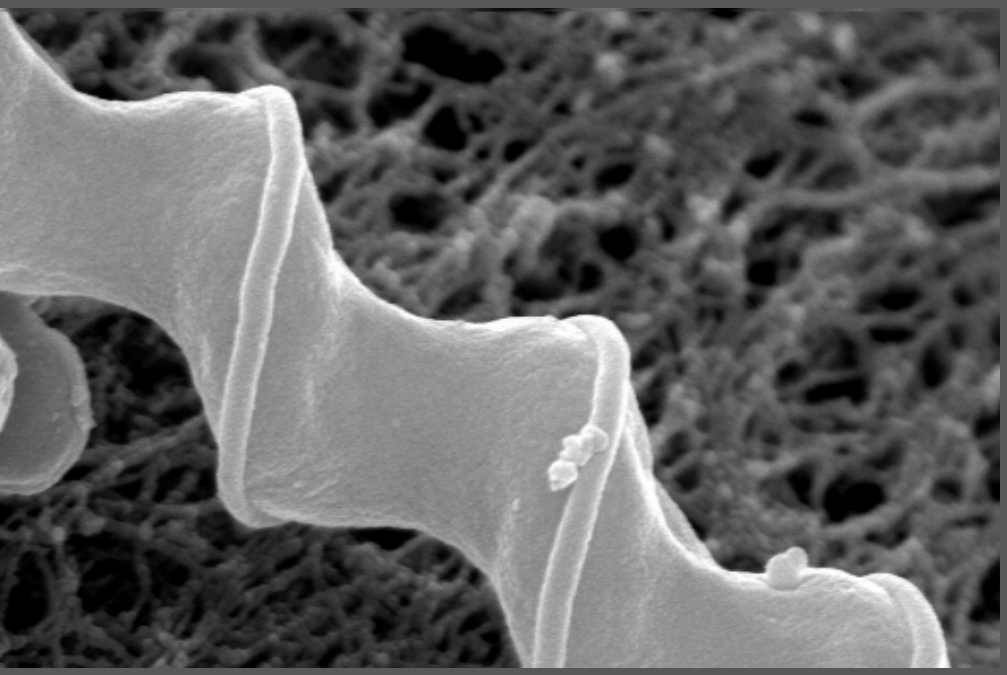
2004 Annual Report of the Swiss Expert Committee for Biosafety SECB



EFBS Eidgenössische Fachkommission für biologische Sicherheit
CFSB Commission fédérale d'experts pour la sécurité biologique
Commissione federale per la sicrezza biologica
Swiss Expert Committee for Biosafety

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Contents

1. Mandate of the SECB

The Swiss Expert Committee for Biosafety (SECB) acts in an advisory capacity on issues concerning the protection of people and the environment in the areas of biotechnology and gene technology.

1.1 Tasks

The SECB advises the Federal Council on the issuing of regulations and the federal and cantonal authorities on matters of enforcement. It is consulted on applications for permits and can make recommendations in this regard. Before doing so, it can request expert statements and commission studies. It also issues recommendations for specialists working with genetically modified or pathogenic organisms, and informs the public about important events in this field. It submits regular reports to the Federal Council on ist activities. Additionally, the SECB monitors new findings and trends in biosafety so that it is in a position to help shape current developments at an early stage.

1.2 Legal foundation

The legal basis for the SECB is furnished by Article 29g of the Federal Law on the Protection of the Environment (LPE)[1] and Article 22 of the Gene Technology Law[2] which came into force on 1 January 2004, as well as Article 29e of the Federal Law on Epidemics[3]. The establishment of the SECB on 1 January 1997 coincided with the entry into force of the Ordinance[4] by which it is governed.

1 Federal Law of 7 October 1983 on the Protection of the Environment, SR 814.01: http://www.admin.ch/ch/d/sr/c814_01.html (in German), not legally binding English translation: http://www.umwelt-schweiz.ch/imperia/md/content/stobobio/biotech/divers/2.pdf

2 Federal Law of 21 March 2003 on Non Human Gene Technology, SR 814.91: http://www.admin.ch/ch/d/sr/c814_91.html (in German), not legally binding English translation: http://www.umwelt-schweiz.ch/imperia/md/content/stobobio/biotech/17.pdf

3 Federal Law of 18 December 1970 on Protection against Contagious Diseases in Humans (Epidemics Law), SR 818.101: http://www.admin.ch/ch/d/sr/c818_101.html (in German)

4 Ordinance of 20 November 1996 on the Swiss Expert Committee for Biosafety, SR 172.327.8: http://www.admin.ch/ch/d/sr/c172_327_8.html (in German)

2. Organisation and structure of the SECB

The SECB is an independent committee of experts whose members are appointed by the Federal Council. The members convene approximately six times a year. If required, additional experts may participate at the meetings. The secretariat is responsible for providing organisational support and technical assistance to the Committee members.

2.1 Composition and methodology

Under the terms of the Ordinance on the SECB, the Committee must be composed of 16 experts with specialist knowledge in the fields of gene technology, biotechnology, environment and health, and represent various conservation/protection and user interests (universities, industry, agriculture and forestry, environmental organisations, consumer organisations).
If required, additional experts may be consulted by the SECB but they are not entitled to vote. Issues requiring more detailed examination are dealt with by working groups. The SECB also commissions studies in order to examine special issues in depth. Since the Committee members represent different disciplines and different conservation and user interests, the Statements issued by the SECB are not necessarily the result of consensus; votes are often taken and minority positions are recorded.

2.2 Meetings

SECB meetings are not open to the public. Depending on the business to be dealt with, representatives of authorities regularly attend the meetings and are available to the Committee for information and discussions. During the period under review the SECB convened six times on the following dates: 6 February, 25 March, 13 May, 24 June, 23 September and 3 December, 2004.

2.3 Cooperation

The SECB works closely with national authorities and also exchanges information with the Swiss Ethics Committee for Non-Human Biotechnology. The Secretariat also liaises with other committees and public offices abroad which are active in related fields.

2.4 Secretariat

The secretariat is responsible for providing organisational support and technical assistance to the Committee members. It prepares for meetings, drafts Statements and responds to a major part of technical enquiries. The responsibilities of the Secretariat also cover public relations activities, contact with the media and reporting on the work of the SECB, as well as attending various international and national meetings. The Secretariat is administratively affiliated to the Swiss Agency for the Environment, Forests and Landscapes (SAEFL). Since 1997, Karoline Dorsch has been Executive Secretary of the SECB and is supported in her work by Julia Link (scientific assistant).

Karoline Dorsch
Ph.D., Microbiologist

studied microbiology in Berne and obtained her doctorate in St. Louis (Missouri, USA), following which she spent several years in the USA and later in Switzerland conducting basic research in the field of microbiology and molecular biology. In 1992 she was appointed Executive Secretary of the Swiss Biosafety Committee SBC. She has been Executive Secretary of the SECB (the successor to the SBC) since its appointment by the Federal Council in 1997.

