Annual Report

of the Federal Expert Committee for Biosafety

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Editor:
Federal Expert Committee for Biosafety FECB
c/o Federal Office for the Environment FOEN
CH-3003 Berne
www.efbs.admin.ch

Edited by:
Federal Expert Commission for Biosafety
Julia Link and Karoline Dorsch
CH-3003 Berne
Phone: +41 (0)31 323 23 12
info@efbs.admin.ch

Printing:
WEBER BENTELI AG
Industrie Bernstrasse Nord
Bernstrasse 10
CH-2555 Brügg (Biel)
Telefon 032 374 36 36

Contents

1. INTRODUCTION

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

1.1 Tasks

The FECB is an independent expert committee. It 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 regarding biosafety matters. If required, 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 relevant events. As the FECB monitors new findings and trends in biosafety, it is in a position to help shape current developments at an early stage. It submits regular reports to the Federal Council on its activities.

1.2 Legal foundation

The legal basis for the FECB 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 Federal Act on Epidemics[3]. These acts establish the tasks of the Federal Expert Committee for Biosafety. The FECB was established on 1 January 1997, at the same time as the entry into force of the Ordinance[4] that governs it.

2. NEWS

2.1 Green gene technology

National Research Programme 59

In late 2006, the Federal Council approved CHF 10 million for the National Research Programme 59 (NRP 59), following the popular vote in favour of a moratorium on the commercial cultivation of genetically modified plants. The NRP 59 will investigate the ecological, legal, social and political benefits and risks of cultivating genetically modified plants. One important question is whether and how the cultivation of genetically modified plants can be reconciled with the objectives of Swiss agricultural and environmental policy[5]. The FECB has supported this programme from its inception, and contributed ideas and comments. The FECB Secretariat is represented in the NRP 59 Steering Committee. The 29 selected projects began in June 2007.

Within the framework of the NRP 59, nine project leaders have joined to form the so-called wheatcluster.ch[6]. Their projects are all based on field trials of genetically modified wheat *(Triticum aestivum)* with an increased resistance to powdery mildew. Six of these projects are primarily concerned with aspects of biosafety. For example, the effective probability of gene flow to wild plants will be investigated, since although it has been established that gene flow to related plants is possible, it has not been established how often this occurs. Further projects investigate whether and how fungal resistance in wheat harms beneficial organisms, and whether the transgenic wheat can be shown to have an indirect effect on insects within the same food network. The field trial projects themselves are discussed in more detail in Chapter 3.1.

2.2 Contained use of organisms

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

On 12 November 2007 the foundation stone was laid in Spiez for the Safety Laboratory[7] of the Federal Department of Defence, Civil Protection and Sport. Highly pathogenic organisms can be handled in the Safety Laboratory, thereby ensuring the protection of both the military and civilian population from biological threats and hazards. The main tasks are diagnosis of human pathogens, analysis of unknown (environmental) samples, training of military biological specialists and civilian laboratory personnel, and the development of new test methods and research projects in medical bioprotection. The laboratory will start operations in 2011. As the first highsecurity laboratory in Switzerland for level 4 human-pathogenic organisms, the Safety Laboratory in Spiez will close a gap in biosafety. If highly pathogenic organisms can be diagnosed in Switzerland, dependency on foreign laboratories will cease, and the risk of accidents during transport will also be minimised. The Institute of Virology and Immunoprophylaxis in Mittelhäusern near Bern, which handles level 4 animal pathogens, has been in existence for some time.

In 2005, the FECB issued a Statement as part of the environmental impact assessment[8] for the Safety Laboratory, focusing particularly on issues of biosafety, and concluded that the Laboratory does not present a risk to people or the environment.

Outbreak of foot and mouth disease

Around Pirbright (UK)[9] foot and mouth disease broke out on several farms within little over a month (August / September 2007). 600 animals had to be slaughtered. The foot and mouth virus has a high survivability in the wild, is highly infectious, and causes major economic damage, since entire stocks must be slaughtered if there is an outbreak. Europe is normally free of foot and mouth disease, but it is endemic in parts of Asia, Africa and Latin America.

Extensive investigations of biosafety were carried out in collaboration with international experts. Switzerland was represented by Christian Griot and Kathrin Summermatter from the Institute of Virology and Immunoprophylaxis (IVI) in Mittelhäusern. The results have been published [10,11].

