

Ministry of Health and Prevention

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Executive Order on securing specific biological substances, delivery systems and related materials¹

Pursuant to Article 1, Article 2, Paragraph 2, Article 4, Paragraph 1 and Article 6, Paragraphs 2 and 3 of Act No. 474 of 17 June 2008 on securing specific biological substances, delivery systems and related materials, the following has been laid down:

Application

Article 1. The provisions in this Executive Order apply to the biological substances, delivery systems and related materials specified in Annex 1, which are included in the system of export controls specified in the regulation on the European Community system of controls for dual-use items (products and technology), which can be used in association with attacks against people and therefore represent a danger to public safety.

Paragraph 2. The Centre for Biosecurity and Biopreparedness can fully or partially exempt specific biological substances, delivery systems and related materials from being included by the provisions in this Executive Order.

Article 2. The Ministry of Health and Prevention can introduce provisions that stipulate that the provisions set forth in this Executive Order are also to include biological substances, delivery systems and related materials that are not included in Article 1, if the biological substances, delivery system and related materials are considered to be usable in association with biological attacks on people and therefore represent a danger to public safety.

Paragraph 2. Resolutions to include other biological substances, delivery systems and related materials, cf. Article 1, are introduced on the basis of professional guidance from The Centre for Biosecurity and Biopreparedness.

Definitions

Article 3. The following definitions apply in this Executive Order:

- 1) Biological substances: these include human pathogens, zoonoses and toxins in the form of viruses, rickettsiae, bacteria, toxins or sub-units of toxins, some fungi and specific genetic elements and genetically modified organisms which can be used in association with biological attacks against people and therefore represent a danger to public safety.
- 2) Possession: to own or have custody of biological substances, delivery systems or related materials included by the Executive Order.
- 3) Dual use: that biological substances, delivery systems or related materials can be used for both legitimate and offensive purposes.

¹ The draft Executive Order has been notified in accordance with Directive 98/34/EC of the European Parliament and the Council (the Information Procedure), as amended by Directive 98/a48/EC.

- 4) Delivery systems: spraying equipment and other unmanned systems which are capable of disseminating certain biological substances.
- 5) Storage unit: single unit for storing specific biological substances, i.e. a closed test tube containing a bacterial culture.
- 6) Professional purpose: research, diagnostics or commercial purposes, which can involve both private and public entities, i.e. university departments, hospital laboratories, biotechnology companies, pharmaceutical entities etc.
- 7) Related materials: materials, equipment and technology which are covered by the relevant international treaties and agreements or included in national control lists and which can be used in the design, development, production or use of biological weapons and their delivery systems.
- 8) Security plan: plan of the measures or precautions to be implemented to prevent, detect and respond to the theft or misuse of certain biological substances, delivery systems and related materials.
- 9) Vulnerability assessment: identification of the threats and security weaknesses associated with the possession, production, use, storage, purchase, sale, transport, transfer and disposal of certain biological substances, delivery systems and related materials.
- 10) Entity: physical or legal entity (an owner and/or independent person), which is responsible for specific biological substances, delivery systems and related materials, including hospitals, institutions, production entities etc. or departments thereof.

General regulations

Article 4. The biological substances, delivery systems and related materials included in the Executive Order may be held, produced, used and stored only if a relevant permit has been obtained.

Permit to hold, produce, use and store etc. certain biological substances, delivery systems and related materials

Article 5. Permits in pursuance of Article 4 are obtained from The Centre for Biosecurity and Biopreparedness.

Paragraph 2. Permits are to be applied for using the forms prepared by The Centre for Biosecurity and Biopreparedness. The forms can be obtained from The Centre for Biosecurity and Biopreparedness or www.biosikring.dk.