Julia Link
lic. phil. nat., Biologist

studied biology at the University of Berne and has worked for the SECB Secretariat since 2000.

2.5 President

Martin Küenzi
Dr. sc. techn., Biotechnologist

After graduating in agricultural technology and obtaining a doctorate in microbiology from the Swiss Federal Institute of Technology (ETH), Zurich, Martin Küenzi worked in the field of microbiology in Zurich and the USA. Following this, he worked in the pharmaceuticals department of Ciba-Geigy/Novartis for a number of years. He was responsible at Novartis for the biotechnological process development and production in Switzerland, and since 2000 has been employed as project leader at Solidago AG, a service company specialising in the development of biotechnological processes for generic drugs. For many years he has also been a member of local, national and international committees that examine biosafety issues in biotechnology. In 2004 the Federal Council appointed him as Chairman of the SECB, following his two-year ad interim chairmanship of the Committee.
Member since 1997.

2.6 Members

All Committee members were reelected by the Federal Council for the 2004 – 2007 term of office.

Daniel Ammann
PD Dr. sc. techn. ETHZ, Chemist

After graduating and obtaining a doctorate in chemistry from the Swiss Federal Institute of Technology, Daniel Amman qualified as a university lecturer (venia docendi) in cell biology. After completing a number of years as a research scientist in clinical chemistry and electrophysiology and lecturing, among other things, in safety, risk analysis and environmental sociology at the ETH, he was additionally appointed chairman of the Swiss Working Group on Gene Technology (SAG), a critical forum on gene technology issues. Since 2004 he has been manager of daniel amman consulting dacon in Zurich.
Member since 1997.

Klaus Ammann
Prof. Dr. phil. nat., plant ecologist

After graduating in biology and obtaining a doctorate in the history of vegetation, Klaus Amman headed the division for Cryptogamics at the University of Berne. He has been Director of the University of Berne Botanical Garden since 1996. In addition, he is involved in Swiss and European projects on gene flow from cultivated plants to their wild relatives, and supports European projects for species protection. He is a member of international committees such as the Teaching Faculty UNIDO and co-editor in chief of Environmental Biosafety Research.
Member since 1997.

Joachim Frey
Prof. dr. ès. sc., bacteriologist

After graduating in chemistry and biochemistry from the Universities of Geneva and Uppsala, Joachim Frey conducted gene technology research on soil and water bacteria in Geneva and Berlin. Since 1987 he has headed a research group within the University of Berne's Institute for Veterinary Bacteriology, studying molecular mechanisms of bacterial pathogenicity and the development of vaccinations. In 2000 he has been appointed full Professor and Director of the Institute for Veterinary Bacteriology.
Member since 2003.

Emmanuel Frossard
Prof. Dr. sc. agr., Agronomist, Plant Nutrition

After graduating in agriculture from the École nationale supérieure d'agronomie et des industries alimentaires in Nancy and completing his doctorate in Lorraine (Institut national polytechnique de Lorraine), Emmanuel Frossard conducted research in Canada in the field of soil sciences. Following this, he lectured in France for many years in the field of soil sciences before moving to the ETH Zurich's Institute of Plant Science to take a professorship in plant nutrition, specialising in the cycle of nutrients in agrarian eco-systems.
Member since 2003.

Felix K. Gmünder
Dr. sc. nat. ETHZ, Microbiologist

After graduating in microbiology and obtaining a doctorate in biotechnology from the ETH Zurich, Felix Gmünder trained as a laboratory manager before heading a diagnostics laboratory for six years. Following this, he worked as a senior research assistant at the ETH, conducting research into animal cell cultures. Since 1990 he has been head of the Safety Division of Basler & Hofmann, Ingenieure und Planer AG, Zurich, responsible for biosafety, safety in the workplace and accident prevention.
Member since 2003.

Angelika Hilbeck
Dr. agr. biol., Ecologist

studied agrarian biology at the University of Stuttgart-Hohenheim and obtained her doctorate in entomology at North Carolina State University. She then conducted laboratory research into the effects of genetically modified plants on non-target organisms in the food chain in Switzerland and, with the aid of EU funding, conducted field research regarding the effects of GMOs on biodiversity in Italy. Since 2001 she has also been involved in work in developing countries, where she collaborates with local scientists to develop methods for studying the ecological impact for risk analysis.
Member since 2001.

Philipp Hübner
PD Dr. phil., Biochemist

graduated and obtained his doctorate in biochemistry from the University of Basle, following which he conducted basic and applied research in Grenoble (France) in the field of microbiology and molecular biology and on the enforcement of foodstuff laws. He qualified as a university lecturer (venia docendi) at the University of Berne in the field of the biochemistry of foodstuffs, and since 2003 has been working as a federally certified food chemist at the Cantonal Laboratories of Basle City.
Member since 2003.

Beatrice Lanzrein
Prof. Dr. phil. nat., Insect and Development Physiologist

studied zoology, chemisty/biochemistry and geography in Berne and Zurich. After her doctorate in insect physiology, she conducted research in the USA and Switzerland as well as spending some time in Kenya on field assignments. Since 1979 she has lectured in zoo-physiology and cell biology at the Institute for Cell Biology at the University of Berne, and is head of a research group studying insect development and reproduction as well as parasitoid-host interactions using physiological, biochemical, cell biology and molecular biology methods.
Member since 2003.

Roman Kuonen
Dr. med. FMH Specialist in General Medicine

studied medicine in Fribourg and Berne and completed his clinical training in Berne as a general practitioner. Since 1989 he has been the main partner in a group practice in Leuk, and a member of "Ärztinnen und Ärzte für Umweltschutz" (Doctors for the Environment), an organisation that promotes an ecological approach to medicine.
Member since 2003.

Pascal Meylan
PD Dr. med. FMH, Clinical Virologist

studied and obtained a doctorate in microbiology, internal medicine and infectious diseases at the Universities of Lausanne and Paris, following which he worked in the USA on research into various pathogens such as the AIDS virus HIV and the Bacillus tuberculosis, during which time he gained practical experience in the field of biosafety. On his return to the University Hospital of Lausanne, he continued his research projects and increasingly devoted his attentions to microbiological diagnostics and biosafety issues.
Member since 2003.

Bernadette Oehen
Dipl. bot., Botanist

joined the WWF Switzerland after graduating in biology from the University of Zurich. During her time with the WWF, she studied the environmental risks of using transgenous plants, as well as further developments in sustainable agriculture. Since 2002 she has worked at the Research Institute for Organic Farming (Forschungsinstitut für Biologischen Landbau/FiBL) in Frick, where she specialises in issues of co-existence and advises producers who opt against using gene technology.
Member since 1997.

