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Swiss Expert Committee for Biosafety SECB

2005 / 2006 Annual Report of the Swiss Expert Committee for Biosafety SECB

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Content

1. Introduction

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 is an independent expert committee that 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 its 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], Article 22 of the Gene Technology Law[2], which came into force on 1 January 2004, and Article 29e of the Federal Law on Epidemics[3]. The SECB was established on 1 January 1997, at the same time as the entry into force of the Ordinance[4] that governs it.

2. 30 years of the Biosafety Committee

1975 saw the foundation of Switzerland's first biosafety committee, as the Kommission für experimentelle Genetik (Advisory Committee on experimental genetics). The SECB used the 30-year anniversary of its founding as the occasion for a celebration[5]. Contributions by various speakers permitted a lively look at the past and future of gene technology and biotechnology.

As well as the history of biosafety committees (see box 1), the anniversary event also addressed current topics such as the ethics of gene therapy, the relationship between politics and science, and the coexistence of genetically modified and common plants in agriculture.

Today, the SECB is still an important tool for evaluating the biological safety of work using genetically modified or pathogenic organisms. Thus, 30 years after the founding of the Kommission für experimentelle Genetik, it still pursues its original aims, as shown in the diverse list of topics and activities, given below.

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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)

5 SECB anniversary event to celebrate 30 years of biosafety committees in Switzerland (in German) http://www.efbs.ch/buwal/de/fachgebiete/fg_efbs/news/2005-12-08-01051/index.html

Box 1: History of the biosafety committees

The beginnings of modern gene technology and biotechnology lie in the 1970s. It can be traced back to the discovery of *restriction enzymes*, which made it possible for the first time artificially to combine DNA from different origins. In 1972 Paul Berg made the first *recombinant DNA*, for which he received the Nobel Prize in 1980. Shortly after these experiments, famous scientists pointed out that recombinant DNA could hold risks for humans and the environment, which needed to be evaluated. In February 1975 the first conference on this took place in Asilomar (California), at which internationally recognised scientists agreed to establish guidelines that should be adhered to in work using recombinant DNA. This laid the foundation stone for biological safety. In Switzerland, Werner Arber called the Kommission für experimentelle Genetik into life, the first biosafety committee in Switzerland. Werner Arber, Daniel Nathans and Hamilton Othanel Smith received the Nobel Prize in 1978 for the discovery of restriction enzymes and their application in molecular genetics.

Due to its expansion into industrial applications and a generally broader range of tasks, in 1986 the Kommission für experimentelle Genetik was replaced by the Swiss Interdisciplinary Committee for Biosafety in Research and Technology (SKBS). Following the introduction of several new gene and biotechnology regulations, in 1997 the Federal Council established the Swiss Expert Committee for Biosafety (SECB) as the successor to the SKBS.

Restriction enzymes: These are molecules of bacterial origin that recognise and cut particular DNA sequences. They serve primarily to detect foreign DNA. Recognition sequences in the endogenous DNA are, by contrast, modified and thus protected from restriction enzymes. In biotechnology, restriction enzymes enable the targeted manufacturing of DNA fragments, which can then be isolated and put together to make new constructions. This produces recombinant DNA.

3. News

3.1 Activities using group 3 and 4 organisms

Group 3 and 4 organisms include highly contagious bacteria (e.g. anthrax, plague, tularaemia, group 3) and viruses (e.g. Ebola, Marburg, group 4), which can pose a severe risk to humans and the environment. In Switzerland it has been found necessary to extend the capacity to diagnose group 3 organisms, and also to permit activities using group 4 viruses. These developments are in part in reaction to the anthrax attacks in the USA, the outbreak of Severe Acute Respiratory Syndrome (SARS), and the spread of avian influenza. They also reflect the increase in travel to countries where the risk of infection with highly contagious viruses is present. Switzerland is currently pursuing various projects that are supported by the SECB.

3.1.1. Safety Laboratory of the Federal Department of Defence, Civil Protection and Sport

The largest project is the plan to build the Safety Laboratory[6] of the Federal Department of Defence, Civil Protection and Sport, in which activities using safety level 4 human-pathogenic organisms can be carried out. This Safety Laboratory will be erected on the site of the existing SPIEZ LABORATORY. The SECB issued a Statement as part of the environmental impact assessment[7] for the Safety Laboratory. The environmental impact assessment examines whether the planned building observes the statutory provisions on environmental protection. In addition, the SECB wrote a letter establishing the fundamental considerations for handling group 4 organisms. The SECB sees human beings as the greatest risk factor in the handling of highly pathogenic organisms. The requirements for the scientists are stringent. To carry out such activities scientists must be part of a broad network with other specialists, as well as have the appropriate training and many years of experience. The SECB considers the affiliation of such a laboratory to existing diagnostic laboratories of university hospitals to be of fundamental importance. Since the planned Safety Laboratory corresponds to the current state of technol-

[6] Safety Laboratory of the Federal Department of Defence, Civil Protection and Sport: http://www.labor-spiez.ch/old/e/index.htm

[7] Environmental impact assessment http://www.bafu.admin.ch/uvp/index.html?lang=de
Ordinance of 19 October 1988 on Environmental Impact Assessment (OEIA): http://www.admin.ch/ch/d/sr/c814_011.html

ogy and fulfils all the conditions of the Containment Ordinance[8] (see also Chapter 4.2) for safety level 3 and 4 laboratories, the construction can be approved from the point of view of biological safety for humans and the environment.

