www.efbs.admin.ch

Activity report

of the
Swiss Expert Committee for Biosafety

Term of office 2008–2011

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Swiss Expert Committee
for Biosafety SECB

Photo: www.aov.admin.ch

Imprint

Editor:
Swiss Expert Committee for Biosafety SECB
www.efbs.admin.ch

Editorial office:
Executive Office of the Swiss Expert Committee for Biosafety SECB
Isabel Hunger-Glaser und Julia Link
c/o Federal Office for the Environment
CH-3003 Bern
Tel.: +41 (0)31 323 03 55 / +41 (0)31 323 23 12
info@efbs.admin.ch

Design and printing:
Druckerei Ruch AG, Ittigen
www.ruchdruck.ch

MIX
Paper from responsible sources
FSC® C031954

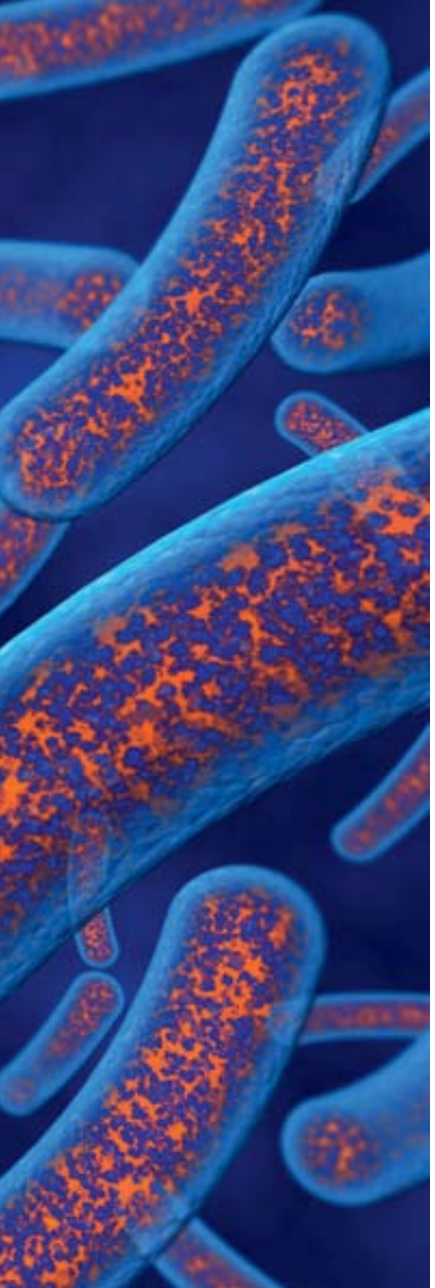
Contents

Consultations

Public relations and education

Annex

Introduction



The Swiss Expert Committee for Biosafety is an independent expert committee. Our field is biotechnology and gene technology and our concern is the protection of people and the environment.

Tasks

We advise the Federal Council in drawing up laws and ordinances, and the federal and cantonal authorities in implementing these regulations. We issue statements on licence applications and write recommendations for specialists working with genetically modified or pathogenic organisms. We carry out studies on current and complex topics of biosafety, and acquire reports from external experts. By concerning ourselves with and issuing statements on new findings, we shape the discourse between professional circles and the authorities, and are able to react in a timely manner if there is a need for action in the biosafety sector. By means of this report, our website, and various events, we inform the Federal Council, practitioners and the general public about our work.

Chair		
Members		
Gene technology	**Healthcare**	**Environment**
Universities		
Business		
Agriculture and forestry		
Environmetal organisations		
Consumer organisations		
Executive Office		

The committee members are appointed by the Federal Council, taking into account the gene technology, health and environment sectors as well as the various interests of protection and usage in the composition of the 16-member body.

Legal foundation

The legal basis for the SECB is furnished by Article 29g of the Federal Act on the Protection of the Environment (EPA)[1], Article 22 of the Gene Technology Act[2], and Article 29e of the Epidemics Act[3]. These acts establish the tasks of the Swiss Expert Committee for Biosafety. The SECB was established on 1 January 1997, at the same time as the entry into force of the Ordinance that governs it[4].

The biohazard warning symbol draws attention to hazards for humans and the environment originating in biological material. These are often pathogenic microorganisms that could cause diseases.

[1] Federal Act of 7 October 1983 on the Protection of the Environment (Environmental Protection Act, EPA), SR 814.01: http://www.admin.ch/ch/d/sr/c814_01.html (in German), not legally binding English translation: http://www.admin.ch/ch/e/rs/c814_01.html

[2] Federal Act 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.bafu.admin.ch/biotechnologie/02618/index.html?lang=en

[3] Federal Act of 18 December 1970 on Protection against Contagious Diseases in Humans (Epidemics Act), 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)

News

Photo: www.acw.admin.ch

SECB projects

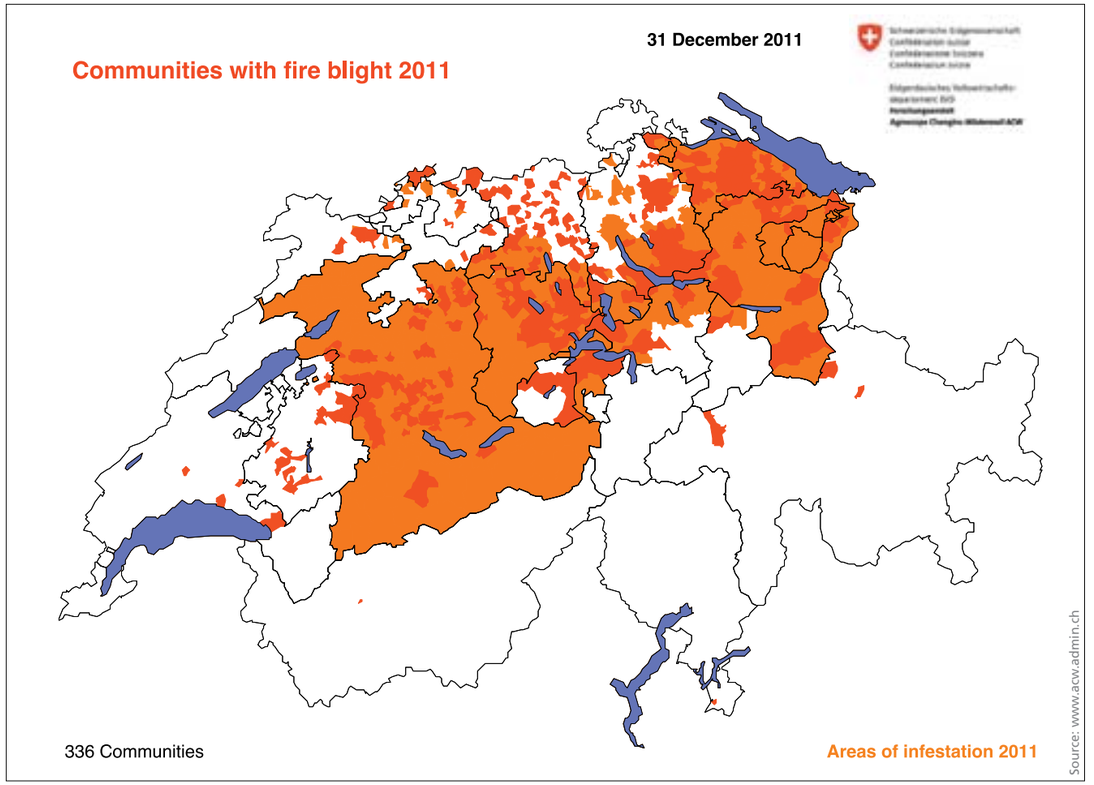
If we consider that a topic is urgent from the viewpoint of biosafety and there is a need for additional research or information, we launch our own projects and commission research. This enables us to acquire knowledge to support our advisory role. Thus, many of our projects have a direct or indirect connection with our other activities.

Programme to monitor the effects of streptomycin in combating fire blight

For some years fire blight has been an increasing problem for fruit farming. The disease is caused by the bacterium *Erwinia amylovora* and inflicts considerable damage on orchards. The most effective treatment of fire blight is currently the antibiotic streptomycin. Although alternative remedies are available, they are less effective.

In January 2008 the antibiotic streptomycin was first licensed in Switzerland for the treatment of fire blight in orchards. This exceptional licence was renewed for 2009, 2010 and 2011. Use of streptomycin is time-limited, and linked to various conditions.

Mindful of the potential spread of antibiotic resistance, we are cautious in our opinion of the use of streptomycin. We consider it important that further issues be considered, in addition to investigating the development of resistance to *E. amylovora*. We have therefore initiated a multidisciplinary monitoring project, in collaboration with various Federal Offices and research institutes as well as other experts. Its main objective is to acquire data that will permit an objective evaluation of the risks associated with the use of streptomycin. Preliminary results show that *E. amylovora* continues to be streptomycin-sensitive even after three years of the antibiotic's use in Swiss orchards. However, experiments with sheep kept on pastures treated with streptomycin have shown that the number of streptomycin-resistant indicator organisms is temporarely increasing. These results underline the necessity of monitoring, which should be continued for several more years.



Areas of infestation (orange) are those areas in which fire blight occurs despite repeated treatments, and total eradication no longer appears possible. The communes affected are marked red, 336 in the year 2011.

Use of *Bacillus thuringiensis* in the environment: detection method and long-term use

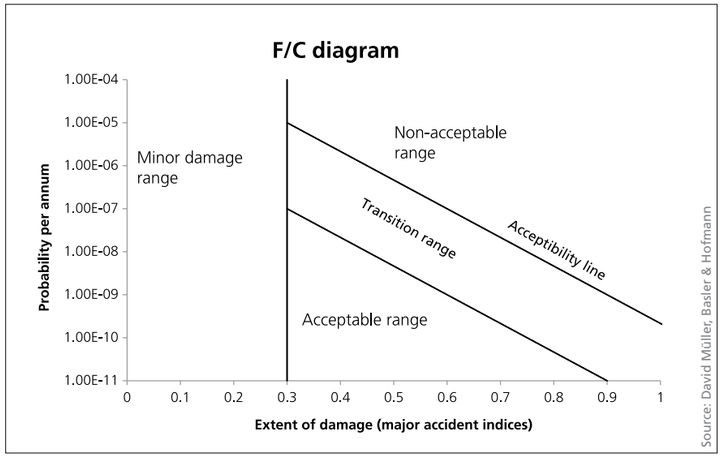
The *Bolle di Magadino (TI)* floods regularly. As a result, there are repeated explosions of the mosquito population *(Aedes vexans* and *Ochlerotatus sticticus).* Since 1988 the area has been experimentally treated with the bacterium *Bacillus thuringiensis israelensis* (Bti) to combat mosquitoes. In 2006 the Bti product VectoBac was approved. At the time we stated that the application of VectoBac should be accompanied by long-term

monitoring. In order to do this, however, a rapid detection method for Bti is needed[1]. As none yet existed, we have supported a project to develop such a method. The new method has been used to detect Bti in almost 100% of the samples tested[2]. The distribution of spores correlated primarily with the number of Bti treatments. There was no continuing accumulation of spores, nor were they transported by water to untreated areas. These results justify the longer-term use of VectoBac.