Barbara Oppliger-Frischknecht
Dipl. ing. agr. ETH, Agronomist

studied agriculture at the ETH Zurich, following which she spent eight years working on agricultural projects in Bolivia and Pakistan. She teaches at Buchs College of Vocational Training, manages projects in various South American countries, and is a member of management of RhyTOP GmbH, an agricultural consultancy. On behalf of the Swiss Consumer Forum, she is also a member of the panel of experts that supports the work of the Agroscope Research Centre in Reckenholz.
Member since 2001.

Doris Rentsch
Prof. Dr. sc. nat., Plant Physiologist

studied biology at the University of Zurich and obtained her doctorate at the ETH Zurich. In 2001, following several years conducting research in molecular biology and plant physiology in Berlin and Tübingen, she took over the Chair of Molecular Plant Physiology at the University of Berne's Institute of Plant Sciences. Her research primarily focuses on transport processes in plants.
Member since 2003.

Didier Trono
Prof. Dr. med., Virologist

studied medicine and obtained his doctorate from the University of Geneva, following which he spent many years in the USA conducting research in various fields of cell biology, virology and genetics. In 1997 he returned to Switzerland to take up a professorship at the University of Geneva's Department of Genetics and Microbiology, where among other things he was involved in research into the pathogenesis of the HIV AIDS virus and appropriate vectors for gene therapies. He has been Dean of the Faculty of Life Sciences at Federal Institute of Technology, Lausanne, since 2004.
Member since 2003.

Jean-François Viret
Dr. ès. sc., Molecular Biologist

studied and obtained his doctorate in genetics and physiology from the University in Lausanne, following which he conducted research in the field of molecular genetics at the Max Planck Institute in Berlin. He then worked for Transgène SA, a company based in Strasbourg, France, and in 1989 moved to Berna Biotech AG in Berne, where he worked in various research and development capacities before being appointed Head of Research Alliances and Bacterial Vaccine Research.
Member since 2003.

3. Issues addressed during 2004

Since the SECB is responsible for identifying developments in biosafety at an early stage and drawing attention to the need for additional action and research, it follows national and international events and scrutinises issues which it regards as of key importance.

3.1 National issues

At the national level, changes in the legislature are of major importance for the SECB, since various legal aspects dictate the Committee's sphere of action.

3.1.1 Gene Technology Law

The Swiss Gene Technology Law[5] (GTL) came into force on 1 January 2004. One of the main aims of the GTL is to implement Article 120 Para. 1 of the Swiss Constitution[6]: "Humans and their environment shall be protected against any abuse of gene technology". In addition the GTL provides for the protection of biodiversity and respect for the dignity of creation. It also contains additional important provisions governing the clear labelling of products containing genetically modified organisms (GMOs), the protection of GMO-free production and freedom of choice. The GTL also contains stricter provisions governing liability. Due to the coming into force of the GTL, additional ordinances need to be amended. Work on these amendments was initiated in the year under review. The aim, among others, is to draw up detailed criteria governing the separation of commodity flows as well as labelling for products containing GMOs, and to lay down conditions governing the release of GMOs for experimental purposes and their commercial release, and the contained use of GMOs.

3.1.2 Guidelines on medical waste disposal

The SAEFL has drawn up guidelines on the disposal of medical waste[7]. Targeted at healthcare institutions including medical practices and hospitals, as well as educational officials, enforcement authorities, nursing and laboratory staff, the guidelines provide information on the safe, environmentally sound treatment of medical waste and in particular hazardous medical waste. The correct disposal of waste is of importance to the SECB insofar as it impinges on biosafety; medical waste can contain pathogenic organisms and is therefore potentially infectious. The disposal guidelines apply only in specific cases to medical waste produced by institutions subject to the Ordinance on the Contained Use of Organisms (see also 4.3): for example, waste from medical microbiology diagnostical laboratories, the disposal of which was the subject of an earlier SECB statement to which the guidelines frequently refer. The SECB welcomes the SAEFL guidelines as a practical instrument that will help to ensure the safe treatment of infectious material.

3.2 International events

Among other international events, the SECB closely followed the appearance of new diseases such as avian flu and SARS.

3.2.1 Avian influenza

Classical avian influenza, also known as avian flu, is an acute, highly contagious fever-type virus which attacks birds and can result in substantial economic losses. In the year under review, a highly pathogenic form of Subtype H5N1 avian influenza broke out in various Asian countries. In several instances, the virus was transmitted to humans and has since caused several deaths (54 as of June 2005). Experts are advising that developments be carefully monitored since the possibility of the virus mutating in the course of time and acquiring the ability to be transmitted from person to person cannot be excluded. The World Health Organisation has also issued an alert warning of a world-wide spread of avian flu[8], [9], [10]. Information for Switzerland is published by the Swiss Federal Office of Public Health (SFOPH)[11]. SECB experts repeatedly point out that flu pandemics similar to the Spanish flu of 1928 could recur, and emphasise that is therefore important to have the requisite information and an appropriate infrastructure in place.

3.2.2 Laboratory accidents with SARS

In 2003 several thousand people contracted SARS, and several hundred died of the disease[12]. SARS stands for Severe Acute Respiratory Syndrome, and is transmitted via air from person to person[13], [14]. The disease is caused by a new virus, the SARS associated corona virus. Intensive efforts are being made world-wide to develop appropriate vaccinations and medication. In the year under review, new outbreaks of SARS occurred in Asia although three of these cases were attributable to laboratory accidents rather than natural sources. World Health Organisation (WHO) experts who examined these cas-

5 Federal Law of 21 March 2003 on Non Human Gene Technology, SR 814.91: http://www.admin.ch/ch/d/sr/c814_91.html (in German), not legally binding English translation: http://www.umwelt-schweiz.ch/imperia/md/content/stobobio/biotech/17.pdf

6 Federal Constitution dated 18 April 1999, Article 120 on Non-Human Gene Technology, SR 101: http://www.admin.ch/ch/d/sr/c101.html (in German)

7 Disposal of medical waste 2004: http://www.umwelt-schweiz.ch/imperia/md/content/abfall/medabf_rl_d.pdf (in German)

8 WHO information and recommendations: http://www.who.int/topics/avian_influenza/en/

9 Further information on avian flu: http://www.cdc.gov/flu/avian/index.htm

10 b-safe provides a summary of the latest information on avian flu at: http://www.b-safe.ch/?mid=1025&pid=1032&lang_id=1

11 SFOPH information on avian flu: http://www.bag.admin.ch/infekt/d/vogelgrippe.htm

12 SFOPH information on SARS: http://www.bag.admin.ch/infekt/d/sars.htm

13 WHO information on SARS: http://www.who.int/topics/sars/en/

14 CDC information on SARS: http://www.cdc.gov/ncidod/sars/news.htm

es came to the conclusion that safety measures were not correctly followed and that the laboratory staff were insufficiently trained. The consequence must be that international biosafety measures must be taken to prevent any recurrence of such laboratory accidents [15]. Activities in laboratories, on which the SECB has also been consulted with regard to the SARS pathogen are currently under way in Switzerland. In the opinion of the SECB, qualified and experienced staff are an essential criterion for activities involving highly pathogenic organisms.

