analysis (see Section 6.1.5). The aim is to formulate overriding ethical principles for approaches to biotechnology in developing and industrialised countries, which would be generally upheld by Switzerland or within the framework of concrete projects.

4.2 Advice on enforcement

4.2.1 Release of GMOs

Release trial using transgenic wheat

In January 2001, a research group at the Federal Institute of Technology's Institute for Plant Sciences in Zurich submitted an application for permission to field-test transgenic wheat for resistance to stinking smut or common bunt (a fungus that affects wheat seeds). The idea was to verify whether data which had been collected by observing the plants in a greenhouse environment could be replicated under natural temperature and weather conditions. The institute also wanted to investigate the interaction between the integrated gene and non-target organisms (other fungi, soil organisms, and insects) as well as aspects of biological safety. The applicant declared that there was no intention to subsequently commercialise this transgenic strain of wheat, but added that the trial would contribute to reducing the use of chemical substances to combat stinking smut.

The trial was initially rejected by SAEFL, following which the institute appealed to the Swiss Department for Environment, Transport, Energy and Communications (DETEC). DETEC granted the appeal and referred the application back to SAEFL with the stipulation that the trial be permitted. Appeals were lodged in turn against this decision. Finally, the trial was stopped by the Federal Court on the grounds of various procedural errors. In July 2003 the institute submitted a new application, which was approved by SAEFL at the end of October 2003. However, yet another appeal was lodged against this decision but turned down by DETEC in February 2004.

In an ethical evaluation it is essential to balance the objectives against the expected or potential effects. However, these objectives must be precisely defined not only to achieve an accurate evaluation of the benefits and drawbacks of a release trial, but also in order to facilitate the public opinion-building process. Yet the objectives cited in both the first and second application were either unclear or of a purely hypothetical nature. In the opinion of the ECNH, the emphasis was on testing effectiveness i.e. field-testing transgenic wheat for resistance to stinking smut, whereas the bio safety tests mentioned in the application played a negligible role.

In its statement on the first application the ECNH declared that any potential risk must be acceptable for the community i.e. in view of the anticipated benefits. This, it felt, should be a general prerequisite for authorisation. In the considered opinion of the ECNH, no concrete statements could be made with regard to the ecological and economic effects of this research project. The discussion primarily focused on the social implications of using an antibiotic-resistant gene, in terms of the signal it would send to researchers. However, a minority within the ECNH believed that the use of this marker gene also posed a qualitative ecological problem. Moreover, in view of the public importance of the test, the fact that no information or communication concept was submitted along with the application was criticised. For political and ethical reasons in particular, the ECNH believed that the timing for approval of the application was unfavourable: for an authorising agency to rule on an individual (and scientifically non-essential) project would be impermissible before the fundamental political debate on regulations governing GMOs was concluded; all the more so since a decision on this debate was imminent.

While the majority of ECNH members voiced no ethical objections to the objectives of the project, a minority believed that the objectives were too unclear to justify it from an ethical standpoint. The majority recommended that the application formulate a more precise and transparent definition of the research objectives, submit an information and communication concept, and publish the comparative data obtained from the greenhouse trial. A minority of members wanted to have these recommendations fulfilled as the condition for approval of the trial. A second minority called for the permit application to be rejected since the intended results were too insubstantial to justify what was regarded, in principle, as the undesirable use of antibiotic-resistant genes and the undefined risks. This minority also disagreed with the trial on the grounds that alternative remedies against stinking smut existed that are more ecologically safe and more economically viable, and that the political timing of such an administrative decision in principle was unfavourable.

In its statement on the revised application in September 2003 the ECNH came to a different conclusion based on additional information and discussions. According to the release ordinance which governs such applications, inadequately designed trials may also be conducted provided that safety and the requisite material resources are assured. Although it was not up to the ECNH to judge whether the release trial was correctly designed from a scientific standpoint or whether adequate consideration was given to the results already obtained from greenhouse and hothouse trials, at the very least members voiced strong doubts in this regard. The ECNH therefore recommended that the release trial be prohibited until these doubts as to the scientific quality and purpose

of the release trial were resolved. In authorisation procedures for animal experiments as well as for clinical research on humans, inadequately designed research projects do not merit approval from an ethical standpoint even if these trials are regarded as safe and the necessary resources to ensure this are available. In its statement the ECNH further recommended that the release ordinance be amended to reflect this view, in order to ensure that the criteria of benefits and the scientific integrity of the project would be given consideration when assessing future applications.