Mosquitoes can be a pest in the Bolle di Magadino. The populations are treated two to three times a year with the biocide VectoBac. This is a granulate product containing spores of the soil bacterium Bacillus thuringiensis israelensis. *Shortly after flooding in the Bolle di Magadino, VectoBac is spread on the flooded areas by helicopter.*

Biorisk register

The biorisk register was developed in collaboration with cantonal enforcement authorities, the Federal Office of Public Health and the SECB in order to quantify biological risks resulting from activities using genetically modified and pathogenic organisms in contained systems (see also page 34–36, Activities in contained systems). A similar register already exists for chemical risks. An analogous register for biological risks is intended to identify possible hazards to humans and the environment and compare them to other anthropogenic risks. Possible emission pathways out of the contained system were identified for three organisms, and the effects calculated. The final risk was presented in a diagram showing the probability of occurrence per year (frequency, F) and the extent of damage (consequence, C). Comparison with a F/C diagram for the example of an ammonia store shows that the greatest possible extent of damage to the affected population, and thus also the risk, is greater than the risk from the organisms investigated in the study. We conclude that although severe damage caused by incidents involving microorganisms is possible, the biological risks for the population and the environment remain within an acceptable limit and in fact tend to be lower than comparable chemical risks. Handling pathogenic organisms, in the SECB's opinion, primarily poses a risk to employees.



Whether the risk is acceptable or not is shown in what is called a frequency/consequence diagram. The calculation is based on the Assessment Criteria I of the Major Accidents Ordinance[3]. A damage index of 0.3 corresponds to 10 fatalities or 100 people injured, while a damage index of 0.1 corresponds to 2–3 fatalities or 20–30 people injured.

Methods to differentiate living and dead cells

Laboratories that work with microorganisms are obliged to disinfect their facilities regularly. Microbial contamination of working surfaces and equipment is tested for specific DNA by taking swab samples. It is important that these tests differentiate between DNA from live or dead organisms. The detection methods used to date generally require a cultivation phase. In the literature, a method using propidium monoacid

[1] A real-time PCR method to quantify spores carrying the *Bacillus thuringiensis* var. *israelensis* cry4Aa and cry4Ba genes in soil, Guidi et al., Journal of Applied Microbiology, Volume 109, Issue 4, p. 1209–1217, October 2010 http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2672.2010.04741.x/pdf

[2] Distribution of Bacillus thuringiensis subsp. israelensis in Soil of a Swiss Wetland Reserve after 22 Years of Mosquito Control, Guidi et al., Applied and Environmental Microbiology, June 2011, pp. 3663–3668

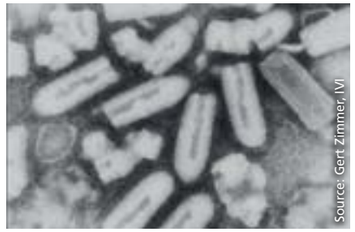
[3] Beurteilungskriterien I zur Störfallverordnung StFV, Richtlinien für Betriebe mit Stoffen, Erzeugnissen oder Sonderabfällen (SAEFL, 1996, in German) http://www.bafu.admin.ch/publikationen/publikation/00554/index.html?lang=de&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1acy4Zn4Z2qZpnO2Yuq2Z6gpJCGdn93f2ym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.pdf

Swab samples are taken at various sites in the laboratory and its surroundings, and tested for the presence of pathogenic organisms. Such investigations provide information about the safety measures taken, as well as the possible risk of contamination for staff.

(PMA), which can penetrate only dead cells, has been described. The Cantonal Laboratory of Basel-Stadt, funded by the SECB, has adapted this method to *Staphylococcus aureus* as a model organism. The research showed that unfortunately this method has only limited potential for determining the number of living *S. aureus* in swab samples. Even though the method did not function well with *S. aureus*, such research approaches are important *per se* because they contribute to improving safety for staff.

Investigation of the tenacity of viruses on different laboratory surfaces

Viruses can survive even under suboptimal conditions. Human pathogenic viruses, for example, can survive outside the human body. We describe this resilience as tenacity. We commissioned a project to analyse the tenacity of viruses on different laboratory surfaces and test the efficacy of various disinfectants. The investigations showed that, for example, the vesicular stomatitis virus (VSV) is highly stable in suspension at room temperature. Even dried on various surfaces, VSV remained infectious at room temperature for up to 48 hours. VSV also demonstrated remarkable resistance to extreme pH values, particularly alkaline ones. Upon heating, however, it was rapidly inactivated. This is important information for minimising the exposure of staff to highly pathogenic viruses.

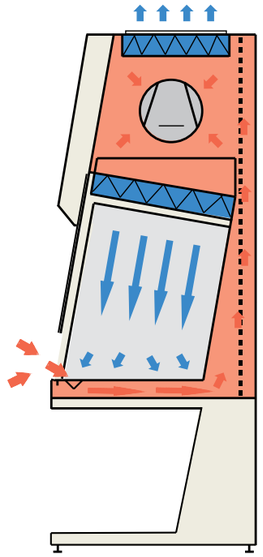


The vesicular stomatitis virus *causes vesicular stomatitis in ungulates. It is a mild viral disease that is quite similar to foot-and-mouth disease in cattle, and is a highly contagious, notifiable epizootic disease. In our study, VSV was used as a model organism.*

As for laboratories, there are different biosafety levels for greenhouses. Different safety measures are prescribed for each of these safety levels, corresponding to the type of activity and the associated risk to humans and the environment. Work using plant pathogens such as Erwinia amylovora, *which causes fire blight, requires at least level 2 safety measures.*

The contained use of plant-pathogenic organisms

Plant-pathogenic organisms are becoming increasingly significant in Switzerland. Examples of such organisms are the fire blight pathogen *(Erwinia amylovora) and Phytophtora ramorum,* which causes Sudden Oak Death. Specific recommendations for the contained use of plant-pathogenic organisms in Switzerland are thus needed, taking the international context into account as well. A study funded by the SECB compares the handling of plant-pathogenic organisms in different countries, looking at selected organisms in detail. It considers the classification of such organisms, organisational and technical safety measures, specific measures for diagnostics, research and transport, and authorisation / notification procedures and inspections. It also compares different organism lists: those of the Containment Ordinance (ContainO), the Plant Protection Ordinance (PlantPO), and the European and Mediterranean Plant Protection Organization (EPPO). We expect this project to provide help for all specialists who work with plant-pathogenic organisms. Selecting appropriate safety measures also protects humans and the environment.



The greater the risk associated with a pathogenic organism, the more stringent are the laboratory safety measures that must be taken to protect humans and the environment. But even highly specific, technical safety measures such as microbiological safety cabinets constitute real protection only if they are regularly serviced and tested.

Maintenance handbook for safety level 2 and 3 laboratories

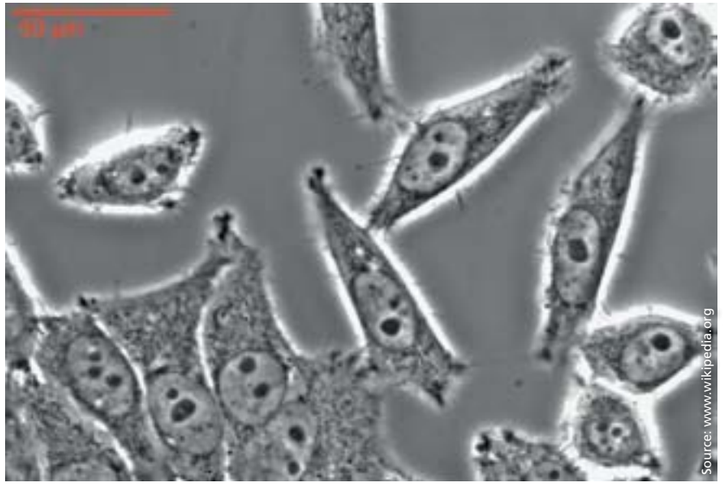
Activities using genetically modified and pathogenic organisms are generally carried out in contained systems. Depending on the species of organism, the laboratories must correspond to a particular safety level and fulfil different safety measures. Switzerland lacks uniform guidelines for the operation and maintenance of these laboratories. To close this gap we are therefore funding the preparation of a handbook for laboratories of biosafety levels 2 and 3 (BSL2 and BSL3 for human, animal and plant sectors). The maintenance handbook details the requirements for the safe operation of biosafety level 2 and 3 laboratories, including the servicing, maintenance and checking of safety-related components and technical systems.

SECB recommendations

If a situation changes, or upon request, we issue recommendations on safety in gene technology and biotechnology.

Safe handling of human and animal cells and cell cultures[4]

With this recommendation, we support users in the risk assessment of the handling of human and animal cells and cell cultures in contained systems. The greatest risk in the handling of cells is their ability to harbour and replicate pathogenic microorganisms unnoticed. Contamination with pathogenic micro-



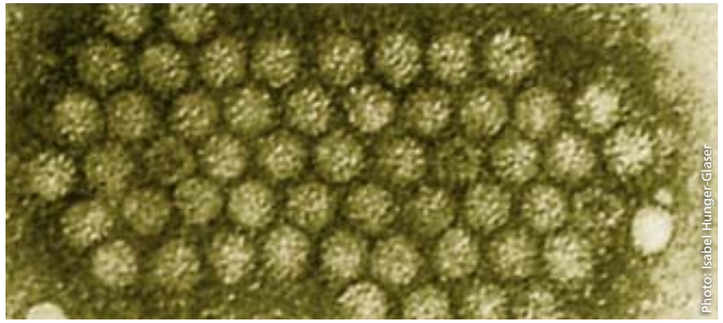
Cell cultures can be obtained from various parental organisms. The more closely a parental organism is related to humans, the greater the risk that the cell culture will be infected. Many established cell lines, such as the HeLa cell line shown in the picture, are commercially available from cell and tissue banks, and have been tested for the absence of selected pathogenic microorganisms.

[4] Recommendation of the SECB on the safe handling of human and animal cells and cell cultures, 2011
http://www.efbs.ch/en/documentation/empfehlungen/index.html

organisms or cross-contamination with other cells can happen quite easily while working. It is therefore not just the assessment of the original risk posed by the cells, but also safe handling to prevent contamination, that is decisive.

Classification of activities using the viruses HBV, HCV, HDV and HGV[5]

This recommendation can be used to classify activities using group 3** hepatitis viruses (HBV and HCV), as well as other hepatitis viruses (HDV and HGV). In it, we refer to the Ordinance on the Contained Use of Organisms and further international classifications. Activities using group 3** viruses are generally assigned to class 3. It has been shown in recent years that the risk of an infection when working with these viruses is very low. Depending on the risk assessment of an activity, it may be possible to work at a lower safety level. In our recommendation we take new findings into account and classify activities according to their risk.