3.3 SECB projects

The SECB may also commission external evaluations and studies in order to obtain more detailed information on topics which are relevant to its work.

3.3.1 Precautionary principle

The precautionary principle states that measures should be taken early to limit adverse effects on people and the environment, even if full scientific certainty of such effects is lacking. This precautionary principle is also enclosed in the Swiss Law on the Protection of the Environment and in the Gene Technology Law. In principle, the precautionary principle refers to a wide range of situations and applications, but recently it has frequently been associated with “green” gene technology. There are no known internationally recognised guidelines or other instruments governing the concrete treatment and application of the precautionary principle. A synthesis paper on the topic has been drawn up in Switzerland up by various government departments [16].

The principle also provides an important guideline for recommendations by the SECB, which in recent years has been examining and deliberating on the topic and its implementation with a view to concrete provisions governing its application. Systematic surveys based on internationally recognised publications on the precautionary principle were conducted within the Committee in order to formulate a range of criteria. As a result of this work, checklists were drawn by general consensus and majority approval of the Committee. These checklists are written up in a position paper, which is currently for internal use, in the form of three criteria sets (criteria on understanding the precautionary principle; criteria for deciding whether or not the precautionary principle should be applied in specific cases; and criteria for application of the precautionary principle).

3.3.2 Experiences with the cultivation of genetically modified organisms

Since being introduced in 1996, there has been steady growth worldwide in the cultivation of GM plants. In terms of biosafety, the effects of such cultivation on the environment are of particular interest. The SECB believes it is important to have the available data in order to assess the risks inherent in the release of such organisms for experimental purposes or their commercial cultivation. Such data and any identified gaps in knowledge can also be used as the basis for further action in the field of biosafety research. In the year under review the SECB deliberated on this topic and commissioned a study with a view to summarising current findings on the possible environmental impact of insect- and herbicide-tolerant GM plants on the basis of concrete examples, using published data and information from authorities in Switzerland and abroad. The compilation paper will focus in particular on the relevance of such findings for Switzerland.

[15] Further information: http://www.b-safe.ch/?mid=&pid=&s=33#newsarticle

[16] The precautionary principle from a national and international perspective. Synthesis paper by the Interdepartmental Working Group on the Precautionary Principle: http://www.bag.admin.ch/themen/weitere/vorsorge/d/synthese.pdf

4. Consultations in 2004

One of the key tasks of the SECB is to advise the authorities and issue statements on request. While the SECB has no decision-making authority, its concerns are often addressed in legislative issues. The recommendations of the SECB are incorporated in official decisions with regard to permit applications.

4.1 Consultations on the legislature

Within the framework of official consultations and hearings, amendments to laws and ordinances are also submitted to the SECB for examination and recommendations.

4.1.1 Ordinance on animal feed and ordinance on foodstuffs

Amendments to these ordinances were prompted by the coming into force of the Gene Technology Law (GTL) and amendments to European Regulations 1829/2003[17] and 1830/2003[18]. The central elements are the obligation to label and the traceability of GMOs. Over and above this, the GTL also provides for the separation of commodity flows of GM and conventional organisms.

The SECB agrees in principle with the amendments to both ordinances and welcomes the bringing into line of Swiss regulations with those of the European Union. The SECB calls for a harmonisation of the wording in both ordinances, since applications for permits to release GM crops commercially are frequently submitted simultaneously for animal feed and foodstuffs. The SECB also recommends that the terms used in the EU guidelines be used. Moreover, the SECB recommends that a glossary be drawn up containing definitions and explanations of terms.

4.1.2 Patent law

The amendment to the patent law primarily involves regulations governing the patentability of biotechnological discoveries and various adjustments in line with international conventions. The draft was once more revised as a result of the findings of the first hearing on the 2002 consultation of the reform of the patent law[19]. The SECB is of the opinion that the revised version contains significant improvements and addresses several of the concerns expressed by the SECB. The definition of patentable characteristics is now significantly more precise and has created much clearer boundaries to exclusion from patentability. This means, for example, that genetic sequences can only be patented if they are associated with a technical application. Patent protection is linked to the patented function, and there is no absolute protection of material as is the case in chemistry. The SECB also views positively the fact that the research privilege as well as the farmer's privilege have been reinforced. Another important point is the introduction of information on origins: if biological material is patentable, its origin must be disclosed. Thus the new law covers the origin of genetic resources as well as traditional knowledge.

4.2 Consultation on permit applications

Applications for permits in various fields are submitted to the SECB for consideration. The Committee issues statements on the release of genetically modified or pathogenic organisms for experimental or commercial purposes, as well as activities involving the contained use of such organisms. Pending permit applications are published in the Federal Gazette and the permit is issued by the relevant federal agencies following a review of the risk assessment and taking into account the statements issued. In addition, the SECB examines permit applications on gene therapies and issues statements on the biological safety of the preparation for the proband as well as for human beings and the environment. A permit also requires the approval of the local Ethics Committee.

4.2.1 Experimental releases

Section 2 of the Release Ordinance[20] (RO), which has been in force since 1999, governs releases of genetically modified or pathogenic organisms for experimental purposes. The aim of the RO is to protect people and the environment against the harmful effects of the use of such organisms in the environment and to preserve biodiversity and the fertility of the soil. Under the terms of Article 7 of the Release Ordinance, experimental releases must be authorised by SAEFL.

Wheat release experiment by the Federal Institute of Technology (ETH), Zurich

Completion of the wheat release experiment[21] signals an end to a topic which has preoccupied the SECB since 2001: The experiment involved the sowing of 1,600 genetically modified KP4 wheat kernels on a plot of land in Lindau-Eschikon[22] measuring 8 square meters, fully fenced in and covered by a

[17] Regulation (EG) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed: http://europa.eu.int/cgi-bin/eur-lex/udl.pl?REQUEST=Seek-Deliver&LANGUAGE=de&SERVICE=eurlex&COLLECTION=oj&DOCID=2003l268p00010023

[18] Regulation (EG) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC: http://europa.eu.int/cgi-bin/eur-lex/udl.pl?REQUEST=Seek-Deliver&LANGUAGE=de&SERVICE=eurlex&COLLECTION=oj&DOCID=2003l268p00240028

[19] Information on the Institute for Intellectual Property: http://www.ige.ch/D/jurinfo/j100.shtm#2

[20] Ordinance dated 25 August 1999 on the Use of Organisms in the Environment (RO), SR 814.911: http://www.admin.ch/ch/d/sr/c814_911.html (in German), not legally binding English translation: http://www.umwelt-schweiz.ch/imperia/md/content/stobobio/biotech/odeb/14.pdf

[21] See also information published by the ETH: http://www.pb.ipw.biol.ethz.ch/crops/wheat/feldversuchaktuell.htm

[22] http://www.ipw.ethz.ch/eschikon/index

bird net. KP4 wheat is resistant to wheat bunt, a fungus that attacks wheat and can cause major harvest losses. In the course of the permit process, the SECB repeatedly stated its position on biosafety [23] and pointed out the critical aspects of the experiment but always voted by a majority to approve the experiment. The last statement issued by the SECB in this regard was in January 2004, after SAEFL [24] had rejected various objections and approved the wheat release experiment by decree on 30 October 2003.