3.1.2 Swiss Regional Laboratory Network

A further project is the Regional Laboratory Network[9], which is composed of six regionally distributed laboratories. The objective of this network is to create decentralised analysis capacities for the initial diagnosis of group 3 human-pathogenic organisms such as anthrax. Thus in extraordinary situations, such as epidemics or terrorist attacks, initial diagnosis and environmental analysis will be secured. Individual laboratories would also like to be able to perform diagnoses of group 4 organisms. The Regional Laboratory Network is embedded in the NBC Plan[10] of the Confederation and Cantons. There is close cooperation with the SPIEZ LABORATORY and various reference centres. The laboratories will correspond to safety level 3. For diagnosing group 4 organisms, a class III biological safety cabinet is also required (see Chapter 4.2.2). The SECB is also represented in the coordinating committee of the Regional Laboratory Network.

Within the Regional Laboratory Network, the SECB gives equivalent weight to the know-how and experience of the employees as to the observation of technical safety measures. It recommends limiting the number of laboratories that handle group 4 organisms to reference centres plus one or two locations that are already associated as diagnostic laboratories. The technical prerequisites are a safety level 3 laboratory that fulfils all the provisions of the containment ordinance and possesses a class III biological safety cabinet.

3.1.3. Guideline “Safety measures for group 4 diagnostics”

The SECB has issued Statements on two Guidelines (see also Chapter 4.2.2) establishing safety measures that must be observed when handling group 4 viruses. It differentiates between the routine handling of samples, and diagnostics that take place in emergency situations where the capacities required to protect humans and the environment are not available. Again, the SECB emphasises here that from its point of view, the training and experience of the personnel are just as important as the observation of constructional and technical safety measures.

3.2 Green gene technology

The use of gene technology and biotechnology in agriculture provokes much discussion and is the subject of many political motions. The Gene Technology Law, which came into force in 2004, newly regulates for the first time various aspects of handling genetically modified organisms. The SECB considers the protection of humans and the environment in this area as well, and issues recommendations on biological safety.

3.2.1 Coexistence Ordinance, Gene technology moratorium, National Research Programme 59

Die Coexistence Ordinance[11] will detail the requirements for the cultivation of genetically modified plants, as well as the protection of production without genetically modified organisms (GMOs), which is anchored in the Gene Technology Law. For example, crossing-out to non-genetically modified organisms must be avoided, and this must be demonstrated by, for example, observing isolation distances. It establishes limits for maximum contamination with GMOs. It also regulates the separation of material flows and the labelling of genetically modified organisms.

The approval of the popular initiative “Food produced by GMO-free agriculture”[12] on 27 November 2005 temporarily halted work on the Coexistence Ordinance. The initiative demands a moratorium on commercial applications of genetically modified organisms in the environment for a period of five years. After the moratorium expires, the Coexistence Ordinance will be reassessed and will include

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[8] Ordinance of 25 August 1999 on the Contained Use of Organisms (Containment Ordinance, CO), SR 814.912, http://www.admin.ch/ch/d/sr/c814_912.html

[9] Diagnostik im B-Bereich – Stand und Perspektiven des Regionallabornetzwerkes; Koordinationskomitee des Regionalen Labornetzwerkes; BAG-Bulletin 33/06, S. 668-672. http://www.bag.admin.ch/dokumentation/publikationen/01435/01795/index.html?lang=de&download=M3wBPgDB/8ull6Du36WcnojN14in3qSbnpWXbWmZnE6p1rJgsYfhyt3NhqbdqIV+baqwbKbXrZ6lhuDZz8mMps2go6fo

[10] NBC protection: Defence against and prevention of nuclear, biological and chemical hazards: http://www.bevoelkerungsschutz.admin.ch/internet/bs/en/home/themen/abcschutz.html

[11] Coexistence Ordinance (in German): http://www.admin.ch/cp/d/4340e972_2@fwsrvg.html

[12] Federal popular initiative “Food produced by GMO-free agriculture”: http://www.admin.ch/ch/d/pore/vi/vi314.html

the results of the National Research Programme "Benefits and Risks of the Deliberate Release of Genetically Modified Plants" (NRP 59)[13].

NRP 59 was approved following the moratorium on gm foods. Its objective is to assess the application potential of plant biotechnology in Switzerland. Issues of the risks and benefits of biotechnology are foremost. The NRP will also treat the problems of risk management at legal, political and administrative levels. Project outlines could be submitted by August 2006. The definitive selection of the projects will take place in May 2007. The SECB Secretariat is represented in the NRP 59 steering committee.

3.2.2 Experience of cultivating genetically modified crops

In the immediate future, there will probably be no commercial cultivation of genetically modified plants in Switzerland. However, the SECB foresees that further experimental releases will be performed. Worldwide, there is now 10 years of experience in cultivating genetically modified crops. Commercial cultivation takes place primarily in the USA, Canada, Argentina, Brazil and China. The SECB was concerned to acquire an overview of existing knowledge and to reveal gaps in knowledge and any further need for action in the area of biosafety. In 2004 it therefore commissioned a study of experience with the cultivation of genetically modified crops. This study was carried out by the Agroscope Reckenholz-Tänikon Research Station (ART) and published in 2006 under the title "Ecological impact of genetically modified crops"[14]. It concentrates on the three insect-resistant or herbicide-tolerant crops maize, rape and soy, which are major crops in Switzerland, and analyses five possible impacts on the environment.