Application for the release of a fungus pathogenic for insects for the biological control of aphids in vegetable cultures

The object of the application was to field-test a pathogenic fungus for the control of aphids and determine the extent to which (a) infections could be released among the aphid population and (b) this fungus could be used to biologically control aphids in vegetable cultures. In accordance with its mandate, the ECNH evaluates exemplary release applications for trials not only on genetically modified organisms but also on pathogenic organisms. However, since this trial appeared to involve no pressing ethical issues, the ECNH decided not to issue a statement.

4.2.2 Commercialisation of GM foodstuffs and animal feed

Vitamin B2 produced on the basis of a GM organism

An application by F. Hoffmann-La Roche AG (which became Roche Vitamins AG on 1 July 2001), Basle, for authorisation to use Vitamin B2 produced on the basis of a GM *Bacillus subtilis* in foodstuffs, was submitted to the ECNH for evaluation by the Federal Office of Public Health. Since the object of the authorisation procedure was the pro-

duction of a chemical vitamin rather than the manufacture of a GM stem of *Bacillus subtilis*, the ECNH declined to issue a statement.

1507 maize

In August 2001 the ECNH was invited to judge the ethical aspects of an application by two companies, Pioneer Hi-bred and Mycogen Seeds, for approval to market 1507 maize which had been genetically modified to render plants resistant to insects and herbicides. The evaluation covered the method of assessing safety and the associated concept of substantial equivalence, application of the precautionary principle, consumer protection and declaration provisions, consumers' freedom of choice, as well as additional aspects related to food safety, biodiversity and social acceptability.

A majority of the ECNH recommended that the application be rejected since it was first necessary to determine the validity and relevance of safety assessments based on the concept of substantial equivalence. It also recommended that alternatives to the selected safety assessment method be examined or developed in order to better address the complexity of reciprocities. Furthermore it criticised the fact that the introduction of declaration thresholds had anticipated a decision in principle which should have been made within the context of a broad public and political debate. It was felt that administrative decisions should not be exploited to force issues. A minority of ECNH members were opposed to rejecting the application but recommended that the evaluations conducted by the applicants be examined and that the safety aspect be assessed based on the result of this examination.

In view of the upcoming legislation, the ECNH recommended that the scope of assessments be broadened

to include the precautionary principle, biodiversity protection and the coherence of decisions as well as safety and consumer protection aspects, and that opportunities for public participation in decisions be improved.

The ECNH also referred to these fundamental deliberations and its recommendations on 1507 maize within the context of the authorisation procedure for Monsanto's Roundup Ready 40-3-2 Soya as well as for Roundup Ready GT73 rapeseed and Roundup Ready GA21 maize.

4.2.3 Commercialisation of living vaccines

EURIFEL FeLV vaccine for cats

The ECNH was asked by the Institute of Virology and Immunoprophylaxis (IVI) and the Swiss Agency for Environment, Forest and Landscape (SAEFL) to state its position on an application for permission to market a GM vaccine against feline leukaemia, particularly in view of the fact that the vaccine contained living organisms.

The ECNH unanimously agreed that the animal ethics questions raised by the production and trial of such vaccines do not exceed those involved in animal experiments in general. In view of this, the ECNH had no major objections to the vaccine's approval. However, the ECNH expressly left open the question of additional ethical considerations on the potential impact of the increased release of such vaccines on the market.

The applicant withdrew the application in the autumn of 2003 due to the fact that the French manufacturer was not prepared to meet the declaration provisions laid down in Switzerland.

5 Publications

5.1 The dignity of animals

In collaboration with the Federal Committee on Animal Experiments, the ECNH published a brochure with the aim of achieving a more concrete definition of the dignity of creation in the case of animals. The brochure on dignity of animals was based on the statements issued by both commissions ahead of the revision of the law on animal protection. It was presented at a press conference in Berne on 21 February 2001, and has since attracted broad interest both in Switzerland and abroad.

5.2 Patents on animals and plants

In December 2001, at the same time as the consultation process on the patent law was launched, the ECNH published its brochure on "Patents on animals and plants: a contribution to discussion." This topic has been the subject of intensive scrutiny by the ECNH ever since the end of 1999, when the Institute for Intellectual Property submitted an initial internal draft on the revision of the patent law. For the purposes of the discussion, animal and plant patenting was initially separated from gene patenting since the two fields involve different ethical issues.