Photo: Felix Gmünder, Basler & Hofmann

The experiment commenced on 18 March, 2004, with the aim of testing the resistance of KP4 wheat to wheat bunt in the open field. The SECB presented its arguments in a newspaper article (see also 5.2.), reiterating its belief that the wheat release experiment posed no significant risk to people or the environment. The Committee visited the experimental site on 24 June, 2004, and was informed how the experiment was progressing. The experiment lasted until 14 July, 2004, and was completed without a hitch. Initial findings are available (as of February 2005) but have not yet been published.

4.2.2 Commercial release

Section 3 of the Release Ordinance [25] governs the commercial release of genetically modified or pathogenic organisms. Depending on the purpose for which the organisms are intended, permits for their release are issued by the Federal Office of Public Health (SFOPH), the Federal Office of Agriculture (FOA), the Federal Veterinary Office (FVO) or the Swiss Agency for Environment, Forest and Landscape (SAEFL).

To date, four GM plants have been approved for commercial release in Switzerland: soya 40-3-2 (herbicide-resistant), Bt176 maize (insect-resistant), Bt11 maize (insect and herbicide resistant) and Mon810 maize (insect-resistant). The permits are limited to the introduction of GM plants for food and animal feed; commercial cultivation of these plants is not permitted in Switzerland. In recent years the SECB has issued statements on other permit applications (Mon810xT25 maize, 1507 maize (both of which contain a gene resistant to insects and herbicides) and GA21 maize (herbicide-resistant), as well as GT73 rapeseed (also herbicide resistant)). However, since these applications are still pending, the SECB cannot report in more detail on its statements. No new applications were submitted in the year under review.

However, this situation may change following the European Commission's decision on 19 May, 2004, to approve the placing on the market of GM Bt11 maize, thereby ending the EU's moratorium on GMO approvals which had been in force since 1998. The possibility of this decision having an effect in Switzerland cannot be excluded, and the SECB may in future be increasingly confronted with such applications.

4.2.3 Contained use

Permit applications for activities involving the contained use of genetically modified or pathogenic organisms are governed by the Containment Ordinance [26] (CO) which is designed to protect people and the environment against harmful effects or nuisances arising from the contained use of such organisms. Contained use is defined as any appropriate containment measure (physical, if necessary supplemented by chemical or biological measures) that impedes or prevents organisms coming into contact with people and the environment. Such measures cover research and diagnostics laboratories as well as greenhouses, livestock systems and industrial production facilities.

According to Article 9 of the CO, authorisation is required for any activity assigned to Class 3 (activities posing a moderate risk to people and the environment) or Class 4 (activities posing a high risk to people and the environment) that involves genetically modified or pathogenic organisms.

As in the previous year, a number of permit applications were

[23] SECB Statements on the wheat release experiment: http://www.umwelt-schweiz.ch/buwal/de/fachgebiete/fg_efbs/rubrik_dokumentation/dok_stell_bewill/unterseite00040/index.html

[24] Chronology of the experiment: http://www.umwelt-schweiz.ch/buwal/de/fachgebiete/fg_biotechnologie/information/dossiers/kp4/index.html

[25] Ordinance dated 25 August 1999 on the Use of Organisms in the Environment, SR 814.911: http://www.admin.ch/ch/d/sr/c101.html (in German), not legally binding English translation: http://www.umwelt-schweiz.ch/imperia/md/content/stobobio/biotech/odeb/14.pdf

[26] Ordinance dated 25 August 1999 on the Contained Use of Organisms, SR 814.912: http://www.admin.ch/ch/d/sr/c814 912.html (in German), not legally binding English translation: http://www.umwelt-schweiz.ch/imperia/md/content/stobobio/biotech/ouc/39.pdf

Box 1: CO Groups and Classes

Assignment of organisms to groups: Organisms are assigned to four groups depending on the risk they present to people, animals and plants. Group 1 organisms present no or a negligible risk (e.g. baker's yeast, yoghurt bacteria), while Group 4 organisms present a very high risk (e.g. Ebola virus, smallpox virus). The criteria for assignment to the four groups include pathogenicity (i.e. the ability of the micro-organism to cause disease), and lethality (ratio of deaths to number of persons infected), mode of infection (i.e. how the disease is transmitted), host range and the availability of appropriate prophylaxis and therapy.

Assignment of activities to classes: The various activities are subjected to a risk assessment and assigned to four different classes. Class 1 activities pose no risk to people and the environment, while Class 4 pose a high risk. The Containment Ordinance lists the different safety measures to be observed depending on the class of activity in order to prevent causing damage to people and the environment. In the case of natural organisms, the group usually corresponds to the activity class. In the case of genetically modified organisms, the various components that make up the organisms must be taken into account.

submitted to the SECB for consideration in 2004. A list of these applications is appended to this Report. The SECB examines and assesses all Class 3 and 4 permit applications. Class 2 applications are submitted to the SECB only if they involve new or special research activities or if they involve requests to waive the safety measures. In such cases the Executive Secretary, acting on behalf of the SECB, is available to the federal agencies in an advisory capacity and regularly attends meetings on biosafety issues held by SFOPH, SAEFL and the Federal Coordination Centre for Biotechnology. The following application for a diagnostic system for Group 2 organisms provides an example of the various other applications.

