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

Berne, April 2004

2003 ANNUAL REPORT OF THE SWISS EXPERT COMMITTEE FOR BIOSAFETY (SECB)

SUBMITTED TO THE FEDERAL COUNCIL AND OTHER INTERESTED PARTIES

c/o Bundesamt für Umwelt, Wald und Landschaft / Office fédéral de l'environnement, des forêts et du paysage / Ufficio federale dell'ambiente, delle foreste e del paesaggio, 3003 Bern
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Introduction

The Swiss Expert Committee for Biosafety (SECB) is a permanent federal advisory committee charged with the task of advising the Federal Council and the competent authorities on questions relating to the protection of people and the environment in the areas of biotechnology and gene technology.

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

The SECB advises the Federal Council on the issuing of regulations and the competent 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 informs the public about important findings and the need for further research, and reports to the Federal Council annually.

Composition and methodology of the SECB

Under the terms of the Ordinance on the SECB, the Committee must be composed of 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 and consumer organisations). A list of the Committee members appointed by the Federal Council for the second period ending 31 December 2003 can be found overleaf.

In the first half of the year reviewed here the Committee consisted of only six members and a permanent expert, following the resignation of various members in 2001 and 2002. Notices inviting new applications for membership were circulated in December 2001 and October 2002. Following an official consultation, a proposal for new members – supported by various federal agencies – was submitted to the Federal Council, and on 27 August 2003 the Federal Council appointed ten new experts covering various fields of expertise. In addition, Martin Küenzi – acting Chairman since the beginning of 2002 – was appointed as Chairman. At the same time, all Committee members were re-elected for the 2004 - 2007 term of office. Vacancies which have existed for some time have now been filled, and the SECB is once more able to draw on the requisite expertise to perform its wide-ranging tasks effectively.

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 as such.

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[1] Federal Law of 7 October 1983 on the Protection of the Environment, SR 814.01
[2] Federal Law of 21 March 2003 on Non Human Gene Technology, SR 814.91
[3] Federal Law of 18 December 1970 on Protection against Contagious Diseases in Humans (Epidemics Law), SR 818.101 (in German)
[4] Ordinance of 20 November 1996 on the Swiss Expert Committee for Biosafety, SR 172.327.8 (in German)

SECB Members

Chairman

Martin T. Küenzi	Dr. sc. techn., *Biotechnologist,* Solidago AG, Muttenz

Members

Daniel Ammann	PD Dr. sc. techn. ETHZ, *chemist,* daniel ammann consulting dacon, Zurich
Klaus Ammann	Prof. Dr. phil. nat., *plant ecologist,* Geobotanical Institute and Botanical Gardens, Berne
Joachim Frey[a]	Prof. dr. ès. sc., *bacteriologist*, Institute for Veterinary Bacteriology, University of Berne, Berne
Emmanuel Frossard[a]	Prof. Dr., *plant nutrition*, Institute for Plant Science, ETH Zurich
Felix Gmünder[a]	Dr. sc. nat. ETHZ, *microbiologist*, Basler & Hofmann AG, Zurich
Angelika Hilbeck	Dr. dipl. agr. biol., *ecologist*, Geobotanical Institute, ETH Zurich, EcoStrat GmbH
Philipp Hübner[a]	PD Dr., *biochemist*, Cantonal Laboratory of Basle City, Basle
Roman Kuonen[a]	Dr. med. FMH, *medical consultant*, Leuk City
Beatrice Lanzrein[a]	Prof. Dr., *insect and development physiologist*, Institute for Cell Biology, University of Berne, Berne
Pascal Meylan[a]	PD Dr. med. FMH, *clinical virologist*, Institute for Microbiology, University of Lausanne, Lausanne
Bernadette Oehen	Dipl. bot., *biologist*, FiBL (Research Institute for Biological Farming), Frick
Barbara Oppliger-Frischknecht	Dipl. ing. agr. ETH, *agronomist*, Swiss Consumer Forum
Doris Rentsch[a]	Prof. Dr., *plant physiologist*, Institute for Plant Science, University of Berne, Berne
Didier Trono[a]	Prof. Dr. med., *virologist*, University of Geneva, Geneva
Jean-François Viret[a]	Dr. ès. sc, *molecular biologist*, Berna Biotech AG, Bern