5.3 Gene technology for food

In its brochure entitled "Gene technology for food", the ECNH discussed the ethical aspects of marketing GM foodstuffs and animal feed. The brochure is based on deliberations on a concrete application and addresses the relevant aspects albeit from a general standpoint. The main focus is on health safety, and the discussion centres primarily on the method for assessing substantial equivalence, consumer protection and the associated provisions governing declaration. Additional issues covered are the application of the precautionary principle as well as consumers' freedom to choose between GM and non-GM products. The brochure was presented at a public meeting of the ECNH on 31 March 2003.

6 Studies and reports on ethics in the non-human area

6.1 Studies commissioned by the ECNH

Within the framework of its budget, the ECNH has the option of commissioning external studies and reports on ethics in non-human biotechnology in order to support its own work.

6.1.1 The precautionary principle

In July 2001 the ECNH commissioned Committee member Klaus Peter Rippe to conduct a study to clarify the concept of precaution as a guiding principle of environmental ethics. The study provides an overview of key texts on the precautionary principle, elaborates on the essential ethical questions and, on this basis, develops propositions that have served as a foundation for further internal ECNH deliberations on the precautionary principle concept.

6.1.2 Patenting of genes

Also in 2001 the ECNH commissioned a group of authors from the Centre for Ethics in Zurich (Norbert Anwander, Andreas Bachmann, Klaus Peter Rippe, and Peter Schaber) to examine the ethical aspects of patenting genes, cells and parts of the human body. The main issues addressed by the report were:

- To what extent does patenting constitute the commercialisation of living creatures?
- The normative significance of the distinction between discovery and invention.
- Genes: the common heritage of mankind.
- The meaning of the term “equity” in relation to genetic resources.

The ECNH used the report as the basis for preparations for the consultation process on the revision of the patent law. The report, published in book form in March 2002, was also intended as a contribution to the public discussion:

- Norbert Anwander, Andreas Bachmann, Klaus Peter Rippe, Peter Schaber, Gene patentieren. Eine ethische Analyse, Paderborn, 2002. (ISBN 3-89785-272-1)

6.1.3 Substantial equivalence

At the end of 2002 the ECNH commissioned Küng – Biotech + Umwelt of Berne to investigate and evaluate literature on the concept of substantial equivalence, with the aim of obtaining additional material for the discussion on the ethical evaluation of GM foodstuffs and animal feed. The contents of this study were incorporated in the brochure entitled “Gene Technology for Food”.

6.1.4 Plant ethics

Angela Kallhoff of the University of Münster in Germany was commissioned by the ECNH to summarize her dissertation and theses on the subject of “Principles of Plant Ethics. The Evaluation of Plant Life in Biology and Philosophy”.

6.1.5 Impact of biotechnology on developing and newly industrialised countries

The ECNH commissioned two studies on "The Impact of Biotechnology on Developing and Newly Industrialised Countries". These studies were used as a point of departure for further discussion. An ethical analysis and systematic overview was compiled by philosopher Dr Johann Ach (Rostock, Germany). A second empirical study was conducted at the Institut Universitaire d'Etudes du Developpement, Geneva, by a team headed by Prof. András November, and presented to the Committee at the end of 2003.

6.2 Ethical reports by SAEFL with contributions by the ECNH

As the coordinating authority for the gene technology bill (Gen-Lex, SAEFL, which bears administrative responsibility for the ECNH, also commissioned its own ethical studies to which the ECNH provided assistance. For the sake of completeness and because the subject matter of these reports is closely related to the work of the ECNH, these studies deserve mention here.

