B SECB CFSB
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Commission fédérale d'experts pour la sécurité biologique
Commissione federale per la sicurezza biologica
Swiss Expert Committee for Biosafety

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2001 ANNUAL REPORT OF THE SWISS EXPERT COMMITTEE FOR BIOSAFETY (SECB)

SUBMITTED TO THE FEDERAL COUNCIL AND OTHER INTERESTED PARTIES

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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 base for the SECB is furnished by Article 29h of the Federal Law on the Protection of the Environment and Article 29e of the Federal Law on Epidemics (EpG), which 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 by which it is governed (the Ordinance on the Swiss Expert Committee for Biosafety).

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. It can request expert statements and commission studies. It also periodically informs the public about important findings and the need for further research and reports to the Federal Council annually.

Composition of the SECB

According to the Ordinance on the SECB, the Committee should be composed of experts representing different conservation and user interests (universities, business, agriculture and forestry, environmental and consumer organisations). A list of the Committee members appointed by the Federal Council for the second term of office ending 31 December 2004 can be found on the next page. Various members tendered their resignations during the second half of 2001 (resignation dates are given in parenthesis after the names of the members concerned), whereupon a notice inviting new applications for membership was circulated among interested parties in December 2001. The elections for new members have yet to take place.

Secretariat

The SECB Secretariat, which is administratively affiliated to the Swiss Agency for the Environment, Forests and Landscape (SAEFL), supports the members of the Committee in their duties, prepares its meetings and draws up the Statements. The Secretariat also maintains contacts with other committees and public offices (both in Switzerland and abroad) with similar areas of responsibility. The Executive Secretary of the SECB is Dr Karoline Dorsch-Häsler. Since February 2001 she has been supported by Mrs Julia Link (scientific assistant, 40%). The responsibilities of the Secretariat also include public relations activities, reporting on the work of the SECB at such events as the biotechnology symposium in Solothurn, and, in particular, attending various international and national meetings (e.g. Karoline Dorsch-Häsler's participation as an invited expert at the Meeting of Technical Experts on Handling, Transport, Packaging and Identification of Living Modified Organisms, held in Paris within the framework of the Cartagena Protocol; information on the status of gene therapy in Switzerland and the regulatory changes of January 2002 at the final meeting of National Research Programme 37 (NFP37) in Fribourg).

Members of the SECB

President	
Riccardo Wittek (11/01)	Prof. Dr. phil. II, Institute of Animal Biology, University of Lausanne
Vice-President	
Geneviève Défago (11/01)	Prof. Dr. sc. nat., Institute of Plant Science, ETHZ, Zurich
Members	
Adriano Aguzzi (08/01)	Prof. Dr. med., Neuropathologist, Director of the Institute of Neuropathology, University Hospital of Zurich
Patricia Ahl Goy (11/01)	Dr. és. sc., Seeds/Biotechnology, Syngenta Seeds AG, Basel
Daniel Ammann	PD Dr. sc. techn., ETHZ, Office for Environmental Chemistry, Zurich
Klaus Ammann	Prof. Dr. phil. nat., University of Berne, Botanical Gardens, Berne
Joachim Frey (11/01)	Prof. dr. ès. sc., Institute of Veterinary Bacteriology, University of Berne
Angelika Hilbeck	Dr. dipl. agr. biol., Ecologist, Geobotanical Institute, ETH Zurich, EcoStrat GMBH
Martin T. Küenzi	Dr. sc. techn., Biotechnology, Solidago AG, Muttenz
Urs Niggli	Dr. sc. techn., Organic Agriculture Research Institute, Frick
Bernadette Oehen	Dipl. phil. II, WWF Switzerland (World Wide Fund For Nature), Zurich
Barbara Oppliger-Frischknecht	Dipl. ing. agr. ETH, Agronomist, Swiss Consumer Forum (KF)
Jean-Claude Piffaretti (11/01)	Prof. dr. ès. sc., Cantonal Institute of Bacterial Serology, Lugano
Jürg E. Schmid (9/01)	Dr. sc. techn., Institute for Plant Science, ETHZ, Lindau
Beat Wipf (11/01)	Dr. sc. nat., Pharmaceutical Research, Preclinical Biotechnology, F. Hoffmann-La Roche AG, Basel
Josef Zeyer	Prof. Dr. sc. nat., Institute of Terrestrial Ecology, ETHZ, Schlieren
Secretariat	
Karoline Dorsch-Häsler (Executive Secretary)	Dr. phil. nat, c/o Swiss Agency for the Environment, Forests and Landscape (SAEFL), Berne
Julia Link	Lic. phil. nat., Biologist, c/o Swiss Agency for the Environment, Forests and Landscape, Berne