[1] Federal Act of 7 October 1983 on the Protection of the Environment (Environmental Protection Act, EPA): 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)

[5] A detailed description of the projects can be found at www.NRP59.ch

[6] wheat-cluster.ch: http://www.konsortium-weizen.ch

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

[8] Environmental impact assessment http://www.FOEN.admin.ch/uvp/index.html?lang=de
Ordinance of 19 October 1988 on the Environmental Impact Assessment (EIAO): http://www.admin.ch/ch/d/sr/c814_011.html (in German)

[9] Pirbright is the location of the national and international Reference Laboratory for Foot and Mouth Disease Virus (FMDV) of the (IAH); and also of Merial, a company that produces vaccines against FMDV and tuberculosis.

[10] Independent Review of the safety of UK facilities handling foot-and-mouthdisease virus http://www.defra.gov.uk/footandmouth/investigations/pdf/spratt_final.pdf

[11] Further information: http://www.defra.gov.uk/animalh/diseases/fmd/investigations/

The investigations showed that the sick animals near Pirbright had contracted a strain of foot and mouth that has existed only in laboratories since 1967, at the Institute for Animal Health and in the laboratories of the company Merial, which suggested that the virus had escaped from the high-security laboratories.

The investigation particularly looked at the condition of the facilities as well as possible escape routes for the virus (air, water, waste, humans, mechanical means, and terrorism). It was concluded that the wastewater system, used jointly by both facilities, was the most likely cause of the escape of the virus, as technical faults were detected there. The report makes various recommendations for improving biosafety. These include measures such as improving the wastewater system, the complete deactivation of wastewater, and better communication and a clear division of responsibility between the two facilities. There were also medium-term recommendations, such as better monitoring of visitors and suppliers, more competencies for the biosafety officer, and the provision of sufficient financial resources.

The knowledge gained from the experience of this serious incident by the FECB can flow into its Statements, particularly if they concern highly pathogenic organisms that may pose a risk to humans, animals and the environment.

Transport of hazardous biological material

In 2006 the FECB commissioned a project to draw up information leaflets on the transport of various types of biological material. These information leaflets were to take international and Swiss regulations into account, and they were to be broadly based, both legally and technically. The main objective, however, was to present the regulations in a clear and understandable way, so that researchers and other users had no problem in applying them. The transport of biological material represents a serious potential hazard if it is not carried out properly. This project was sufficiently advanced in 2007 that the interested parties (federal and cantonal agencies) could be consulted. The idea, conception and result of the project received much positive feedback both in Switzerland and abroad. After the desired modifications have been made, the document will be downloadable from the FECB website in 2008.

2.3 Changes at the FECB

New FECB Secretariat

At the end of March 2007, the Committee said goodbye to its Executive Secretary of many years, Karoline Dorsch-Häsler, on her retirement. The virologist and molecular biologist took up her post in 1992, within the FECB's predecessor Committee, the SKBS (Swiss Interdisciplinary Committee for Biological Safety). Her great professional and personal commitment ensured continuity and the smooth transition from a Committee of the Swiss Academies with an interest in biosafety to an extraparliamentary Committee. Her many years of work for the biosafety committees have also had a significant impact on biosafety in Switzerland, and contributed to the perception of the FECB as an independent committee in whose judgement the authorities have confidence.

At the beginning of October 2007, Isabel Hunger-Glaser took up her position as Executive Secretary of the FECB. She is a cell and molecular biologist with experience both in academic research and in industry, two fields that are very important in her new work. Julia Link, biologist and scientific assistant of the FECB since 2001, now becomes Assistant Secretary.

Until Isabel Hunger-Glaser took up her post, Julia Link ensured, with great skill and engagement, that the FECB was able to continue its work unhindered, and that its Statements were submitted professionally and punctually.

Election of Committee Members

The 1996 Ordinance on Committees[12] stipulates that members of extraparliamentary commissions must be re-elected after a 4-year term of office, to serve a maximum of 12 years. Seven members resigned at the end of 2007: the Chair, Martin Küenzi, and members Daniel Ammann, Klaus Ammann, Emmanuel Frossard, Roman Kuonen, Bernadette Oehen and Didier Trono. Most of them had served on the Committee since its inception in 1997. The Chair, Martin Küenzi, can look back on a long and interesting time in the service of biosafety, since becoming a member in 1986 of the then newly founded SKBS. In 2002, during a politically difficult time, he took over the Chair *ad interim*, until being officially elected Chairman. He has chaired the Committee with aplomb and great commitment.