Secretariat

Karoline Dorsch-Häsler (Executive Secretary)	Ph.D., *microbiologist*, SECB Secretariat c/o Swiss Agency for the Environment, Forests and Landscape (SAEFL), Berne
Julia Link	Lic. phil. nat., *biologist*, SECB Secretariat c/o Swiss Agency for the Environment, Forests and Landscape (SAEFL), Berne

Secretariat

The SECB Secretariat, which is administratively affiliated to the Swiss Agency for the Environment, Forests and Landscape (SAEFL), is responsible for supporting the members of the Committee in their duties, preparing for Committee meetings, and drafting Statements. It also liaises with other committees and public offices in Switzerland and abroad, which are active in related fields. The Executive Secretary of the SECB is Dr Karoline Dorsch-Häsler. Julia Link (scientific assistant) supports her in her work. 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 conventions.

[a] These new members were elected to the SECB on 27 August 2003.

Meetings

During the period under review the SECB convened four times in Berne on the following dates: 17 March, 2 June, 20 October and 9 December 2003.

Legislation relating to biosafety

The following events took place during the year under review which are of relevance to biosafety in Switzerland as well as to the overall focus of the SECB:

Gen-Lex

Legislation work related to the Gen-Lex motion[5] reached its final phase in 2003. Following the decision in 2001 to create a Gene Technology Law[6] (GTL), the law itself was approved by parliament[7] on 21 March 2003. The SECB has been following the Gen-Lex motion since 1998 and has issued various Statements in this regard, most recently in 2002 during consultations with the parliamentary Science and Education Committees, which gained nation-wide attention due to the documentary film entitled "Mais im Bundeshuus" ("Corn in the Houses of Parliament") which documents the historical background to the Gene Technology Law.

The main purpose of the Swiss GTL, which came into force on 1 January 2004, is to protect people and the environment against abuses of gene technology, to conserve biological diversity and ensure respect for the dignity of living beings. It also provides for additional important elements such as the protection of production free of genetically modified organisms (GMOs) and freedom of choice, as well as the clear labelling of products containing GMOs. The GTL also contains stricter provisions governing liability.

Cartagena Protocol / Cartagena Ordinance

Since the **coming into force of the Cartagena Protocol on Biosafety**[8] (Cartagena Protocol) on 11 September 2003, movements of genetically modified organisms have been internationally regulated. The Protocol – the first instrument binding under international law to govern the safety of genetically modified organisms – was ratified by Switzerland on 26 March 2002. In addition to governing the safe use and transport of GMOs, the Protocol aims to promote international information exchange in this area. To this end the Biosafety Clearing-House[9] was created, with a view to facilitating the exchange of scientific, technical, environmental and legal information on GMOs and providing support in the implementation of the Protocol. The ordinance on transboundary movements of genetically modified organisms – also known as the **Cartagena Ordinance** – established the foundation for implementation of the Cartagena Protocol under Swiss law. This Ordinance was drawn up in line with the corresponding European Union regulation. The SECB discussed the Ordinance during the official consultation process and declared its approval in principle.

Regulations governing genetically modified foods

In September 2003, the European Union approved the two following **new regulations on genetically modified food and feed**:

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[5] Gen-Lex motion: http://www.parlament.ch/afs/data/d/gesch/1996/d_gesch_19963363.htm (in German)
[6] Federal Law of 21 March 2003 on Non Human Gene Technology, SR 814.91 (in German)
[7] The following Internet site provides additional information on the parliamentary debate on the Gen-Lex: http://www.parlament.ch/homepage/do-dossiers-az/do-gen-lex.htm (in German)
[8] Cartagena Protocol: http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf
[9] Biosafety-Clearinghouse: http://bch.biodiv.org/Pilot/Home.aspx

- Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[10]
- Regulation (EC) 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/EU[11]

Although not legally binding for Switzerland, the EU Regulations are important due to the country's major interest in harmonising regulations, particularly those governing the declaration of genetically modified organisms (GMOs), identity preservation and the fixing of thresholds.

The use of GMOs in the food industry is a major preoccupation among the general public. This is reflected, for instance, in the **people's initiative "For GM-free food products"**, submitted on 18 September 2003, which calls for a five-year moratorium on the commercial release of genetically modified, propagable plants, plant parts and seeds for agricultural, horticultural or forestry applications, as well as on genetically modified animals destined for the production of food and other agricultural produce. This initiative would affect the import of food and feed able to germinate (rape seeds, soy beans, maize kernels etc.).