Meetings

The Committee held five meetings during the period covered by this report. These took place in Berne on 6 February, 26 April, 29 June, 28 August and 11 November 2001.

Activities of the SECB in 2001

The SECB tackled a variety of issues during 2001 and issued a number of Statements, some of which are merely listed in tabular form (see Appendix). Since the Committee members represent a range of conservation and user interests and come from different disciplines, the Statements are not necessarily the result of consensus: votes are often taken and minority positions are recorded as such.

Advice relating to legislation

Gen-Lex

In submitting the "Gen-Lex" Motion in 1996, the National Council and Council of States (the lower and upper chambers of the Swiss Parliament) called for the remaining gaps in the existing legislation on non-human gene technology to be filled, thus setting in motion the (still ongoing) Gen-Lex procedure. Having already (during the first and second official consultation) scrutinised the proposals of the Federal Council, which wanted gene technology to be regulated within the framework of the existing Environmental Protection Law, the SECB continued to track the progress of the Gen-Lex in 2001. The Council of States' Committee for Science, Education and Culture studied the Federal Council's Gen-Lex Bill between April 2000 and April 2001 and reached a majority decision to deviate from this proposal and create a special, all-encompassing Gene Technology Law.

The SECB was kept informed of the ongoing procedure by SAEFL and followed the debate about the Gene Technology Law, which was intended to streamline the regulations governing non-human gene technology. In the view of the SECB, however, the encompassing Gene Technology Law ultimately merely results in a duplication of existing regulations, since the same rules are laid down in the Environmental Protection Law for pathogenic organisms and again in the encompassing Gene Technology Law for genetically modified organisms. The mandate of the SECB is enshrined in Article 17 of the Gene Technology Law and in Article 29h of the Environmental Protection Law.

The Council of States unanimously adopted a draft Gene Technology Law on 26 September 2001, thus referring the matter to the other chamber. The SECB addressed a letter to the National Council's advisory committee, which held its preliminary debate on the Gene Technology Law on 8 November 2001. In this letter the SECB expressed the wish to continue monitoring this matter in an advisory capacity. Further information on the parliamentary debate (in German) is available on the internet at:
http://www.parlament.ch/poly/Framesets/D/Frame-D.htm (Dossiers A-Z; Gen-Lex).

Ordinance on Clinical Trials with Therapeutic Products

The new Law on Therapeutic Products entered into force on 1 January 2002. This Law regulates the handling of medicinal products and medical devices. Responsibility for enforcement at the federal level rests with the newly created Swiss Agency for Therapeutic Products (Swissmedic). A series of implementing ordinances have been drafted for the purpose of enforcing the Law on Therapeutic Products, including the Ordinance on Clinical Trials with Therapeutic Products.

Taking into consideration the framework provided by the Law on Therapeutic Products and the existing regulations of the Intercantonal Office for the Control of Medicines (IKS), this Ordinance not only covers trials involving conventional therapeutics but also those involving somatic gene therapy. Its aim is to afford protection to individuals participating in such experiments and to ensure the quality of clinical trials. The SECB will issue statements on trials involving somatic gene therapy in accordance with Art. 17, para. 2b.