The Federal Council has now appointed seven new members of the FECB for the 2008-2011 term, and has confirmed the members who stood for re-election. Care was taken to ensure a balanced composition of the Committee (see 5.1.1). The following are newly elected:

• Ahl Goy Patricia, Dr. ès. sc., biologist, Syngenta Crop Protection AG, Basel

• Engels Monika, Prof. Dr. med. vet., veterinarian / virologist, Institute of Virology, Vetsuisse-Faculty Zurich

• Lang Andreas, Dr. phil. II, Department of Geosciences, University of Basel, Basel

• Mäder Paul, Dr. phil. II, Dipl. Ing. agr. ETH, FiBL (Research Institute of Organic Agriculture), Frick

• Rigling Daniel, Dr. phil. II, biologist, Federal Institute for Forest, Snow and Landscape Research, Birmensdorf

• Stamp Peter, Prof. Dr. sc. agr., agronomist, Agronomy and Plant Breeding, Institute of Plant Science, ETH Zurich, Zurich

• Tonolla Mauro, PD Dr. phil. II, microbiologist, Institute of Microbiology, Bellinzona

The FECB's new Chair is the previous Vice-Chair, Pascal Meylan, physician and clinical virologist.

At the final meeting and dinner in the year under report, the FOEN thanked the Chair, the other retiring members and the Executive Secretary for their important work in the cause of biosafety.

3. CONSULTATIONS

3.1 The Release Ordinance[13]

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

[12] Ordinance on Extraparliamentary Commissions, Governing Bodies and Federal Representatives: http://www.admin.ch/ch/d/sr/1/172.31.de.pdf (in German)
[13] Ordinance of 25 August 1999 on the Handling of Organisms in the Environment (Release Ordinance, RO), SR 814.911: http://www.admin.ch/ch/d/sr/c814_911.html in German, an English version will shortly be available online under http://www.admin.ch/ch/e/rs/8.html)

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.

Release of genetically modified wheat strains and hybrids between these wheat strains and jointed goatgrass (applications B07001, B07002 and B07004[14])

Aim of the trials:

Within the framework of the NRP 59, field trials of genetically modified wheat will take place in 2008–2010 on sites at the research institutes Agroscope Reckenholz-Tänikon (ART) in Zurich-Affoltern and Agroscope Changins-Wädenswil (ACW) in the Commune of Pully. This project of the wheatcluster.ch[15] takes an interdisciplinary approach. It investigates various aspects of the benefits and risks of fungal resistance in wheat, and questions about the biology of plant resistance. Three different types of experiments are planned (macroplots, microplots and reproduction) using about 20 different strains, of which nine have been genetically modified. In addition, there will be demonstration plots, where for safety reasons genetically modified varieties will not be used. Experiments in biosafety and the observance of safety measures are given a high value.

In the application B07001, the barley genes for chitinase and glucanase are inserted into the wheat genome. They are quantitative resistance genes with a very broad spectrum of action but do not give complete resistance. They act against all organisms which have chitin and β-(1,3)-glucane in their cell walls. Wheat also naturally contains genes that code for chitinase and glucanase. The project will specifically investigate the fungal resistance of genetically modified wheat in the field, and how effective it is against fungal diseases. The study will also clarify various aspects of biosafety.

In the application B07002, various genetically modified strains of wheat will be produced, each of which expresses one of the seven Pm3 alleles from wheat. The Pm3 gene occurs naturally in wheat in seven variations (alleles) and confers resistance to the mildew pathogen *Blumeria graminis* f. sp. *tritici*. The project will investigate whether the individual strains really do have an improved resistance to mildew. It will also analyse the effect of the additional gene on the plant's performance (e.g. its yield), and study the influence of the resistance behaviour on the environment. In addition it will investigate biosafety aspects, such as the impact on non-target organisms.

In connection with the possible risks of genetically modified crops, a recurring question is possible outcrossing to other crops or related wildtypes. One of the few possible crossing-out partners of wheat is jointed goatgrass *(Aegilops cylindrica)*. Application B7004 aims to produce hybrids of jointed goatgrass and the different genetically modified wheat strains used in applications B07001 and B07002, in the greenhouse and in the field. The project intends to clarify whether and how the transgenes spread, and whether they can be detected over several generations in the genome of *Aegilops cylindrica*.

The FECB drew on external experts in the discussion of these projects. They were two German specialists with experience in the assessment of genetically modified wheat, and an additional expert from organic agriculture. The FECB addressed the safety aspects, especially the safety of the introduced genes and regulatory elements, the gene products (including looking at possible toxicity or allergenicity of these products), and various effects of the genetically modified plants on the environment (effects on and interaction with non-target organisms, pollen flight, persistence of genetically modified plants in the environment, etc.). The safety measures proposed by the applicants were included in the risk assessment.

The majority of the committee members concluded that the experiments could be carried out, but with various additional conditions. For example, crops within a radius of 200 m may not be used as seed, and random samples should be taken from this area and investigated for the presence of transgenes. After harvesting, ploughing should be carried out, and the fields should be monitored for volunteers in subsequent years. The FECB also asked for additional information to be submitted.