The different hepatitis viruses pose varying threats to humans. While it is possible to be vaccinated against human hepatitis B virus, there is still no vaccine available for hepatitis C virus. Neither virus is usually transmissible via droplet infection.

Treatment and disposal of waste produced when handling genetically modified or pathogenic organisms in contained systems[6]

Where work is done, waste is produced. This includes laboratories, greenhouses, animal houses and production facilities. In this recommendation we tackle the various requirements for safe inactivation and disposal of wastes, so that neither humans nor the environment are at risk. We aim to simplify practical application, and harmonise enforcement. We combine the wastes into different groups and describe, for each waste group, the most suitable inactivation and disposal process according to the state of technology. This may be inactivation on site or incineration in a special waste disposal plant. The complex transport regulations are also taken into consideration.

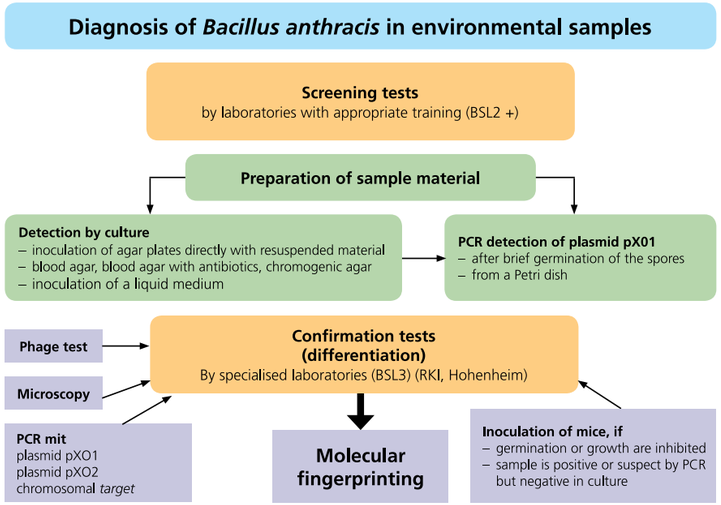
[5] Recommendation of the SECB on the classification of activities using the viruses HBV, HCV, HDV and HGV, 2011 http://www.efbs.ch/en/documentation/empfehlungen/index.html

[6] Recommendation of the SECB on the treatment and disposal of waste produced in contained systems, 2009 http://www.efbs.ch/en/documentation/empfehlungen/index.html

Biological wastes may be infectious. They are therefore collected in separate containers, which are labelled with the biohazard warning symbol. These containers must be sealable and are generally inactivated on site.
Some wastes such as needles, ampoules, pipettes, scalpel blades, empty glass tubes, slides, etc. may harbour a particular risk of injury. Such wastes are described as Sharps and must be collected and disposed of in special, tested waste containers.

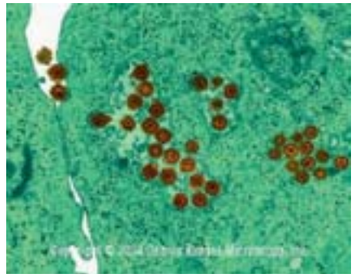
Work at sites that may be contaminated with anthrax

The new recommendation is intended for construction companies and other corporate bodies active at sites that may be contaminated with anthrax spores. These are primarily former tanneries and knackers' yards. Our recommendation contributes to harmonising procedures in Switzerland. The recommendation provides basic information about anthrax and on issues that must be clarified before construction can start, as well as on safety measures for workers.



Source: Wolfgang Beyer, Universität Hohenheim

The diagnosis of anthrax from environmental samples is complex and costly and involves various detection methods and if necessary animal experiments[7].



Various viruses can be used as viral vectors. They are modified to contain only a minimum of genetic information, and not to be infectious or be able to reproduce. However, they are able to take up particular alien genes, thus creating a recombinant viral vector. They depend on living cells for their propagation. Afterwards, recombinant viral vectors can be purified and used for a variety of research purposes.

Classification of work with genetically modified viral vectors[8]

Genetically modified viral vectors are very often used in medical-microbiological research laboratories. Different safety measures may need to be employed, depending on the type of genetic modification. Our recommendation uses concrete examples to address the classification of frequently used viral vectors, and of the risk assessment on which the classification is based.

[7] The complete diagram on diagnosing Bacillus anthracis spp. can be found in: Mikrobiologische Diagnostik, 2nd edition, 2009, ed. B. Neumeister, H. K. Geiss, R. W. Braun, P. Kimmig, pp. 386-397, ISBN: 978-3-13-743602-7

[8] Recommendation of the SECB on the classification of work with genetically modified viral vectors, 2009 http://www.efbs.ch/en/documentation/empfehlungen/index.html

Risk assessment of activities using oncogenic and cytokine-encoding sequences[9]

This recommendation is intended to support users in the risk assessment for the safe handling of cytokine- and oncogene-coding sequences in contained systems.

Transport of genetically modified and pathogenic organisms

On our homepage we offer a user-friendly transport guideline[10], which provides practical instructions for the transport, import and export of genetically modified and pathogenic organisms. It is based on the different national and international regulations, and gives a summary of sets of rules, which are very long and complex in the original. We follow ongoing developments in this area and are available to answer any questions from the relevant federal authorities, principally the Federal Roads Office and the Federal Office of Transport.

Sample material being shipped must be correctly packed. It is clearly in the interests of the sender to have the samples arrive undamaged. In addition, it is important for the safety of those who are responsible for transport. In the case of biological material, which may be infectious, three-fold packaging is required.

[9] Recommendation of the SECB on the risk assessment of activities using oncogenic and cytokine-encoding sequences http://www.efbs.ch/en/documentation/empfehlungen/index.html

[10] Further information about transport on our homepage: http://www.efbs.ch/index.php?id=146&L=3

National Research Projects (NRP)

NRP 59: Benefits and Risks of the Deliberate Release of Genetically Modified Plants

The NRP 59 examines the benefits and risks of genetically modified (GM) plants in the ecological, social, economic, legal and political conditions of Switzerland[11]. In recent years we have gathered information on the different research projects, particularly following the experiments carried out as part of the wheat-cluster.ch (see also Experimental releases of genetically modified organisms, p.37). We took special interest in issues of biosafety. From the SECB's point of view it is important for both benefits and risks to be given equal attention. In 2011 various Workshops were held, at which the results of the projects were presented and discussions held with researchers, the authorities and other stakeholders. The SECB's Executive Secretary, Isabel Hunger-Glaser, took part in these Workshops.

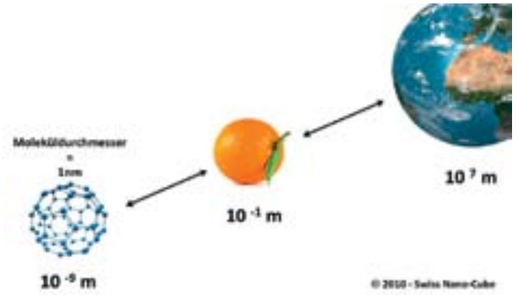
Fungal infestation is a problem in wheat. This is why research is being done into disease-resistant plants. The wheat field experiments are testing two different forms of resistance to mildew, one using specific resistance genes, the other via two general resistance genes from barley.

[11] Further information on the NRP 59 on the internet: http://www.nrp59.ch/e_index.cfm

The SECB visited both the release site at Reckenholz, shown here, and the experiment in Pully. The researchers explained to us the different experiments and showed us the safety measures.

NRP 64: Opportunities and Risks of Nanomaterials

The NRP 64 hopes to be able to bridge the gaps in our current knowledge on nanomaterials. Opportunities and risks for human health and the environment resulting from the manufacture, use and disposal of synthetic nanomaterials need to be better understood[12]. The NRP 64 consists of three modules: biomedical research, environmental research, and other fields (technically based). In all modules, the life cycle (production – use – disposal) of nanomaterials plays an important role, primarily for assessing their safety. Located at the interface between chemistry/physics and biology/medicine, the NRP 64 is a strongly interdisciplinary project. Only artificial nanomaterials are studied. Peter Gehr, President of the Steering Committee of NRP 64, presented various projects to us.

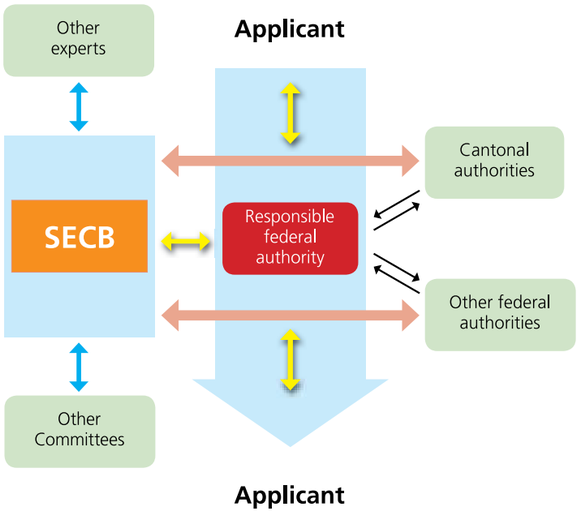


1 nanometre (nm) = 1 billionth of a metre (m) has the same relation to the diameter of an orange as the orange has to the diameter of the Earth. Nanomaterials develop new properties, which may be associated with new risks.

[12] This and further information on NRP 64 on the internet: http://www.nfp64.ch/D/Seiten/home.aspx

Consultations

One of our key tasks is to advise the Federal Council, Federal Offices, cantonal authorities and enforcement agencies on various issues of biosafety. Draft laws and ordinances, and licence applications for activities using genetically modified or pathogenic organisms, are submitted to us for our opinion. Depending on the area of responsibility and the topic, the procedure is described in various laws and ordinances.



Once an application has been submitted to the responsible authority, it is passed on to other Federal Offices and specialist agencies. One of these is the SECB. We generally discuss the application at one of the committee meetings, and then draw up our statement.

Legislation

As an extraparliamentary committee[1] we belong to the decentralised Federal Administration, and our opinion is sought on proposed amendments to legislation, at the latest as part of the office consultation procedure. We are sometimes included earlier in the procedure, so that the committee members' specialist knowledge can be taken into consideration at the drafting stage.

Ordinance on the Contained Use of Organisms

The Ordinance on the Contained Use of Organisms (ContainO)[2] is one of the most important Ordinances for our work. We receive a great number of notifications and licence applications every year (see also Activities in contained systems, p. 34, and Annex, p. 61–65) for our opinion. Many of our members are themselves also active in research and are therefore directly affected by this Ordinance.

The Ordinance on the Contained Use of Organisms is being revised and adapted to the provisions of the Gene Technology Act. Preliminary work started in 2007, and we have since issued statements several times on various drafts. Our concern is to ensure that activities using pathogenic and genetically modified organisms in laboratories, greenhouses, animal houses and production facilities are carried out safely, and that a high level of protection is guaranteed for both humans and the environment. At the same time we would like to minimise the administrative burden to the applicants as far as possible. It is our view that genetically modified organisms of group 1 pose an extremely low risk and we have therefore suggested to the Federal authorities that the notification procedure should be simplified. We would also like simplification of the handling of natural organisms of group 2. Such organisms are widely prevalent in nature. When they are used in contained systems, the protection of staff is paramount for us.