Paragraph 3. Permit applications are to be signed by the manager responsible, cf. Article 6. The application is to contain at least the following information:

- 1) Name and address of person, entity, institution or similar.
- 2) Department in which the biological substance, delivery system or related materials are present.
- 3) Name and training of the person responsible for security, cf. Articles 11 and 12.
- 4) Purpose and required scope of permit, cf. Articles 6 and 7.
- 5) Information on security circumstances, cf. Article 17.
- 6) Information on storage circumstances, cf. Article 15.

Article 6. Permits can be issued only to persons, including legal entities, who have professional and legitimate grounds for obtaining a permit for the substances etc. included in Articles 1 and 2.

Paragraph 2. Legal entities are to appoint a natural person who, together with the legal entity, shall be responsible for ensuring compliance with the provisions on the biological substances, delivery systems and related materials included in Articles 1 and 2, cf. Article 11.

Article 7. Permits can be issued for a single biological substance, delivery system or related material or for groups of biological substances, delivery systems or related materials.

Paragraph 2. Permits can be issued for a limited period, or for as long as the activity for which the permit is issued continues, cf., however, Article 9.

Paragraph 3. Permits can also be issued for diagnostic investigations which involve the biological substances included in the Executive Order, cf. Annex 1. These biological substances are to be disposed of within 14 days of the completion date of the investigation, unless permits for the specific biological substances have been obtained.

Article 8. The Centre for Biosecurity and Biopreparedness can, in association with the issuing of permits, set special requirements relating to the storage, disposal, stocking, security circumstances and training of personnel, including persons responsible for security, which supplement the requirements specified in the Executive Order.

Article 9. Changes in an entity's activities which have a significant importance for permit issuance are to be reported to The Centre for Biosecurity and Biopreparedness.

Paragraph 2. The Centre for Biosecurity and Biopreparedness can fully or partially suspend permits issued in accordance with Article 4 if the requirements set pursuant to Article 8 are not complied with or if it is established that the entity no longer complies with permit eligibility conditions.

Paragraph 3. The Centre for Biosecurity and Biopreparedness can fully or partially suspend or change previously issued permits if warranted by significant public safety considerations.

Paragraph 4. The deadlines for the disposal of substances etc. after permits have expired are set by The Centre for Biosecurity and Biopreparedness, cf. Article 8.

Accountability and training

Article 10. Entities are responsible for complying with the regulations specified in the Executive Order and with any conditions or requirements set out in issued permits.

Article 11. Entities are responsible for ensuring that one or more of the entity's staff is appointed as security manager. Such employees are also to be approved by The Centre for Biosecurity and Biopreparedness. Documentation is to be submitted confirming that the staff responsible for security consent to information being obtained on any criminal record they may have.

Paragraph 2. The entity is responsible for ensuring that a suitable replacement is appointed before a security manager leaves his/her position, and that this person is approved by The Centre for Biosecurity and Biopreparedness.

Article 12. The person appointed as security manager by the entity is to attend a training course offered by The Centre for Biosecurity and Biopreparedness. This is provided free of charge.

Paragraph 2. The person appointed as security manager by the entity is to ensure that all persons who have access to the biological substances, delivery systems and related materials included in the Executive Order are familiar with the regulations in the area as well as with the guidelines issued by The Centre for Biosecurity and

Biopreparedness. These guidelines can be obtained from The Centre for Biosecurity and Biopreparedness or www.biosikring.dk.

Paragraph 3. The person appointed as security manager by the entity is to record anyone who has access to the biological substances included in the Executive Order. The list should be available to The Centre for Biosecurity and Biopreparedness on request at all times.

Article 13. Unregistered persons are to be permitted access to biological substances included in the Executive Order only if accompanied by a registered person, cf. Article 12, Paragraph 3, whereby the responsibility shall be borne by the registered person.

Article 14. The Centre for Biosecurity and Biopreparedness may require a security evaluation of persons working with specified biological substances, delivery systems or related materials for which a permit has been issued in accordance with Article 4 if the work directly relates to weapons production or testing.