A minority of the members expressed opposition to carrying out the trials. Their reasons included the argument that some of the planned investigations into biosafety could equally well be performed in a greenhouse, and that this therefore did not adhere to the step-by-step procedure required by Art. 6 of the Gene Technology Act[16]. This stipulates that the desired information should be obtained through experiments in contained systems if possible. Furthermore, they argued that the allergenic, toxic and immunogenic properties of the genetically modified plants had not been adequately characterised.

The Federal Office for the Environment conditionally approved the applications on 4 September 2007[17]. After receipt of the additional demands and the issue of a new decree on 6 February 2008[18] the wheat was sown on 30 April 2008 at the Reckenholz site. Appeals are pending for the Pully site.

Control of fire blight with streptomycin

Fire blight is caused by the bacterium *Erwinia amylovora*. The disease spreads very easily and causes severe damage to fruit trees and other rosaceous plants such as hawthorn, mountain ash, *cotoneaster* and pyracantha. Fire blight first occurred in Switzerland in 1989 and has been an increasing problem for fruitgrowers, causing damage worth millions of francs (in 2007, CHF 35 to 40 million). The main regions affected are in eastern and central Switzerland. The year 2007 was marked by an extremely severe strike[19], which can be attributed to the warm, humid weather during the blossoming period.

[14] http://www.FOEN.admin.ch/biotechnologie/01756/01757/index.html?lang=de (in German)
[15] For a more detailed description of the projects, see http://www.konsortium-weizen.ch
[16] 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
[17] FOEN decrees of 3.9.2007 on the applications
B07001 http://www.news-service.admin.ch/NSBSubscriber/message/attachments/9449.pdf,
B07002 http://www.news-service.admin.ch/NSBSubscriber/message/attachments/9451.pdf and
B07004 http://www.news-service.admin.ch/NSBSubscriber/message/attachments/9452.pdf
[18] FOEN decrees of 6.2.2008 on the applications
B07001 http://www.news-service.admin.ch/NSBSubscriber/message/attachments/10991.pdf,
B07002 http://www.news-service.admin.ch/NSBSubscriber/message/attachments/10992.pdf and
B07004 http://www.news-service.admin.ch/NSBSubscriber/message/attachments/10993.pdf
[19] Outbreak in Switzerland 2007 http://www.info-acw.ch/prognosen/ fire blight/befch_de.htm

There are only a few available means for fighting fire blight, and none of them is sufficiently effective to eradicate the disease completely. Streptomycin, an antibiotic that belongs to the family of aminoglycosides, has proved itself – at an average efficacy of 80% – to be the most successful means of fighting fire blight, and is used over large areas in various countries, notably the USA and Israel. The use of streptomycin is not permitted in the European Union. Special permission has been given, with strict conditions, for the experimental use of streptomycin in Germany, Holland and Greece. Use is also planned in Austria.

At several meetings, the FECB discussed the use of streptomycin to combat fire blight, and also commissioned an expert report[20]. The committee looked primarily at the possibility that using streptomycin could lead to a further spread of resistance to antibiotics. Behind this is the fear that low concentrations of streptomycin enters the soil and there exerts a continuous selection pressure on soil microorganisms. It is problematic, above all, that transposable DNA elements as plasmids, integrons and transposons often contain resistance genes against several antibiotics. Thus, bacterial strains could be created with increased frequency that contain genes conferring resistance to antibiotics used in human and veterinary medicine. The possibility that *E. amylovora* develops resistance to streptomycin may however be minimised, since its use takes place within a limited time and place – thus there is no continuous selection pressure.

A majority of the FECB membership opposed using streptomycin, primarily because not enough data were available to be able to evaluate the risk of its use. Any further spread of antibiotic resistance genes is undesirable. Efforts are underway in human and veterinary medicine to stem the overuse/abuse of antibiotics. Preventive treatment of livestock is prohibited. This stance should lead the way for the rest of agriculture to follow. The efficiency of streptomycin (80%) is too low to eradicate fire blight. In addition there are various alternative treatments (such as antagonistic bacteria, alumina preparations and growth regulators with an efficacy of up to 70%), which should be pursued further.

A minority of FECB members was in favour of using streptomycin. For one thing, streptomycin now has negligible significance in human medicine; for another, the quantity of streptomycin proposed would make up only approximately 0.6% of the total of antibiotics consumed. Streptomycin is excreted by streptomycetes (soil bacteria), and thus is already present in the soil, where it is presumably degraded. A timelimited, experimental approval of streptomycin could also be used to acquire new information, and targeted supporting research could answer open questions. This research should focus on the magnitude of streptomycin's contribution to the spread of antibiotic resistance. During the period of use of streptomycin, alternative methods should also be researched. It would be very important that the authorisation be limited in terms of time and place, and be linked to strict conditions.