[1] General information on extraparliamentary committees
http://www.admin.ch/dokumentation/gesetz/ko/index.html?lang=de, in German
[2] Ordinance of 25 August 1999 on the Contained Use of Organisms (ContainO), SR 814.912
http://www.admin.ch/ch/d/sr/c814_912.html

Ordinance on Occupational Safety in Biotechnology

The Ordinance on Occupational Safety in Biotechnology OOSB[3] is to some extent a sister Ordinance to the ContainO. It regulates the same activities, but focuses on the protection of staff. Many of the necessary safety measures correspond to those of the ContainO. We accompanied the revision of the Ordinance from the outset, and lobbied for a simple and user-friendly notification and licence application procedure.

Amendment of the Gene Technology Act: extension of moratorium

Since 2005 there has been a moratorium in Switzerland on the commercial cultivation of genetically modified plants in Swiss agriculture, which was originally set at 5 years as a transitional provision in the Federal constitution.

In 2008 an amendment of the Gene Technology Act was submitted to us for an opinion; it provided for an extension of the moratorium by three years to 2013. The main reason given was that the National Research Project 59 on the Benefits and Risks of the Deliberate Release of Genetically Modified Plants (NRP 59) ought to have ended before the moratorium ran out – which was not the case in 2010 – so that the results could be included as scientific foundations for further decisions. We were and are of the opinion that the results of NRP 59 cannot be the sole determining factor for answering questions relevant to the moratorium. Hence an extension of the moratorium cannot be justified in terms of biosafety.

The Federal Council favoured an extension of the moratorium. The National Council and the Council of States followed this recommendation and their final vote approved the amendment of the Gene Technology Act[4].

Plant Protection Products Ordinance

In the Ordinance on the Placing on the Market of Plant Protection Products[5] (PlantPPO), we are primarily interested in the organism-specific provisions. Our statement on the Revision of the PlantPPO called attention to the fact that an Ordinance mostly concerned with chemical agents and products has only limited applicability to the regulation of organisms. Macroogranisms in particular were to be given greater weight in the Plant Protection Products Ordinance. Their use in plant protection raises numerous issues of biosafety. Alien invasive macroorganisms can cause particularly severe problems. The requirements for applications for plant protection products that contain macroorganisms should be formulated more explicitly. This is already the case for microorganisms.

[3] Ordinance of 25 August 1999 on Occupational Safety in Biotechnology (OOSB), SR 832.321 http://www.admin.ch/ch/d/sr/c832_321.html

[4] Further information on amendments to the Gene Technology Act on the Internet: http://www.parlament.ch/D/Suche/Seiten/legislaturrueckblick.aspx?rb_id=20090056

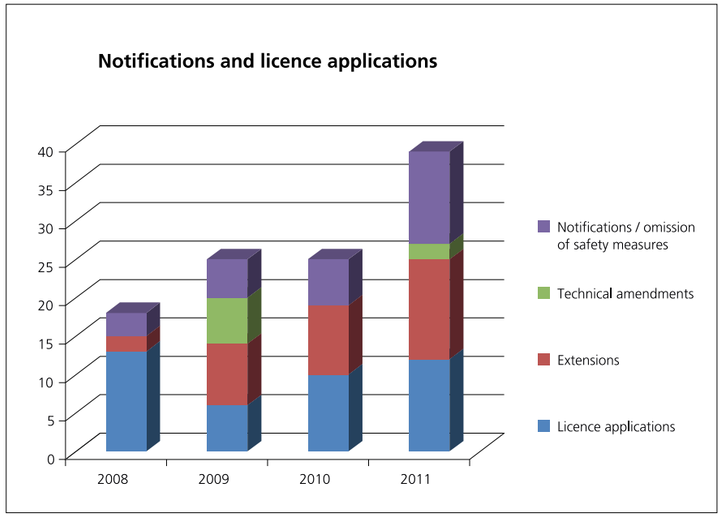
[5] Ordinance of 12 Mai 2010 on the Placing on the Market of Plant Protection Products (Plant Protection Products Ordinance, PlantPPO), SR 916.161 http://www.admin.ch/ch/d/sr/c916_161.html

Switzerland is not alone in Europe in having a moratorium on the cultivation of genetically modified plants. Eight European countries have currently issued prohibitions on cultivating genetically modified MON810 maize, which has been authorised in the EU since 1998 and has been repeatedly found to be safe by the European Food Safety Authority (EFSA). The countries refer to the safeguard clause of the EU release directive, and to new publications that provide foundations for the presumption that MON810 maize poses a hazard for humans and the environment. A majority of the SECB does not share this opinion.

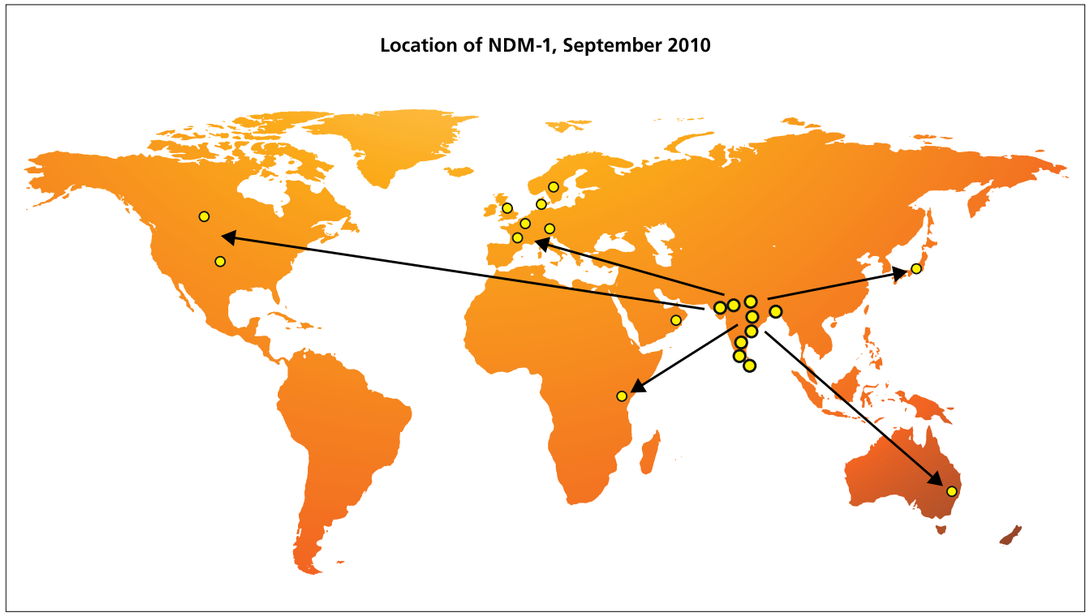
Activities in contained systems

Anyone who carries out activities using genetically modified or pathogenic organisms in contained systems is obliged to report this. The contact point for these notifications is the Federal Coordination Centre for Biotechnology. Activities that carry only a negligible or small risk must be notified; but activities carrying a moderate or high risk require authorisation. We give our opinion on all licence applications and on the notifications that make applications for particular safety measures to be omitted, or where the classification is unclear (see List of Statements page 61–65).

We often issue statements as examples on activities using particular organisms, as the the two examples illustrate:



The SECB primarily issues statements on class 3 and 4 licence applications, extensions of licences, and on substantive modifications. The applications discussed are increasing in number and make up a significant part of our work.



NDM-1 resistant bacteria were first identified in India and Pakistan. From there they spread, via patients from these countries, to England and other European countries and to North America, Japan, Africa and Australia. The map is based on data from T. Walsh (ICAAC 2010) and G. Cornaglia (Metallo-β-lactamases: a last frontier for β-lactams? *The Lancet infectious diseases, Volume 11, Issue 5, May 2011, pp. 381–393).*

Multiresistant bacteria / NDM-1

In 2010 there were several cases in India and Pakistan of patients infected with NDM-1 positive bacterial strains. NDM-1 stands for *New Delhi Metallo-beta-lactamase* and is an enzyme that makes bacteria resistant towards various beta-lactam antibiotics. Such antibiotics have commonly been used against bacteria that were already resistant to other antibiotics. We were asked to make a statement on the classification of activities using such bacterial strains and the necessary safety measures. Multiresistant bacteria pose a long-term problem for our healthcare system that must be taken seriously. In addition to NDM-1 positive *Klebsiella* and *E. coli* strains, increasing numbers of vancomycin-resistant *Staphylococcus aureus* and extremely resistant *Mycobacterium tuberculosis* strains have been observed. These strains are no longer confined to hospitals, but affect the public at large. In these situations their multiplication is therefore virtually uncontrolled. However, if such multiresistant bacteria are being researched in laboratories, no spread of antibiotic resistance should be expected if the usual safety measures are followed.

Cultivation of blood cells from sick patients

We received a query about the safety measures needed and the classification of activities using primary blood cells from hepatitis patients. The cells are cultivated and biochemically investigated. Two of our recommendations (Safe handling of human and animal cells and cell cultures / Classification of activities using HBV, HCV, HDV and HGV, see p. 21 and 22) address the classification of such activities, distinguishing between the kind of cells used and how they are handled. From the point of view of biosafety, there is a difference between multiplication of the cells alone, or deliberate multiplication of the microorganisms – in this case the hepatitis viruses – contained in a cell as well. If only the cells are being grown, the risk is small and correspondingly fewer safety measures need be observed. For cells that could contain hepatitis viruses, the risk for laboratory staff is no greater than for hospital staff who are in contact with hepatitis patients.

Experimental releases of genetically modified organisms

Despite the Swiss moratorium on cultivating genetically modified crops, which will last until 2013 (see p. 32), experimental releases of genetically modified plants may be carried out. Such field trials require a licence under the Release Ordinance. No new licence applications have been submitted in Switzerland since the revised Release Ordinance came into force in 2008. However, experimental releases of genetically modified wheat[6] continued; these had been applied for under the old Release Ordinance and approved by the Federal Office for the Environment in September 2007, and we had issued detailed statements on them.

Wheat field experiments

Various research groups at several Swiss universities and research institutes collaborate in the "wheat-cluster.ch"[7] and, under the umbrella of the NRP 59, have carried out field trials of genetically modified wheat and hybrid wheat x goatgrass plants. The field trials took place in 2008–2011 on the grounds of the research institutes Agroscope Reckenholz-Tänikon (ART) in Zurich-Affoltern and Agroscope Changins-Wädenswil in Pully. The trials investigated various questions of transgenic fungal resistance in wheat, effects on non-target organisms, and the general biosafety of the plants used.

Every year a report is drawn up and supplementary documents submitted for the following year's experiments. We were primarily concerned with whether the experimental biosafety continues to be ensured. We have approved the continuation of the trial each year by a majority of the committee.

