Order on the control of certain substances that can be used in connection with biological attacks on animals

Pursuant to § 1, § 4(2) and § 7(2) of the Act on control of animal pathogens, cf. Consolidating Act No 475 of 15 May 2014, and by authorisation under § 7(5) of Order No 511 of 23 April 2015 on the duties and powers of the Danish Veterinary and Food Administration, the following is laid down subsequent to negotiations with the Minister for Health and the Elderly:

Chapter

Scope

§ 1. This Order contains provisions on the control of certain substances that can be used in connection with biological attacks on animals.

(2) The Order applies to the biological substances listed in Annex 1.

Authorisation

§ 2. Powers that are assigned to the Minister for the Environment and Food in accordance with § 2, § 3 and § 5(1), (4) and (5) of the Act on control of animal pathogens are exercised by the Centre for Biosecurity and Biopreparedness.

Definitions

§ 3. For the purposes of this order, the terms below shall have the following meanings:

1) Animal pathogens: certain viruses, bacteria and mycoplasma and certain genetic elements and genetically modified organisms that can be used in connection with biological attacks on animals.

2) Possession: owning or having one of the biological substances referred to in Annex 1 in one's keeping.

3) Storage unit: single unit for storing specific biological substances, i.e. a closed test tube containing a bacteria culture.

4) Professional purposes: research, diagnostics or commercial purposes, which can involve both private and public entities, i.e. university departments, laboratories, biotechnology companies, and pharmaceutical entities.

5) Control plan: plan of the measures or precautions to be implemented to prevent, detect and respond to the theft or misuse of biological substances, cf. Annex 1.


7) Entity: legal person, including laboratory, institution, production entity or department thereof responsible for biological substances.

Permits to possess, produce, use and store biological substances that can be used in connection with attacks on animals

§ 4. The biological substances included in Annex 1 may only be possessed, produced, used and stored following the issuing of a permit by the Centre for Biosecurity and Biopreparedness.

(2) Applications for permits are made by submitting an application form to the Centre for Biosecurity and Biopreparedness. The application form can be obtained from the Centre for Biosecurity and Biopreparedness or at www.biosikring.dk.

(3) An application for a permit shall be signed by the head of security, cf. § 5(2). The application shall contain, as a minimum, the following information:

1) name and address of the entity,

2) department of the entity where the biological substance will be located,

3) name and training of head of security, cf. § 5(2) and § 9,

4) purpose and requested extent of permit, cf. § 5(1) and § 6,

5) information about storage conditions, cf. § 13, and
6) information about security conditions, cf. § 15.
(4) The Centre for Biosecurity and Biopreparedness shall make a decision no later than four weeks after the application and all necessary information have been received.
(5) The deadline in accordance with (4) may be extended on one occasion if, due to the nature of the case, it is not possible to make a decision before the deadline expires. If the deadline is extended, the applicant will be informed of this and the final date for when a decision will subsequently be made before the expiry of the deadline. The grounds for the extension and the deadline laid down in connection with this shall be stated in the notification.
(6) The exceeding of the deadline in accordance with (4) or the extended deadline in accordance with (5) does not mean that the applicant may consider a permit to be granted.
(7) Once the Centre for Biosecurity and Biopreparedness has received an application and all necessary documents, the Centre for Biosecurity and Biopreparedness will send a receipt to the applicant, containing information regarding:
1) the deadline for processing the case, cf. (2) and (3),
2) the fact that the applicant must not commence the operation until the party in question has received a permit for this from the Centre for Biosecurity and Biopreparedness, and
3) appeal options.

§ 5. A permit to possess, produce, use and store the substances included in Annex 1 may only be granted to entities that have a professional and legitimate purpose in receiving permission.
(2) Permits may be issued for a period determined in advance, or for as long as the activity for which the permission is granted continues, cf. however § 8(2) and (3).
(3) Permits may also be granted for diagnostic investigations that could involve the biological substances included in Annex 1. Such biological substances shall be disposed of no later than within 14 days of the investigation ending, unless a permit is obtained from the Centre for Biosecurity and Biopreparedness with regard to the specific biological substance.

§ 6. Permits, cf. § 4(1), may be granted for a single biological substance or for groups of biological substances.
(2) Permits may be issued for a period determined in advance, or for as long as the activity for which the permission is granted continues, cf. however § 8(2) and (3).
(3) Permits may also be granted for diagnostic investigations that could involve the biological substances included in Annex 1. Such biological substances shall be disposed of no later than within 14 days of the investigation ending, unless a permit is obtained from the Centre for Biosecurity and Biopreparedness with regard to the specific biological substance.

§ 7. The Centre for Biosecurity and Biopreparedness may, in association with the issuing of a permit, cf. § 4(1), attach special requirements relating to the permit, including storage, disposal, stocking, security circumstances and training of personnel, which supplement the requirements specified in the Order.