In late January 2008 the Federal Office of Agriculture approved a time- and place-limited use of streptomycin, under strict conditions[21]. A concept is currently being drawn up for monitoring the development of antibiotic resistance on the plots of land treated.

Approval of plant protection products

Plant protection products are agents and preparations intended for: a. protecting plants and plant products from harmful organisms or their effects; b. affecting the life processes of plants in a way other than a nutrient, such as a phytoregulator; c. conserving plant products; d. destroying undesirable plants; e. influencing undesirable plant growth (Art. 3, Ordinance on Plant Protection Products, PSMV[22]).

The licensing authority for plant protection products is the Federal Office of Agriculture. The FECB is asked for its opinion on applications for marketing plant protection products, if these products consist of or contain organisms. These include genetically modified organisms, as well as pathogenic microorganisms and macroorganisms.

In the FECB's view, non-genetically modified organisms – so-called natural organisms – must also be evaluated. Good regulation is important, since although organisms used as plant protection products are often microorganisms that occur in Switzerland, the strains used may have been isolated in other countries or on other continents, and these organisms must not harm the environment. Such plant protection products are often used for biological pest control. It is therefore important, on the one hand, that these products be tested and be safe, but on the other, that the barrier not be placed so high that biological pest control is no longer possible.

Two plant protection products which the FECB approved are described below as examples.

Agree WP

The plant protection product Agree WP from Andermatt Biocontrol contains the bacterium *Bacillus thuringiensis aizawai* as an active ingredient, and is effective against many insect pests. These bacteria produce a protein similar to the one inserted into genetically modified maize to make it resistant to the corn borer. Agree WP is intended to be used against various caterpillars in different crops (fruit, berries, vegetables, viticulture, horticulture, forestry). The FECB studied the file and determined that numerous studies of the mode of action of Agree WP had been carried out, particularly of the impact on non-target organisms and possible environmental impacts. The committee has no concerns in terms of biosafety.

Blossom Protect

A further application is for the use of a new agent against fire blight (approved in Austria since 2005). It is a product based on a fungus similar to yeast *(Aureobasidium pullulans)*, which is intended to protect the plants against infection during their blooming period. Blossom protect is currently considered the best alternative to streptomycin, and the Committee recommended a time-limited approval of the product; this was granted on 19 February 2008 by the Federal Office of Agriculture.

Revision of the Release Ordinance

On 1 January 2004 the Gene Technology Act[23] came into force; this regulates the handling of genetically modified animals, plants and other organisms. The act's provisions need to be implemented in ordi-

[20] See J.-C. Piffaretti, 29 October 2007: Expertise sur une possible utilisation en Suisse de l'antibiotique streptomycine pour traiter le feu bactérien. Le point de vue de la résistance aux antibiotiques. (in French)

[21] Combating fire blight with streptomycin: http://www.blw.admin.ch/dokumentation/00016/00261/index.html?lang=de&msg-id=17006

[22] Ordinance of 18 May 2005 on Placing on the Market of Plant Protection Products; SR 916.161 http://www.admin.ch/ch/d/sr/c916_161.html (in German)

[23] 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

nances. The FECB submitted a commentary on the modifications in the first interdepartmental consultation in 2006, and now in the second interdepartmental consultation in the year under report, had the opportunity to make another Statement. In most cases, this concerns the modification of details. The revision of the Release Ordinance is almost complete, and it will probably come into force in 2008.

3.2 The Containment Ordinance[24]

The Containment Ordinance 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.

Permit applications

In accordance with the Containment Ordinance, the different activities involving genetically modified organisms and natural organisms undergo a risk assessment and are assigned to four different classes, in order to avoid any possible harm to humans and the environment. Different safety measures must be adhered to according to the class. Authorisation is necessary for group 3 activities (moderate risk to humans and the environment) e.g. activities involving tuberculosis bacteria or hepatitis C viruses; and class 4 activities (high risk to humans and the environment), e.g. activities using Ebola virus or pox viruses. Such permit applications are always assessed by the FECB. Class 1 or 2 activities (no risk, or negligible risk) need only be notified, but not strictly assessed. However, the FECB advises the authorities to evaluate class 1 or 2 notifications as well, if new methods are being applied and if no comparable trial has yet been assessed, or if the applicant wishes to omit certain safety measures. A list of the applications assessed in 2007 is given in the Annex to this report.

Many of the applications submitted in 2007 concerned licences that had come up for renewal after five years, in accordance with the Containment Ordinance. For most of these applications new evaluations were not necessary.