Biosafety – SECB topics

In addition to its central task of advising the Federal Council and authorities on the protection of people and the environment in the field of biotechnology and gene technology, the SECB also addresses more general issues related to biosafety.

Precautionary principle

As in the previous year, the SECB continued to deliberate on the precautionary principle. This principle is enshrined in the Law on the Protection of the Environment (Art.1, Para.2: *Early precautions should be taken to limit effects which could become harmful or constitute a nuisance*) as well as in the Gene Technology Law (Art. 2, Para. 1: *Early precautions should be taken to prevent hazards or impairment that may be caused by genetically modified organisms*). The aim of the studies commissioned by the SECB is to provide an overview of current international definitions and interpretations of the precautionary principle and examine various methodical approaches, as well as formulate a basis for more in-depth discussion within the SECB. A more concrete formulation of the precautionary principle is to be obtained by means of checklists. A positioning paper will allow the SECB to decide when the precautionary principle should be applied and how it should be applied in individual cases.

Biological pest control

The SECB mandate also covers the assessment of risks related to pathogenic organisms, for example in the area of pest control. Products marketed for the purposes of biological pest control must be approved by the Federal Office for Agriculture (FOA) as plant protection agents under the terms of the Ordinance on Plant Protection. The SECB issues Statements on plant protection agents containing genetically modified organisms. However, since biosafety issues are also related to pathogenic and exotic organisms, the SECB has launched a discussion on this subject, which is to be continued in greater depth.

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[10] Regulation (EC) No. 1829/2003: http://europa.eu.int/cgi-bin/eur-lex/udl.pl?REQUEST=Seek-Deliver&LANGUAGE=en&SERVICE=eurlex&COLLECTION=oj&DOCID=2003l268p00010023

[11] Directive (EG) Nr. 1830/2003: http://europa.eu.int/cgi-bin/eur-lex/udl.pl?REQUEST=Seek-Deliver&LANGUAGE=en&SERVICE=eurlex&COLLECTION=oj&DOCID=2003l268p00240028

Advice relating to the Release Ordinance (RO)

The Ordinance on the Release of Organisms into the Environment (RO), which has been in force since 1999, regulates two key aspects of the use of genetically modified and pathogenic organisms in the environment, namely: the release of such organisms for experimental purposes, and their commercial release. Both types of permit application are forwarded to the SECB for consideration.

Experimental releases

Section 2 of the Release Ordinance governs releases of genetically modified or pathogenic organisms for experimental purposes. Under the terms of Article 7 of the Release Ordinance, such experimental releases must be authorised by SAEFL.

New application by the Swiss Federal Institute of Technology Zurich (ETH) for "Field trial of transgenic KP4 wheat varieties"

The aim of this trial is to field-test transgenic wheat plants containing a gene that encodes the so-called killer protein (KP4) which renders them resistant to stinking smut (*Tilletia tritici*), and to investigate various aspects of biosafety as well as interactions with non-target organisms.

Following an initial permit procedure[12], which the Federal Court referred back for re-assessment after identifying various procedural errors, a new revised application was submitted in June 2003.

The SECB was asked to issue a Statement on the new application, on the objections to the application and the ETH's response to these objections. In these three Statements the SECB stated that it had found no significant new aspects relating to biosafety. It commented on a few specific aspects and referred to its Statement issued in September 2001. The trial was approved by majority vote. The SECB website[13] provides a summary of all SECB Statements.

The authorising body for the experimental release of GM wheat is SAEFL, which approved the application on 30 October 2003 subject to strict safety precautions[14].

Commercial release

Section 3 of the Release Ordinance 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).

No new applications for commercial release were submitted in the year under review.

