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| lueng |  | **Document name**       |
|  |  | **Reference number /version (optional)**  |
| Risk assessment form for biological agents & toxins (BARA) | **Date (year-month- day)**  |
| * **Note! This form cannot be used for genetically modified micro-organisms1**
* This form can be used for identification and characterization of risks involved in work with known microorganisms and toxins.
* The biological agent(s) should be characterized in Part A. Each type of method involving biological agents(s) should be evaluated in Part B. Note that more than one Part A might be needed for different activities with the same organism. B1 applies in the laboratory setting and B2 when performing animal experiments.
* For relevant legislation, see AFS 2018:4 ‘Smittrisker’.
* For chemical and environmental risk assessments, see the risk assessment form in "KLARA"
* **When finished, print, sign and place this form in the lab so that each researcher can consult it before conducting experiments**
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| Part ACHaracterization of the organism(s) |
| **Department (section)**      | **Person responsible for work environment**       |
| **Room number(s)**       |
| **Lab co-ordinator (if applicable)**       |
| [ ]  Virus [ ]  Bacteria [ ]  Toxin2 [ ]  Cell line [ ]  Fungi [ ]  Protozoa [ ]  Other        |
| **Name of group, organism,** **subgroup, type, strain designation(s):** |       |
| [ ]  Risk group 13 [ ]  Risk group 23 [ ]  Risk group 33 [ ]  Not applicable  |
| [ ]  Not genetically modified[ ]  Genetically modified- This form cannot be used for this purpose, unless it is a spontaneous modification1. Please read the supplemental information above. |
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| **Type and origin of the sample:**  |

 |       |
| **Special properties of the particular strain(s):** | [ ]  antibiotic resistance? *elaborate:*      [ ]  virulence factors? *elaborate:*      [ ]  resistance against drying? *elaborate:*      [ ]  resistance against heat? *elaborate:*      [ ]  resistance against disinfectants? *elaborate:*      [ ]  risk for allergic reactions? *elaborate:*      [ ]  risk for pregnant employees? *elaborate:*      [ ]  Other; *please elaborate:*       |
| **Symptoms if infected** (e.g. disease spectrum): |       |
| **The possible consequences and their severity if the employer is exposed to the infectious agent:** |       |
| [ ]  Low infectious dose [ ]  High infectious dose. Please comment, eg numbers of particles |
| **Natural route of infection:** | [ ]  aerosol [ ]  skin contact [ ]  mucous membrane contact [ ]  injection (skin puncture) [ ]  dust [ ]  ingestion [ ]  other       |
| **Possible routes of transmission in the lab:** | [ ]  aerosol [ ]  skin contact [ ]  mucous membrane contact  [ ]  injection (skin puncture) [ ]  dust [ ]  ingestion [ ]  other       |
| **Available treatment**(e.g. first choice antibiotics, if applicable): |       |
| **Available immuno-prophylactic measures:** |       |
| **Survival of the organism in the environment:** |       |

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| Part B1Risk assessment- laboratory work | Reference number /version (optional):       |
| **General description of the work:** |       |
| **Method description(s) including type of work (cultivation etc):** Please elaborate or attach |       |
| **Which part(s) of the handling possesses the highest risk of infection?** e.g. propagation, sonication, centrifugation, use of needles  |       |
| **Safety procedures to minimize the risk of laboratory infections:**e.g. minimize volumes, evaluate if a less pathogenic strain can be used, how to avoid aerosols and sharp objects |       |
| **Expected time of risk for exposure4:** |       |
| **Handling procedures for the organism:**[ ]  **Work in a biological safety cabinet**5[ ]  Class 1. [ ]  During the whole method. [ ] During parts of the method, which?     [ ]  Class 2. [ ]  During the whole method. [ ] During parts of the method, which?     [ ]  **Protective gloves** [ ]  During the whole method. [ ] During parts of the method, which?     [ ]  **Protective clothing**. Please specify:      **Other**, please elaborate:       |
| **Does the method involve hazardous chemicals (including isotopes)?** | [ ]  No[ ]  Yes. Name of the risk assessment:       |
| **How is liquid waste handled?** Does it contain mixed sources eg antibiotics/chemicals that need special considerations? 6 |       |
| **How is solid waste handled?**6 |       |
| **Suitable disinfection method of lab area/biosafety cabinet:** |       |
| **If immunization is available, are all personnel working in this lab vaccinated?** | [ ]  Yes[ ]  No. Why:       |
| **Emergency procedures:****In case of accident, spill, theft etc.** |       |
| **Name and phone number of contact person (in case of accident):** |       |
| **Have you considered the experiments in view of laboratory biosecurity7 and dual-use?** | [ ]  Yes[ ]  No, Why:      [ ]  Not applicable. Why:       |
| **Based on the answers above, the activity/organism will be handled in:**[ ]  Biosafety level 18[ ]  Biosafety level 29  Registered? [ ]  Yes [ ]  No.  The lab is marked with BSL2 sign? [ ]  Yes [ ]  No.[ ]  Biosafety level 310  |
| **How many employees are performing the experiments (or otherwise involved)?** |       |
| **Are there employees needing special consideration?** e.g. pregnant employees, dish washing personnel, cleaners, service personnel |       |
| **Handling and safety instructions available?**11 | [ ] Yes, which?       [ ]  No, why?       |
| **Other information** |       |
| **Name in print:**Note! it is recommended that more than one person evaluates the organism and the risks |       |
| **Signature:** (person responsible for work environment) |  |