SECB sees this study as providing a broad overview of the situation worldwide, and contributing to the careful risk analysis of genetically modified crops. Nevertheless, the different agricultural cultivation systems, and the difficulty of establishing a basis for comparison, make it problematic to extrapolate the results to the Swiss context. Not all the Committee members share the authors' final conclusions or their interpretation of the data.

3.3 Nanotechnology and synthetic biology

Nanotechnology is commonly used as an inclusive term for all branches of technology involving materials at a scale of less than 100 nanometres (= 10^{-9} m). It currently comprises a very broad spectrum of applications and products. But as yet there is little uniformity of nomenclature and definition. Nanotechnology is generally regarded as key to numerous branches of technology in the 21st century. However it is clear that, alongside its promise, nanotechnology holds certain risks. Since the SECB's tasks include following new developments and identifying needs for action or research, it is also concerned with developments in nanotechnology. The committee has discussed this topic at several meetings, with various invited speakers. In principle, nanotechnology and nanoparticles fall within the SECB's remit only in connection with biological systems capable of reproduction, or if nanoparticles have an impact on humans and the environment. Nanobiotechnology is of particular interest to the SECB. This discipline aims to apply biological materials in technical nanosystems and also to use nanotechnological developments in the life sciences. There is as yet no consensus about whether synthetic biology should be viewed as a part of nanotechnology. This field artificially reproduces biological systems and thus also uses materials containing nanoparticles.

The SECB has a seat in the Confederation's advisory board for the "Swiss Action Plan for the risk assessment and management of synthetic nanoparticles"[15]. The Action Plan's objectives include coordinating national and international activities for risk evaluation and risk management of synthetic nanomaterials. It will also establish precautionary measures to protect employees, consumers and the environment.

3.4 Transport of pathogenic or genetically modified organisms

If the transport of pathogenic or genetically modified organisms is incorrectly performed, it poses a risk to humans and the environment. The United Nations Model regulations on the Transport of Dangerous Goods[16] are the authority here. These model regulations, also known as the *Orange Book*, provide the basis for the transport of dangerous goods by all transport services. They group dangerous goods into

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[13] NRP 59 - Benefits and Risks of the Deliberate Release of Genetically Modified Plants, http://www.snf.ch/E/targetedresearch/researchprogrammes/newNRP/Seiten/_xc_nfp59.aspx

[14] Ecological impacts of genetically modified crops, ART-Schriftenreihe 1: http://www.art.admin.ch/dms_files/03017_de.pdf

[15] Action plan "Risk assessment and risk management of synthetic nanoparticles": http://www.bafu.admin.ch/chemikalien/01389/01393/01394/index.html?lang=en

[16] UN Model regulations on the Transport of Dangerous Goods, 14th revised edition, http://www.unece.org/trans/danger/publi/unrec/rev13/13nature_e.html

different classes, set requirements for packaging, labelling and marking, and establish additional safety measures that must be observed when transporting dangerous goods.

Since the international regulations are often difficult to interpret and put into practice, there remains some lack of clarity around the transport of genetically modified or pathogenic organisms. Enquiries made to the SECB have shown that there is a need in Switzerland for a practical concretisation of the regulations. The SECB raised the subject of transport at several conferences for biosafety officers, and led a coordination meeting of federal and cantonal authorities involved in the transport of such organisms, to ensure a harmonised procedure. The aim is to develop broadly based, solution-oriented transport instructions and information leaflets. These will take especial note of the experience and needs of the users.

3.5 Avian influenza

Since December 2003, classical avian influenza, also known as bird flu, has repeatedly caused illness in poultry stocks, primarily in various Asian countries. With single outbreaks in Hungary and Turkey, however, bird flu also reached Eastern Europe in 2005 and occurred in a few African countries in 2006.

This continues to be an animal disease, primarily affecting domestic poultry and water fowl. Humans are rarely infected, and then only if they have had close contact with diseased domestic poultry. According to information from the World Health Organization (WHO), as of 11.4.2007[17] 291 people worldwide have been infected with the avian influenza virus, of whom 172 have died. This gives a lethality of 59.1%. Avian influenza and its spread are being observed with concern by both human and veterinary medicine. Mutation of the virus could lead to an increased transmissibility from human to human. There is (as yet) no vaccine available.

Switzerland has been shown to be free of avian influenza. Intensive monitoring of wildfowl and migratory birds, which may also be carriers of the virus, is carried out. The ban on keeping poultry outdoors, introduced in the 2005/2006 winter, was a precautionary measure taken to protect poultry in Switzerland from infection by migratory birds.

Specialists within the SECB consider the H5N1 virus to have pandemic potential and advise monitoring the situation carefully. The various public information releases and leaflets from the FOPH[18] (human health) and the FVO[19] (animal health), whose advice must be followed if a pandemic occurs in Switzerland, are a good aid at present. Among other things, the SECB has considered the disposal of materials that could be contaminated with H5N1, and has been able to respond to the concerns of waste disposal companies and cantonal representatives.

