MEETING OF THE STATES PARTIES TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

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Items 5 of the provisional agenda
Consideration of ways and means to enhance national implementation, including enforcement of national legislation, strengthening of national institutions and coordination among national law enforcement institutions

SURVEILLANCE OF THE RESEARCH, DIAGNOSTIC AND PRODUCTION ACTIVITIES WITH PATHOGENIC AND GENETICALLY MODIFIED ORGANISMS IN SWITZERLAND

Submitted by Switzerland

Introduction

1. The implementation of appropriate biosafety measures through legislation regulating biological research, diagnostics and production facilities is a relevant obligation to the Convention. We are therefore presenting an overview of the legal framework and enforcement structure in Switzerland that ensure that laboratories working with genetically modified and pathogenic organisms comply with state-of-the-art bio-safety concepts and safety measures to ensure protection of the human population and the environment.

Legal basis

2. Based on three laws (on epidemics, non-human gene technology and protection of the environment), activities involving the contained use of genetically modified organisms and pathogenic organisms in laboratories, production facilities, greenhouses and premises housing animals are regulated by three specific ordinances. These are:

(i) "Ordinance on contained use of Organisms of 25 August 1999"[1]

(ii) Protection of working personnel – "Ordinance on Occupational Safety in Biotechnology of 25 August 1999 OOSB"

(iii) Protection from major accidents – "Ordinance on Protection against Major Accidents of 27 February 1991"

3. These ordinances define the various protection objectives for research, diagnosis or production activities. Activities must be notified or licensed according to their potential risks to human health and environment. Some of the ordinances and laws are currently in the process of revision.

Notification, licensing and inspection of activities

4. Anyone who carries out activities with pathogenic or genetically modified organisms has to notify (in the case of activities with organisms in risk groups 1 and 2, i.e. low risk) or obtain a licence (in the case of activities with organisms in risk groups 3 and 4) from the relevant authority. The notification, licensing and inspection procedure is depicted in figure 1. Project managers who intend to carry out such activities are required to notify or submit an application for the corresponding licence to the Federal Coordination Center for Biotechnology (FCCB). This can be done electronically by accessing the ECOGEN Internet database. They are required to assess the level of risk and classify the activities according to the risk group of the organisms (1 to 4), the genetic modifications and the kind of activity. There are 4 different levels, ranging from level 1 (no or only negligible risk to human beings and the environment) to level 4 (high risk). Levels 2 and 3 imply a low or moderate risk. According to the classification of the activity, safety measures must be implemented ranging from safety levels 1 to 4. General safety measures have to be implemented for all classes of activities. The home page of the FCCB contains numerous relevant documents and information on bio-safety, including lists of organisms, guides for bio-safety officers and safety concepts (see Appendix 1).

5. The FCCB distributes incoming documents to the offices and bodies cited in the respective ordinances for consultation. The relevant authorities then decide on the appropriate classification based on the submitted documentation, and communicate their decision to the applicant (risk groups 1 and 2) or issue a permit (risk groups 3 and 4). The relevant authority for organisms that are pathogenic for human beings is the FOPH, while the FOEN is responsible for all other areas. The laboratories are inspected by the relevant cantonal authorities. The FCCB stores all documentation and periodically publishes notified and authorised activities on its web site.