Being fundamentally in agreement with the Ordinance, the SECB merely made a number of minor remarks on various articles and expressed the desire also to be permitted to issue statements on trials involving therapeutic products that are based on conventional organisms. Such trials have hitherto also been monitored by the Gene Therapy working group of the SKBS, a committee which has made various proposals.

Implementation Aid for the Disposal of Medical Wastes (SAEFL draft)

This Implementation Aid is intended to facilitate the handling and environmentally sound disposal of wastes from healthcare facilities (hospitals, doctors' practices, nursing departments, medical laboratories, community nursing services, etc.). Its aim is to provide practical guidelines for the classification and control of medical wastes, to describe the state of the art with regard to the collection, temporary storage and treatment of medical wastes and to ensure the occupational safety of persons responsible for the disposal of medical wastes. Thus the wastes are subdivided into different groups according to their composition and infectivity and specific methods of disposal are described.

The SECB welcomed the Implementation Aid as a comprehensive and practical guideline for the disposal of many types of medical waste. However, the Committee also pointed out that it excludes medical wastes generated by activities falling within the scope of the Containment Ordinance (CO) (e.g. diagnostic and research laboratories), noting that the boundary between open and closed systems (i.e. release and contained use) is not always clear. The Implementation Aid should therefore specify where the boundaries lie. In its Statement the SECB also proposed certain clarifications and focused on characterisation and the handling of special wastes.

Advice relating to the Release Ordinance

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 (Section 2) and placing on the market (Section 3). Both types of permit application are forwarded to the SECB for consideration.

Releases for experimental purposes

According to Article 7 of the Release Ordinance, releases for experimental purposes must be authorised by SAEFL. The following permit application was submitted to SAEFL in 2001 by the Swiss Federal Institute of Technology Zurich (ETH Zurich).

Field performance of transgenic KP4 wheat varieties (Application of the ETH Zürich)

SECB Statement

The intention of the planned trial is to field-test transgenic wheat plants containing a gene for resistance to stinking smut (*Tilletia tritici*, also known as common bunt). This is a highly infectious seed-borne fungal disease which can result in severely reduced crop yields. The resistance gene is derived from a double-stranded RNA virus that infects *Ustilago* strains and encodes the KP4 killer toxin. KP4 has the ability to inhibit the growth of fungal mycelia and thereby interrupt the life cycle of the fungus. Besides studying the activity of KP4 in relation to the resistance of transgenic wheat plants to *T. tritici* under field conditions, various aspects of biosafety and interactions with non-target organisms are to be investigated. There are no plans at present to place these transgenic wheat plants on the market in this form.

The SECB Statement looked in some detail at various aspects of the application (see http://www.umwelt-schweiz.ch/imperia/md/content/ekah/SECB/35.pdf). It assessed the genetic modifications of the wheat (*kp4* gene, *bar* gene [selectable marker], *bla* gene [antibiotic resistance marker]), the expression of the *kp4* gene (mode of action, toxicity and possible effects of the KP4 protein) and the environmental impact (effects on non-target organisms, gene transfer, persistence of the transgenic plants in the wild), and the safety measures observed.

Although the ensuing debate was, at times, highly-charged, all of the Committee members ultimately came to the conclusion that in view of the trial's location, the size of the area involved (8 m^2) and the nature of the trial (i.e. basic research), the planned field trial does not pose an appreciable risk to people or the environment.

The majority of the Committee (9 members) were therefore in favour of the trial going ahead – subject, however, to a number of conditions being imposed (extension of the buffer strip around the plot, information on crops growing in neighbouring fields, analysis of the soil for the presence of the transgene and a detailed outline of the biosafety tests).