6.2.1 The value and dignity of "low" animals and plants. Ethical deliberations on the constitutional principle of the "dignity of creation"

To date, publications on a more concrete definition of the dignity of creation have focused almost exclusively on animals and, in particular, on ver-

tebrates, and have not discussed the implications of protecting the dignity of creation in the case of plants and "low" animals. SAEFL therefore commissioned theologians Andrea Arz de Falco and Denis Müller (both ECNH members) to provide a more detailed basis for discussion on a more concrete definition of the dignity of creation in the case of "low" animals and plants. The authors were asked to take into account the wide array of material which had already been produced on the "dignity of creation", in order to contribute to the legal enforcement of this constitutional provision. This report, which was published in German and French:

- Andrea Arz de Falco/Denis Müller: Wert und Würde von "niederen" Tieren und Pflanzen, Ethische Überlegungen zum Verfassungsprinzip der "Würde der Kreatur", Freiburg i. Ue., Universitätsverlag, 2001. (ISBN 3-7278-1363-6)
- Andrea Arz de Falco/Denis Müller: Les Animaux Inférieurs et les Plantes ont-ils Droit à notre Respect? Réflexions éthiques sur la Dignité de la Créature, Genève, Editions Médecine et Hygiène, 2002. (ISBN 2-88049-176-2)

6.2.2 Ethical balancing of interests in the field of gene technology

Peter Schaber and Philipp Balzer, two Zurich-based philosophers, were also commissioned by SAEFL to conduct a study on the ethical balancing of interests in the field of gene technology as a follow-up to the 1998 study, compiled by Philipp Balzer, Klaus Peter Rippe and Peter Schaber, on a more concrete definition of the dignity of creation. Since the first study was predicated on a hierarchical understanding of living things, the second study aimed to determine whether a true balance of interests was in fact possible, where the boundaries of such a balance of interests lie, and why a hierarchical approach should be favoured over an egalitarian approach. The study defends the hierarchical approach.

7 Networking

Since its inception in April 1998, the ECNH has succeeded in forging contacts in the field of non-human biotechnology both in Switzerland and in Europe. During this time the two Chairs and the Executive Secretary have taken part in numerous selected discussion groups and conventions on non-human biotechnology. The following lists only a few of the ECNH's key contacts.

7.1 Collaboration with other federal commissions

In accordance with its mandate, the ECNH collaborates with other Switzerland-wide commissions whose tasks are related to non-human biotechnology and gene technology.

7.1.1 Swiss Expert Committee on Biosafety

In June 2001 the Swiss Expert Committee on Biosafety and ECNH convened for a half-day meeting to discuss each body's position on the application by the Federal Institute of Technology Zurich for the release of transgenic wheat, and to determine differences and commonalities in their evaluations. Over and above this, information is exchanged between the two committees primarily via the two secretariats, both of which report administratively to SAEFL, and by communicating the minutes of each other's meetings. In December 2003, with a view to optimising collaboration, the two Presidents and secretariats of the committees convened for the first time. The plan is to hold these meetings on a regular basis.

7.1.2 Federal Committee on Animal Experiments

The two committees formed a joint working group for a more concrete definition of the constitutional term "the dignity of creation" within the framework of the animal protection law. The result of this collaboration was the brochure entitled "The Dignity of Animals". The ECNH also works with the Federal Committee on Animal Experiments on the ethical evaluation of killing animals in animal experiments.

7.1.3 Swiss National Advisory Committee on Biomedical Ethics

The Presidents and secretariats of both committees meet at least twice a year for the purposes of exchanging information. In addition, the two committees convened in August 2003 for a joint half-day meeting on the ethical aspects of patenting. In March 2003, delegations from the both committees jointly participated in roundtable discussions with the Institute for Intellectual Property on issues related to patenting and ethics.

7.2 Collaboration with federal administration offices

The frequency of contacts with various federal offices whose work is related to non-human biotechnology varies depending on the priorities pursued by the ECNH. Following approval of the Gen-Lex (gene technology bill), there was less of a requirement to advise the Swiss Agency for Environment,

Forest and Landscape (SAEFL), which is responsible for the administration of the ECNH, in preparation for the law on gene technology. With the discussion on the ethical aspects of permitting GM foods and animal feed, the focus shifted instead to the Federal Office of Public Health (SFOPH) and the Federal Office for Agriculture (FOAG). The Federal Veterinary Office (FVO) is the contact partner for issues pertaining to animal ethics. The ECNH has also been in regular contact with the Institute for Intellectual Property (IIP) as a result of the round-table discussions on "Patenting and Ethics" in association with the revision of the patent law. Initial contacts were forged with the Swiss Agency for Development and Cooperation and the State Secretariat for Economic Affairs to address the issue of "The Impact of Biotechnology on Developing and Newly Industrialised Countries". Another important contact for the ECNH is the Centre for Technology Assessment TA-Swiss, which reports to the Swiss Science and Technology Council. To facilitate information exchange between TA-Swiss and the ECNH, the Executive Secretary has been invited to attend meetings of the TA-Swiss management committee since 2000. Since 2002 B. Sitter-Liver has been a member of this committee. In addition, A. Arz de Falco and B. Sitter-Liver contributed to the TA-Swiss publication on "Assessment of the Consequences of Technology and Ethics".