The FECB has now been concerned for about 11 years with the evaluation of activities in contained systems. It found reason to object to only a very small proportion of the projects. Each year approx. two to three projects (of a total of 300 notified projects, 16 class 3 licence applications in 2007) had to be given a higher classification than the researchers had intended. In some cases, further safety measures, such as a safety cabinet or an air lock, were required.

List of cell lines

The Containment Ordinance (Art. 22) mandates the Federal Office for the Environment (FOEN), to keep lists that classify organisms according to their risk to humans and the environment. These lists are intended to simplify and harmonise enforcement of the Containment Ordinance and the associated Ordinance on Occupational Safety in Biotechnology. Following the earlier publication of lists of bacteria, viruses, fungi and parasites, the cell lines recorded as part of notifications and licence applications to the FOEN have now been listed. Classification of the cell lines was carried out on the basis of international lists and the SKBS list. The FECB examined this list and modified it where necessary, with the prerequisite that the provisions of the Containment Ordinance are consistently adhered to when working with cell cultures. The draft list has already been published on the Internet[25].

Revision of the Containment Ordinance

As for the Release Ordinance, the provisions of the revised Gene Technology Act (2004) must also be implemented in the Containment Ordinance. The FOEN began to revise the Containment Ordinance in 2007. Here, too, the FECB was able to offer its opinion at an early stage. It will continue to accompany the revisions, and will be able to submit a Statement on the draft as part of the interdepartmental consultation and the public consultation process.

3.3 Gene therapy trials and trials of genetically modified vaccines

Gene therapy is understood as the introduction of one or more foreign genes into cells of the human body (somatic gene therapy) in order to assume the function of defective genes. Trials in which the therapeutic genes are transferred into cells or tissue *in vitro*, before they are introduced into the patient's body (called *ex vivo* trials), are regulated under the Ordinance on the Transplantation of human organs, tissue and cells[26] and require authorisation from the Federal Office of Public Health. Conversely, *in vivo* gene therapies involve introducing the therapeutic genes directly into the patient's body using vectors. Such trials, as well as vaccination trials using genetically modified organisms, are regulated under the Ordinance on Clinical Trials of Therapeutic Products.[27] The FECB issues Statements on all these trials. After consulting the FECB and various federal offices, such trials are authorised by Swissmedic[28].

No new applications, properly speaking, were submitted in the FECB's reporting year. The only application submitted (2007GT2001: *A phase I/II trial to compare the immunogenicity and safety of 3 DNA C prime followed by 1 NYVAC C boost to 2 DNA C prime followed by NYVAC C boost, EV03)*, to test an HIV vaccine, is very similar to a previous application. No new questions concerning biosafety arose, and the results of the previous study gave no indication of specific risks to humans and the environment.

4. TRAINING AND PUBLIC RELATIONS

The FECB considers continuing training as one of the most important prerequisites for the safe handling of pathogenic organisms. It therefore participates actively in biosafety training.

To make the FECB's work known, FECB members and the Secretariat regularly report on the work of the FECB at conferences and events.

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

[25] Draft list of cell lines: http://www.FOEN.admin.ch/biotechnologie/01744/01753/index.html?lang=de

[26] Ordinance of 16 March 2007 on the transplantation of organs, tissues, and cells of human origin (Ordinance on transplantation): http://www.admin.ch/ch/d/sr/810_211/index.html (in German)

[27] 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

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

4.1 Conferences for biosafety officers

Biosafety Officers (BSO) are responsible for monitoring biosafety in facilities that handle genetically modified or pathogenic organisms[29]. 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 FECB are involved in running these courses.

In 2007, for the first time in several years, no introductory event for biosafety officers took place due to lack of demand; in the previous 10 years, 100–150 people regularly took part in this conference. One reason for the small number of interested people is the fact that a large number of biosafety officers have been trained in the past years and thus a level of saturation has been reached.

The FECB Secretariat did however participate in other courses on issues of biosafety, put on 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 FECB[30].

4.2 Biosafety Curriculum

The Containment Ordinance requires facilities to employ a biosafety officer to monitor biosafety, but does not lay down details of the prerequisites. Legal bases must be created, and requirements established, so that the facilities can establish a more uniform and targeted training of BSOs. With this in mind, in April 2007 the Federal Offices of the Environment, Public Health and Civil Protection (FOEN, FOPH and FOCP) commissioned the drawing up of a training plan for Biosafety officers (BSOs) in Switzerland, the *Biosafety Curriculum*. A working party, made up of federal and cantonal representatives and the FECB, supported the project.

The *Biosafety Curriculum* illustrates the possible contents and duration of the course and annual training. It harmonises with existing national and international courses on offer. The duration and content may vary according to the safety level of the facility. The course should have a modular structure and be composed of compulsory and optional units. The BSO course should acquire certification in the medium term, and be in harmony with BSO courses at least at European level. The course must first be recognised by the Confederation and the cantons. Before the *Biosafety Curriculum* can be implemented, the authorities still have various things to clarify.