Those Committee members who declared themselves opposed to the trial going ahead (2 members) or else abstained (2 members) mentioned, *inter alia*, the fact that the molecular characterisation of the *kp4* gene had not yet been completed and that the presence of an antibiotic-resistance marker gene was undesirable; moreover, a permit application of this kind was said to be politically inopportune with the Gen-Lex procedure still in progress.

Biosafety considerations aside, a minority of the Committee held the view that the status of conventional wheat production in Switzerland would decline, that the approach embarked upon in selecting the *kp4* gene is very complex and costly and that alternative methods were available for combating *T. tritici*. Consequently, sustainable improvements would not be achieved via this approach, they maintained.

SAEFL ruling

SAEFL ruled against the experimental release, attributing its rejection of the application in part to product safety concerns (molecular characterisation of the *kp4* gene, information on the expression of the insert, interactions with non-target organisms and the environment) and to the presence of an antibiotic resistance gene.

Responses from the members of the SECB

Following the negative decision from SAEFL, Committee President Riccardo Wittek, Vice-President Geneviève Défago and members Patricia Ahl Goy, Joachim Frey, Jean-Claude Piffaretti and Beat Wipf resigned from the SECB. These resignations were not primarily precipitated by the decision itself, but by the reasoning behind it and the conflicting safety assessment produced by SAEFL, which came to the conclusion that the trial had an "incalculable damage potential". The resigning members objected to the fact that SAEFL had for the third time in succession rejected an experimental release application after the majority of the Committee had reached the conclusion that these particular experimental releases posed no appreciable risk to people or the environment. This stance was felt to be tantamount to a *de facto* moratorium on experimental releases in Switzerland and, moreover, it raised the question as to whether SAEFL needed the advisory function of the SECB. A further criticism levelled by all Committee members concerned the lack of communication between SAEFL and SECB – this notwithstanding the fact that the SECB had wished to be apprised of SAEFL's decision in advance.

Those members of the SECB who have not tendered their resignations are likewise of the opinion that the communication between government agencies and the SECB needs to be improved. The majority of the non-resigning members accepted the SAEFL decision, however, construing it as a step towards implementation of the precautionary principle –albeit that the precautionary principle was not, strictly speaking, on the agenda during the relevant SECB meetings concerning the wheat field-trial application. This majority regard SAEFL as the competent licensing authority, which receives advice in its decision-making from the SECB. They therefore find it legitimate for the Agency to choose not to follow the majority recommendation of the Committee and to attach different weight to the safety aspects of a trial.

Placing on the market

Depending on the intended use of the organisms, the permit is issued either by the Swiss Federal Office of Public Health (SFOPH), the Federal Veterinary Office (FVO) or the Agency for the Environment, Forests and Landscape (SAEFL).

Although the SECB has considered various applications for placing on the market, not all of these application procedures have been concluded during the year under review.

Placing on the market of the microbial product BICHEM DC 2000 GL BIOSOCK (Company: Plumettaz SA)

This application concerns a product based on a bacterial mixture which is to be used to destroy organic wastes, and more particularly to degrade fats, oils and grease in municipal and industrial treatment plants and collection systems. The product contains a bacterium belonging to risk group 2, *Enterobacter cloacae*, meaning that a permit is required in order

to place it on the market. In several countries (Europe, USA) this product has already been on the market for a number of years (NB: *Enterobacter cloacae* is classified in group 1 in the USA).

The SECB has given detailed consideration to this application, but it is unable to elaborate further on its recommendations as the procedure is still ongoing and the competent licensing authority has yet to reach a decision.

Discussion of the use of the 35S CaMV (cauliflower mosaic virus) promoter in transgenic crops

The 35S CaMV promoter is employed in many transgenic crops as a ubiquitous promoter that induces high levels of expression. The SECB decided to discuss this issue because reservations regarding the safety of this promoter had been voiced on various occasions and because during the year under review the Committee had dealt with various applications for placing on the market of transgenic crops destined for human and animal consumption in which this promoter had been used.

