Instructions for completing Form for changes to the licence

General guidelines

- The form for changes to the licence is used to report changes under an existing licence.
- Changes under an existing licence must be sent to Centre for Biosecurity and Biopreparedness (CBB) before the amendment is intended to be implemented.
- The form field, "The company's own notes" is for internal notes and records. The field is not read by the CBB.

1. Contact information

The field box must include the company's and the site's name, address, telephone number and number of production unit (P number), for which the company holds the controlled material.

2. Information on biosecurity on the site

The field box must include the CBB licence number and the name and personal registration number of the biosecurity officer. The CBB licence number is printed on the licence.

3. Categories of the form for changes to the licence

First, indicate by ticking the category, to which the form for changes to the licence relates. Several categories may be indicated. Ticking may then be supplemented with explanatory comments on each category:

a. Additional material related to the existing licence

In the "Biological substance" field, specify which additional controlled biological substances the company wishes to add to the existing licence.
In the "Quantity" field, specify the number of closed storage containers at the time of application, if this is known.

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

In the "Comments" field, specify any additional relevant information.

In the "Delivery systems and/or related materials" field, specify the controlled delivery agents and/or related material, which the company wishes to add to the existing licence.

In the "Quantity"field, specify the quantity.

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

In the "Comments" field, you may specify additional relevant information.

In the "Description of purpose and schedule" fields, describe the purpose of the activity/activities. If the person/s is/are bound by time constraints, identify a schedule: e.g. 3 years for a PhD project.

In the "The main responsible for the project" field, indicate the name, education degree and job description of the company's main participants.

In the "Associates related to the purpose/activity" field, indicate the names of any companies collaborating on the activity/project described. In addition, specify the CVR number and the name of a contact person from the company.

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

If there are significant changes to the existing licence, a reviewed vulnerability assessment and security plan must be attached as Appendices.

b. Change of biosecurity officer

Name, personal registration number and workplace contact information of the new biosecurity officer must be specified in this box. Specify the education degree, job description and employment conditions of the biosecurity officer.

If a biosecurity officer leaves the position, the name of this person and their personal registration number must be specified.

c. Changes in the company

This describes changes in the company, which may affect the existing licence: e.g. a description of new building extensions; the moving of controlled material to another building; a change of address; possible closure etc. In the event of closure, the disposal of controlled material must be accounted for.

If there are significant changes to the existing licence, a reviewed vulnerability assessment and security plan must be attached as Appendices.

d. Other changes to the existing licence

In the box, provide a short description of the factors underlying the need to change the existing licence. It may be that the company wants the work/project to be extended for one year due to maternity leave, or because one/several participant/s has/have been replaced.

4. Signature

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

The responsible manager 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 right people sign.

5. Sent by registered mail

The form shall be sent by registered mail to:

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

Guide to completing the form by company type

The guide includes the most common types of company subject to Executive Order no. 981 of 15 October 2009, concerning the protection of certain biological substances, delivery agents and related material. Distributors of biological substances and other companies not included in this guide are asked 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
1-2	Must be completed	Must be completed	Must be completed	Must be completed	Must be completed
Section 3	Relevant section must be completed	Relevant section must be completed	Relevant section must be completed	Relevant section must be completed	Relevant section must be completed
Section 4	Must be completed	Must be completed	Must be completed	Must be completed	Must be completed