§ 8. Changes to the entity’s activities that are of significance for the permit issued to the entity, cf. 4(1), shall be notified to the Centre for Biosecurity and Biopreparedness.
(2) The Centre for Biosecurity and Biopreparedness can fully or partially suspend permits issued in accordance with § 4(1) if the entity does not comply with the requirements set pursuant to § 7 or if it is established that the entity no longer complies with permit eligibility conditions.
(3) The Centre for Biosecurity and Biopreparedness can fully or partially suspend or change previously issued permits if significant public safety considerations call for permit suspension.
(4) The deadline for the disposal of biological substances included in Annex 1 after the suspension of a permit is set by the Centre for Biosecurity and Biopreparedness.

Accountability and training

§ 9. An entity that receives a permit in accordance with § 4(1) shall have at least one head of security employed. The head of security shall be approved by the Centre for Biosecurity and Biopreparedness. Documentation is to be submitted confirming that the head of security consents to information on any criminal record they may have being obtained by the Centre for Biosecurity and Biopreparedness.
(2) The entity is responsible for ensuring that a suitable replacement is appointed before a head of security leaves his/her position, and that this person is approved by the Centre for Biosecurity and Biopreparedness.

§ 10. The person appointed head of security is to attend one of the Centre for Biosecurity and Biopreparedness’s training courses. These are provided free of charge.
(2) The head of security shall ensure that the persons with access to the biological substances included in Annex 1 are familiar with the rules in the area and that they are familiar with the guidelines issued by the Centre for Biosecurity and Biopreparedness in the area. These guidelines can be obtained from the Centre for Biosecurity and Biopreparedness or www.biosikring.dk.
(3) The person appointed head of security is to record anyone who has access to the biological substances included in Annex 1. The list should be presented to the Centre for Biosecurity and Biopreparedness on request at all times.

§ 11. Persons not registered, cf. 10(3), may only be given access to the biological substances included in Annex 1 where they are accompanied by a registered person and are under the responsibility of this person.
§ 12. Where a permit has been issued in accordance with § 4(1) and the possession, production, use or storage of the biological substance the permit concerns has a direct relationship to weapons production or testing, the Centre for Biosecurity and Biopreparedness may require a security evaluation of persons involved in the work.

Storage and transport

§ 13. Biological substances included in the Order, cf. Annex 1, are to be stored in such a way as to prevent theft and misuse.

§ 14. The transport of the biological substances included in Annex 1 shall take place in accordance with the applicable provisions for the transport of hazardous goods. For road transport, ADR's (European Agreement concerning the International Carriage of Dangerous Goods by Road) regulations for class 6.1 and 6.2 apply (UN numbers 3172, 3373, 3462 or 2900); for railway transport, RID's (Regulations concerning the International Carriage of Dangerous Goods by Rail) regulations for class 6.1 and 6.2 apply (UN numbers 3172, 3373, 3462 or 2900); for sea transport, IMDG's (International Maritime Dangerous Goods Code) regulations for class 6.1 and 6.2 apply (UN numbers 3172, 3373, 3462 or 2900), and for air transport, ICAO-TI's (Technical Instructions for the Safe Transport of Dangerous Goods by Air) regulations for class 6.1 and 6.2 apply (UN numbers 3172, 3373, 3462 or 2900).

(2) The entity is to ensure that the carriers, forwarding agents, etc. used by the entity are aware of their responsibility to secure the goods in their custody.

(3) Carriers, forwarding agents, etc. must ensure that shipments of biological substances included in Annex 1 are transported, stored whilst in transit and transferred to the recipient in such a way as to prevent theft, misuse and loss. They must also ensure that unauthorised persons cannot come into contact with such biological substances.

Control

§ 15. When applying for a permit, cf. § 4(2) and (3), the entity shall prepare a vulnerability assessment and control plan, which will form part of the consideration of the application.

(2) The control plan is to include:
   1) Registration procedures in association with stocks,
   2) Disposal procedures,
   3) Accident procedures,
   4) Access control systems,
   5) Technical security barriers, including alarm systems, technical inspections of alarms, etc.,
   6) Security assessment of selected persons, cf. § 12,
   7) Securing of sensitive information, including storage of information relating to technology, storage of substances, etc. and personnel and visitor information (IT and document security), and
   8) Exercises or training courses.

(3) The control plan is to be maintained on an ongoing basis and must be available to the Centre for Biosecurity and Biopreparedness on request.

Registration and disposal, purchase, sale or other form of transfer of biological substances

§ 16. The entity shall keep a register of the biological substances included in Annex 1 for which the entity is responsible. The register is to be updated on an ongoing basis, but at least once a quarter. The register and other documents regarding the permit shall be stored for a minimum of five years from the date of issue of the permit.

(2) The entity shall report the stock of the registered biological substances to the Centre for Biosecurity and Biopreparedness at least once a year. Stock movements are to be registered in accordance with the procedure stipulated by the Centre for Biosecurity and Biopreparedness.

(3) Where requested by the Centre for Biosecurity and Biopreparedness, the entity shall be able to present the register referred to in (1) at any time.

§ 17. The disposal, purchase, sale or other form of transfer of biological substances included in this Order, cf. Annex 1, shall be reported to the Centre for Biosecurity and Biopreparedness within 14 working days of the date of disposal, purchase, sale or transfer, stating the nature, quantity and sender or recipient.