The FECB welcomes the Curriculum Biosicherheit. From the Committee's viewpoint the course is particularly important for facilities with higher safety levels. The practical training must have high priority. However, some Committee members are rather critical of compulsory training of BSOs in safety level 1 facilities.

4.3 Meetings of European Advisory Committees on Biosafety

Second Meeting of European Advisory Committees on Biosafety in the Field of the Deliberate Release of GMOs

After the Netherlands Committee on Genetic Modification (COGEM) organised the first meeting in January 2006 in Amsterdam of European biosafety advisory committees concerned with the release of genetically modified organisms, Slovenia was now the host. About 15 countries participated in the Meeting in Ljubljana (Slovenia) in May 2007, as well as members of the GMO Panel of the European Food Safety Authority (EFSA). Switzerland was represented by the Secretariat and the Chair of the FECB.

The Meeting's special focus was on genetically modified trees. Further topics included biofuels, which are gaining importance both in Europe and the USA and Canada, and various novel genetic technologies where the end products do not contain foreign genes although they use gene technological procedures. Such technologies raise questions about the regulation and the definition of genetically modified organisms.

Networking was an important feature of this Meeting too. From the FECB's viewpoint, an exchange of experience with other committees is very important, since Switzerland is not able to benefit directly from an exchange of experience within EU member states. In addition, various countries are addressing very similar topics, and share the same problems.

Meeting of European Advisory Committees on Biosafety of Contained Use of Genetically Modified Microorganisms

Switzerland has only one Committee for Biosafety, which is responsible for both contained systems and for the release or marketing of GMOs and pathogenic organisms. In contrast, many European countries have separate committees to deal with releases and for contained systems. At the first Meeting of European Advisory Committees on Biosafety of Contained Use in Berlin in June 2007, the Committees introduced themselves and their areas of activity to one another. Representatives from nine different countries took part.

Topics for discussion included the classification of work using lentivirus vectors, strains of influenza virus, and phytopathogenic organisms. It was also interesting to note that the EU Guidelines are being implemented very differently from one country to another. The FECB was able to acquire information at first hand on various issues in the biosafety of contained systems, most of which are also significant for Switzerland. The presentation of the FECB Executive Secretary on the transport information leaflets project met with great interest.

[29] 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

[30] Biosafety institute b-safe, http://www.b-safe.ch/?mid=1027&pid=1119

5. ANNEXES

5.1 Organisation and structure of the FECB

The FECB 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 in the meetings. The secretariat is responsible for providing organisational support and technical assistance to the Committee members.

Composition and methodology

Under the terms of the Ordinance on the FECB, 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 FECB but they are not entitled to vote. Issues requiring more detailed examination are dealt with by working groups. The FECB 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 FECB are not necessarily the result of consensus; votes are often taken and minority positions are recorded.

Meetings

FECB meetings are not open to the public. Depending on the business to be dealt with, representatives of federal and cantonal authorities regularly attend the meetings and are available to the Committee for information and discussion. In 2007 the FECB met five times, on the following dates: 26 January, 3 May, 26 June, 13 September and 2 November 2007.

Cooperation

The FECB works closely with national authorities and also exchanges information with the Federal Ethics Committee for Non-Human Biotechnology[31]. In addition, the Secretariat liaises with other committees and public offices abroad that are active in related fields.

5.2 FECB members

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 FECB, as well as attending various international and national meetings. The Secretariat is administratively affiliated to the Federal Office for the Environment (FOEN). Karoline Dorsch was Executive Secretary of the FECB from its foundation in 1997 to March 2007. Since October 2007 Isabel Hunger-Glaser has been Executive Secretary, and Julia Link – previously scientific assistant – Assistant Secretary.

Karoline Dorsch, Ph.D., *Microbiologist*, studied microbiology in Berne and obtained her doctorate in St. Louis (Missouri, USA), after which she spent several years in the USA (Columbia University and
New York University) and later at the University of Zurich and the ETH Zurich, conducting basic research in microbiology and molecular biology. In 1992 she was appointed Executive Secretary of the Swiss Biosafety Committee (SKBS). She has been Executive Secretary of the FECB (the successor to the SKBS) since its appointment by the Federal Council in 1997.

Isabel Hunger-Glaser, Dr. phil. nat., *molecular biologist*. Isabel Hunger-Glaser graduated at the University of Bern and then spent several years in academic research in the field of signal transduction in parasites and cancer cells (microbiology and biochemistry). After conducting research in the United States (UCLA), she worked in industry. At Crucell, formerly Bernabiotech, she was Biosafety Coordinator and responsible for environment and health protection. Since October 2007, she has been Executive Secretary of the FECB.