Box 2: Terminology of bird flu

Influenza virus H5N1: The cause of clinical avian influenza may be the two subtypes H5 and H7 of influenza virus A, of which a total of 16 H subtypes and 9 N subtypes are known. In avian influenza viruses we distinguish between high pathogenicity (HPAI) and low pathogenicity (LPAI) variants, which differ from one another in their clinical picture and their lethality. In the outbreaks so far described, viral mutations have effected a switch from LPAI to HPAI.

Pathogenicity: describes qualitatively the ability of an organism to cause disease.

Virulence: describes quantitatively the ability of an organism to cause a disease, i.e. the degree of pathogenicity.

Lethality: describes the fatal outcome of a disease. The lethality rate is calculated from the number of persons who die of a particular disease, divided by the number of people suffering from that disease. However, it is very difficult to determine accurately the actual number of sick people.

[17] Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO, http://www.who.int/csr/disease/avian_influenza/country/cases_table_2007_04_11/en/index.html

[18] FOPH information on bird flu (in German): http://www.bag.admin.ch/influenza/01119/01128/index.html?lang=de

[19] FVO information on bird flu (in German): http://www.bvet.admin.ch/gesundheit_tiere/00276/index.html?lang=de

4. Consultations

4.1 The Release Ordinance[20]

The aim of the Release Ordinance is to protect people and the environment from harmful effects of handling genetically modified or pathogenic organisms, and to conserve biological diversity and the fertility of the soil. Experimental releases of genetically modified or pathogenic organisms are regulated by the Release Ordinance (Chapter 2, Section 2 RO), as is the marketing of such organisms (Chapter 2, Section 3 RO). Experimental releases must be authorised by the FOEN. For marketing, a permit is issued, by the Federal Office of Public Health (FOPH), the Federal Veterinary Office (FVO), or the Federal Office for the Environment (FOEN), according to the purpose of use.

4.1.1 Revision of the Release Ordinance

On 1 January 2004 the Gene Technology Law[21] came into force, which regulates the handling of genetically modified animals, plants and other organisms, and thus also contains provisions on the labelling of genetically modified organisms, separation of material flows and monitoring. These new regulations must now be implemented at the level of ordinances. The SECB contributes to such revisions, and throughout the procedure it has several opportunities to comment on the individual articles. From the SECB's point of view, the revision of the Release Ordinance provides an opportunity to harmonise Swiss legislation – where this is sensible and possible – with that of the European Union. Furthermore, experience in enforcement can be included and the authorisation procedures modified. The SECB lays great emphasis on terms being defined clearly and the ordinance being understandable, both in terms of the subject and in the language used. The revised Release Ordinance will enter into force on 1.1.2008 at the earliest.

4.1.2 ProteqFlu-Te: vaccine against equine influenza

This veterinary medication[22], which is already available in Europe under the trade name ProteqFlu-Te[23], will be used in Switzerland to vaccinate horses against equine influenza and tetanus. The vaccine has several components, including a toxoid of *Clostridium tetani*, i.e. the deactivated form of the toxin that causes tetanus. Toxoids have lost their danger, but produce an immune reaction and thus give vaccine protection. The tetanus toxoid is not particularly prominent in the SECB's risk assessment, since it has already been used for some years as a vaccine. The other components are genetically modified vectors, which are derived from a weakened canary pox virus. These vectors contain two different genes, derived from one European and one American variant of the equine influenza virus H3N8. They contain information to form the virus envelope proteins, components of the external structure that enclose the viral DNA. These envelope proteins are recognised by the horse's immune system and thus give protection as a vaccine. In contrast to the usual vaccination with deactivated viruses, which produce a relatively short period of protection, the use of this live vaccine will cause a more comprehensive immune reaction and thus give longer-term protection. The SECB's job was to evaluate whether the use of these genetically modified vectors poses a risk to humans, animals or the environment. The vectors cannot reproduce in mammalian cells and are not excreted. Extensive investigations have also shown that ProteqFlu-Te is well tolerated by horses and gives efficient protection. Therefore the SECB recommended that the Federal Veterinary Office approve this application.

4.1.3 VectoBac: preparation to combat mosquitoes

The Magadino Valley and the Lac de Gruyère regularly suffer rising water levels and overflow. This leads to the explosive hatching of mosquito larvae and a resulting plague of mosquitoes. To combat these mosquitoes a preparation with the trade name VectoBac[24] is used. VectoBac is a biopesticide, whose active ingredient consists of live spores of the soil bacterium *Bacillus thuringiensis israelensis* (Bti), which are capable of forming Bt-toxins. These act very specifically and are lethal to species of mosquito that are widespread in these places.

The SECB assessed this application, giving attention to various environmental and biosafety aspects, and recommended it for approval. From the SECB's point of view VectoBac is distinguished by the

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[20] Ordinance on the Release of Organisms into the Environment of. 25 August 1999 (Release Ordinance, RO), SR 814.911: http://www.admin.ch/ch/d/sr/c814_911.html

[21] Federal Law of 21 March 2003 relating to Non-human Gene Technology (Gene Technology Law, GTL): SR 814.91, http://www.admin.ch/ch/d/sr/c814_91.html

[22] Authorised medicinal products for veterinary use: http://www.emea.eu.int/vetdocs/vets/Epar/proteqfluTe/proteqfluTe.htm

[23] Application for authorisation to market ProteqFlu-Te (in German): http://www.admin.ch/ch/d/ff/2006/8453.pdf

[24] VectoBac: Product information from the manufacturer, Valent Biosciences http://www.valentbiosciences.com/learning_center/learning_center.asp?lc_section=vectobac&flash=vectobac

facts that its host spectrum is restricted to mosquitoes, it acts very rapidly, and it has a very low toxicity. Studies in birds and aquatic organisms have shown that Bt-toxins generally have no toxic effect in vertebrates. The fact that the average lifespan of Bti spores in the soil is only two months, thus inhibiting the development of VectoBac-resistant mosquitoes, was also important in the SECB's positive assessment. The SECB remains concerned however that long-term monitoring of the use of VectoBac should be carried out, keeping a special lookout for the development of resistance. The application, which is subject to the Ordinance on Biocidal Products[25], was approved in a decree of 2 June 2006[26].