Storage and transport

Article 15. Biological substances, delivery systems and related materials included in the Executive Order are to be stored in such a way so as to prevent theft and misuse.

Article 16. Biological substances included in the Executive Order, cf. Article 1 are to be transported in accordance with current regulations 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 2814, 3373, 3172 and 3462); 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 2814, 3373, 3172 and 3462); for sea transport, IMDG's (International Maritime Dangerous Goods Code) regulations for class 6.1 and 6.2 apply (UN numbers 2814, 3373, 3172 and 3462), 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 2814, 3373, 3172 and 3462).

Paragraph 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.

Paragraph 3. Carriers, forwarding agents etc. must ensure that shipments of biological substances, delivery systems and related materials included in this Executive Order 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, delivery systems and related materials.

Security

Article 17. Entities which apply for permits are to prepare a vulnerability assessment and a security plan, which will be included in the permit application evaluation. The assessment and plan are to be prepared on a designated form which can be obtained from The Centre for Biosecurity and Biopreparedness or www.biosikring.dk.

Paragraph 2. The security 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 evaluation of selected persons where required, cf. Article 14.
- 7) Securing of sensitive information, including storage of information relating to technology, storage of substances etc. and personnel and visit information (IT/document security).
- 8) Drills/training.

Paragraph 3. The security 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 of biological substances, delivery systems and related materials

Article 18. The entity is to maintain registers/inventories of the biological substances, delivery systems and related materials included in this Executive Order for which it is responsible. The register/inventory is to be updated on an ongoing basis, at least once a quarter. Registers and other documents relating to permits are to be stored for a minimum of five years.

Paragraph 2. The entity is to report stock levels 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.

Paragraph 3. The entity must make registers/inventories available to The Centre for Biosecurity and Biopreparedness on request.

Article 19. Any purchase, sale, transfer or disposal of biological substances, delivery systems and related materials included in this Executive Order is to be reported to The Centre for Biosecurity and Biopreparedness within 14 working days of the purchase, sale, transfer or disposal, specifying the type, volume and shipper/recipient.

Paragraph 2. The entity is responsible for ensuring that disposal takes place in such a way that biological substances, delivery systems and related materials cannot represent a danger to human safety.

Paragraph 3. The entity must set out procedures for the disposal of the biological substances, delivery systems and related materials included in the Executive Order, cf. Article 17, Paragraph 2.

Accidents and loss

Article 20. The Centre for Biosecurity and Biopreparedness is to be immediately informed if the following occurs:

- 1) Theft, misuse or loss of the biological substances, delivery systems and related materials included in the Executive Order.
- 2) Suspicion of release of the biological substances included in the Executive Order.
- 3) Discovery of or suspicion of the presence of biological substances, delivery systems and related materials included in the Executive Order.

Paragraph 2. Unauthorised persons are to be kept out of all areas where there are uncontrolled occurrences of biological substances included in the Executive Order, until The Centre for Biosecurity and Biopreparedness has ensured that measures have been implemented to counter the potential danger.

Control

Article 21. The Centre for Biosecurity and Biopreparedness monitors and carries out inspections to ensure compliance with the provisions in this Executive Order.

Article 22. The Centre for Biosecurity and Biopreparedness may prohibit the possession, production, use and storage of the biological substances, delivery systems and related materials included in the Executive Order, until the requirements set by The Centre for Biosecurity and Biopreparedness are complied with.

Appeals, penalties, entry into force and transition provisions

Article 23 Decisions made by The Centre for Biosecurity and Biopreparedness in accordance with this Executive Order may be appealed within four weeks to the Ministry of Health and Prevention.

Article 24. Violations of Article 4, Article 8, Article 9, Paragraphs 1 and 4, Articles 10–16, Article 17, Paragraph 3, Articles 18–20 and Article 22 will be fined, unless other legislation deems that other penalties apply to the violation.