Julia Link, lic. phil. nat., *Biologist*, studied biology at the University of Berne and has worked for the FECB Secretariat since 2001.

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

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 and from October 2006 to October 2007 he was visiting professor at the Delft University of Technology (NL). In addition, he is involved in Swiss and Euro-

[31] Federal Ethics Committee on Non-Human Gene Technology (ECNH): http://www.ekah.admin.ch/en/index.html

pean 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 ICGEB, and co-editor of Environmental Biosafety Research. Chair Section Biodiversity European Federation of Biotechnology, Steering Committee Public Research and Regulation Initiative. Member since 1997, previously also a member of SKBS.

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*. 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. Since 2006 he has been Managing Director of Basler & Hofmann Singapore, and works in Southeast Asia as biorisk consultant. 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 and 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, Associate Professor, 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 the 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, after 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, after 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.

5.3 List of Statements

Consultations in 2007: Summary of all FECB Statements

Consultations on the legislature

Amendment of the Ordinance on Genetically Modified Food	05/2007
Total revision of the Epidemics Act	05/2007
Revision of the Release Ordinance	07/2007

Consultations on permit applications

Marketing

Approval of Solbac, biocidal product	05/2007
Marketing of Agree WP, plant protection product	05/2007
Approval of Mellonex, biocidal product	10/2007
Incorporation of macroorganisms *(Amblyseius californicus, Amblyseius degenerans, Typhodromips swirskii)* as agents in Annex 1 of the Ordinance on Biocidal products	11/2007
Modifications to the production of Proteqflu-Te	11/2007
Use of streptomycin to combat fire blight	11/2007

Field trials

B07001, B07002, B07003: Release of genetically modified wheat strains and hybrids between these wheat strains and jointed goatgrass	07/2007

Contained use of organisms

Permit applications

A050721, S. Schaerer, ACW Changins	01/2007
A060121, A. Trkola, University of Zurich	01/2007
A060110, R. Zufferey, EPFL Lausanne	02/2007
A000611, D. Schultze, IKMI, St. Gallen, supplement	02/2007
A060138, N. Ruggli, IVI, Mittelhäusern	02/2007
A060155, M. Polymenidou, University of Zurich	02/2007
A060662, S. Antonarakis, University of Geneva	02/2007
A060678, F. Negro, University of Geneva	02/2007
A050003, A. Summerfield, IVI Mittelhäusern, supplement	04/2007
A060005, A. Zahn, Zurich, supplement	04/2007
A070500, M. Heim, University of Basel	04/2007
A070020, B. Thuer, IVI	04/2007
A070076, K. Mölling, University of Zurich	06/2007
A040014, P. Sander, Zurich, supplement	07/2007
A060514, G. Pfyffer, Lucerne, supplement	07/2007
A070023, John McKinney, EPFL Lausanne	07/2007
A070027, S. Cole, EPFL Lausanne	07/2007
A070041, R. Speck, University of Zurich, supplement	11/2007

Applications for renewal of permit

A060114/3, G. Pantaleo, University of Lausanne	02/2007
A060145, F. Lefort, Ecole d'Ingénieurs de Lullier, Juissy	05/2007
A070083/3, B. Gottstein, University of Bern	06/2007
A070080/3D, A. Dubois, Allschwil BL	07/2007
A070138, M. Moser, Prionics, Schlieren ZH	08/2007
A070172/3, W.-D. Hardt, ETH Zurich	09/2007
A000760/3, A000761/3, A000763/3, A. Aguzzi, University of Zurich	09/2007
A070172, W.-D. Hardt, Zurich	09/2007
A030004, N. Schürch, Labor Spiez	11/2007

Notifications

A070521, D. Pinschewer, University of Zurich	04/2007
A070510, M. Chanson, CMU Geneva	04/2007
A070042, D. Rigling, WLS research institute Birmensdorf	07/2007
A060677, M. Bünter, ACW Wädenswil	10/2007

Gen therapy

2007GT2001: A phase I/II trial to compare the immunogenicity and safety of 3 DNA C prime followed by 1 NYVAC C boost to 2 DNA C prime followed by NYVAC C boost (EV03), and Amendment 1	02/2007 05/2007

Advice on practice and enforcement

Statement on the List of cell lines	02/2007
Statement on waste disposal in the University Hospital, Zurich	07/2007
FECB Commentary on the "Curriculum Biosicherheit"	10/2007
Statement of the FECB on the declassification of organisms *(Trichoderma harzianum, Paecilomyces lilacinus, Zygosaccharomyces bailii)*	11/2007