7.3 International network

7.3.1 The European Non-Human Bioethics Committees platform

Guideline 2001/18/EC of the European Union (EU) allows member states to address the ethical aspects of regulations governing the release and commercialisation of GMOs. The Dutch Committee for Genetic Modification (COGEM) set itself the goal of rendering this provision operable and elaborating concepts, criteria and procedures for an ethical framework. K. P. Rippe and A. Willemsen attended a workshop organised by COGEM with this objective in mind. The meeting prompted representatives of the seven participating countries to set up an information exchange platform for the European Bioethics Commissions. The ECNH was therefore invited to organise the next meeting.

Between 25 and 26 September 2003, the ECNH hosted the second meeting of the European Bioethics Committees in Berne. Unlike the first meeting, the subject matter for the second meeting was extended to include the field of non-human bioethics and the number of invitees was increased. Thirty participants representing bioethics committees in twelve European countries attended the meeting. In addition, ten invited representatives of the Swiss administration and federal commissions took part in the discussions. Information was exchanged with regard to the ethical debate on the release of GMOs, transgenic animals, transgenic foodstuffs and patenting in the field of biotechnology. The meeting also discussed the relationship of ethics and participative methods as well as the role of ethics in public debate. The second meeting succeeded in firmly establishing this new discussion platform. Since similar topics are clearly addressed by many different commis-

sions simultaneously, the aim in future is to provide an early opportunity to exchange information on ethical discussions.

Participants from Belgium volunteered to organise the next meeting in Brussels. At the request of participants, the platform will continue to be autonomous i.e. independent of EU structures, since the various bioethics committees are consulted by their governments. This does not, however, exclude the possibility of tabling EU topics on the agenda of future meetings and inviting EU representatives to attend.

7.3.2 European Society for Agricultural and Food Ethics

The European Society for Agricultural and Food Ethics (EurSafe) also became an important discussion platform for international networking. The society was created in 1999 at the initiative of Dutch and Danish experts in ethics. The ECNH has been represented at every annual congress to date. Between August 2000 and the autumn of 2002, A. Arz de Falco was a member of the EurSafe Executive Committee.

8 Public information work

8.1 Public events

8.1.1 Public meetings on the release of GMOs

On 2 May 2000 the ECNH members met for the first time in public. It selected a public meeting format at which it could present the work and culture of the ECNH and conduct a public discussion on the issues at stake. The theme for this first public meeting was selected based on a current topic, "Should genetically modified organisms (GMOs) be released into the environment? The options: approval – moratorium – ban". Some 200 representatives of political, government, industrial and environmental organisations, as well as interested members of the lay public, took up the invitation to the meeting in Berne. The first part involved a discussion among Committee members on different ethical positions, while the second part opened the discussion to the floor. The event was met with keen interest by the public and the media alike. Following the meeting, the ECNH published a statement in which the majority called for a moratorium on release trials with GMOs (see Section 4.1.3).

8.1.2 Press conference on the dignity of animals

On 21 February 2001, the ECNH and the Federal Committee on Animal Experiments held a press conference at which they presented their joint brochure, "The Dignity of Animals". The aim was to present the practical problems of implementing the constitutional concept of the dignity of creation and to outline the ethical aspects. Approximately 60 persons attended the press conference.

8.1.3 Public meeting on patents on animals and plants

Based on highly positive feedback on its first event, the ECNH accepted an invitation from the University of Fribourg to hold another public discussion as part of the Science et Cité festival week. Accordingly, on 5 May 2001, the ECNH invited the public to a discussion on "The Patenting of Animals and Plants. Ethical Deliberations on the Protection of Intellectual Efforts in the Field of Biotechnology". The University of Fribourg assisted the ECNH in its preparations for the event. The ECNH compiled for discussion a thesis paper and designed a model on patenting which took into account ethical criteria. To enable a critical analysis of this complex subject, experts from the fields of industry, non-government organisations, agriculture, research and ethics were invited to state their

position on the ECNH theses. The discussion was then opened to the public. This Saturday afternoon discussion, too, invited major interest. Following the event the University of Fribourg invited participants to an aperitif.