Paragraph 2. The penalty for violations of Article 4, Article 8, Article 9, Paragraphs 1 and 4, Articles 15–16 and Article 19, Paragraphs 1–2 can, if aggravating circumstances exist, rise to imprisonment for up to 2 years, if the violation has been committed intentionally or through the exercise of gross negligence, where the violation results in persons being significantly injured, property being significantly damaged or the environment being significantly harmed or results in the risk of these occurring, or a financial benefit for the persons involved or others, including savings, is achieved or intended to be achieved.

Paragraph 3. Entities etc. (legal entities) can be deemed to bear a criminal liability in accordance with the regulations in chapter 5 of the Penal Code.

Article 25. The Executive Order shall come into effect on 1 October 2009.

Paragraph 2. Entities in possession of biological substances, delivery systems and related materials included in the Executive Order upon entry into force of this Order are to submit a permit application within 6 months of the date of entry into force if they wish to continue to remain in possession thereof. Otherwise, the biological substances, delivery systems or related materials are to be destroyed in a safe way, cf. Article 19.

Paragraph 3. Entities which have submitted an application within the period specified in Paragraph 2 have a temporary permit, which will apply until The Centre for Biosecurity and Biopreparedness has reached a decision relating to the application.

Ministry of Health and Prevention,

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List of biological substances, delivery systems and related materials

1. Biological substances

Human pathogens, zoonoses and toxins as follows:

a. Viruses, whether natural, enhanced or modified, in the form of isolated live cultures or of materials, including living materials which are intentionally inoculated or contaminated with such cultures, as follows:

1. Chikungunya virus;
2. Crimean-Congo virus (Crimean-Congo hemorrhagic fever);
3. Dengue fever virus;
4. Eastern equine encephalitis virus;
5. Ebola virus;
6. Hantaan virus;
7. Junin virus;
8. Lassa fever virus;
9. Lymphocytic choriomeningitis virus;
10. Machupo virus;
11. Marburg virus;
12. Monkey pox virus;
13. Rift Valley fever virus;
14. Tick-borne encephalitis virus (Russian spring-summer encephalitis);
15. Variola virus;
16. Venezuelan equine encephalitis virus;
17. Western equine encephalitis virus;
18. White pox (Variola minor);
19. Yellow fever virus;
20. Japanese encephalitis virus;
21. Kyasanur Forest disease virus;
22. Louping ill virus;
23. Murray Valley encephalitis virus;
24. Omsk haemorrhagic fever virus;
25. Oropouche virus;
26. Powassan virus;
27. Rocio virus;
28. St Louis encephalitis virus;
29. Hendra virus (Equine morbillivirus);
30. South American hemorrhagic fever virus (Sabia, Flexal, Guanarito);
31. Hemorrhagic fever with lung and renal syndrome virus (Seoul, Dobrava, Puumala, Sin Nombre);
32. Nipah virus.

b. Rickettsiae, whether natural, enhanced or modified, either in the form of isolated live cultures or of materials, including living materials, which are intentionally inoculated or contaminated with such cultures, as follows:

1. Coxiella burnetii;
2. Bartonella quintana (Rochalimaea quintana, Rickettsiae quintana);
3. Rickettsiae prowazekii;
4. Rickettsiae rickettsii.

c. Bacteria, whether natural, enhanced or modified, in the form of isolated live cultures or of materials, including living materials, which are intentionally inoculated or contaminated with such cultures, as follows:

1. Bacillus anthracis;
2. Brucella abortus;
3. Brucella melitensis;
4. Brucella suis;
5. Chlamydia psittaci;
6. Clostridium botulinum;
7. Francisella tularensis;
8. Burkholderia mallei (Pseudomonas mallei);
9. Burkholderia pseudomallei (Pseudomonas pseudomallei);
10. Salmonella typhi;
11. Shigella dysenteriae;
12. Vibrio cholerae;
13. Yersinia pestis;
14. Epsilon toxin produced types of Clostridium perfringens;
15. Enterohemorrhagic Escherichia coli, serotype O157 and other verotoxin produced serotypes.