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[12] Additional information on the chronology of the application can be found at http://www.umwelt-schweiz.ch/buwal/eng/fachgebiete/fg_biotechnologie/information/dossiers/kp4/index.html

[13] SECB Statements on the experimental release of GM wheat: http://www.umwelt-schweiz.ch/buwal/eng/fachgebiete/fg_efbs/rubrik_dokumentation/dok_stell_bewill/unterseite00040/index.html

[14] Decree, see http://www.umwelt-schweiz.ch/imperia/mdcontent/buwalcontent/folder/03-10-30eth/1.pdf (in German)

Application for commercial release of a vaccine consisting of a genetically modified organisms against feline leukaemia (EURIFEL® FeLV)

The SECB previously reported on this application in 2002, which relates to a recombinant vaccine against feline leukaemia, one of the most widespread diseases among domestic cats which, in the absence of a vaccination, is often terminal. This vaccine is designed to offer an alternative to existing products, including a vaccine based on a genetically engineered protein as an antigen. In its Statement the SECB came to the conclusion that, particularly in view of the high host specificity, the vaccine posed no significant risk to human beings or the environment, and recommended that the application be approved. The application was withdrawn in November 2003 since the French manufacturer was unable to comply with Swiss regulations governing declaration.

Advice related to the Containment Ordinance[15] (CO)

The purpose of the Containment Ordinance is to protect people and the environment against harmful effects or nuisances arising from the contained use of organisms. Contained use is defined as any containment measure that prevents organisms escaping into the environment. Such measures cover research and diagnostics laboratories as well as industrial and production facilities.

Permit applications

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. For exclusively diagnostic activities assigned to Classes 3 and 4 involving pathogenic, non-GM organisms, a permit is required for the first-time activity only.

In 2003 a number of new permit applications were submitted to the SECB for consideration pursuant to Article 15, Para. 15 of the CO. A list of these applications is appended to this Report. Pending permit applications are published in the Federal Gazette (Article 15, Para. 2d, CO) and the permit is issued by the relevant federal agencies (SFOPH or SAEFL, Article 16 CO) following a review of the risk assessment and taking into account the Statements issued (Article 18, CO). The SECB examines and assesses all Class 3 and 4 applications. Class 2 applications are forwarded to the SECB only if new or special research activities are involved. Karoline Dorsch-Häsler is available to the federal agencies in an advisory capacity, acting on behalf of the SECB, 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 4 organisms provides an example of the various other applications.

Permit application by the St. Gallen Institute for Clinical Microbiology and Immunology – Diagnostics Class 4

The applicant wishes to conduct a diagnosis of various viruses which cause internal bleeding or are otherwise highly pathogenic for people (e.g. Ebola virus, Marburg virus, Lassa fever virus, smallpox virus etc.) and are classified as Group 4 organisms. However, these organisms are to be neither cultivated nor used as reference strains for analyses. Up to now, samples for diagnosing such organisms have had to be sent abroad.

The SECB commented on the viruses used and their classification, the various analytical methods and legal foundations, and in particular discussed the planned safety precautions

[15] Ordinance dated 25 August 1999 on the Contained Use of Organisms, SR 814.912

and laboratory infrastructure. The SECB unanimously agreed on the necessity of the activities proposed in the application and recommended that it be approved subject to various conditions. The application was authorised by the relevant federal agency (SFOPH), with conditions, in July 2003.

Application for amendments to the CO and PEDM

Since formulation of the CO[16] and PEDM[17] the importance of diagnostics involving Group 4 pathogenic organisms has significantly grown due to the increase in travel to tropical zones as well as the greater risk of bio-terrorism, and demand for such diagnostic options is rising accordingly. The SECB therefore believes there is a need to formulate differentiated legal foundations for diagnostics involving Group 4 organisms, in order to ensure more flexible laying down of safety provisions and to eliminate certain grey areas. The SECB stated this view in a letter to SAEFL and SFOPH supplementary to its Statement on the above application.

List of organisms

Under the terms of Article 22 of the CO, a list must be kept of organisms and biosafety systems classified according to the risk they pose for people and the environment, and made available to the public. The classification took account of existing lists, particularly those kept by the EU. To date, classified lists on bacteria[18] and parasite[19] have been published.

Fungus list

The fungus list was drawn up on behalf of SAEFL by J. Nicolet (Faculty of Veterinary Medicine, University of Berne) in conjunction with J. Bille (Institute of Microbiology, University of Lausanne) and D. Gindrat (Institute for Plant Cultivation Research, Changins) based on internationally recognised lists, and submitted to the SECB for consideration. The SECB agrees in principle with the list and has commented on only a few minor aspects concerning phytopathogenic fungi.