The debate over the CaMV 35S promoter was prompted by a paper by Kohli *et al*. (The Plant Journal 1999, 17: 591-601), who established during an analysis of transformation experiments involving rice plants that in several cases the same 19-basepair palindromic sequence could be detected for the CaMV 35S promoter at various gene loci. The authors referred to this sequence as a "hotspot for recombination". A discussion paper was subsequently published by Ho *et al.* (Microbial Ecology in Health and Disease 1999, 11: 194-197) highlighting fears about potential risks for people and the environment, which in turn provoked a number of critical responses (Hull *et al*., Microbial Ecology in Health and Disease 2000, 12:1-5; Morel J.-B. and Tepfer M., Biofutur 2000, 201: 32-35).

Kohli *et al.* did indeed succeed in demonstrating a hot spot for recombination in their studies, though this is in all probability not attributable to a recombination mechanism within the CaMV 35S promoter, but rather can be explained firstly by the method of transformation (particle acceleration), which employs large quantities of free DNA, and secondly by the design of the trial – and in particular the presence of three gene-expression cassettes, stacked in series, with a total of three of these promoter sequences.

As far as the safety of the 35S CaMV promoter is concerned, the SECB has taken into consideration the following factors, *inter alia*:

- Plants themselves contain a large number of transposons and mobile elements, which can give rise to a diversity of recombination events. The mobility of these endogenous gene sequences can, for example, be triggered by stress (heat/cold, dry/wet conditions, injuries, pathogens, etc.). Activation of such endogenous elements appears to be more likely than a recombination event induced by the CaMV 35S promoter.
- "Natural" plants infected with CaMV contain both encapsulated and free DNA and are therefore in this respect no different from transgenic plants which contain this promoter (Covey *et al.*, Nucleic Acids Research 1981, 9(24): 6735-47).
- There is no evidence to date that the consumption of genetically modified products containing a CaMV 35S promoter sequence has resulted in horizontal gene transfer. Nor has it yet been demonstrated that inserted sequences can "jump" back out of the genome.

- No signs of genetic instability have been observed to date in the transgenic plants that contain this promoter.

Based on the available data and the considerations outlined above and according to the current state of knowledge, the SECB is of the opinion that the use of the CaMV 35S promoter poses no appreciable risk to people or to the environment.

Advice relating to the Containment Ordinance

Applications for permits

According to Article 9 of the Containment Ordinance (CO), authorisation is required for any activity assigned to class 3 (activity posing a moderate risk to people and the environment) or class 4 (activity posing a high risk to people and the environment) that involves genetically modified or pathogenic organisms. For diagnostic activities assigned to classes 3 and 4 that involve pathogenic, non-genetically modified organisms, it is sufficient to obtain a permit for the first activity.

The SECB has once again received various permit applications for consideration during 2001 pursuant to Art. 15, para. 2c of the CO. A list of these applications is appended to the present report. The receipt of permit applications is published in the Federal Gazette (Art. 15, para. 2d, CO) and the permit is issued by the relevant federal agencies (SFOPH or SAEFL, Art. 16, CO) following examination of the risk assessment and taking into account the Statements received (Art. 18, CO). The SECB evaluates all class 3 applications. In addition, various class 1 and class 2 applications are also evaluated by the Executive Secretary. Class 2 applications are only forwarded to the SECB in special cases. In connection with these applications, Karoline Dorsch-Häsler also makes herself available to the federal agencies (and especially SAEFL) in an advisory capacity, acting on behalf of the SECB, and she regularly takes part in the coordination meetings of SFOPH, SAEFL and the Federal Coordination Centre for Biotechnology.

Specific Statements

Besides issuing Statements on various permit applications, the SECB also addressed other topics falling within the ambit of the Containment Ordinance, thereby fulfilling its advisory function. In the course of 2001 the SECB published a number of Statements, which are primarily directed at experts from the relevant sections.

