Instructions for completing Application form

General guidelines

- A form is completed for each location (address).
- 1-2 biosecurity officer/s is/are appointed for each location (address).
- Applications must be accompanied by a vulnerability assessment and security plan, attached as Appendices.
- "The company's own notes" field is for internal notes and records. The field is not read by CBB.

1. Specification of category

a. Controlled material

Tick off the category of controlled material for which a licence is being applied for. See Appendix 1 of the Executive Order[1] (Control list).

b. Laboratory diagnostics

Box 1.b must only be ticked off by clinical microbiology departments and other diagnostic laboratories, who are capable of isolating controlled microorganisms as part of diagnostic investigation. Diagnostic laboratories, which at the time of applying are in possession of controlled material, and which wish to continue to store this material, must also tick the "biological substance" field. Types of material must also be identified.

If the laboratory wishes to store controlled material beyond the time involved in the diagnostic investigation, licence for this must be applied for, within 14 days, from the Centre for Biosecurity and Biopreparedness using a form for changes to the licence.

c. Retailer

Box c must only be ticked by retailers of controlled material. Retailers must also tick off the relevant types of controlled material in box 1 a.

2. Contact information

a. The company's contact information

In the box, specify the company's name, address, telephone number and CVR number (the Central Business Register).

b. The site's (department/production location) contact information

If the site for storing the controlled material has an address other than that of the company, specify the site's name, address, telephone number and any production unit number (P number).

All companies with the same CVR number also have one or more P numbers. This number identifies the physical location, from where the company operates, and may be the same number as, or different from, the companies' main address. Information on CVR and P numbers can be found on www.CVR.dk.

3. Information on the biosecurity officer

The name, personal registration number and work contact information of the biosecurity officer, which the company appoints, shall be specified in the box. Please also specify the education degree, job description and employment conditions of the biosecurity officer.

One of the conditions of a CBB licence is that appointed biosecurity officers must participate in a free, mandatory CBB one-day course. If the appoint-

1 Annex 1 to Executive Order no. 981 of 15 October 2009.

ed biosecurity officers have not already participated in the course, please also send a course registration form prior to, or simultaneously with, the application. The form can be downloaded from www.biosikring.dk/eng.

4. Information on any additional biosecurity officers

The CBB recommends that two biosecurity officers are appointed to cover holidays, illness etc., but it is not a requirement that the company has several biosecurity officers.

If an additional biosecurity officer is appointed, fill out boxes as described in Section 3.

5. Information on the responsible manager

The name and workplace contact information of the responsible manager shall be added to the box.

The responsible manager is an authorised signatory of the company and it is the responsible manager, who signs the application on behalf of the company. See Section 9.

6. Information on biological substances, delivery systems and/or related material

a. The type of biological substances, quantity and storage location

In the "Biological substance" field, specify which controlled biological substances the company is applying to possess. (See the control list.)

In the "Quantity" field, specify the number of closed storage containers at the time of application, if known.

In the "Building" and "Room" fields, specify number of the building and room or the precise location of the building and room.

In the "Comments" field, additional relevant information may be specified.

b. The type of delivery systems and/or related material, quantity and storage location

In the "Delivery systems and/or related materials" field, specify the controlled delivery systems and/ or related material the company possesses. (See the control list.)

In the "Quantity" field, specify the quantity at the time of application, if known.

In the "Building" and "Room" fields, indicate the exact location of the controlled delivery systems and/or related material.

The box beneath must only be ticked off if the toxins applied for do not include production of toxins and the toxins do not exceed the amounts specified in Table 1. at biosikring.dk/eng/What is subject to control?

In the "Comments" field, additional relevant information may be specified.

7. Description of purpose

Companies must demonstrate a legitimate purpose, if they wish to be licensed to work with controlled material. For this they must prepare a detailed description of the purpose and a schedule.

a. Description of purpose and schedule

Use the box to describe the purpose of the activity/ activities. If the person/s is/are limited by time constraints, indicate a schedule: e.g. 3 years for a PhD project. The licence is awarded to cover activities up to a maximum of 5 years. Diagnostic laboratories, which do not wish to save pure isolates may receive a permanent licence.

b. The main responsible for the the project

In the box, specify the name, education degree and job description of the main person, who is primarily responsible for the activity.

c. Associates related to the purpose/activity

In the box, specify the names of any companies, who are collaborating on the described work/project. In addition, specify the CVR number and the name of a contact person from the company.

d. Total resource consumption of the purpose/ activity

The box must only be completed by companies, who require project-related activities with controlled biological substances. In this box, specify how the activity is, or shall be, funded. The estimated total resource consumption is specified as the company's own financing, together with any external funding, including salary resources. The names of external donors (foundations, companies and partners) and the amounts contributed must be specified.

8. Appendix

A vulnerability assessment and security plan must be attached to the application as Appendices. Exempted are applications for possession, use and storage of toxins. Contact CBB for the form and instructions.

9. Signature

Date, name and signature of the responsible manager and of the site's biosecurity officer.

The person signing on behalf of the company is an authorised signatory for the company and, together with the biosecurity officer, is responsible for ensuring that the company complies with biosecurity legislation and any conditions or requirements stipulated by the CBB for the licence being applied for.

It is the company's responsibility to ensure that the correct people sign.

10. Send by registered mail

Please send the application form together with the vulnerability assessment and security plan, by registered mail to:

The Centre for Biosecurity and Biopreparedness
Statens Serum Institut
Artillerivej 5
DK-2300 Copenhagen S

Guide to completion of the form by company type

The guide includes the most common types of companies subject to Executive Order no. 981 of 15 October 2009 concerning the protection of certain biological substances, delivery systems and related material. Distributors of biological substances and other companies not included in this guide are requested to contact the Centre for Biosecurity and Biopreparedness for guidance.

	Licence to possess biological substances	Licence to possess related material	Licence for diagnostics	Retailers of related material with stock in Denmark	Retailers without stock in Denmark
Section 1	1a	1a	1b	1a and 1c	1a and 1c
Section 2-5	Must be completed	Must be completed	Must be completed	Must be completed	Must be completed
Section 6	6a	6b	Not to be completed.	6b	6a or 6b
Section 7	7a-7b Possibly 7c-7d	7a-7b Possibly 7c-7d	7a-7b	7b	7b
Section 8	Attached	Attached	Attached	Attached	Attached
Section 9	Must be completed	Must be completed	Must be completed	Must be completed	Must be completed