Guidelines

Under the terms of Article 29 of the CO, guidelines on the enforcement of this ordinance may be issued if required, in particular with respect to risk assessment and safety measures and their quality assurance. Such guidelines, which are primarily aimed at enforcement authorities, provide assistance in clarifying unspecific legal terms and help to standardise enforcement practices.

Draft guideline on the status, tasks and responsibilities of biosafety coordinators

The aim of the guideline is to create a basis for formulating the concrete tasks, duties and responsibilities of biosafety coordinators in individual organisations, and to provide concrete indications as to the content of a biosafety coordinator's obligations appropriate to the wide range of tasks performed by different institutions and laboratories. The SECB declared its approval of the draft.

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[16] Ordinance dated 25 August 1999 on the Contained Use of Organisms (CO), SR 814.912
[17] Ordinance of 25 August 1999 on the Protection of Employees against the Dangers of Micro-Organisms (PEDM), SR 832.321
[18] Classification of bacteria: http://www.umwelt-schweiz.ch/imperia/md/content/stobobio/biotech/15.pdf
[19] Classification of parasites: http://www.umwelt-schweiz.ch/imperia/md/content/stobobio/biotech/12.pdf

Draft guideline on biosafety in diagnostic laboratories

The aim of this guideline is to ensure biosafety in diagnostic laboratories. Following an introduction to the legal foundations and a summary of the scope of application of individual provisions, the guideline should provide concrete indications of the aspects of diagnostic laboratories to be addressed in order to optimise biosafety. The SECB welcomed this guideline in principle, but suggested improvements that should facilitate its practical implementation.

Draft guideline on an operational safety concept according to CO

Appendix 4 of the CO requires compliance with a safety concept. The aim of the guideline is to provide concrete details and help organisations subject to the CO to set up a safety concept.

From the SECB's standpoint, the guideline in its present form is primarily relevant for (production) operations, where an error or accident could potentially pose a risk to the environment due to the large volumes of micro-organisms with which such operations work. In its Statement the SECB commented on the situation in diagnostic and reference laboratories, where the volume of pathogenic micro-organisms and hence their environmental relevance is relatively low but where greater attention must be devoted to employee protection. Furthermore, the SECB drew attention to the existing provisions and possibilities of improvement in terms of the guideline's compatibility with the CO, and recommended some minor changes.

Advice relating to gene therapy

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[20], and specifically by Section 5 of the Ordinance on Clinical Trials of Therapeutic Products[21]. Clinical trials of this type involving somatic gene therapy require authorisation.

The SECB issues Statements on the biological safety of the preparation for the persons being treated as well as for human beings and the environment in general. The SECB Working Group on Gene Therapy, comprising two SECB members and a number of other experts, examined two applications in the year under review.

Anti-HIV vaccines, Phase I

Both trials involve administering anti-HIV vaccines, the first of which uses a highly attenuated vaccinia vector (NYVAC C), and the second a modified vaccinia vector (MVA.HIV-A). Both vectors express various HIV antigens and cannot replicate in humans. Particular attention was paid to the fact that healthy persons were to be treated in these Phase 2 trials. The SECB Working Group on Gene Therapy commented on several aspects and approved both trials subject to various conditions.

Leukaemia cases in gene therapy

In January 2003 the SECB Internet site reported on a treatment in France involving gene therapy for the severe inherited immune deficiency X-SCID, which caused a stir due to the fact that two children had developed leukaemia. The X-SCID treatment involved the use of

[20] Federal law of 15 December 2000 on Therapeutic Products, SR 812.21
[21] Ordinance of 17 October 2001 on Clinical Trials with Therapeutic Products (OClin), SR 812.214.2

a retroviral vector, and it is assumed that there is a link between this vector and the cases of leukaemia. None of the gene therapy trials conducted in Switzerland uses a retroviral vector. Any new trials using retroviral vectors are to be assessed on a case-by-case basis.

Events

Meeting for Biosafety Coordinators

The Meeting for Biosafety Coordinators[22] , organised by the SECB, SAEFL and SFOPH, was held in Berne on 30 October 2003. The aim of this event is to provide an introduction to the work of biosafety coordinators. Various topics relating to risk assessment were addressed and information was provided about past inspections and the tasks of the Federal Coordination Centre for Biotechnology. On behalf of the SECB, its president Martin Küenzi presented an overview of general issues relating to biosafety, while Executive Secretary Karoline Dorsch-Häsler focused on the topic of risk analysis.