We also visited both testing sites and were able to see the numerous safety measures that have been put in place both to protect the environment and also, to a large extent, to protect the experiment itself. We noted with concern the partial destruction of the

[6] Federal Office for the Environment licences for the applications B07001, B07002 and B07004 http://www.bafu.admin.ch/biotechnologie/01756/08902/index.html?lang=de

[7] You can find further information on the individual projects on the wheat-cluster.ch website http://www.konsortium-weizen.ch/, as well as at the NRP 59 http://www.nfp59.ch/d_index.cfm

One safety measure involves covering the wheat fields with bird nets. This protects the fields from voracious birds, as well as preventing the birds from carrying away genetically modified grains or plants.

field at the Reckenholz site in 2008 and the Pully site in 2009 and 2010. Even though not all committee members have unreservedly supported the experimental releases, it is our opinion that experimental releases are needed. They provide additional knowledge that cannot be obtained in contained systems. For Switzerland as a research location it is important to be able to carry out trials in our own country.

Experimental releases of invasive alien plants

Neophytes are alien plant species that have been introduced since 1500 and are now established in the wild[8]. We understand invasive alien neophytes to be plants from other continents or regions, which spread so rapidly in Switzerland that they adversely affect biodiversity or could endanger humans, animals and the environment. Handling particular invasive plants in the environment is prohibited in Switzerland. If an experimental release is still needed, special authorisation is required from the Federal Office for the Environment. We received three such special authorisations for our opinion.

It makes sense to carry out field trials of invasive plants. These trials improve our knowledge of the ecology of invasive plants and their potential for spreading. It is however important to adhere to safety measures such as the careful training of staff, to prevent any spread via pollen or subsequent treatment with herbicides. We particularly supported the application for a neophyte garden for training purposes. In this way, staff responsible for combating neophytes were able to receive targeted training.

[8] See the definition of the Swiss Commission for Wild Plant Conservation: http://www.cps-skew.ch/english/invasive_alien_plants/black_list_watch_list.html

Common Ragweed *(Ambrosia artemisiifolia)*

Giant Hogweed *(Heracleum mantegazzianum)*

Himalayan Balsam *(Impatiens glandulifera)*

Staghorn Sumac *(Rhus typhina)*

Garden Lupin *(Lupinus polyphyllus)*

Giant Goldenrod *(Solidago gigantea)*

Narrow-Leaved Ragwort *(Senecio inaequidens)*

Warty-Cabbage *(Bunias orientalis)*

Handling particular invasive neophytes in the environment, such as Common Ragweed (Ambrosia artemisiifolia), Giant Hogweed (Heracleum mantegazzianum), Himalayan Balsam (Impatiens glandulifera), Staghorn Sumac (Rhus typhina), Narrow-Leaved Ragwort (Senecio inaequidens) and Giant Goldenrod (Solidago gigantea), are prohibited under the Release Ordinance. Their handling in the environment, such as for research purposes, requires an exceptional licence. Other species are on the Black List because they are harmful to humans and the environment. Their presence and their spread must be prevented. There are also invasive neophytes that are already causing harm in neighbouring countries, and the spread of which in Switzerland must be monitored. They include the Garden Lupin (Lupinus polyphyllus) and Warty-Cabbage (Bunias orientalis). They are kept on a Watch List. We are primarily concerned with exceptional authorisations for invasive neophytes that are prohibited under the Release Ordinance.

Marketing of genetically modified and pathogenic organisms

Placing genetically modified and pathogenic organisms on the market requires a licence. Different authorisation procedures may apply, depending on the product, and a different regulatory body may be the lead authority when sending us the applications for our opinion.

Tolerances for traces of genetically modified organisms

In Switzerland, the possibility that foodstuffs may contain traces of genetically modified organisms that are authorised in other countries cannot be ruled out. The Ordinance on Genetically Modified Foodstuffs[9] therefore permits traces of genetically modified organisms that are unintentionally present in a foodstuff up to a proportion of 0.5 % per ingredient. The Federal Office of Public Health examines the food safety of such traces and we receive their report for our opinion. The three requests for tolerance submitted so far all concern genetically modified maize. We have no misgivings concerning food safety, and the majority opinion is that the tolerances sought for maize pose no threat to humans, animals or the environment. Some of our members have doubts about the tolerance limits for germinable material only. Some members consider it justifiable to trust European judgements, in particular those of the EFSA[10].

List of tolerated materials

Designation, identification marker	Limitations/conditions
NK603 maize MON-ØØ6Ø3-6	none
GA21 maize MON-ØØØ21-9	none
1507 maize DAS-Ø15Ø7-1	none

So far, traces of three genetically modified maize varieties have been licensed, and included in Annex 2 of the Ordinance on Genetically Modified Foodstuffs. The genetic modification of the three maize varieties makes them tolerant to the herbicide glyphosate. 1507 maize is also resistant to corn borer. In other countries these maize varieties are already authorised as foodstuffs. In Switzerland only unintentional traces are tolerated, provided they do not exceed the level of 0.5 %.

[9] FDHA Ordinance of 23 November 2005 on Genetically Modified Foodstuffs (GMFO), SR 817.022.51, http://www.admin.ch/ch/d/sr/c817_022_51.html, in German.

[10] European Food Safety Authority EFSA. http://www.efsa.europa.eu/. The EFSA receives requests for scientific evaluations from the European Commission, the European Parliament and EU member states.

The genetically modified soy variety 40-3-2 "Roundup Ready" (MON-Ø4Ø32-6) is fully licensed in Switzerland, as well as the maize varieties MON810 (MON-Ø81Ø-6), Bt176 (SYN-EV176-9) and Bt11 (SYN-BTØ11-1).

Marketing as animal feed

The Federal Office for Agriculture is responsible for the licensing of genetically modified animal feed. After giving approval for the tolerance of traces of 1507 maize in foodstuffs, we received an application for the authorisation of 1507 maize as animal feed. We approved this application by a majority as well, because the risk to humans and the environment is negligible. Two members did not vote in favour of authorisation because they consider various test procedures to be insufficient, in particular those concerning long-term effects, and felt that more recent studies give indications of non-negligible impacts from 1507 maize.

List of licensed genetically modified starting products and feed material

Description	Starting products and feed material	Date of approval
GTS soy (Monsanto)	all	20 December 1997
Bt 176 maize (Syngenta)	all	6 January 1998
Bt 11 maize (Syngenta)	all	14 October 1998
MON810 maize (Monsanto)	all	27 July 2000
all genetically modified organisms licensed in the EU	Maize gluten	
all genetically modified organisms licensed in the EU	Maize gluten feed	
all genetically modified organisms licensed in the EU	Corn cob meal	
all genetically modified organisms licensed in the EU	Soy extraction grist	
all genetically modified organisms licensed in the EU	Soy cakes	

Genetically modified animal feed must be licensed by the Federal Office for Agriculture. Licensed feedstuffs are included in the GMO Feed list 1 (Annex 1 of the FOAG Ordinance on GMO Feed Lists, SR 916.307.11). The licensing procedure for 1507 maize is still ongoing.

Plant protection products

Applications for plant protection products that contain organisms are submitted to us for our opinion by the Federal Office for Agriculture. The Plant Protection Products Ordinance[11, 12] is the primary authority for such applications. The applications are often submitted in accordance with the OECD guidelines[13]. In each case, the agent (e.g. a new organism) must first be approved and included in Annex 1 of the Plant Protection Products Ordinance, and then the product. We pay particular attention to those plant protection product applications in which new organisms are used. These are often microorganisms, but sometimes macroorganisms are used. We have issued statements on a total of twelve applications.

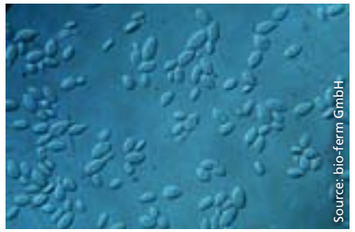
Where bacteria are included in Annex 1 of the Plant Protection Products Ordinance, it is important that only the specific strain is licensed, not the whole species. Both the mode of action and the specificity of individual strains may differ widely. A further important criterion is the origin of the strain and thus whether it is native or not. If the agent is already being used in other countries with a climate and geography similar to Switzerland, we base our evaluation on this experience and the results of existing studies. This applies to several plant protection products that we have evaluated (for a list, see Annex p. 65 and 66).

Madex Max is a plant protection product used to combat codling moth larvae (Cydia pomonella) *in fruit. The active ingredient in Madex Max is a codling moth granulovirus. These viruses are widespread throughout the world and have been used in Switzerland for some time. Because there is a danger that codling moths will become resistant to individual products, it is important to use new virus strains. The product has been shown to be effective and biologically safe. We approved the licensing of the product.*

[11] Ordinance of 12 May 2010 on the Placing on the Market of Plant Protection Products (Plant Protection Products Ordinance, PlantPPO) 916.161 http://www.admin.ch/ch/d/sr/c916_161.html, in German.

[12] The European Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market is often referred to (http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31991L0414&model=guichett), although it has now been repealed by the new Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market (http://eur-lex.europahttp://eur-lex.europa.eu/Notice.do?val=504604%3Acs&lang=en&list=504604%3Acs,&pos=1&page=1&nbl=1&pgs=10&hwords=).

[13] OECD Guidance for Industry Submissions for Microbial Pest Control Products and their Microbial Pest Control Agents http://www.oecd.org/dataoecd/60/6/30919600.pdf



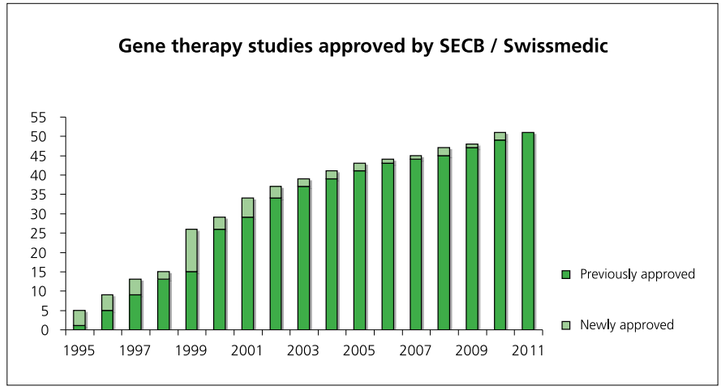
The plant protection product Blossom Protect contains the yeast-like fungus Aureobasidium pullulans. *Blossom Protect acts against fire blight and is used as an alternative to the antibiotic streptomycin for treating fire blight. We approved the licensing of Blossom Protect, but pointed out that monitoring in the environment would be desirable and the strains used should be characterised more precisely.*

We also issued Statements on two plant protection products containing macroorganisms, the parasitic hymenoptera species Eretmocerus mundus and Eretmocerus eremicus. *They parasitise the larvae of whiteflies and are used in the cultivation of vegetables and ornamental plants. Both organisms have been used in various European countries for several years. These macroorganisms pose no risk to humans or the environment. We approved the licensing of both plant protection products.*