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| Part B2Risk assessment-Animal handling | Reference number /version (optional):       |
| **Ethical permission nr** |       |
| **General description of the work**  |       |
| **Method description(s) including type of work (oral lavage etc):** Please elaborate or attach |       |
| **Which part(s) of the handling possesses the highest risk of infection?** e.g use of needles/scratching |       |
| **Safety procedures to minimize the risk of laboratory infections:** e.g. minimize volumes, evaluate if a less pathogenic strain can be used, how to avoid aerosols and sharp objects |       |
| **Expected time or risk for exposure:** |       |
| **Handling procedures:**[ ]  **Work in a biological safety cabinet**5 Class 1 [ ]  During the whole method. [ ] During parts of the method, which?     Class 2 [ ]  During the whole method. [ ] During parts of the method, which?     [ ]  **Protective gloves** [ ]  During the whole method. [ ] During parts of the method, which?      [ ]  Special type?     [ ]  **Protective clothing** Please specify:      [ ]  **Mouth protection** Please specify:      **Other**, please elaborate:       |
| **How do you avoid cross infections within the animal facility?** |       |
| **Does the method involve hazardous chemicals (including isotopes)?** | [ ]  No[ ]  Yes. Name of the risk assessment:       |
| **Liquid waste:**6Please specify type of liquid waste generatedHow is liquid waste handled? |       |
| **How is solid waste handled (including bedding material)?**6 |       |
| **Suitable disinfection method of lab area/biosafety cabinet:** |       |
| **If immunization is available, are all personnel working with this method vaccinated? Including facility personnel.** | [ ]  Yes[ ]  No. Why:       |
| **Emergency procedures:**In case of accident, spill, theft etc. |       |
| **Name and phone number of contact person (in case of accident):** |       |
| **Have you considered the experiments in view of laboratory biosecurity7 and dual-use?** | [ ]  Yes[ ]  No. Why:      [ ]  Not applicable. Why:       |
| **Who is in charge of inventory control?** |       |
| **Based on the answers above, the activity/organism will be handled in:**[ ]  Biosafety level 18[ ]  Biosafety level 29  Registered? [ ]  Yes [ ]  No. The room is marked with BSL2 sign? [ ]  Yes [ ]  No. |
| **Will facility personnel perform the experiments/parts of the experiments?** | [ ]  No[ ]  Yes. Have they been informed about the risks involved?[ ]  Yes [ ]  No, why?       |
| **How many employees are performing the actual experiments (or otherwise involved)?** |       |
| **Are there employees needing special consideration?** e.g. facility personnel, pregnant employees, dish washing personnel, cleaners, service personnel |       |
| **Handling and safety instructions available?**11**Often specified by the facility management** | [ ] Yes, which?       [ ]  No, why?       |
| **Other information** |       |
| **Name in print of the persons involved in the assessment of risks.** Note! it is recommended that more than one person evaluates the risks |       |
| **Signature** (person responsible for work environment) |  |

1 Please see <https://www.hr-webben.lu.se/arbetsmiljo/mikrobiologiska-risker-och-gmm/genetiskt-modifierade-mikroorganismer-gmm>

2 This form should be used for toxins only when they are expressed in the micro-organism (meaning that you also have to mark one more option in this row). Toxins, independent on if they are produced from micro-organisms or from plants/animals or of other sources should otherwise be treated as chemical agents and risk assessments for these shall be made in KLARA.

3 Lists of biological agents in different risk groups can be found at <https://www.av.se/arbetsmiljoarbete-och-inspektioner/publikationer/foreskrifter/smittrisker-afs-20184> in Swedish). Special regulations apply and extensive risk assessment is required when working with biological agents in risk group 3.

4 Describe if the work is performed rarely or regularly, for short or long periods.

5 Note the difference between a class 1 cabinet with uncirculated airflow away from the operator that is discharged to the atmosphere after filtration through a HEPA filter providing good operator protection and a class 2 cabinet with recirculated airflow protecting both the operator and the product.

6 Follow LU:s rules for waste handling <http://www.medarbetarwebben.lu.se/stod-och-verktyg/lokaler-och-parkering/avfall-farligt-avfall-och-kallsortering>

7 Laboratory biosecurity describes the protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release. Things to consider; physical protection e.g. unauthorized entry, personnel suitability/reliability e.g. biosecurity training to personnel, and pathogen accountability e.g. inventory, labeling, tracking and inactivation of cultures. Dual-use refer to research that, based on current understanding, can be reasonably anticipated to provide knowledge, products or technologies that could be directly misapplied by others to pose a threat to public health, agriculture, plants, animals, the environment or material.

8 Protective measures for each level can be found at <https://www.av.se/arbetsmiljoarbete-och-inspektioner/publikationer/foreskrifter/smittrisker-afs-20184>, page 15-17

9 Work with biological agents in risk group 2 must at least be conducted in biosafety level 2 (BSL2) laboratories and requires prior notification to the Swedish Work Environment Authority. The BSL2 laboratory must be clearly marked with a biohazard

sign and “Skyddsnivå 2”.

10 Work with biological agents in risk group 3 must at least be conducted in biosafety level 3 (BSL3) laboratories and requires prior notification to the Swedish Work Environment Authority. Special regulations apply, and extensive risk assessment is required.

11 Handling and safety instructions in writing must be provided for the use of infectious agents and otherwise when necessary for the prevention of ill-health or accidents. This means that written handling and safety instructions are obligatory at containment level 2 and

upwards. In addition, supplementary, specially adapted instructions may often be needed for the individual use, depending on

the risks which it specifically entails.