Risk assessments

Classification of work with genetically modified viral vectors

In this Statement, which for the time being is only available in English, the SECB undertook a classification of work with viral vectors based on the following viruses: lentiviruses, retroviruses, Semliki Forest and Sindbis viruses, and adenoviruses (see also http://www.umwelt-schweiz.ch/imperia/md/content/ekah/SECB/23.pdf).

Although all of the viruses on which these vectors are based belong to risk group 2, certain activities involving these vectors may be assigned to a lower group since they have been rendered safer following deletions of specific sequences. A higher classification becomes

necessary if the insert falls into a higher risk group. The SECB has based its classification for the most part on existing classification systems abroad.

Revision of the SCBS list of viruses

The SECB advises SAEFL on the compilation of lists for the classification of organisms. The list of bacteria was complete in 2000 (see http://www.umwelt-schweiz.ch/imperia/md/content/stobobio/biotech/ouc2/2.pdf and http://www.umwelt-schweiz.ch/imperia/md/content/stobobio/biotech/ouc2/3.pdf), and work is in progress on the classification of viruses, parasites and fungi. The Swiss Interdisciplinary Committee for Biosafety in Research and Technology (SCBS) had already compiled the lists of organisms in 1992. The virus list has now been revised, with various existing lists and classifications from abroad being incorporated.

The SECB members were basically in agreement with the classification, but made a number of minor comments, in particular with regard to the legend to the list of plant-pathogenic viruses and the classification of highly virulent animal-pathogenic viruses (e.g. foot and mouth disease or African swine fever).

Diagnostics

BSE diagnostics: classification and safety measures

When performing BSE diagnostics and working with prion-containing material, different safety measures need to be observed at the three stages of transport, analysis and disposal.
In its Statement (http://www.umwelt-schweiz.ch/imperia/md/content/ekah/SECB/38.pdf), the SECB looked into the regulatory framework, classification and the safety measures to be implemented.

As far as the classification of prion proteins is concerned, the SECB adopts the classification system used in the corresponding EU Directive and makes a distinction between activities undertaken in the area of BSE diagnostics and activities in reference laboratories. In its Statement, the SECB compiled a table of those safety measures that need to be observed when handling sample material, ranging from sampling at the abattoir through to inactivation (decontamination with NaOH, on-site autoclaving, incineration as "special waste") and final disposal. Incineration as special waste is the safest form of inactivation according to the current state of knowledge and this is therefore the method recommended by the SECB.

Disposal of waste in clinical microbiology diagnostic laboratories

The SECB Statement systematically reviews the disposal of waste in clinical microbiology diagnostic laboratories, which are governed by the Containment Ordinance. In addition, it comments on the nature of the waste and on the disposal containers to be used, as well as on the specific options available for inactivation and disposal (see http://www.umwelt-schweiz.ch/imperia/md/content/ekah/SECB/39.pdf).

As far as the nature of the waste is concerned, the SECB makes the distinction between liquid and solid cultures (containing pathogenic or genetically modified microorganisms), diagnostic samples and consumables. It advocates strict compliance with the provisions of the CO, which requires the presence of an autoclave on site for the purposes of inactivation. In addition, direct incineration as "special waste" (i.e. without prior inactivation) may be

appropriate. For certain material, and especially for diagnostic samples, direct incineration as "special waste" (i.e. without prior inactivation) may be appropriate. Following complete inactivation, the term "special waste" is only applied to wastes that are nauseating or odour-intensive, as well as to any consumables with the potential to cause injury.

Special events

Information Meeting for Biosafety Coordinators

On 7 May 2001 a meeting was held in Fribourg for biosafety coordinators, organised by the SECB, SAEFL and SFOPH. Alongside presentations by the Federal Coordination Centre for Biotechnology, various topics relating to risk assessment were addressed and information was provided about past inspections and the tasks of the biosafety coordinator.

