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| KI-Logo_pos_sv | | Version 8 (Dec 2018) | | **Document name:** |
|  | |  | | **Reference number /version (optional):** |
| Risk assessment form for biological agents & toxins (BARA) | | | | **Date (year-month- day):** |
| * This form can be used for identification and characterization of risks involved in work with known microorganisms and toxins * For risk assessment of blood and other human sample material you may use the risk assessment form ‘[HUMRA](https://internwebben.ki.se/en/biosafety)’ * The biological agent should be characterized in Part A. Each type of method involving biological agents should be evaluated in Part B. Note that more than one form A might be needed for different microorganisms using the same method or more than one form B might be needed for different activities with the same microorganism. Form B1 applies in the laboratory setting and form B2 when performing animal experiments. * For relevant legislation, see AFS 2018:4 ‘Smittrisker’. * For chemical risk assessments, read more and find risk assessment form "KLARA": [https://ki.se/en/staff/chemical-safety](%20https:/ki.se/en/staff/chemical-safety%20) * **Note that this form cannot be used for genetically modified microorganisms[[1]](#footnote-1)!**   **When finished, print and place this form in the lab so that each researcher can consult it before conducting experiments** | | | | |
| A) CHaracterization of the organism(s) | | | | |
| **Department:** | | | **Group leader /PI:** | |
| **Room number(s):** | | | | |
| **Lab responsible person (if applicable):** | | | | |
| Virus  Bacteria  Toxin[[2]](#footnote-2)  Cell line  Fungi  Protozoa  Other | | | | |
| **Name of group, organism,**  **subgroup, type, strain designation(s), etc.:** |  | | | |
| Risk group 1[[3]](#footnote-3)  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. | | | | |
| **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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| B1) Risk assessment- laboratory work | | Reference number /version (optional): |
| **General description of the work:** |  | |
| **Method description(s) including type of work (cultivation etc.):**  Please elaborate. |  | |
| **Which part(s) of the handling possesses the highest risk of infection?**  E.g. propagation, sonication, centrifugation or 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 or how to avoid aerosols and sharp objects. |  | |
| **Expected time of risk for exposure[[4]](#footnote-4):** |  | |
| **Handling procedures for the organism:**  **Work in a biological safety cabinet4**  Class 1[[5]](#footnote-5)  During the whole method. During parts of the method, which?  Class 24  During the whole method. During parts of the method, which?  **Protective gloves.** Specification of gloves**[[6]](#footnote-6)**  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)[[7]](#footnote-7)?** | No  Yes, which?      , which risk statements?       Does the handling of dangerous chemicals need a separate risk assessment? If yes; name of the risk assessment: | |
| **Liquid waste[[8]](#footnote-8):**  Please specify type of liquid waste generated  How is liquid waste handled?  Does it contain mixed sources e.g. antibiotics/chemicals that need special considerations? | No  Yes, which?      , how should this be handled? | |
| **How is solid waste handled?**  Please specify type of solid waste generated.  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 biosecurity[[9]](#footnote-9) and dual-use?** | Yes  No, Why:  Not applicable. Why: | |
| **Based on the answers above, the activity/organism will be handled in:**  Biosafety level 1[[10]](#footnote-10)  Biosafety level 2[[11]](#footnote-11)  Approved notification?  Yes  No.  The laboratory is marked with a BSL2 sign?  Yes  No.  Biosafety level 3[[12]](#footnote-12) | | |
| **How many employees are performing the experiments (or otherwise involved)?** |  | |
| **Are there employees needing special consideration?**  E.g. pregnant employees, dish washing personnel, cleaners, and service personnel. |  | |
| **Handling and safety instructions available?[[13]](#footnote-13)** | Yes, which?        No, why? | |
| **Other information:** |  | |
| **Name in print.**  Note that it is recommended that more than one person evaluates the organism and the risks. |  | |
| **Signature; Group leader:** |  | |

**This form was composed by the Biosafety Committee at KI.**

**If you have further questions, please read more at** [**https://ki.se/en/staff/biosafety**](https://ki.se/en/staff/biosafety)**, or send an e-mail to** [**mailto:biosakerhet@ki.se**](mailto:biosakerhet@ki.se)