4.2 The Containment Ordinance [27]

The Containment Ordinance (CO) regulates activities using genetically modified or pathogenic organisms in contained systems, and 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 limits 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.

4.2.1 Permit applications

To ensure that activities involving genetically modified organisms avoid any possible harm to humans and the environment, the activities undergo a risk assessment and are assigned to four different classes. Different safety measures must be adhered to according to the class. Authorisation is necessary for group 3 (moderate risk to humans and the environment) and class 4 (high risk to humans and the environment) activities. Such permit applications are assessed by the SECB. If new research is planned, or if the applicant wishes to omit certain safety measures, the SECB also assesses group 2 notifications. A list of these applications and notifications is enclosed with this report (see Appendix). The following applications are given as examples:

Plant-pathogenic quarantine organisms

One of the objectives of the *European Plant Protection Organisation* (EPPO)[28] is to protect plants from pathogens and pests that could harm both crops and wild plants. The introduction of such pathogens into natural ecosystems and agriculturally exploited areas should be avoided. The EPPO therefore keeps two "*alert lists*" of organisms that are under quarantine. The A1 list contains organisms that are not yet present in the EPPO region, while the organisms on the A2 list include those that may already appear locally in the EPPO region.

In Switzerland various groups are engaged in the diagnosis of such quarantine organisms. Many are developing diagnostic tests that will permit the unambiguous identification of quarantine organisms, and the monitoring of such organisms in Switzerland. The SECB assesses the classification of the organisms and helps to determine safety measures that must be taken when handling such organisms. Activities using organisms that are not yet present in Switzerland must minimise the risk of their escape into the environment. In addition, insects that might contribute to spreading the organisms must be combated. Different safety measures are appropriate according to the species and risk assessment of the organisms.

Classical swine fever

Classical swine fever is a viral animal disease that is difficult to control and can cause substantial damage. It breaks out sporadically and can result in whole herds in the affected areas having to be destroyed. The pathogen of classical swine fever is the subject of a range of research applications by the Institute of Virology and Immunoprophylaxis (IVI)[29]. They include investigations of the immunology and the mechanism of infection, and the development and testing of new recombinant, i.e. genetically modified vaccines. These activities are performed in the IVI's high-security wing, which has the highest

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[25] Ordinance of 18 May 2005 on biocidal products (OBP), SR 813.12, http://www.bag.admin.ch/themen/chemikalien/00531/01460/01493/index.html?lang=en

[26] Marketing of the insecticidal product VectoBac® http://www.bafu.admin.ch/biotechnologie/01760/01761/index.html?lang=de&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1acy4Zn4Z2qZpnO2Yuq2Z6gpJCEdIJ5gGym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.pdf

[27] Ordinance of 25 August 1999 on the contained use of organisms (Containment Ordinance, CO), SR 814.912, http://www.admin.ch/ch/d/sr/c814_912.html

[28] European Plant Protection Organisation http://www.eppo.org/

[29] IVI research project on classical swine fever: http://www.ivi.ch/research/projects/_content_/csf_en_en.html

safety level of a laboratory in terms of the environment. Since the virus is unable to cause disease in humans, work may be carried out inside the high-security wing under less stringent conditions. For such applications, the SECB issues Statements on the classification of the organisms and assesses whether protection of humans and the environment is assured. The question of whether the genetic modification will result in a higher risk is particularly important here.

HSV amplicon vector

This application was submitted to the SECB with the request that the classification be assessed. The applicants perform various activities with an amplicon vector system (see box). The amplicon vectors contain different genes and are inserted into cell cultures or directly into animals (cats and mice), where their function is investigated. The goal is to develop new gene therapeutic methods for which these amplicon vectors will be used. Similar vectors are already being used for clinical trials of gene therapy. The applicant wishes to work with the amplicon vector under the conditions of safety level 1, since it involves a safe vector.

In its Statement, the SECB differentiates various activities involving this amplicon vector. Fundamentally it approves classification into class 1. However, it states that the risk of an activity is principally dependent on the genes and gene sequences inserted into the vector. Therefore, in general, a case-by-case risk assessment and classification must be performed, whenever gene (sequence)s that we can assume constitute a greater risk (for example, oncogenes and cytokine sequences) are being used. Such activities are classified into class 2.

Box 3: HSV-1 amplicon vectors

This vector has been derived from a bacterial plasmid and in addition contains parts of a virus, Herpes Simplex Virus 1 (HSV-1). It is therefore referred to as HSV-1 amplicon vector. Vectors are used as gene ferries: they allow genes to be inserted in a targeted way into cell cultures or other organisms. The HSV-1 amplicon vector, however, also contains sequences of HSV-1 in addition to the genes to be transferred. These sequences are necessary for the reproduction and packaging of viruses. They ensure that the genes to be transferred reproduce and can be packed in HSV-1 envelope proteins into virions – individual virus particles. The amplicon vector itself is unable to reproduce.