Joint meeting with the Federal Ethics Committee on Non-human Gene Technology (ECNH)

The first-ever joint meeting of the SECB and ECNH was held on 29 June 2001 at the instigation of both committees. The main topic of the meeting was the application filed by the Swiss Federal Institutes of Technology (ETH) for approval of a field trial of transgenic wheat and the different perspectives of the two committees. Following a presentation of each committee's Statement on this application, the various options were discussed and a number of points of contact between the committees were identified. Several themes – such as the precautionary principle and sustainability – are of relevance to both the SECB and the ECNH, and joint meetings will continue to be held at regular intervals in the future.

Public relations activities

A number of Committee members took part in various meetings and reported on the work of the SECB via presentations or podium discussions during 2001.

As part of a general restructuring of the internet concept at SAEFL, the SECB has revised and updated its own internet presence. Most of the Statements and Recommendations issued by the SECB can be accessed on the internet at www.SECB.ch. In addition, the SECB website contains dates and agendas of meetings, annual reports and other topical information.

Swiss Expert Committee for Biosafety

Interim President	Executive Secretary
Dr Martin Küenzi	Dr Karoline Dorsch-Häsler

Appendix

Advice relating to legislation	
Statement on the Fees Ordinance for the Containment and Release Ordinances	30 January 2001
Statement on the Ordinance on Clinical Trials with Therapeutic Products	23 July 2001
Statement on the draft of the SAEFL's "Implementation Aid for the Disposal of Medical Wastes"	31 July 2001

Advice relating to the Release Ordinance (RO)	
Placing on the market	
Mise dans le commerce du produit microbien BICHEM DC 2000 GL BIOSOCK (Company: Plumettaz SA)	10 May 2001
Placing on the market of transgenic maize (T25xMON810 maize) for the purposes of food and animal feed (Company: Pionneer Hi-Bred / Dow AgroSciences)	29 June and 9 November 2001
Placing on the market of transgenic maize (1507 maize) for the purposes of food and animal feed (Company: Pionneer Hi-Bred)	9 November 2001
Experimental releases	
Statement on the application from the ETH: Field performance of transgenic KP4 wheat varieties	5 September 2001

Advice relating to the Containment Ordinance (CO)	
Permit applications	
A010007/3: Diagnostic en microbiologie clinique de bactéries, champignons	January 2001
A010014/3: Diagnostic *in vitro* and *in vivo* cultivation of Naegleria	January 2001
A000231/3: Diagnostic and national reference activities of the Institute of Veterinary Bacteriology, University of Berne	January 2001
A010093/3: Study of the effect of oligonucleotides and cellular receptor interaction partners on the absorption and replication of HIV-1 in cell culture	February 2001
A000226/3: Clinical microbiology diagnostics	April 2001
A010099/3: Utilisation de vecteurs lentiviraux pour le transfert de gènes dans le système nerveux central	April 2001
A010230/3: Molecular dissection of lentiviral assembly and release	April 2001

A010337/3: Identification of the influenza A virus proteins whose function is inhibited by human MxA protein.	July 2001
A010338/3: Suppression of HCV replication by interference with cell signalling events and viral transcription	September 2001
A010381/3: Identification and characterisation of Mycobacterium tuberculosis virulence and pathogenicity genes	November 2001
A010382/3: Infection studies	November 2001
A000760/3: Biochemical binding studies with BSE and CJD prions	November 2001
A000761/3: Susceptibility of transgenic mice expressing mouse-bovine chimeric PrP to BSE prions	November 2001
A000762/3: Swiss National Reference Centre for Prion Diseases	November 2001
Risk assessments	
Classification of work with genetically modified viral vectors	21 August 2001
Revision of the list of viruses	September 2001
Diagnostics	
SECB Statement on BSE diagnostics: classification and safety measures	18 April 2001
Statement on the disposal of waste in clinical microbiology diagnostic laboratories	November 2001