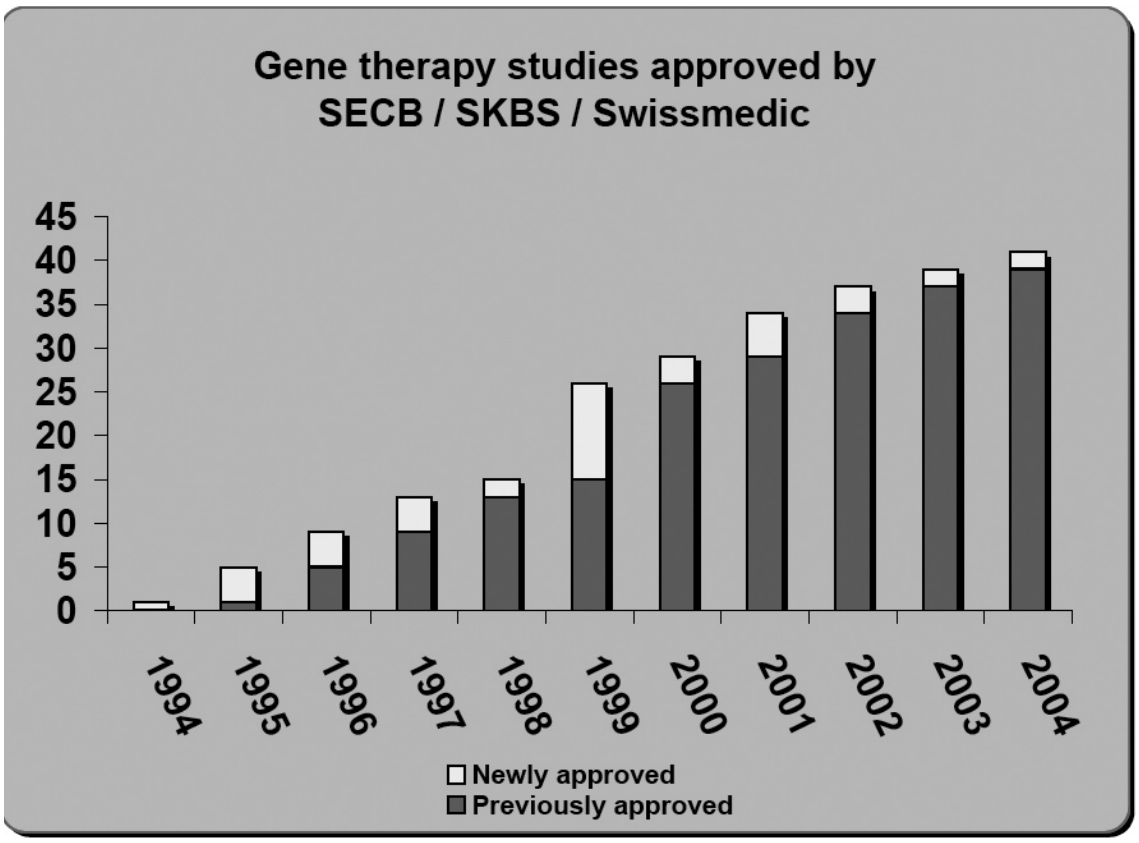
Application by a laboratory school

This application is for a Class 2 activity and was submitted to the SECB for consideration because the laboratory school requested permission to waive the safety measure which stipulates use of a biological safety cabinet.

Under the terms of the CO, medical-microbiological diagnostics are generally assigned to Class 2 and individual safety measures, including provision of a biological safety cabinet, may be altered, substituted or omitted. Unless the activity involves organisms which can be transmitted through the air (airborne) or which pose a risk of aerosol formation, from a biosafety standpoint there is no reason why a biological safety cabinet cannot be waived. This is the practice in a number of laboratories. The SECB was therefore of the opinion that the application should be approved.
However, the SECB accords high priority to education and training as well as biosafety. And since laboratory schools are educational and training centres, the SECB nevertheless recommends that biological safety cabinets be set up in the long term. After all, a comprehensive training course must familiarise students with working in a biological safety cabinet. In the course of future activities, they may come into contact with Group 3 airborne organisms, for which a biological safety cabinet is essential.

4.2.4 Gene therapies

Gene therapy is defined as the introduction of one or more foreign genes into cells of the human body (somatic gene therapy) . The applications of gene therapy are primarily in the field of classical hereditary diseases such as cystic fibrosis, multifactorial genetic illnesses such as cancer, heart disease and acquired illnesses such as AIDS. It is expected that, when introduced into the body, these foreign genes will take over the function of defective genes or act as a vaccination. More than 1000 clinical gene therapy trials have been conducted on people since 1989 in various countries around the world, including 41 in Switzerland. To date, however, their success has been limited. Nevertheless, expectations in gene therapy remain high.



From: SECB, Karoline Dorsch
The data of the SKBS have been used until 2002.

In vivo gene therapies

In vivo gene therapy trials, i.e. trials in which the genes to be transferred are directly inserted in the patient's body by means of vectors, are governed by the Federal Law on Therapeutic Products[27], and specifically by Section 5 of the Ordinance on Clinical Trials of Therapeutic Products[28], and require authorisation from Swissmedic, the Swiss Agency for Therapeutic Products[29]. The HIV vaccination is an example of such a gene therapy.

Gene therapy trial Phase I: HIV vaccination

The aim of this trial, launched in 2003, is to test a vaccination against the AIDS virus HIV (Human Immunodeficiency Virus) on healthy volunteers. The vector (living vaccine) contains a gene of the subtype HIV C (see Box 2). This gene contains information which is recognised by the immune system. The aim is to make the organism develop antibodies that render it immune to (i.e. vaccinated against) HIV infection. This trial uses the prime boost vaccination method (see Box 2): First, the proband is injected with a plasmid (prime) containing the same HIV gene sequences as the vector used to boost the living vaccine. Participants in this trial receive a certificate confirming their participation and declaring the possible presence of HIV antibodies. The SECB approved the trial, stipulating that binding provisions be drawn up in Switzerland for long-term observation of such probands.

[27] Federal Law of 15 December 2000 on Medicinal Products and Medical Devices (Law on Therapeutic Products), SR 812.21: http://www.admin.ch/ch/d/sr/c812 21.html (in German)

[28] Ordinance dated 17 October 2001 on Clinical Trials with Therapeutic Products, SR 812.214.2: http://www.admin.ch/ch/d/sr/c812 214.html (in German)

[29] Swissmedic: http://www.swissmedic.ch/

Box 2: Explanations of gene therapy terms

Hematopoietic stem cells: These are the cells responsible for the generation of blood cells, and are mainly found in the bone marrow. Stem cells continually renew themselves through cell division, and also form blood progenitor cells that develop into various types of blood cells.

HIV C subtype: The HI virus is grouped into different subtypes (A-H, O) whose incidence is not equally spread throughout the world. Subtype C is the most commonly transmitted virus world-wide.

Clinical trials: A (gene therapy) medicament must undergo various development phases before being approved. Clinical trials are assigned to Phase I (the earliest phase) to Phase IV.

Plasmids: Plasmids are ring-shaped DNA molecules that originally came from bacteria.

Prime boost vaccination: This method involves a dual injection procedure: firstly, volunteers are injected with a vaccine (primary injection) that prepares the immune system. This effect is then refreshed and boosted by additional «booster» injections at a defined later stage or defined regular intervals.

Vector: Vectors are also referred to as gene carriers. They are used to transport foreign genes to an organism or cell. Vectors are usually modified viruses or plasmids.