4.2.2 Guidelines

The Containment Ordinance provides that if necessary, guidelines for the implementation of the Ordinance can be issued. Such guidelines put indefinite legal terms into concrete form and permit uniformity of practice.

Safe animal husbandry in contained systems in accordance with the CO

The objective of this Guideline is to concretise the safety requirements that must be adhered to when handling genetically modified or pathogenic organisms in animal facilities. The Guideline will primarily serve as an instrument for the federal authorities and the cantonal enforcement agencies, but is also aimed at new project leaders. The safety measures are listed separately for different animal groups (small mammals, large mammals, arthropods, other invertebrates, birds and aquatic animals), as well as by the safety level in question. They are categorised according to the possible escape routes from contained systems (air, waste, water, vectors). The SECB lays great weight on case-by-case risk assessment, and also underlines the significance of the Animal Protection Law. The Guideline has not yet been published.

Guideline on the use of a microbiological safety cabinet when handling human-pathogenic microorganisms

For activities involving human-pathogenic microorganisms there is a risk that aerosols will form and thus increase the risk of infection for laboratory personnel. This risk is minimised if such activities are performed in a microbiological safety cabinet. Microbiological safety cabinets possess a directional airflow and filters that hold back microorganisms. According to the equipment, biological safety cabinets of classes I, II and III[30] serve to protect people, the environment and products. This Guideline

[30] Information on biological safety cabinets can be found, for example, in *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) 5th Edition: http://www.cdc.gov/OD/ohs/biosfty/bmbl5/Appendix%20A_Greenbook%20for%20BMBL_Final.pdf

describes the type of activity and microorganisms for which a biological safety cabinet is necessary. The SECB considers this Guideline to have been compiled very carefully and thoroughly, and to provide significant help for practice.

Safety measures in human-medical microbiological diagnostics laboratories

Specific safety measures must be adhered to for the diagnostics of pathogenic microorganisms. Most of the microorganisms analysed demonstrate a low or moderate risk to humans and the environment. The risk is markedly influenced by whether pathogenic organisms have been enriched and whether they are transmissible aerogenically (through the air). The guideline specifies the safety measures that are necessary for such diagnostic activities, describes them for specific types of sample, and explains the conditions under which particular safety measures can be modified or omitted. The SECB particularly welcomes the advice of the different types of clinical sample, and is generally of the opinion that this document could be a valuable aid, particularly to the relevant authorities.

4.3 Gene therapy trials

Gene therapy is understood as the introduction of one or more foreign genes into cells of the human body (somatic gene therapy). Once in the body, these foreign genes are supposed to assume the function of defective genes. Somatic gene therapy is differentiated into *in vivo* and *ex vivo* gene therapies. In the latter, the therapeutic genes are transferred into cells or tissue *in vitro* – i.e. outside the human body – before they are introduced into the patient's body. Conversely, in *in vivo* gene therapies, the therapeutic genes are introduced directly into the patient's body using vectors. Such trials are regulated under the Ordinance on Clinical Trials of Therapeutic Products[31] and authorised by Swissmedic[32].

Treatment of primary cutaneous C-cell lymphoma: example of an in vivo gene therapy trial

Primary cutaneous C-cell lymphomas (CTCL) are a form of malignant skin lymphoma. CTCL is a rare, chronic disease, with a good prognosis for cure. The lymphomas mostly occur locally and are currently treated with radiotherapy or chemotherapy. A new approach, a gene-therapeutic treatment with interferon-γ (IFN-γ), will now be tested. Interferons are the body's own protein messengers, formed by cells of the immune system. Interferon-γ is already available as a medication and is used in various ways to treat tumours because it inhibits their growth. For this treatment the therapeutic IFN-γ gene, carried in a vector, is injected directly into the affected areas. This is a Phase II clinical trial that involves up to a hundred test subjects and tests the efficacy at increasing doses. Only a few subjects take part in Phase I trials; here the tolerability of the medicament is foremost.

The SECB issued a Statement on the biosafety of the therapeutic product for the test subjects as well as in terms of humans and the environment, in particular assessing the properties of the vector and data on the distribution of the vector in the body and its excretion. In its Statement the SECB recommended the application be approved, but requested that the test subjects be examined every quarter year and that the trial be continued as long-term monitoring.

Guideline on gene therapy

This guideline covers the possible risks to humans and the environment (although not to the test subjects themselves) in gene therapy trials. It is guide for applicants and describes the information necessary to determine the risks that might arise from gene therapy. It focuses on the risks from the possible excretion of the preparation from humans into the environment. This could result in the release of the vectors or plasmids used. The SECB gives particular attention to the ability of the gene-therapeutic organism to reproduce, and the possibility that it might reacquire the ability to replicate.

5. Training and conferences

The SECB considers continuing training as one of the most important prerequisites for the safe handling of pathogenic organisms. It has therefore repeatedly emphasised this point in its Statements to the licensing authorities. Concretely, it contributes by participating actively in biosafety training, and by highlighting the work of the SECB at conferences and events.