Gene therapy trials

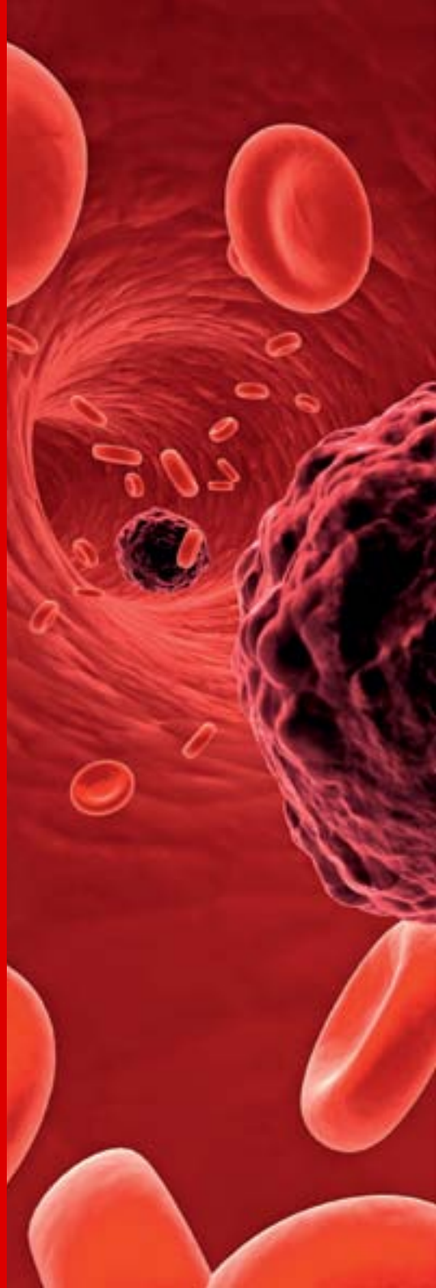
Gene therapy trials are evaluated by the Gene Therapy Working Group, which includes external experts in addition to the Chair and the Executive Secretary. The regulatory authority is Swissmedic, the Swiss agency for the authorisation and supervision of therapeutic products. We have issued statements on: a DNA vaccine against bird flu, a Phase I vaccine trial against HIV, a test of various vectors for their immunogenicity, a gene therapy study against "critical limb ischemia", and a study in which patients with metastatic melanoma were treated with Allovectin.

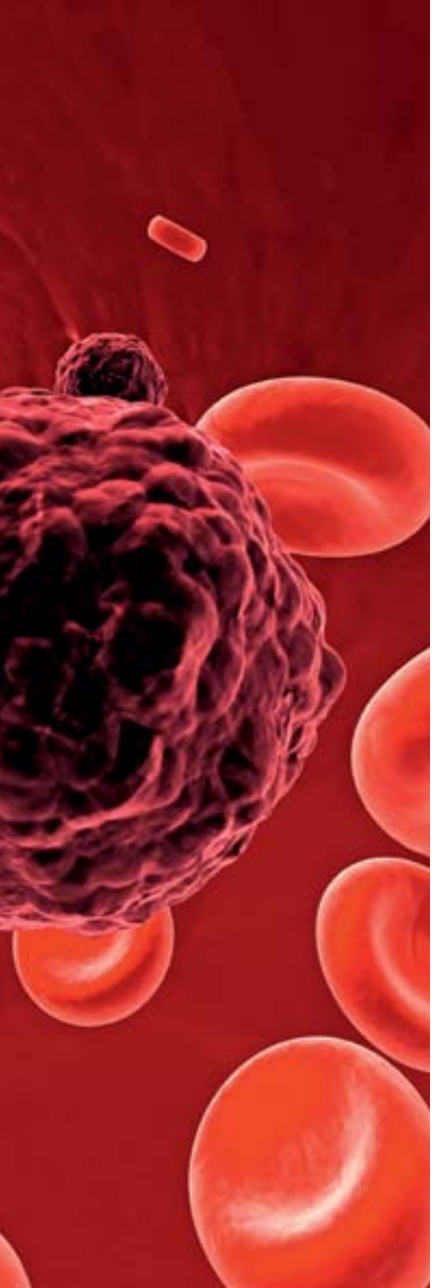
The diagram shows that the number of applications submitted for gene therapy studies is decreasing. This decline began when the Therapeutic Products Act came into force in 2002 and Swissmedic became active as regulatory authority, increasing the administrative effort required to make applications. Shortly afterwards the EU decided, in contrast to the USA, to demand the same safety requirements and administrative documents for Phase I as for more advanced Phase trials. Since then the effort for researchers has become so great that virtually no new gene therapy studies are submitted. Only very large companies can afford such studies.



Gene therapy trials have been carried out in Switzerland since 1995. The number of new applications is decreasing. The SECB evaluated such applications before Swissmedic became the official regulatory authority.

Public relations and education





Conferences

The organisation of and participation in conferences is a further SECB task, serving the exchange of knowledge in the biosafety sector.

SMS

The *Swiss Microbial Safety Meeting* SMS was first held in 2008 in Bellinzona as a Swiss conference on safety in handling microorganisms. The background to this meeting, which was organised by the *Istituto cantonale di microbiologia (TI),* the Swiss Society for Microbiology (SGM) and us, was the growing concern of a significant number of microbiologists with issues of biosafety. Exchange of information between researchers and biosafety specialists is therefore necessary, particularly for more junior scientists. The Meetings are held biennially, with alternating local organisers. The second SMS took place in 2010 in the Spiez Laboratory.

MEACB

There are national biosafety committees in various countries. On the co-initiative of the SECB, joint *Meetings of European Advisory Committees on Biosafety* (MEACB) have been held since 2006 at intervals of about a year. These events offer the members of European biosafety committees the opportunity to exchange experience and information, to discuss various aspects of biosafety, and to forge links. In 2011 we organised the fifth MEACB in Bern[1], covering the whole spectrum of topics including talks about handling pathogenic and genetically modified organisms in contained systems (including gene therapy) and in the field (including plant protection).

[1] Information and programme of 5th Joint Meeting of European Advisory Committees on Biosafety in the field of contained use and deliberate release of pathogenic and genetically modified organisms http://www.efbs.ch/de/dokumentation/veranstaltungen/meacb/meacb-2011/index.html

Photos: Isabel Hunger-Glaser

The MEACB 2011 was held on 23 and 24 may in the Burgerratssaal of the Kultur-Casino in Bern, and was attended by people from all regions of Europe, and even one visitor from Saudi Arabia. The Chair Pascal Meylan (picture right) and various SECB members (Patricia Ahl Goy in the picture) and the Executive Secretary moderated the five themed sessions.

EBSA

The European Biosafety Association (EBSA)[2] was founded in 1996 and has members from more than 24 European countries, as well as other regions worldwide. Its aims are to improve knowledge about biosafety and foster the exchange of experience between the various actors. The EBSA runs several Working Groups, responsible for example for communications, or the organisation of the annual conference. This is held in a different European country each year. The EBSA is headed by an eight-member Council, to which our Executive Secretary also belongs. Her involvement in the EBSA is central for the SECB's network and international cooperation with other European biosafety professionals.

[2] More information on the European Biosafety Association EBSA on their website http://www.ebsaweb.eu/

Internet presence and publications

On our website **www.efbs.admin.ch** we provide information about the members and our work. We make news announcements on the homepage. The website also carries publications about studies that we have initiated or supported. There is also a flyer giving a brief presentation about the SECB, which can be downloaded from the website or ordered from us in paper form.

This logo indicates documents from the SECB.

Training

One of the key factors in the safe handling of genetically modified and pathogenic organisms is the status of staff training. Although technical and organisational safety measures are important, biological risks are particularly minimised if staff know what they are working with, the specific risks of this work, and what they need to look out for, so that they protect themselves and others, and the environment. We therefore support a range of training courses.

Swiss Biosafety Network

The Swiss Biosafety Network[3] (SBNet) is an independent national organisation for biosafety officers in various positions. Founded in 2005 by a small group of biosafety officers, SBNet has been a legal association since 1 July 2010, with a growing number of members. The SBNet Annual meeting is devoted to a special, practical topic of biosafety, which changes each year, and therefore serves as a training course and the opportunity to exchange experience. Our Executive Secretary, herself a founder member of SBNet and as a former biosafety officer fully familiar with their duties, is a member of the SBNet committee and has a significant involvement in organising and running these events.

At the 2011 Annual Meeting of the Swiss Biosafety Network, *Sean Kaufmann from Emory University (Atlanta, USA) gave a lecture on "Advanced Training Concepts for Biological Risk Mitigation".*

[3] Further information on the Swiss Biosafety Network and its events: http://www.swissbiosafety.ch/

Photo: Felix Gmünder, Basler & Hofmann

The practical part of the training course is of great importance. Participants practise, for example, working in a biosafety cabinet, in complete BSL3 protective clothing.

Photo: Kathrin Summermatter, IVI

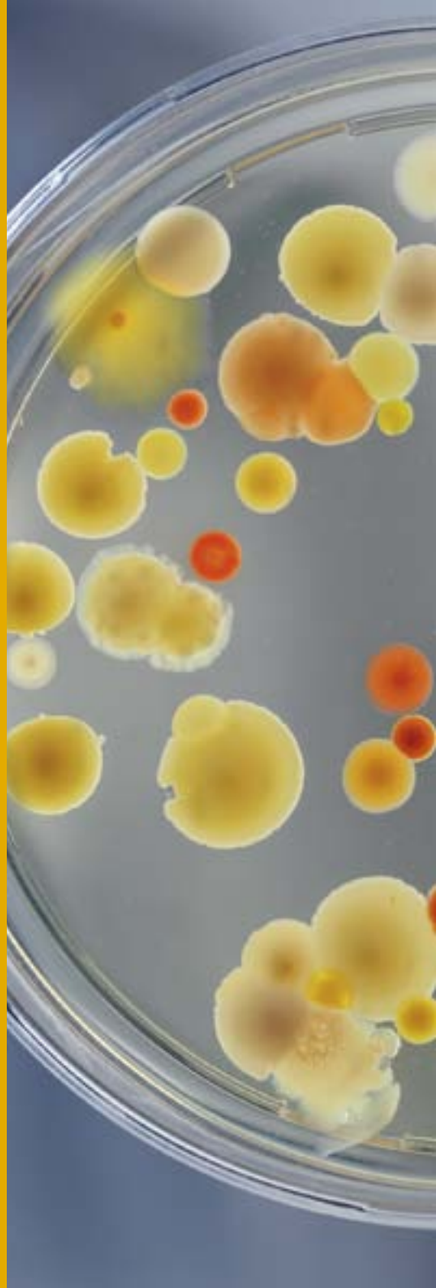
An emergency training in a BSL3 laboratory (BSL3 training course).

Biosafety Curriculum

Biosafety Officers have an important function in facilities that work with genetically modified and pathogenic organisms. The expectations of their specialised knowledge and expertise are high. At the same time they serve as the internal and external contacts for questions to do with biosafety. To meet all these requirements, a training programme, the "Biosafety Curriculum"[4], has been developed collaboratively by the Federal Office of Public Health, the Federal Office for the Environment, Suva, the SECB, ERFA Bio (Intercantonal experience exchange group of services involved in bio and gene technology) and the SBNet (Swiss Biosafety Network). This provides usually three training courses every year for safety levels 1, 2 and 3.