[1] http://www.umwelt-schweiz.ch/imperia/md/content/stobobio/biotech/ouc2/1.pdf

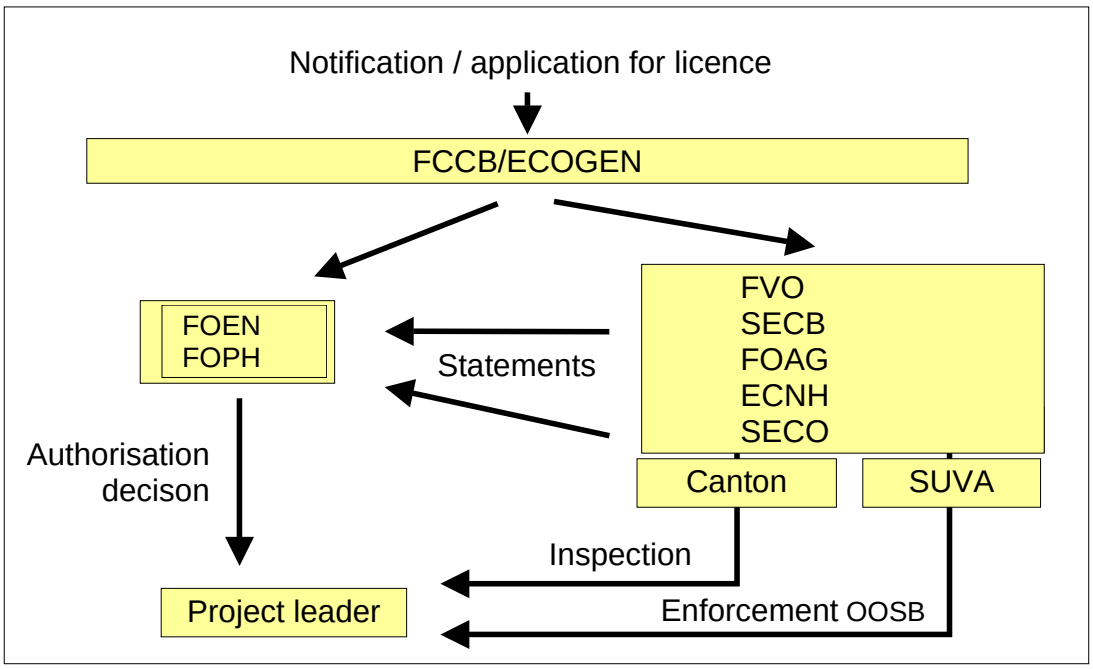

Figure 1. Notification, licensing and inspection procedure for activities with genetically modified and pathogenic organisms in research and diagnostic laboratories, greenhouses and production facilities according to Swiss law. Abbreviations: FOEN, Federal Office for the Environment; FOPH, Federal Office of Public Health; FVO, Federal Veterinary Office; SECB, Swiss Expert Committee for Biosafety; ECNH, Swiss Ethics Committee on Non-human Gene Technology; FOAG, Federal Office for Agriculture; SECO, State Secretariat for Economic Affairs; FCCB, Federal Coordination Center for Biotechnology; SUVA, Executive agency for occupational safety; OOSB, Ordinance on Occupational Safety in Biotechnology. Non-confidential information is entered directly into the ECOGEN system via a web site.

Swiss Expert Committee for Biosafety SECB

6. The SECB is a permanent federal advisory committee. It plays an important role in advising the Federal Council and federal authorities on the drafting of laws, ordinances, guidelines and recommendations. It advises the federal and cantonal authorities on the enforcement of these regulations. It issues statements on licence applications and recommendations on safety measures for studies using genetically modified or pathogenic organisms. Detailed information can be found on its web site (Appendix 1).

Authorisation for highly contagious animal diseases

7. The aims of the Swiss Federal Veterinary Office (SFVO) in the field of animal health encompass the control and monitoring of diseases which pose a risk to livestock, could be transmitted to humans, could have a serious economic impact or could compromise international trade. Therefore all activities in a laboratory involving highly contagious animal diseases (OIE list A) require authorisation by the SFVO. The legal bases are the law and the ordinance on animal diseases. This legislation forms the basis on which risk assessments (in accordance with

the Contained Use Ordinance) and the current situation with regard to highly contagious animal diseases are carried out. A permit is only issued if the cantonal veterinary office gives its approval.

Annex I

INTERNET ADDRESSES OF THE BODIES INVOLVED IN THE ENFORCEMENT OF LEGISLATION GOVERNING CONTAINED USE

Federal Coordination Centre for Biotechnology
http://www.umwelt-schweiz.ch/buwal/eng/fachgebiete/fg_biotechnologie/national/bureau/index.html)

ECOGEN
http://www.ecogen.ch

Swiss Expert Committee for Biosafety
http://www.efbs.ch

Federal Office for the Environment
http://www.umwelt-schweiz.ch/buwal/eng/info/buwal/organisation/abteilungen/abt_stoffe/index.html

Federal Office of Public Health
http://www.bag.admin.ch/themen/medizin/00708/index.html?lang=de

SUVA
www.suva.ch

Federal Veterinary Office
http://www.bvet.admin.ch/index.html?lang=en

Federal Office for Agriculture
http://www.blw.admin.ch/index.html?lang=en

Cantonal Offices
http://www.umwelt-schweiz.ch/buwal/eng/fachgebiete/fg_biotechnologie/adresse/can/index.html

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