Ex vivo gene therapy

Ex vivo gene therapy trials involve the transfer of therapeutic genes in vitro (in a test-tube) to cells or tissues which are then implanted in the patient's body. Because this procedure in principal corresponds to transplantation, such trials are governed by the Ordinance on the Control of Transplants[30]. The Federal Office of Health (FOH) is responsible for authorising such trials. The following example illustrates this type of gene therapy trial:

Somatic gene therapy trial for chronic granulomatosis, Phase I/II

Chronic granulomatosis is a congenital immunodeficiency that prevents sufferers from forming the activated oxygen required to kill off pathogens in the blood. Chronic granulomatosis patients repeatedly suffer from life-threatening bacterial and fungal infections. The illness is diagnosed in childhood, and even when symptoms are treated with antibiotics and/or preventive antibiotics are administered, most sufferers are under the age of 25 since less than 50 percent reach adulthood. The aim of gene therapy treatment is to enable the blood cells of affected children to regain their ability to activate oxygen. A vector is used to introduce a foreign gene into harvested hematopoietic stem cells (see Box 2) as a substitute for the defective function. If this procedure is successful, the genetically modified stem cells are then replanted into the affected patient.

The aim of this trial is to examine the reaction of blood cells to the genetic modification, determine whether the foreign gene is performing ist function, and study the behaviour of the corrected stem cells in the bodies of affected children. At the same time, naturally, the clinical benefits to the affected children will be examined, including their ability to combat previously chronic infections. The SECB examined the safety of the vector in particular, and concluded in ist statement that the trial could be conducted. However, it expressed a wish for the trial to be monitored by an independent advisory board and for the SECB to be informed in the event of serious unforeseen developments and side-effects.

4.3 Advice on practice and enforcement

Another SECB field of activity involves advising experts and authorities on issues related to enforcement and practice – for instance guidelines, lists of organisms and risk assessments (see Box). These statements are usually highly branch-specific and are not intended for broad publication. In the year under review the SECB collaborated on the drawing up of virus lists and issued a statement on diagnostics guidelines which, however, are still in the early stage of formulation

[30] Ordinance on the Control of Transplants, SR 818.111.3: http://www.admin.ch/ch/d/sr/818_111_3/ (in German)

Box 3: Guidelines and lists of organisms according to the CO and RO

Guidelines: Both the Release Ordinance (RO) and the Containment Ordinance (CO) provide for guidelines on their respective enforcement, and in particular on risk assessment and safety measures as well as quality assurance. Such guidelines are designed to provide concrete definitions of legal terminology and enable cohesive implementation. On the one hand, they ensure a significant level of legal equivalence and security, and on the other hand they ensure solutions that are flexible and adaptable to individual cases. By observing the guidelines, federal law is legally enforced but alternative solutions are not excluded.

Lists of organisms: The Containment Ordinance and Release Ordinance require lists to be kept of organisms and biological safety systems according to the risk they pose to people and the environment (see also Box 1). The classification takes existing lists into account, particularly those kept by the EU. In the year under review the list of fungi [31] was added to the existing lists of bacteria [32] and parasites [33].

Risk assessment under the terms of the Containment Ordinance includes an assessment of the potential damage to people and the environment, the extent of such damage, and the probability of occurrence. To this end, organisms must be assigned to a specific group and activities to a specific class (see Box 1). In a few complex cases, difficulties may be encountered in classification. The SECB issues specific statements providing the basis for classification and safety measures, as illustrated by the following example from the year under review:

Risk assessment and safety measures for activities involving oncogenic or cytokine-encoding sequences

Oncogenes are gene sequences responsible for forming various proteins in the body. Their common denominator is the role they play in turning a healthy cell into a tumour cell: Cell growth is no longer regulated in the normal manner, allowing the cells to multiply unchecked. Cytokines are used for intercellular communication and act as signal transmitters, regulating a wide range of functions including the immune system. Cytokines implanted in a vector or organism can, for example, affect the pathogenicity of the vector or organisms. Animal experiments involving oncogenic or cytokine-encoding gene sequenes have produced some unexpected results, e.g. the development of malignant tumours. In ist statement, primarily aimed at experts, the SECB defined the safety measures to be observed for activities involving such gene sequences in order to protect people and the environment from harmful effects. The classification of activities (see Box 1) depends on the oncogenic or cytokine-encoding gene sequence as well as the selected vector and ist attributes.

4.4 Queries to the SECB

In addition to issuing statements on amendments to the law, permit applications and issues concerning practice and enforcement, the SECB also answers other queries from various parties. Frequently, these take the form of preliminary investigations regarding applications or parliamentary questions. In the year under review the SECB deliberated on the following issues:

4.4.1 Query Graf 04.1061: Organic seeds: Protection against GM contamination

The basis of this query is Article 7 of the Gene Technology Law (GTL) concerning non-GMO production and freedom of choice. The query[34] requested clarification on the extent to which the GTL offers producers of basic seeds protection against any undesired transboundary mixing with GMOs, and what concrete steps are taken to prevent such an occurrence. The response was written by SAEFL and submitted to the SECB for consideration. The SECB recognises that some farmers in border regions farm land on both sides of the border and that consequently the transboundary movements of agricultural products will increase, and recommends that the possibility of conducting analyses along the border be examined. At the same time, however, the SECB draws attention to the fact that, while seed analyses are important in terms of quality assurance, they offer no protection against undesired mixing. In its response on behalf of the Federal Council, SAEFL points out that the GTL offers good protection within Switzerland but has no influence over farming practices in neighbouring countries, although these countries also impose a legal requirement to obtain approval for experimental releases. Efforts are under way to formulate cohesive regulations that will address the problem of undesired transboundary mixing.

[31] List of fungi: ://www.umwelt-schweiz.ch/imperia/md/content/stobobio/biotech/19.pdf

[32] List of bacteria: http://www.umwelt-schweiz.ch/imperia/md/content/stobobio/biotech/15.pdf

[33] List of viruses: ://www.umwelt-schweiz.ch/imperia/md/content/stobobio/biotech/12.pdf

[34] Full query as well as Federal Council's response: http://www.parlament.ch/afs/data/d/gesch/2004/d_gesch_20041061.htm

[35] http://www.ethz.ch/research/index

[36] See also various publications: http://www.pa.ipw.agrl.ethz.ch/

4.4.2 Research application by the Federal Institute of Technology (ETH), Zurich

Professor U. Suter, Vice Chairman of Research at the ETH Zurich, has asked the SECB to state its position on an ETH-funded research project[35]. For some years, a research team at the ETH's Institute for Plant Sciences has been conducting research into the natural resistance of apple genes to apple scab[36]. This research is to be continued with the aim of finding additional resistance genes and decoding their mechanisms. The research team wishes to use only gene sequences already present in apples. The SECB expressed keen interest in this project and called it forward-looking. If this project is successful, it could lead to the development of a genetically modified apple that contains neither the antibiotics-resistance gene used to date nor any other gene or regulatory sequences foreign to the species. To ensure a successful experimental release possibly at a late time point, the SECB recommends that the mechanism of resistance be understood and that the potential for out-crossing of a genetically modified apple by examined. However, such a step is not yet within the team's reach. The project, which was launched in April 2005, is limited to identifying and determining the characteristics of a second resistance gene and the method for implanting two resistance genes in one apple variety.