d. The following toxins and sub-units of these toxins:

1. Botulinum toxins;
2. Clostridium perfringens toxins;
3. Conotoxin;
4. Ricin;
5. Saxitoxin;
6. Shiga toxin;
7. Staphylococcus aureus toxins;
8. Tetrodotoxin;
9. Verotoxin and shiga-like ribosome activated proteins;
10. Microcystin (Cyanginosin);
11. Aflatoxins;
12. Abrin;
13. Cholera toxin;
14. Diacetoxyscirpenol toxin;
15. T-2-toxin;
16. HT-2-toxin;
17. Modeccin;
18. Volkensin;
19. Viscum album Lectin 1 (Viscumin).

Note 1:

No controls are imposed on botulinum toxins or conotoxins in product form, which comply with all of the following criteria:

1. *they are pharmaceutical specialties for human use in the treatment of diseases;*
2. *they are fully pre-packaged for distribution as pharmaceutical products;*
3. *they are permitted by a governmental authority to be marketed as a pharmaceutical product.*

Note 2:

No controls are imposed on vaccines or immunotoxins.

e. Fungi, whether natural, enhanced or modified, either in the form of isolated live cultures or of materials, including living materials, which are intentionally inoculated or contaminated with such.

1. *Coccidioides immitis*;
2. *Coccidioides posadasii*.

Genetic elements and genetically modified organisms as follows:

a. Genetically modified organisms or genetic elements which contain nucleic acid sequences associated with the pathogenicity from the organisms specified under points a–c and e in the above list of biological substances.

b. Genetically modified organisms or genetic elements which contain nucleic acid sequences as coding for any of the toxins specified under point d, or sub-units of toxins of these.

Note 1:

Genetic elements include chromosomes, genomes, plasmids, transposons and vectors, whether genetically modified or not.

Note 2:

For nucleic acid sequences associated with the pathogenicity from each of the microorganisms specified under points a–c and e in the above list of biological substances, each sequence is understood to be specific to the micro-organism specified, and which:

- a. *in itself or via its transcription or translation products represents a significant risk to human health; or*
- b. *is known to make a specified micro-organism (or any other organisms in which it can be inserted or integrated in other way) more able to cause serious harm to human health.*

Note 3:

*Limitations do not apply to nucleic acid sequences which are associated with the pathogenicity from enterohemorrhagic *Escherichia coli*, serotype O157, and other verotoxin produced strains in addition to those which code for verotoxin or sub-units thereof.*

2. Delivery systems

Spray or mist systems which are specifically designed or modified for installation on aircraft, craft which are lighter than air or unmanned aircraft, and specially constructed components for these, as follows:

a. Complete spray or mist systems which, based on a liquid suspension, can produce initial drops 'VMD' of less than 50 µm at a flow velocity of more than two litres per minute;

b. Spray systems or combinations of aerosol generating units which, based on a liquid suspension, can produce initial drops with a 'VMD' of less than 50 µm at a flow velocity of more than two litres per minute;

c. Aerosol generating units which are specially designed for installation in the systems specified under point a and b.

Note 1:

Aerosol generating units are devices which are specially designed or modified for installation on aircraft, i.e. jets, rotating drum atomizers and equivalent devices.

Note 2:

Controls are not imposed on spray or mist systems and associated components which have been proven not to disseminate biological agents in the form of infectious aerosols.

Note 3:

The drop size for spray equipment or jets which are specially designed for use on aircraft, craft which are lighter than air or unmanned aircraft are measured in accordance with one of the following methods:

- a. doppler laser method;*
- b. forward laser diffraction method.*

Note 4:

'VMD' is the volume mean diameter, and for water-based systems it is equivalent to the mass mean diameter (MMD).