[4] Further information on the Biosafety Curriculum
http://www.bafu.admin.ch/biotechnologie/01744/02964/index.html?lang=de

Annex



Organisation and structure of SECB

The SECB is an independent expert committee. The Federal Council appoints the members in a personal capacity, taking into account their areas of expertise as well as balancing the gender and language make-up. We meet six to seven times a year. Depending on the business, we invite federal and cantonal authorities and specialists, for the exchange of information and discussions.

The committee and how it works

Our Committee is made up of 16 people who have specialist expertise in the areas of gene technology and biotechnology, environment and health, and who represent different user and conservation interests (universities, business, agriculture and forestry, environmental organisations, consumer organisation).

As needed, we can hear additional experts and invite them to our meetings. Issues that require more detailed review are dealt with in our Working Groups. To investigate special topics in depth we commission studies. Since the committee members come from different subject areas and represent different user and conservation interests (see Table, p. 10), our opinion is not always unanimous; we sometimes take a vote and record minority views.

Executive Office

The SECB Executive Office provides both technical and organisational support. It prepares meetings, drafts statements, and responds to most of the technical enquiries. The responsibilities of the Executive Office also include 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 Executive Office is administratively affiliated to the Federal Office for the Environment (FOEN). The Executive Secretary is Isabel Hunger-Glaser. She is supported by Julia Link, her scientific assistant and deputy.

Photo: Patricia Ahl Goy

The SECB members do not always share all standpoints, but the discussions are held in mutual respect of each other's points of view. It is important to us to give space to minority opinions. Good cooperation is encouraged by specific topical meetings in a different environment, here at the Alpine Research Station in Piora.

Photo: Felix Gmünder

The SECB meets about seven times a year for a day-long meeting. The Executive Office keeps the minutes of these meetings. The Committee often reaches decisions by consensus after detailed discussions.

Cooperation

We work closely with national and cantonal authorities and also exchange information with other extraparliamentary committees such as the Federal Commission for NBC Protection[1] and the Federal Ethics Committee on Non-Human Biotechnology[2]. The Executive Office also liaises with other committees and public offices abroad that are active in related fields, such as the German Central Committee on Biological Safety[3] and the Dutch Commission on Genetic Modification[4].

[1] Federal Commission for NBC Protection (ComNBC), http://www.bevoelkerungsschutz.admin.ch/internet/bs/de/home/themen/abcschutz/organisation/komabc.html

[2] Federal Ethics Committee on Non-Human Biotechnology (ECNH), www.ekah.admin.ch

[3] Central Committee on Biological Safety (ZKBS), http://www.bvl.bund.de/DE/06_Gentechnik/03_Antragsteller/06_Institutionen_fuer_biologische_Sicherheit/01_ZKBS/gentechnik_zkbs_node.html

[4] Netherlands Commission on Genetic Modification (COGEM), http://www.cogem.net/index.cfm/en/cogem/

Resignations of various members and new elections

The last SECB meeting in this term and this composition. The committee is saying goodbye to retiring members.

At the end of their term of office, we are saying goodbye to several members of the SECB. We thank Angelika Hilbeck, Philipp Hübner, Beatrice Lanzrein, Paul Mäder, Barbara Oppliger, Doris Rentsch and Peter Stamp warmly for their tireless work and their huge commitment to the SECB.

As of 1.1.2012 the Federal Council appointed the following new members to the Committee: Dirk Dobbelaere, Eric Dumermuth, Urs Klemm, Brigitte Mauch-Mani, Monika Maurhofer, Kathrin Mühlemann and Nicola Schoenenberger. We welcome the new members to the SECB and wish them great success and enjoyment in this important work.

Chair	
Pascal Meylan	Prof. associé, Dr. med. FMH, Clinical virologists Institut de Microbiologie, CHUV Lausanne

Members	
Patricia Ahl Goy	Dr. ès Sciences, Biologist Syngenta Crop Protection AG, Basel
Monika Engels	PD Dr. med. vet. FVH, Veterinarian and Virologist Institute of Virology, Vetsuisse Faculty Zurich
Joachim Frey	Prof. dr. ès. sc., Bacteriologist Institute of Veterinary Bacteriology, University of Bern
Felix Gmünder	Dr. sc. nat. ETHZ, Microbiologist and Riskologist Basler & Hofmann Singapore Pte Ltd, Singapore
Angelika Hilbeck	Dr. dipl. agr. biol., Ecologist Institute of Integrative Biology, ETH Zurich
Philipp Hübner	PD Dr. phil. II, Biochemist, Cantonal Chemist Cantonal Laboratories of Basel-Stadt
Andreas Lang	Dr. rer. nat., Biologist Department of Geosciences, University of Basel
Beatrice Lanzrein	Prof. Dr. phil. nat., Insect and Development Physiologist Institute of Cell Biology, University of Bern
Paul Mäder	Dr. phil. II, Dipl. Ing. agr. ETH, Agronomist Research Institute for Organic Farming (FiBL), Frick
Barbara Oppliger-Frischknecht	Dipl. ing. agr. ETH, Agronomist Swiss Consumer Forum
Doris Rentsch	Prof. Dr. sc. nat., Plant physiologist Institute of Plant Sciences, University of Bern
Daniel Rigling	Dr. phil II, Biologist Swiss Federal Institute for Forest, Snow and Landscape Research (WSL), Birmensdorf
Peter Stamp	Prof. Dr. sc. agr., Agronomist Institute of Plant Sciences, ETH Zurich
Mauro Tonolla	PD Dr. phil II, Microbiologist Istituto cantonale di microbiologia, Bellinzona
Jean François Viret † (2009)	Dr ès sc., Molecular biologist Research Department, Berna Biotech AG, Bern

Executive Office	
Executive Secretary: Isabel Hunger-Glaser	Dr. phil. nat., Microbiologist SECB c/o Federal Office for the Environment, Bern
Scientific assistant: Julia Link	lic. phil. nat., Biologist SECB c/o Federal Office for the Environment, Bern

List of Statements

Consultations on legislation

Name	Date
Statement on the amendment of the Plant Protection Product Ordinance (1st office consultation)	09/2011
Statement on the revision of the Ordinance on the Disposal of Animal By-Products (hearing)	11/2010
Statement on the revision of the Ordinance on the Contained Use of Organisms (Hearing)	10/2010
Statement on the revision of the Ordinance on Occupational Safety in Biotechnology (Hearing)	10/2010
Statement on the revision of the Ordinance on the Contained Use of Organisms (Draft, May 2010)	06/2010
Statement on the revision of the Ordinance on the Contained Use of Organisms (Office consultation)	04/2010
Statement on the revision of the Ordinance on Occupational Safety in Biotechnology (Office consultation)	04/2010
Statement on the revision of the Plant Protection Product Ordinance (Hearing)	12/2009
Statement on the revision of the Ordinance on the Contained Use of Organisms (preliminary consultation)	09/2009
Statement on the revision of the Ordinance on the Contained Use of Organisms	02/2009
Statement on revision of forms for notifications and applications under the ContainO	02/2009
Statement on an extension of the GMO moratorium (amendment of the Gene Technology Act)	10/2008
Statement on the Gene Therapy Guideline / GMO environmental data and the supplements on gene therapy products with antibiotic resistance	10/2008

Consultation on activities in contained systems

SECB Recommendations

Name	Date
Recommendation of the SECB on the risk assessment of activities using oncogenic and cytokine-encoding sequences	2011
Recommendation of the SECB on the safe handling of human and animal cells and cell cultures	2011
Recommendation of the SECB on the classification of activities using HBV, HCV, HDV and HGV	2011
Recommendation of the SECB on the classification of work with genetically modified viral vectors	2009
Recommendation of the SECB on the treatment and disposal of waste produced in contained systems	2009

Statements on notifications and licence applications for pathogenic and genetically modified organisms

2011

Licence applications

Name	Date
A110664, Thuer Barbara, Institute of Virology and Immunoprophylaxis	12/2011
A110654, Strasser Marc, Spiez Laboratory	11/2011
A110652, Ruggli Nicolas, Institute of Virology and Immunoprophylaxis	11/2011
A110598, Zimmer Gert, Institute of Virology and Immunoprophylaxis	09/2011
A110585, Kuntzen Thomas, University of Zurich, Institute of Virology	08/2011
A110546, Zimmer Gert, Institute of Virology and Immunoprophylaxis	07/2011
A110555, Summerfield Artur, Institute of Virology and Immunoprophylaxis	06/2011
A110542, Zimmer Gert, Institute of Virology and Immunoprophylaxis	06/2011
A110530, Schürch Nadia, Spiez Laboratory	05/2011
A110529, Strasser Marc, Spiez Laboratory	05/2011
A110523, Stertz Silke, University of Zurich	04/2011
A110502, Schürch Nadia, Spiez Laboratory	03/2011
A090046, Aguzzi Adriano, USZ, Institute of Neuropathology	02/2011

Extensions

Name	Date
A070078, Gottstein Bruno, University of Bern, Institute of Parasitology	11/2011
A060678, Negro Francesco, Université de Genève Centre Médical Universitaire (CMU)	11/2011
A070080, Dubuis Olivier, Viollier AG, Allschwil	11/2011
A060121, Trkola Alexandra, University of Zurich, Institute of Medical Virology	10/2011
A060135, Summerfield Artur, Institute of Virology and Immunoprophylaxis	10/2011
A060114, Pantaleo Giuseppe, CHUV Département de médecine	10/2011
A000205, Thuer Barbara, Institute of Virology and Immunoprophylaxis	08/2011
A060086-01, Wittenbrink Max, University of Zurich, Institute of Veterinary Bacteriology	07/2011
A060642, Schrenzel Jacques, Hôpital Universitaire Genève (HUG)	06/2011
A060061-02, Bodmer Thomas, University of Bern, Institute for Infectious Diseases	04/2011
A060512, Moradpour Darius, CHUV Département de médecine	04/2011
A050704, Kaiser Laurent, Hôpital Universitaire Genève (HUG)	03/2011
A000126, Frey Joachim, University of Bern, Institute of Veterinary Bacteriology	02/2011
A060563, Wick Lukas, Biosynth AG	02/2011
A060033, Günthard Huldrich, USZ, Division of Infectious Diseases and Hospital Epidemiology	02/2011

Technical amendments

Name	Date
A081018, Auwerx Johan, EPFL, Institut interfacultaire de Bioingénierie	12/2011
A070532, Shimshek Derya, Novartis Pharma AG, Basel	12/2011
A050681, Foti Michelangelo, Université de Genève, Centre Médical Universitaire CMU	11/2011
A070500, Heim Markus, University of Basel, Institute of Medical Microbiology	09/2011