4.4.3 NRP project: The benefits and risks of releasing genetically modified organisms

The aim of the National Research Programmes (NRP) run by the State Secretariat for Education and Research[37] (SSER) is to promote research that "addresses issues of national importance and is capable of making a scientifically sound and innovative contributions to resolving pressing social or economic problems". During every review period, several of the proposals submitted are selected and subjected to a scientific examination. During this review period, the SECB was asked to deliberate and state its position on the proposal for a project to study the "Benefits and risks associated with the release of genetically modified organisms in the environment"[38]. The SECB discussed the project in depth and drew attention to various aspects which are not, however, permitted to be published during the current process. The Federal Council will decide on whether to include this topic in the new NRP in the summer of 2005.

[37] State Secretariat for Education and Research: http://www.sbf.admin.ch/htm/index-d.html

[38] Summary of national research projects: http://www.sbf.admin.ch/htm/forschung/nfp-d.html

5. Public relations activities

The SECB has the legal mandate to conduct a dialogue with the public. On the one hand the Committee targets interested experts who themselves work in the field of biosafety, thereby contributing, for example, to education in this field. On the other hand the SECB also holds presentations, publishes newspaper articles, maintains a website and issues this Annual Report for the broader public which is interested in such issues.

5.1 Education and seminars

The SECB believes that good training and qualifications are the most important criteria for handling pathogenic organisms. With this in mind, it also regularly draws attention to this issue in its statements to the competent authorities. It makes a concrete contribution through the active involvement of the Executive Secretary and other SECB members in training in biosafety. In addition, congresses and events provide an ideal platform for reporting on the work of the SECB and exchanging experiences in the field of biosafety. The following are some of the events in which the SECB participated in the year under review:

Meeting for Biosafety Coordinators: This annual event provides an introduction to the legal aspects of the work of biosafety coordinators[39]. Various risk assessment issues were addressed and information was provided on inspections and the tasks of the Federal Coordination Centre for Biotechnology. The SECB provided an overview of the general aspects of biosafety and expressed its opinion on risk analysis.

Continuing education course in biosafety[40], University of Geneva "Cadres réglementaires nationaux en matière de biosécurité": This course was designed for experts in various fields who are dealing with plant biotechnology and seek to expand their know-how in biosafety.

Biosafety Institute b-safe: The Biosafety Institute[41] offers courses on biosafety to raise awareness among expert personnel and the general public of the biological risks and the associated safety measures to be taken. At the same time, the courses aim to standardise training and promote the dissemination of information.

International Symposium on the Biosafety of Genetically Modified Organisms[42], Montpellier: This symposium provides experts in various fields with diverse perspectives and interests to share information and exchange ideas on matters concerning the biosafety of GMOs. It is designed for scientist and industry representatives, policy makers, regulators and NGOs interested in recent scientific research with GMOs, and is held every two years. The theme of the 2004 event was "How Scientific Research Informs Biosafety Decisions". As part of the programme, the SECB organised a meeting with biosafety committees from various countries with a view to promoting the exchange of ideas. The event was very favourably received.

5.2 Website and publications

Website: The SECB Internet site at www.efbs.ch provides details on Statements and Recommendations issued by the SECB. It also publishes additional information such as schedules of meetings, agendas, annual reports and the latest news.

SECB brochure: In the year under review the SECB published a brochure presenting itself and its work and illustrating this work by means of case studies. The brochure is available from the SECB Secretariat.

Newspaper article on wheat: Coinciding with the approval of the wheat release experiment, the SECB published an article in the "Neue Züricher Zeitung" NZZ (NZZ dated 31.3.2004, see also Section 4.2.1) entitled "Prüfstein der biologischen Sicherheit- Unterschiedliche Expertenurteile zum Freisetzungsversuch".

[39] Programme of events and presentations: http://www.umwelt-schweiz.ch/buwal/eng/fachgebiete/fg_biotechnologie/national/bso/unterseite00386/index.html

[40] http://www.unige.ch/formcont/AAdiplomant/sciences_biosecuri_a_04.html

[41] b-safe website: http://www.b-safe.ch/?mid=1025&pid=1001

[42] Symposium information: http://www.inra.fr/gmobiosafety/

6. Appendix

Consultations in 2004: Summary of all SECB Statements

Consultations on the legislature	
Ordinance on Phytosanitary Products	01/2004
Ordinance on Feed	08/2004
Ordinance on Food	08/2004
Patent Law	10/2004
Consultations on permit applications	
Experimental releases	
Objections to the experimental release of KP4 wheat by the ETZ Zurich	01/2004
Contained use of organisms	
A030217/3, Th. Kündig, University Hospital Zurich	01/2004
A030218/2, V. Thiel, Cantonal Hospital St. Gallen	01/2004
A030137/1, V. Thiel, Cantonal Hospital St. Gallen	01/2004
A030010/3, A. Aguzzi, University Hospital Zurich	02/2002
A040014/3D, R. Zbinden, University of Zurich	03/2004
A040015/3, P. Sander, University of Zurich	03/2004
A04000373D, F. Baggi Menozzi, University of Zurich	03/2004
A040011/3A, G. Vogel, Cantonal Laboratories of Basle City	03/2004
A020034/2D, B. Specht, BiG Basle	03/2004
A030187/3, Th. Klimkait, University of Basle	05/2004
A040024/3D, B. Oesch, Prionics AG, Zurich	07/2004
A040069/3, M. Strasser, Spiez Laboratory	07/2004
A030179/3, A. Oxenius, ETH Zurich	09/2004
A000085/2D, S. Gautsch, Cantonal Laboratory of Basle City	10/2004
A000070/3D, R. Frei, University Hospital Basle	10/2004
A040118/2, R. Zahn, Alicon AG, Schlieren	12/2004

Gene therapies	
Somatic gene therapy trial for chronic granulomatosis, Phase I/II	06/2004
HIV vaccination DNA C / NYVAC C (EuroVacc 02), Phase I	06/2004
Vaccination against house dust allergy, Phase I/II	09/2004
Advice on practice and enforcement	
Safety measures of rodents exposed to third-generation HIV-based vectors	06/2004
Position paper regarding the classification of an activity implying the manipulation of plasmids encoding full length HIV genomes	07/2004
Safety measures in diagnostic laboratories	08/2004
Risk assessment and safety measures for activities involving oncogenic or cytokine-encoding sequences	12/2004
Queries to the SECB	
04.1061 Query, Graf: “Protection of organic seeds against GMO contamination”	06/2004
NRP Proposal: “The benefits and risks of releasing genetically modified organisms”	11/2004
Internal ETH research application: “Genetic modified apple resistant to apple scab”	11/2004