3. Related materials

Equipment and technology which can be immediately used in the handling of pathogenic biological materials including toxins as follows:

a. Complete facilities for biological containment at containment level BSL3 or BSL4;

Note:

The specifications in Danish Working Environment Authority Executive Order No. 864 of 10 November 1993 on biological agents and working environments apply to containment level P3 and P4 (BSL3, BSL4, L3, L4).

b. Fermentors which can be used for the cultivation of pathogenic microorganisms, viruses or which can produce toxins without deriving aerosols and which have a total capacity of minimum 20 litres;

Note:

Fermentors include bioreactors, chemostats and systems with continuous through flow.

c. Centrifugal separators which can carry out continuous separation without the derivation of aerosols, with all the following properties:

1. flow velocity of more than 100 litres/hour;
2. components of polished stainless steel or titanium;
3. one or more seals in the steam containment area; and
4. can be sterilized in place in the closed state.

Note:

Centrifugal separators include decanting vats.

d. Filtration equipment with cross (tangential) flow and components as follows:

1. Filtration equipment with cross (tangential) flow, which can carry out the separation of pathogenic microorganisms, viruses, toxins or cell cultures without deriving aerosols, with both of the following properties:
 - a. a total filtering area of at least 1 m²; and
 - b. can be sterilized or disinfected in place;

Note:

In association with d.1.b, sterilising means the elimination of all viable microbes in the equipment using physical agents (i.e. steam) or chemical agents. Disinfection means the destruction of the potential infectivity of microbes in the equipment using germicidal chemical agents. Disinfection and sterilisation differ from sanitation, sanitation being cleaning procedures which are implemented to reduce microbe levels in the equipment, without this necessarily leading to the total elimination of the infectivity or viability of the microbes.

2. Filtration components with cross (tangential) flow (i.e. modules, elements, cassettes, cartridges or plates) with a filtering area of at least 0.2 m² for each component and which is designed to be used in the filtration equipment with cross (tangential) flow specified in point. d1;

Note:

Controls are not imposed on equipment for reverse osmosis as specified by the manufacturer.

e. Freeze drying equipment which can be sterilised by steam, with a condensation capacity of more than 10 kg of ice in 24 hours and under 1,000 kg of ice in 24 hours;

f. The following protection and encapsulation equipment:

1. Protective suits (fully or partial) or hoods with permanently attached external air supply in stationary systems which operate under positive pressure;

Note:

Controls are not imposed on suits which are to be used with built-in breathing equipment.

2. Class III biological safety cabinets or isolation equipment with similar performance standards;

Note:

Isolation equipment includes flexible isolators, drying chambers, anaerobic chambers, glove boxes and laminar flow hoods (closed with vertical flow).

g. Chambers designed for aerosol challenge testing using microorganisms, viruses or toxins and with a capacity of at least 1 m³.

h. Biological detection systems which have been specially developed or modified for the detection or identification of biological weapons for use in warfare and specially developed components thereof.

i. Technology which can be directly used for the development of biological weapons or for offensive usage. The technology required for the development, production or use of products which are controlled in this annex is controlled in accordance with the provisions for these products.

Technology which is required for the development, production or use of a controlled product, remains controlled even when used in a product which is not controlled.

There are no controls on technology which is required as a minimum for the installation, operation, maintenance (inspection) and repair of products which are not subject to control, or which have been previously issued with a permit.

There are no controls on information which is already in the public domain or represents basic scientific research, or which is required as a minimum for patent applications.

Note:

Technology is defined as specific information required for the development, production or use of a product. Information is 'technical data' or 'technical assistance'. 'Technical assistance' can take different forms such as instructions, skills, training, practical experience and consultant services and can include the transfer of technical data. Technical data can take the form of drawings, plans, diagrams, models, formulae, tables, design plans and specifications, manuals and instructions written or stored on other media or equipment such as diskettes, tape or ROMs.