Notification / omission of safety measures

A110105, Thorens Bernard, University of Lausanne, CIG – Center for Integrative Genomics Centre	12/2011
A110097, Czekalski Nadine, Swiss Federal Institute of Aquatic Science and Technology EAWAG	11/2011
A100339, Patocchi Andrea, Agroscope Changins-Wädenswil	11/2011
A030107, Petersen Carl, Ecole Polytechnique Fédérale de Lausanne (EPFL), School of Life Sciences	09/2011
A110082, Kuhn Roger, Zurich University of Applied Sciences, Wädenswil	09/2011
A110515, Aebischer Patrick, EPFL, School of Life Sciences	07/2011
A070041, Speck Roberto, USZ, Division of Infectious Diseases and Hospital Epidemiology	06/2011
A060034, Schneggenburger Ralph, EPFL, Brain Mind Institute	05/2011
A110029, Makia Ntoh Divine, Institute for Biopharmaceutical Research Inc. (IBR AG)	03/2011
A100471, Hoerstrup Simon P., USZ, Division of Surgical Research, Cardiovascular Research	03/2011
A090556, Hagen Alexander, Prionatis AG, Alpnach Dorf	02/2011
A100889, Kretzschmar Titus, Delenex Therapeutics AG, Schlieren	02/2011
A100428, Costa Nuno, Uni/ETH, Zurich	02/2011

2010

Licence applications

Name	Date
A100423, Pieters Jan, University of Basel Biozentrum / Pharmazentrum	10/2010
A100846, De Matteo Walter, Istituto Biochimico SA, Lamone	09/2010
A100818, Salmon Patrick, Université de Genève, Centre Médical Universitaire	06/2010
A100337, Hangartner Lars, University of Zurich, Institute of Laboratory Animal Science	06/2010
A100357, Hangartner Lars, University of Zurich, Institute of Laboratory Animal Science	06/2010
A100811, Hächler Herbert, University of Zurich, Institute for Food Safety and Hygiene	05/2010
A100312, McCullough Kenneth, Institute of Virology and Immunoprophylaxis	03/2010
A100319, Gagneux Sebastien, Swiss Tropical and Public Health Institute, Medical Parasitology / Infection Biology	03/2010
A100290, Dehio Christoph, Swiss Tropical and Public Health Institute, Medical Parasitology / Infection Biology	02/2010
A100285, Heikenwälder Mathias, USZ, Institute of Neuropathology	01/2010

Extensions

A060514, Pfyffer Gaby, Kantonsspital Luzern, Institut für med. Mikrobiologie	11/2010
A050703, Aebi Markus, ETH Zurich, Institute of Microbiology	11/2010
A050619, Strubin Michel, Université de Genève, Centre Médical Universitaire (CMU)	06/2010
A050602, Trono Didier, EPFL, Integrative Bioscience Institute LVG – Laboratory of virology and genetics, Lausanne	04/2010
A050601, Trono Didier, EPFL, Integrative Bioscience Institute LVG – Laboratory of virology and genetics, Lausanne	04/2010
A050600, Trono Didier, EPFL, Integrative Bioscience Institute LVG – Laboratory of virology and genetics, Lausanne	04/2010
A990006, Gottstein Bruno, University of Bern, Institute of Parasitology	02/2010
A050568, Piguet Vincent, Université de Genève, Centre Médical Universitaire (CMU), Geneva	02/2010
A050570, Petrini Orlando, Istituto Cantonale di Microbiologia, Bellinzona	02/2010

Notifications / omission of safety measures

Name	Date
A060064, Arni Stephan, USZ, Division of Thoracic Surgery	12/2010
A100889, Kretzschmar Titus, Delenex Therapeutics AG	12/2010
A100834, Leitgeb Claudio, USZ, Sicherheit und Umwelt	08/2010
A100392, Zamboni Nicola, ETH Zurich, Institute of Molecular Systems Biology	07/2010
A100355, Kaiser Stefan, Harlan Laboratories Ltd.	06/2010
A100331, Colombi Jolanda, Spital Rheinfelden	03/2010

2009

Licence applications

Name	Date
A090240, Zimmer Gert, Institute of Virology and Immunoprophylaxis	11/2009
A090233, Ruggli Nicolas, Institute of Virology and Immunoprophylaxis	11/2009
A090116, Russmann Eberhard, Roche Diagnostics AG	08/2009
A090115, Russmann Eberhard, Roche Diagnostics AG	08/2009
A090067, Hofmann Martin A., Institute of Virology and Immunoprophylaxis	05/2009
A080138, Pieters Jean, University of Basel, Institute of Medical Microbiology	01/2009

Extensions

Name	Date
A020206, Bruckner Lukas, Institute of Virology and Immunoprophylaxis	04/2009
A000221, Siegrist Hans H., Institut Neuchâtelois de Microbiologie	03/2009
A040010, Aguzzi Adriano, USZ, Institute of Neuropathology	02/2009
A040014, Zbinden Reinhard, University of Zurich, Institute of Medical Microbiology	01/2009
A040015, Sander Peter, University of Zurich, Institute of Medical Microbiology	01/2009
A040003, Böttger Eric C., University of Zurich, Institute of Medical Microbiology	01/2009
A030085, Joergens Sven, Crucell, Berna Biotech AG	01/2009
A081041, Bagutti Claudia, Kantonales Laboratorium BS	01/2009

Technical amendments

Name	Date
A040024, Moser Markus, Prionics AG	10/2009
A000070, Frei Reno, University Hospital Basel, Mikrobiologielabor	08/2009
A080146, Luban Jeremy, Université de Genève, Centre Médical Universitaire	08/2009
A050003, Summerfield Artur, Institute of Virology and Immunoprophylaxis	08/2009
A020132, Butot Sophie, Nestlé Suisse SA Centre de Recherche Nestlé	08/2009
A030085, Joergens Sven, Crucell, Berna Biotech AG	01/2009

Notifications / omission of safety measures

Name	Date
A090026, Burgdorf Knut, Lonza AG Walliser Werke	11/2009
A050678, Fussenegger Martin, ETH Zurich, Department of Biosystems Science and Engineering	11/2009
A090117, Soltermann Alex, USZ, Institute of Surgical Pathology	07/2009
A081059, Baader, Manuel, BioFocus DPI AG	03/2009
A10088, Cornelis Guy R., University of Basel Biozentrum / Pharmazentrum	02/2009

2008

Licence applications

Name	Date
A081010, Telenti Amalio, CHUV – Département de médecine de laboratoire – Institut de Microbiologie	11/2008
A030162, Zurbriggen Andreas, University of Bern, Institute of Animal Neurology	10/2008
A080181, Manz Markus, Institute for Research in Biomedicine, Bellinzona	10/2008
A080173, Bürki Kurt, University of Zurich, Institute of Laboratory Animal Science	09/2008
A080146, Luban Jeremy, Université de Genève, Centre Médical Universitaire (CMU)	08/2008
A080138, Pieters Jean, University of Basel, Institute of Medical Microbiology	08/2008
A080072, Oxenius Annette, ETHZ, Department of Biology, Institute of Microbiology	05/2008
A080057, Gerlach Jörn Tilman, USZ, Division of Gastroenterology and Hepatology	04/2008
A080056, Pluschke Gerd, Swiss Tropical and Public Health Institute, Basel	04/2008
A070042, Rigling Daniel, Swiss Federal Institute for Forest, Snow and Landscape Research (WSL), Landscape Department	04/2008
A050718, Luban Jeremy, Institute for Research in Biomedicine, Bellinzona	04/2008
A070271, Bille Jacques, CHUV – Département de médecine de laboratoire – Institut de Microbiologie	02/2008
A080012, Hölzle Ludwig E., University of Zurich, Institute of Veterinary Bacteriology	02/2008

Extensions

Name	Date
A040069, Strasser Marc, Spiez Laboratory	11/2008
A030187, Klimkait Thomas, University of Basel, Institute of Medical Microbiology	11/2008

Notifications /omission of safety measures

Name	Date
A080210, Moelling Karin, University of Zurich, Institute of Medical Virology	11/2008
A060615, Frey Brigitte, University of Bern, Department of Nephrology and Hypertension DURN, DKF	11/2008
A020034, Karrer Hans-Peter, Bildungszentrum Gesundheit Basel-Stadt	03/2008

Consultation on experimental releases of genetically modified organisms

Name	Date
Wheat field trials B07001, B07002, B07004	
Statement on the supplements 2010	01/2010
Statement on the supplements 2009	01/2009
Statement on complaint against experimental release in Pully 2008	05/2008
Statement on additional documentation requested 2008	01/2008

Consultation on experimental releases of invasive organisms

Name	Date
Neophyte garden Schwarzenburg	07/2011
CABI application Senecio	03/2011
ETH application Senecio	03/2010

Consultation on marketing of genetically modified organisms

Name	Date
Statement on marketing 1507 maize as animal feed	08/2011
Statement on tolerance of traces of 1507 maize	02/2011
Statement on tolerance of traces of GA21 maize	08/2010
Statement on tolerance of traces of NK603 maize	11/2008

Consultation on plant protection products

Name	Date
Statement on XenTari P8007	12/2011
Statement on Carpovirusine Evo 2 P8181	11/2011
Statement on Madex Twin P8167	11/2011
Statement on Madex Top P8174	11/2011
Statement on Proradix P7917	11/2010
Statement on Helicovex P7932	09/2010
Statement on Eretline e P 7930	03/2010

Statement on Eretline m P7931	03/2010
Statement on Madex Max P7934	01/2010
Statement on Blossom Protect II P7676	12/2008
Statement on Blossom Protect I	01/2008
Statement on codling moth granulovirus Cydia pomonella	12/2008

Consultation on gene therapy

Name	Date
Statement of the SECB on Study 2010GT1002: Essai clinique de Phase Ib randomise en double aveugle visant a evaluer l'effet de la competition antigenique sur l'immunogenicite de VIH-1 Gag/Pol: Comparaison de 2 vaccins contre le VIH, rAd5 gag/pol Env A/B/c et rAdS gag/pol	07/2010
Statement of the SECB on Study 2010GT2001: Restropective Safety Survey in patients included in Phase I-II NV1FGF Clinical Trials	05/2010
Statement of the SECB on Study 2009GT3003: Phase I, open-label, dose escalation study to evaluate the safety, tolerability and immunogenicity in healthy adults of a DNA plasmid vaccine for H5 avian influenza (VGX-3400) administered by intramuscular injection followed by electroporation	02/2010
Statement of the SECB on Study 2009GT1001: A phase Ib trial to evaluate the safety and immunogenicity of heterologous primeboost vaccine regimes (NYVAC-B I rAd5 vs. rAD5 I NYVAC-B) in healthy, HIV-I uninfected, Ad5 seronegative adult participants	05/2009
Statement of the SECB on Study 2007GT3003: A randomized double-blind placebo-controlled group study of efficacy and safety of 4 administrations of XRP0038/NV1FGF 4 mg at 2-weeks intervals on amputation or any death in critical limb ischemia patients with skin lesions	02/2008
Statement of the SECB on 2007GT3002: A Phase 3 Clinical Trial to evaluate the safety and efficacy of the treatment with 2 mg intralesional Allovectin-7 compared to Dacarbazine or Temozolomide in subjects with recurrent metastatic melanoma	01/2008