[31] Ordinance of 17 October 2001 on Clinical Trials of Therapeutic Products (VKlin), SR 812.214.2, http://www.admin.ch/ch/d/sr/c812_214_2.html

[32] Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/

5.1 Conferences for biosafety officers

As their title implies, biosafety officers have the task of monitoring biosafety in facilities that handle genetically modified or pathogenic organisms[33]. Different safety measures may be necessary, according to the type of facility and activity. The Containment Ordinance stipulates that basic and continuing training for biosafety officers must be provided. The Secretariat and Chair of the SECB are involved in running these courses.

5.1.1 Basic course for biosafety officers

This annual event is an introduction to the work of the biosafety officer[34]. It addresses various topics of risk assessment and provides information about inspections and on the tasks of the Federal Coordination Centre for Biotechnology. The SECB provides an overview of general and legal aspects of biosafety, comments on risk analysis, and treats specific topics such as the transport of genetically modified or pathogenic organisms.

5.1.2 Continuing education courses for biosafety officers

As a supplement to the basic courses, continuing education courses for biosafety officers were held in 2005 and 2006. These addressed a range of topics.

Technical biosafety measures: production facilities

This event was held at Berna Biotech Ltd. The SECB introduced the theme of the event and gave an overview of the risks that arise in large-scale work. Information was provided on the implementation of statutory requirements, as well as on the various technical possibilities and safety considerations in the construction of production facilities. The safety measures of Berna Biotech were also demonstrated and the facility viewed.

Risk assessments

Risk assessments are the starting point for a guarantee of biosafety. This event considered various risk assessments in depth. The SECB presented its Statement on "Risk assessment of activities with oncogenic and cytokine-encoding sequences"[35]. The risk assessment of work using attenuated strains, parasites, cell cultures and cell lines was also addressed.

Waste management in research and diagnostic laboratories

The course covers the disposal of waste from research and diagnostics (microorganisms, plants, animals, GMOs). Emphasis is placed both on the applicable laws and on the methods of waste treatment and disposal. The course is aimed at biosafety officers as well as other persons who work with biological agents. It is carried out by the Biosafety Institute b-safe, in collaboration with the Federal Office for the Environment (FOEN), the Federal Office of Public Health (FOPH) and the SECB[36]. The SECB provides information on its Statement on Waste disposal in medical microbiology diagnostic laboratories[37], which was updated in 2006.

5.2 Conference of European Biosafety Advisory Committees

In January 2006 in Amsterdam the Netherlands Commission on Genetic Modification (COGEM)[38] organised a first meeting of European biosafety advisory committees[39] concerned with the release of genetically modified organisms. The initiative for such a meeting came from COGEM and the SECB. One of its objectives was networking and the exchange of experience between the different European biosafety advisory committees. In addition, the role of the European Food Safety Authority (EFSA), selected research programmes in individual countries, and various scientific topics relating to the release of genetically modified organisms, were discussed. SECB considers that the exchange of experience with other committees is very important, as it has been found that very similar topics and problems are often being encountered.

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[33] See also the FOEN's Guidelines, *Biosafety Officers (BSO). Status, duties and responsibilities*: http://www.bafu.admin.ch/publikationen/index.html?lang=en&action=show_publ&id_thema=6&series=VU&nr_publ=4404

[34] Meeting programmes and presentations: http://www.bafu.admin.ch/biotechnologie/01744/02964/index.html?lang=en

[35] Risk assessment of activities with oncogenic and cytokine-encoding sequences: http://www.efbs.ch/imperia/md/content/efbs/stellungnahmen/1.pdf

[36] Biosafety Institute b-safe: http://www.b-safe.ch/?mid=1027&pid=1119&lang_id=1

[37] Statement of the SECB, Waste disposal in medical microbiology diagnostic laboratories: http://www.efbs.ch/imperia/md/content/efbs/stellungnahmen/2.pdf

[38] Netherlands Commission on Genetic Modification (COGEM): www.cogem.net

[39] 1st International Meeting of the European Biosafety Advisory Committees dealing with the deliberate release of GMOs

6. Annexes

6.1 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.

6.1.1 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.

6.1.2 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 discussion. During the period under review the SECB convened twelve times, on the following dates: 20 January 2005, 10 March 2005, 10 May 2005, 23 June 2005, 20 September 2005, 17 November 2005, 26 January 2006, 16 March 2006, 4 May 2006, 27 June 2006, 12 September 2006 and 7 December 2006.

6.1.3 Cooperation

The SECB works closely with national authorities and also exchanges information with the Swiss Ethics Committee for Non-Human Biotechnology [40]. In addition, the Secretariat liaises with other committees and public offices abroad that are active in related fields.

6.2 SECB members

6.2.1 Secretariat

The secretariat is responsible for providing organisational support and technical assistance to the Committee members. It prepares 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 Federal Office for the Environment (FOEN). 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 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 2001.

6.2.2 Chair

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 microbiology in Zurich and the USA. Subsequently, he worked in the pharmaceuticals department of Ciba-Geigy/Novartis for a number of years. He was responsible at Novartis for

[40] Swiss Ethics Committee on Non-human Gene Technology (ENCH): http://www.ekah.ch/buwal/eng/fachgebiete/fg_ekah/index.html

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 Chair of the SECB, following his two-year interim chairmanship of the Committee. Member since 1997.

6.2.3 Members

The current term of office began on 1. 1. 2004 and extends until 31. 12. 2007.