Public relations activities

Since the SECB is engaged in highly specific matters pertaining to biosafety – as is reflected in its Statements and events (Meeting for Biosafety Coordinators, etc.) – public relations activities are also primarily aimed at professional interest groups rather than towards the lay public.

Presentations

Various Committee members as well as the Executive Secretary attended events and discussed topics relating to biosafety (e.g. television interview on *in vitro* synthesis of the polio virus for the TV programme *Menschen, Technik, Wissenschaft* (SF DRS), February 2003 [Karoline Dorsch]; European Enforcement Project (EEP) Meeting in Thun, presentation on *in vitro* synthesis of the polio virus [Karoline Dorsch]).

Internet

The SECB website at www.efbs.ch provides details on Statements and Recommendations issued by the SECB, as well as other relevant information on the dates and agendas of meetings, annual reports and other news.

Swiss Expert Committee for Biosafety

Chairman	Executive Secretary
Dr. Martin Küenzi	Dr. Karoline Dorsch-Häsler

[22] The programme and various presentations are provided under http://www.umwelt-schweiz.ch/buwal/eng/fachgebiete/fg_biotechnologie/national/bso/unterseite00088/index.html#sprungmarke0

Annex: Summary of SECB Statements

Advice relating to legislation	
Application to amend the CO as well as the PEDM with respect to Class 4 diagnostic activities	March 2003
Swiss Academy for Natural Sciences pamphlets: Gene technology under Swiss law	April 2003
Cartagena Ordinance	August 2003
Advice relating to the Release Ordinance (RO)	
Commercial release	
Commercial release of a vaccine containing genetically modified organisms against feline leukaemia (EURIFEL)	February 2003
Experimental releases	
Statements on the application by the ETH Zurich, which was resubmitted but was substantially unchanged in terms of content, on field trials of genetically modified KP4 wheat varieties.	September / October 2003
Advice relating to the Release Ordinance (RO)	
Permit applications	
A020003/3D: Medical-microbiological diagnostics	January 2003
A020132/3: Evaluation and validation of detection methods; evaluation of typing methods; organisation of challenge tests	January 2003
A020003/3D: Diagnosis of prion diseases/BSE	January 2003
A020160/4D: National reference centre for the monitoring and diagnosis of haemorrhagic fever and imported virus infections	March 2003
A020003/3D: Bacteriological diagnostics	March 2003
A020003/3D: Diagnosis of bacterial pathogens assigned to Risk Group 3	March 2003
A020203/3: Biochemical studies with BSE	March 2003
A020208/3: Virus inactivation studies with West Nile Virus	March 2003
A030073/2: Construction and testing of living attenuated recombinant measles virus vaccine vector expressing different immunogens of the SARS virus	July 2003
A020191/3: Use of lentiviral vectors expressing (i) siRNAs for the inhibition of cellular genes, (ii) Cytomegalovirus genes for the detection of anti-CMV cellular immune response, and (iii) Nef to study its effects on Fas and Fas ligand expression in macrophages	July 2003
A030082/3A: Virulence studies of knockout strains of *Myco-bacterium tuberculosum*	July 2003
A030094/3A: Cultivation and storage of the quarantine organism *Xylella fastidiosa*	August 2003

A0000221/3D: Laboratory diagnosis of infections diseases	August 2003
A020206/4D: Quality controls of immunobiological products for application in veterinary medicine	September 2003
A030032/3: Research in the field of food infection and intoxication pathogens	September 2003
A020003/3D: Detection of viral infections in humans	September 2003
A030162/3: Diagnosis and research into transmissible spongiform encephalopathy (TSE) in animals	November 2003
List of organisms	
Fungus list	April 2003
Guidelines	
Draft guideline on the *definition of status, tasks and responsibilities of biosafety coordinators*	September 2003
Draft guideline on *biosafety in diagnostic laboratories*	November 2003
Draft guideline on an *operational safety concept according to CO*	November 2003
Advice relating to gene therapy	
Anti-HIV vaccine (Phase I gene therapy trial with attenuated vaccinia virus [NYVAC])	June 2003
Anti-HIV vaccine (Phase I gene therapy trial with modified vaccinia virus [MVA])	October 2003