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| * This form, B2) Risk assessment- animal handling, specifies the animal experiments and is not needed if you only perform laboratory work. * You should specify the laboratory work that leads up to a culture of the microorganism in BARA form part B1) Risk assessment- laboratory work. Exclude part B1) if you do not cultivate the microorganism before the animal experiment. * Several risk assessments might be needed that corresponds to one ethical permit. | | |
| **Ethical permission nr** | | |
| B2) Risk assessment-Animal handling | | Reference number /version (optional): |
| **General description of the work** |  | |
| **Method description(s) including type of work (oral lavage etc.):**  Please elaborate |  | |
| **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 or how to avoid aerosols and sharp objects. |  | |
| **Expected time or risk for exposure[[14]](#footnote-14):** |  | |
| **Handling procedures for the organism:**  **Work in a biological safety cabinet4**  Class 1[[15]](#footnote-15)  During the whole method. During parts of the method, which?  Class 24   During the whole method. During parts of the method, which?  **Protective gloves.** Specification of gloves**[[16]](#footnote-16)**  During the whole method. During parts of the method, which?  **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)[[17]](#footnote-17)?** | No  Yes, which?      , which risk statements?       Does the handling of dangerous chemicals need a separate risk assessment? If yes; name of the risk assessment: | |
| **Liquid waste[[18]](#footnote-18):**  Please specify type of liquid waste generated  How is liquid waste handled?  Does it contain mixed sources e.g. antibiotics/chemicals that need special considerations? |  | |
| **How is solid waste handled?**  Please specify type of solid waste generated.  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?**  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 biosecurity[[19]](#footnote-19) and dual-use?** | Yes  No. Why:  Not applicable. Why: | |
| **Who is in charge of inventory control (mandatory)?** |  | |
| **Based on the answers above, the activity/organism will be handled in:**  Biosafety level 1[[20]](#footnote-20)  Biosafety level 2[[21]](#footnote-21)  Approved notification?  Yes  No.  The laboratory is marked with a BSL2 sign?  Yes  No.  Biosafety level 3[[22]](#footnote-22) | | |
| **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. pregnant employees, dish washing personnel, cleaners, and service personnel. |  | |
| **Handling and safety instructions available?[[23]](#footnote-23)**  Often specified by the facility management | Yes, which?        No, why? | |
| **Other information:** |  | |
| **Name in print.**  Note that it is recommended that more than one person evaluates the organism and the risks. |  | |
| **Signature; Group leader.** |  | |

**This form was composed by the Biosafety Committee at KI. If you have further questions, please read more at** [**https://ki.se/en/staff/biosafety**](https://ki.se/en/staff/biosafety)**, or send an e-mail to** [**mailto:biosakerhet@ki.se**](mailto:biosakerhet@ki.se)

1. Please see [https://ki.se/en/staff/biosafety](https://ki.se/en/staff/biosafety%20) for more information or AFS 2018:9: “[Contained Use of Genetically modified Microorganisms](https://www.av.se/en/work-environment-work-and-inspections/publications/foreskrifter/contained-use-of-genetically-modified-micro-organisms-afs-20112eng-provisions/)” for relevant legislation [↑](#footnote-ref-1)
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 can be made in KLARA. [↑](#footnote-ref-2)
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/?hl=2018:4> (in Swedish). Special regulations apply and extensive risk assessment is required when working with biological agents in risk group 3. [↑](#footnote-ref-3)
4. Describe if the work is performed rarely or regularly, for short or long periods. [↑](#footnote-ref-4)
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 [↑](#footnote-ref-5)
6. For more information about gloves, please see [https://ki.se/en/staff/biosafety](https://ki.se/en/staff/biosafety%20) and [https://ki.se/en/staff/chemical-safety](https://ki.se/en/staff/chemical-safety%20%20)  [↑](#footnote-ref-6)
7. Risk statements for dangerous chemicals can be retrieved from the MSDS (material safety data sheet) section 15 or from the bottle/container, for example ‘Flammable’, ‘Causes burns’ etc [↑](#footnote-ref-7)
8. Waste management and sewage rules at KI can be found at the KI homepage <https://ki.se/en/staff/laboratory-waste>. [↑](#footnote-ref-8)
9. 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. [↑](#footnote-ref-9)
10. Protective measures for each level can be found at <https://www.av.se/arbetsmiljoarbete-och-inspektioner/publikationer/foreskrifter/smittrisker-afs-20184/?hl=2018:4>, page 15-17 [↑](#footnote-ref-10)
11. 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”. [↑](#footnote-ref-11)
12. 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. [↑](#footnote-ref-12)
13. 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 mandatory at biosafety 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. [↑](#footnote-ref-13)
14. Describe if the work is performed rarely or regularly, for short or long periods. [↑](#footnote-ref-14)
15. Note the difference between a class 1 cabinet with unrecirculated 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 protecting both the operator and the product. [↑](#footnote-ref-15)
16. For more information about gloves, please see <https://ki.se/en/staff/biosafety> and <https://ki.se/en/staff/chemical-safety> [↑](#footnote-ref-16)
17. Risk statements for dangerous chemicals can be retrieved from the MSDS (material safety data sheet) section 15 or from the bottle/container, for example ‘Flammable’, ‘Causes burns’ etc. [↑](#footnote-ref-17)
18. Waste management and sewage rules at KI can be found at the KI homepage <https://ki.se/en/staff/laboratory-waste>. [↑](#footnote-ref-18)
19. 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. [↑](#footnote-ref-19)
20. Protective measures for each level can be found at <https://www.av.se/arbetsmiljoarbete-och-inspektioner/publikationer/foreskrifter/smittrisker-afs-20184/?hl=2018:4>, page 15-17 [↑](#footnote-ref-20)
21. 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”. [↑](#footnote-ref-21)
22. 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. [↑](#footnote-ref-22)
23. 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 mandatory at biosafety 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. [↑](#footnote-ref-23)