8.1.4 Public meeting on the patenting of genes

On 26 March 2002, the ECNH held a public discussion in Berne on the "Patenting of Genes". The event revolved primarily around the study commissioned by the ECNH on "Gene Patenting: An Ethical Analysis", against the background of preparations for the revision of the patent law. Since the discussion focused on the ethical aspects of legislation but not on legal provisions per se, it was decided not to invite external experts. ECNH members gave short presentations of the central ethical considerations before opening the debate to the public.

8.1.5 Public meeting on GM foods and animal feed

On 31 March 2003 the ECNH held a public discussion in Berne on "Gene Technology for Food". At the same time it used the opportunity to present its new brochure with the same title. The first part of the event featured presentations by ECNH members on the various ethical aspects to be considered for the commercialisation of GM foods and animal feed. The areas discussed included consumer protection and the associated provisions governing the declaration of GM products, the concept of substantial equivalence, the interpretation of the precautionary principle and freedom of choice. The second part was once more opened to the large public audience.

8.2 Website

The ECNH's website at www.ekah.ch was launched in the spring of 2000 in German, French and English and in 2003 an Italian version was introduced. The website provides interested parties with information on the mandate of the ECNH, current members, statements and publications by the committee, and reports commissioned.

9 Budget and fees of Committee members

The ECNH was appointed by the Federal Council but is administratively subordinate to the Substances, Soil and Biotechnology Division of SAEFL. Since the beginning of 2002 the Committee has operated on a defined budget within this department. The ECNH has an annual budget of CHF 200,000 at its disposal for the exercise of its mandate. The money is spent on public information work, external research, studies and reports as well as publications. The ECNH is fully autonomous in terms of the contents of its tasks

In accordance with the ordinance on non-parliamentary commissions as well as advisory organs and representations of the confederation, members of the Committee receive compensation. Persons under contract to an employer receive CHF 200.-- per meeting day, and self-employed persons receive twice this amount.

February 2004

On behalf of the Federal Ethics Committee on Non-Human Gene Technology

PD Dr. Klaus Peter Rippe
Chair

Ariane Willemsen, lic. iur., M.A.
Executive Secretary

External Guest Speakers at ECNH Meetings between 2000 and 2003

Hansjürg Ambühl

Head of the Humanitarian Aid for Africa Section of the Swiss Development and Cooperation Agency
The effects of biotechnology on developing and newly industrialised countries; GM foods and the example of the famine crisis in Southern Africa, guest speaker at the ECNH meeting held on 19 June 2003

Migues Baumann

Swissaid
Non-human gene technology and patenting; expert at the public meeting held in Fribourg on 5 May 2001

Konrad Becker

Head of Patent and Trademark Department, Novartis
Non-human gene technology and patenting; information and discussion in view of the ECNH statement on the consultation procedure for the patent bill; guest speaker at the ECNH meeting held on 22 June 2000, expert at the public meeting held in Fribourg on 5 May 2001

Ignaz Bloch

Cantonal Veterinary Surgeon for Basle Country
Analysis of the ethical aspects of creating chimeras, discussion with guests from the field of enforcement, ECNH meeting held on 7 May 2002

Barbara Bordogna-Petriccione

Réseau Interdisciplinaire Biosécurité (RIBios), c/o Institut Universitaire d'Etudes du Développement, University of Geneva
Co-author with Andrés November and Mirko Saam of an empirical study for the ECNH on the effects of biotechnology on developing and newly industrialised countries, presentation of the study at the ECNH meeting held on 13 October 2003

Kurt Bürki

Head of the Institute for Laboratory Animal Science, University of Zurich
The making of chimeras: information on the status of science and research; guest speaker at the ECNH meeting held on 7 May 2002

Fernand Cucho

National Councillor, Canton of Jura
Non-human gene technology and patenting; expert at the public meeting held in Fribourg on 5 May 2001

Angela Kallhoff

University of Münster, Germany
Principles of plant ethics: the evaluation of plant life in biology and philosophy; guest speaker at the ECNH meeting held on 17 January 2003
Summary of her dissertation on the topic and literature list presented to ECNH, November 2002