(2) The entity is responsible for disposal, cf. (1), taking place in such a manner that the biological substances cannot become a danger to animal safety.
Accidents and loss

§ 18. The Centre for Biosecurity and Biopreparedness is to be informed immediately if the following occurs:
1) Theft, misuse or other loss of biological substances included in Annex 1.
2) Suspicion of release of the biological substances included in Annex 1.
3) Discovery or suspected presence of the biological substances included in Annex 1.

(2) Unauthorised persons are to be refused access to all areas where there are uncontrolled occurrences of biological substances included in Annex 1, until the Centre for Biosecurity and Biopreparedness has ensured that measures have been implemented to counter the potential danger.

Control

§ 19. The Centre for Biosecurity and Biopreparedness monitors and carries out inspections to ensure compliance with the provisions in this Order.

Appeals, penalties, entry into force and transitional provisions

§ 20. Decisions made by the Centre for Biosecurity and Biopreparedness pursuant to this Order may be appealed against to the Appeal Centre for Food, Agriculture and Fisheries.

§ 21. Unless a more severe penalty is warranted under other legislation, a person who violates § 4(1), § 5(2), § 6(3.2), § 8(1) or (4), §§ 9-11, §§ 13-14, § 15(3), §§ 16-18 or § 22(2) shall be punished by a fine.

(2) The penalty may increase to two years’ imprisonment if the infringement was committed wilfully or through gross negligence, and said infringement:
1) results in or leads to harm to human or animal health, damage to property or the environment or the risk of this, or
2) achieved or intended to achieve a financial benefit for the parties concerned or others, including savings.
(3) Companies, etc. (legal persons) may be rendered criminally liable in accordance with the rules of Chapter 5 of the Penal Code.

§ 22. This Order shall enter into force on 1 July 2016.

(2) Entities that possess the biological substances included in Annex 1 at the date of this Order entering into force shall submit an application for a permit no later than six months after the date of entry into force, cf. § 4(2) and (3), if the entity wishes to continue to possess the biological substances. Otherwise, the biological substances shall be destroyed in a safe manner, cf. § 17(2), before the expiry of the six-month deadline referred to.

(3) Entities that have submitted an application, cf. (2), will be issued a temporary permit, which will apply until the Centre for Biosecurity and Biopreparedness has reached a decision relating to the application.

Annex 1

List of controlled biological substances.

Animal pathogens

A. Viruses, whether they are natural, enhanced or modified, either in the form of isolated living cultures or in the form of material that includes living material that has been deliberately inoculated or contaminated with such cultures, as follows:

1) African horse sickness virus.
2) African swine fever virus.
3) Avian influenza viruses, which are:
   a) uncharacterised, or
   b) defined in Annex I(2) to Directive 2005/94/EC (OJ L 10, 14.1.2006, p. 16) as a strong pathogen as follows:
      i) Type A virus with an intravenous pathogenicity index in six-week old chickens greater than 1.2, or
      ii) Type A virus of subtype H5 or H7 with genome sequences codifying for multiple basic amino acids at the cleavage site of the haemagglutinin molecule similar to that observed for other HPAI viruses, indicating that the haemagglutinin molecule can be cleaved by a host ubiquitous protease.
4) Bluetongue virus.
5) Foot and mouth disease virus.
6) Goat pox virus.
7) Porcine herpes virus (Aujeszky's disease).
8) Swine fever virus (Hog Cholera virus).
9) Lumpy Skin Disease virus.
10) Newcastle disease virus.
12) Sheep and goat plague.
12) Enterovirus type 9 in swine (swine vesicular disease virus).
13) Rabies virus and all other members of the Lyssavirus family.
14) Rinderpest virus.
15) Sheep pox virus.
16) Teschovirus A.
17) Vesicular stomatitis virus.

B. Bacteria, whether natural, enhanced or modified, either in the form of isolated live cultures or as materials, including living materials, which are deliberately inoculated or contaminated with such cultures, as follows:
   1) Mycoplasma capricolum subspecies capripneumoniae (type F38).
   2) Mycoplasma mycoides subspecies mycoides SC (small colony biotype).

Note 1:

No controls are imposed on vaccines.

**Genetic elements and genetically modified organisms**

Genetically modified organisms or genetic elements which contain nucleic acid sequences associated with the pathogenicity from the organisms specified under points A-B in the above list of animal pathogens.

Note 1:

Genetic elements include organisms in which the genetic material (nucleic acid sequences) has been altered in a manner that does not occur naturally by reproduction or natural recombination. This includes organisms that are wholly or partially artificial.

Note 2:

Genetic elements include, inter alia, chromosomes, genomes, plasmids, transposons, and vectors, whether genetically modified or unmodified or wholly or partially produced by chemical synthesis.

Note 3:

For nucleic acid sequences associated with the pathogenicity from each of the microorganisms specified under points A-B in the above list of animal pathogens, each sequence is understood to be specific to the microorganism specified, and which:

1) in itself or via its transcription or translation products represents a significant risk to animal health; or
1) is known to make a specified microorganism (or any other organisms in which it can be inserted or otherwise integrated) more able to cause serious harm to animal health.

**Official notes**