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 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 ammann 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 Ammann headed the division for Cryptogamics at the University of Berne. From 1996 to 2006 he was Director of the University of Berne Botanical Garden From October 2006 to October 2007 he is visiting professor at the Delft University of Technology (NL). 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 was 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 soil science. Following this, he lectured in France for many years in soil science before moving to the ETH Zurich's Institute of Plant Science to take up 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 on 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 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 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.

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 "Ärtzinnen und Ärzte für Umweltschutz"

(Physicians for the Environment), an organisation that promotes an ecological approach to medicine. Member since 2003.

Beatrice Lanzrein, Prof. Dr. phil. nat., *Insect and Development Physiologist*, studied zoology, chemistry/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 zoological 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 biological methods. 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 *Bacillus tuberculosis*, gaining practical experience in the field of biosafety. On his return to the University Hospital of Lausanne, he continued his research projects and increasingly gave his attention 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 transgenic plants, as well as further developments in sustainable agriculture. Since 2002 she has worked at the Research Institute for Organic Farming (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, after 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 the 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 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.

6.3 List of Statements

Consultations in 2005 and 2006: Summary of all SECB Statements

Consultations on the legislature	
Revision of the Release Ordinance	10/2005 04/2006
Coexistence Ordinance	06/2005 12/2005
Implementing legislation relating to the Transplantation Law	02/2006 08/2006
Consultations on permit applications	
Marketing	
Marketing of Vectobac	06/2005
Marketing of Proteqflu-Te	12/2006
Contained use of organisms	
A040513/3, O. Cazelles, Changins	04/2005
A050600/3, A050601/3, A050602/3, D. Trono, Lausanne	05/2005
A50570/3D, R. Peduzzi, Bellinzona	05/2005
A050560/3, R. Schmidt, Sion	05/2005
A050568/3, V. Piguet, Geneva	07/2005
A050619/3 M. Strubin, Geneva	09/2005
A050655/3, G. Greub, Lausanne	10/2005
A050656/3, J.-C. Piffaretti, Bellinzona	10/2005
A050660/3, F. Lefort, Jussy	11/2005
A050621/3, Ch. Schelp, Liebefeld	11/2005
A050673/3, G. Pluschke, Basel	12/2005
A050703/3, M. Aebi, Zurich	02/2006
A050003/3, A. Summerfield, Mittelhäusern	02/2006
A060642/3D, J. Schrenzel, Geneva	02/2006
A050703/3, M. Aebi, Zurich	02/2006
A050003/3, A. Summerfield, Mittelhäusern	02/2006
A050718/3, J. Luban, Bellinzona	03/2006
A050704/4D, L. Kaiser, Geneva	04/2006
A050691/3, J. Böni, Zurich	04/2006
A000554/1, C. Fraefel, Zurich	04/2006
A050704/4D, L. Kaiser, Geneva	04/2006
A050691/3, J. Böni, Zurich	04/2006
A050021/4, A. Summerfield, Mittelhäusern	05/2006
A060008/3, A. Summerfield, Mittelhäusern	05/2006
A060514/3D, G. Pfyffer, Lucerne	05/2006
A040011/3, Addendum, G. Vogel, Basel	05/2006
A060512/3 A060513/2 D. Moradpour, Lausanne	07/2006
A060005/3 A040191/3, Addendum R. Zahn, Schliern	07/2006

A060033/3, M. Fischer, Zurich	07/2006
A060558/2, J. Entenza, Lausanne	08/2006
A060563/3, L. Wick, Staad	09/2006
A050567/3, B. Duffy, Wädenswil	09/2006
A060060/3D, J.D. Tratschin, Mittelhäusern	10/2006
A030004/3D, Addendum, N. Schürch, Spiez	11/2006
A060061/3D, Th. Bodmer, Bern	11/2006
A060135/3, A. Summerfield, Mittelhäusern	12/2006
A060115/3, N. Ruggli, Mittelhäusern	12/2006
A060096/3, A. Summerfield, Mittelhäusern	12/2006
A060106/3, U. Karrer, Zurich	12/2006
A060642/3D, J. Schrenzel, Geneva	12/2006
A040069/3D, Addendum, M. Strasser, Spiez	12/2006
A050721/2, S. Schaerer, Changins	01/2007
A060121/3, A. Trkola, Zurich	01/2007
A060110/2, R. Zufferey, Lausanne	02/2007
Gene therapies	
Instructions for gene therapy / GMO environmental data Guideline in accordance with Art. 26, para. 2 VKlin	11/2006
2006GT2001: Phase II clinical trial of intra-lesional administration of TG1042 (adenovirus Interferon γ)	10/2006
Advice on practice and enforcement	
Environmental impact assessment Safety Laboratory Spiez	11/2005
Institute of Virology and Immunoprophylaxis: application for omitting HEPA filters	10/2005
Enquiry concerning diagnostics for group 4 organisms	02/2005
Transport of infectious biological agents: Statement on the information leaflet issued by the Amt für Abfall, Wasser, Energie und Luft Zurich	05/2006
Supplements to Environmental impact assessment, Safety Laboratory Spiez	08/2006
Guidelines for using a biological safety cabinet	07/2006
Safety measures in human medical microbiological diagnostic laboratories	07/2006
Safety requirements Documents for group 4 diagnostics, Statement for the FOPH	04/2006
Quantified risk analysis of biological risks	03/2006