Urs Klemm

Deputy Director and Head of the Food and Consumer Durables Division of the Swiss Federal Office of Public Health (SFOPH)
Discussion of the ethical aspects of commercialising genetically modified (GM) foods and animal fodder, ECNH meeting held on 25 June 2002

Valentin Küng

Küng – Biotech + umwelt, Berne
Terminological analysis and overview of the status of R&D in the field of plant biotechnology (terminator and genetic use restriction technologies/GURTs); guest speaker at the ECNH meeting held on 25 June 2002
Study on substantial equivalence, presentation to the ECNH meeting held on 28 November 2002

Luc Magnenat

Cantonal Veterinary Office, Geneva
Analysis of the ethical issues involved in creating chimeras, discussion with guests representing the field of enforcement; ECNH meeting held on 7 May 2002

Matthias Meyer

Ambassador, Head of the Trade/Development Task Force, State Secretariat for Economic Affairs (seco)
Effects of biotechnology on developing and newly industrialised countries, guest speaker at the ECNH meeting held on 19 June 2003

Urs Pauli

Microbiology and Hygiene Section of the Food Science Department, Swiss Federal Office of Public Health (SFOPH)
Discussion of the ethical aspects of commercialising genetically modified foods and animal fodder, ECNH meeting held on 25 June 2002

François Pythoud

Biotechnology and Flux of Substances Section, Swiss Agency for the Environment, Forests and Landscape (SAEFL)
"The effects of biotechnology on developing and newly industrialised countries", information on the Cartagena Protocol, the Biodiversity Convention, and access and benefit sharing, ECNH meeting held on 28 November 2003

András November

Réseau Interdisciplinaire Biosécurité (RIBios), c/o Institut Universitaire d'Etudes du Développement, University of Geneva
Co-author with Barbara Bordogna-Petriccione and Mirko Saam of an empirical study for the ECNH on the effects of biotechnology on developing and newly industrialised countries, presentation of the study to the

ECNH meeting held on 13 October 2003

Andrea Raps

Biotechnology and Flux of Substances Section, Swiss Agency for the Environment, Forests and Landscape (SAEFL)
Information on the renewed application by the Federal Institute of Technology, Zurich, for permission to release a transgenic wheat; guest speaker at the ECNH meeting held on 27 August 2003

Christoph Rehmann-Sutter

University of Basle, Office for Ethics in the Biosciences
Introduction to gene technology and patenting, identification of ethical problems; guest speaker at the ECNH meeting held on 9 May 2000, expert at the public meeting held in Fribourg on 5 May 2001

Mirko Saam

Réseau Interdisciplinaire Biosécurité (RIBios), c/o Institut Universitaire d'Etudes du Développement, University of Geneva
Co-author with Barbara Bordogna-Petriccione and Andrés November of an empirical study commissioned by the ECNH on the effects of biotechnology on developing and newly industrialised countries; presentation of the study at the ECNH meeting held on 13 October 2003

Christoph Sautter

Institute for Plant Sciences, Federal Institute of Technology, Zurich
Non-human gene technology and patenting; expert at the public meeting held in Fribourg on 5 May 2001

Jørgen Schlundt

Director of the Food Safety Department, Coordinator of the Food Safety Programme at the World Health Organisation (WHO) in Geneva
Overview of the complexity of issues involved in "Biotechnology, food and development aid/cooperation"; guest speaker at the ECNH meeting held on 26 February 2003

Martin Schrott

Food Department, Biotechnology Group, Swiss Federal Office of Public Health (SFOPH)
Discussion of the ethical aspects of commercialising genetically modified food and animal feed; ECNH meeting held on 25 June

Hans Sigg

Cantonal Veterinary Office, Zurich
Analysis of the ethical aspects of creating chimeras, discussion with guests representing the implementation field; ECNH meeting held on 7 May 2002

Walter Smolders

Intellectual Property Department, Syngenta, Basle
Overview of the status of research and perspectives in the field of plant biotechnology at Syngenta ECNH meeting held on 25 June 2002

Theodor Weber

Transplantation and Human Research Section, Swiss Federal Office of Public Health (SFOPH)
Analysis of the ethical aspects of creating chimeras, discussion with guests representing the field of enforcement; ECNH meeting held on 7 May 2002

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