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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Consideration of national, regional and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogens and toxins

REGISTRATION AND LICENSING OF FACILITIES AND PERSONS HANDLING BIOLOGICAL MATERIALS

Submitted by Germany

Introduction

1. Ever since the development of the science of microbiology in the second half of the 19th century, the protection of humans, animals and plants from infection by naturally occurring pathogens has become the subject in Germany to statutory regulation. Different governmental responsibilities for public, occupational, animal, and plant health have resulted in a wide range of regulations governing the handling of biological materials. The main features common to all regulations are the registration, licensing and supervision of both facilities and persons involved in handling such materials.

Biological Agents Ordinance[1] (Biostoff-Verordnung[2])

2. The Biological Agents Ordinance transposes into German law the EU Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work[3]. Employers must notify the competent authority of any activities involving risk group 2, 3 or 4 biological agents that are carried out for the first time. The notification must be made at least 30 days prior to the beginning of such work. Risk group 2 to 4 classified agents are contained in

[1] http://www.baua.de/nn_74828/de/Themen-von-A-Z/Biologische-Arbeitsstoffe/Rechtstexte/pdf/biological-agents-ordinance.pdf
[2] http://bundesrecht.juris.de/biostoffv/BJNR005010999.html
[3] http://europa.eu/eur-lex/pri/en/oj/dat/2000/l_262/l_26220001017en00210045.pdf

Annex III of the Directive, which currently lists 150 bacteria, 155 viruses, 69 parasites and 27 fungi.

3. Additional notification must take place at the beginning of work involving each subsequent group 3 biological agent in so far as the agent is not contained in Annex III, as well as at the beginning of work involving each subsequent group 4 biological agent. A list of workers due to work with group 3 or 4 biological agents must be maintained, indicating the type of work to be done. The list must be made available to the competent authority at its request.

Protection Against Infection Act (Infektionsschutzgesetz[4])

4. Any person wishing to import or export pathogens to and from the territory covered by this Act, store, supply or work with them there requires an authorization from the competent authority. Generally, pathogens as well as material containing pathogens may only be supplied to persons who hold an authorization. The Act defines a pathogen as any agent capable of replication (virus, bacterium, fungus, and parasite) or any other transmissible biological agent capable of causing an infection or communicable disease in human beings.

5. An authorization is not required by persons who are licensed to exercise the profession of physician, dental surgeon or veterinary surgeon for microbiological tests conducted in their own practice for the purpose of exploratory medical or veterinary diagnosis using cultural methods that are restricted to the primary culturing and who employ methods that are not geared to detecting specific pathogens that are subject to notification to the competent authority, in so far as such tests are performed for the direct treatment of own patients. The Act lists 53 pathogens that are subject to notification.

Animal Pathogen Ordinance (Tierseuchenerregerverordnung[5])

6. The Ordinance is based on the Animal Infectious Disease Act[6]. Any person wishing to work with, acquire or supply an animal pathogen requires an authorization from the competent authority. An authorization is not required for diagnostic tests or therapeutic measures carried out by physicians, veterinarians or animal hospitals and clinics. Animal pathogens as well as material containing animal pathogens may only be transferred to a person or an entity possessing an authorization.

Animal Pathogen Import Ordinance (Tierseuchenerreger-Einfuhrverordnung[7])

7. The Ordinance names 12 animal pathogens whose importation is subject to the prior consent of the Federal Ministry of Food, Agriculture and Consumer Protection as well as authorization by the supreme authority of a Federal State. Authorization by the supreme authority of a Federal State is also required for the importation of a further 108 bacteria, viruses, fungi and protozoa listed in two annexes to the Ordinance. Importation may be authorized only for scientific purposes or the manufacture of sera, vaccines, and diagnostics. In the case of certain agents transfer to other persons or facilities will be explicitly prohibited.

[4] http://bundesrecht.juris.de/ifsg/BJNR104510000.html
[5] http://www.gesetze-im-internet.de/tierseucherv/index.html
[6] http://bundesrecht.juris.de/viehseuchg/BJNR005190909.html
[7] www.bundesrecht.juris.de/tierseuchereinfv/BJNR019600971.html

Phytosanitary Ordinance (Pflanzenbeschauverordnung[8])

8. The Ordinance is based on the Plant Protection Act[9] and refers to Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community[10]. Annex I of the Directive lists more than 100 harmful organisms (bacteria, viruses and virus-like organisms, fungi, insects, mites, nematodes) whose introduction into and spread within any EU Member States or certain protected zones inside the Community are banned. The competent authorities may also ban the importation of other harmful organisms. Such import and movement bans may include plants, plant products and other items that are infested with pests.

9. The competent authority may, on request, where there is no risk of spreading harmful organisms, authorize exemptions from import and movement bans for scientific purposes, experimental purposes or plant breeding projects on a case-by-case basis.

Genetic Engineering Act (Gentechnikgesetz[11])

10. The establishment and operation of genetic engineering facilities where genetic engineering work at security level 3 or 4 is to be carried out require a facility authorization. The authorization allows conducting genetic engineering work as specifically referred to in the authorization.

11. The establishment and operation of genetic engineering facilities where genetic engineering work at security level 1 or 2 is to be carried out as well as the initial genetic engineering work planned must be notified to the competent authority before the planned start of construction.

12. Further genetic engineering work at security level 1 may be carried out without further information of the competent authority. Further genetic engineering work at security level 2 must be notified to the competent authority before the planned start of such work. Any further genetic work at security level 3 or 4 requires an authorization by the competent authority on a case-by-case basis. In 2007 a total of 5347 security level 1 to 4 genetic engineering facilities existed in Germany.

Registration, approval procedures and responsibilities

13. One feature common to all registration and licensing procedures is the acquisition of data, including *inter alia*:

(i) the location,

(ii) the name of the biological agent,

[8] http://www.bundesrecht.juris.de/pflbeschauv_1989/index.html
[9] http://bundesrecht.juris.de/pflschg_1986/index.html
[10] http://eur-lex.europa.eu/LexUriServ/site/en/consleg/2000/L/02000L0029-20060414-en.pdf
[11] http://www.gesetze-im-internet.de/gentg/BJNR110800990.html

(iii) the purpose and nature of the work and/or facility, and

(iv) information on the authorization holder and/or facility operator.

14. Before any authorization to handle biological agents or operate a facility can be granted, applicants must satisfy the competent authorities that:

(i) they possess the necessary reliability and professional competence, and

(ii) the envisaged premises or installations are appropriate for the type and scope of the activities planned.

15. At the federal level, responsibility for pertinent legislation lies with the Federal Ministry of Labour and Social Affairs, the Federal Ministry of Health and the Federal Ministry of Food, Agriculture and Consumer Protection. Under the German Constitution, the Federal States are responsible for ensuring that the legislation is fully implemented. In practice it is the competent authority at regional and local level - i.e. public health, veterinary, plant protection or occupational health and safety authority - that issues an authorization, maintains a register of persons and facilities, and exercises the necessary supervision.

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