

**Service Biosafety and Biotechnology (SBB)**

**BIOLOGICAL INCIDENT - REPORT FORM\_v20181130**

 **in the context of a contained use of genetically modified and/or pathogenic organism(s)**

**Instructions:** This form should be completed by the principal investigator of the lab, supervisors and/or the person involved in the incident.

This form has been created to optimize the assessment and management of health and safety consequences posed by a bio-incident. In addition it creates data for lessons learnt, which increase awareness and may prevent similar incidents.

The form can be submitted by email (contained.use@scienscano.be) or anonymously via [the online bio-incident notification tool](https://limesurvey.wiv-isp.be/index.php?sid=48368&newtest=Y&lang=en).

**Note:** A submission is not an official notification to all competent authorities. To see the legal notification requirements, consult [the online bio-incident notification tool](https://limesurvey.wiv-isp.be/index.php?sid=48368&newtest=Y&lang=en) on [www.biosafety.be](http://www.biosafety.be).

Information collected within this report will be retained according to SBB’s Privacy Policy.

|  |  |
| --- | --- |
| **DATE OF INCIDENT** |  |
| **BRIEF DESCRIPTION OF THE INCIDENT:** |
| **ORGANISM(S) INVOLVED IN THE INCIDENT:**Amount/concentration (of the organism(s)) involved in the incident:….. | [ ]  Unknown |
| **IDENTIFICATION OF THE INCIDENT:**Please indicate the steps that have led to the identification of the bio-incident*(please indicate the order in time with numbers: 1 for the first step in identification, 2 for the second step in assessment of the bio-incident, …)*(A) Immediate identification: [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 (B) Environmental sampling: [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5(C) Human sampling: [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5(D) Surveillance[[1]](#footnote-1): [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5(E) Medical follow-up: [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 |
| **WORK-RELATEDNESS OF THE INCIDENT:** [ ] 100% | [ ]  likely | [ ] unlikely | [ ]  unknown | [ ]  under investigation |
| **CONTEXT OF THE INCIDENT:** |
| TYPE OF ACTIVITY:[ ] R&D (human) [ ] R&D (veterinary / animal health)[ ] R&D (plant)[ ] Diagnostics (human)[ ] Diagnostics (veterinary / animal health)[ ] Diagnostics (plant)[ ] Clinical trial (human)[ ] Clinical (veterinary)[ ] Quality control[ ] Production[ ] Other: *(please specify)* [ ] Unknown | TYPE OF FACILITY AND CONTAINMENT LEVEL:[ ]  Laboratory [ ] L1 / [ ] L2 / [ ] L3 / [ ] L4[ ]  Animal facility [ ] A1 / [ ] A2 / [ ] A3 / [ ] A4[ ]  Greenhouse [ ] G1 / [ ] G2 / [ ] G3[ ]  Large scale facility [ ] LS1 / [ ] LS2 / [ ] LS3 / [ ] LS4[ ]  Hospital room [ ] HR1 / [ ] HR2 / [ ] HR3 [ ]  Other: [ ]  Unknown |
| **ADDITIONAL INFORMATION:**1. Number of (possible) exposed person(s): …. | [ ] Unknown
2. Number of infected person(s): .… | [ ] Unknown / under investigation
3. Route of exposure (if an infection is confirmed): [ ]  Infectious air (aerosols) | [ ]  Splashes and/or droplets | [ ]  Parenteral inoculation (sharps injury) | [ ]  Contact ( [ ] mucous membrane or [ ]  skin) | [ ]  Unknown
4. Total days of disability per person as a result of the incident? …. | [ ]  Unknown
5. Function(s) of person(s) involved in incident: [ ] Technician | [ ] Researcher | [ ] Animal keeper |[ ] Plant keeper | [ ] Student |[ ] Maintenance personnel | Other: *(please specify)*
6. Seniority of each person involved (years): .... | [ ]  Unknown
7. Were the persons involved trained in biosafety?

[ ] Yes, general biosafety training | [ ] Yes, specific biosafety training |[ ]  No | [ ] Unknown1. Personal protective equipment (PPE) worn at the time of the incident: [ ]  Lab coat | [ ]  Gloves | [ ]  Respiratory mask | [ ]  Goggles | [ ]  Unknown | Other: *(please specify)*
2. Was there in addition a secondary transmission (to another person or animal host) outside the laboratory? [ ] Yes |[ ]  No |[ ]  Unknown

Please indicate the general workload with the involved (micro-)organism(s) if diagnostics, quality control of R&D is applied (time of incubation / culturing not included):A. in the context of R&D [average number of hours/week]:(1) *in vitro: …*(2) *in vivo*: …B. in the context of diagnostics/quality control [average number of positive diagnostic samples per year]: |
| **CAUSE OF THE INCIDENT:** [ ] human error | [ ] technical error |[ ] unknown | [ ] other: *(please specify)*The incident is related to :[ ]  Procedure [ ]  Personal protective equipment [ ]  Equipment [ ]  Infrastructure [ ]  Sharps [ ]  Spill / Splashes [ ]  Loss of primary containment (falcons, flask, petri dish, …) [ ]  Bites and/or scratches from an infected animal [ ]  Other: *(please specify)*[ ]  UnknownDue to: [ ] non-compliance (of SOPs)? | [ ]  not enough experience | [ ]  not enough biosafety training |[ ]  not enough follow-up | [ ]  too much work (workload) | [ ]  lack of space | [ ]  lack of adapted equipment and materials | [ ]  lack of knowledge of the biological risks related to the activity | [ ]  lack of attention /absence of mind, being distractedDescribe briefly the rationale of the incident:[ ] Unknown |
| **PREVENTIVE MEASURES:**(A) Please describe briefly the measures already taken to contain the biological risk(s) of the incidentWas there an emergency plan available? [ ] Yes |[ ]  No |[ ]  UnknownType: [ ]  internal | [ ]  externalEffectiveness of the emergency plan(s)? [ ] sufficient |[ ]  insufficient, please substantiate: (B) Please describe briefly the corrective action(s) / measures that have been / will be taken to prevent similar incidents in the future: |
| **CONCLUSION:**TYPE OF INCIDENT:[ ]  Incident without exposure | [ ]  Incident with exposure, without infection | [ ]  Laboratory-acquired infection [ ] Release in the environment | [ ] Theft | [ ] Uncertain |[ ] Other: *(please specify)*With (possible) [ ]  negligible / [ ]  low / [ ]  moderate / [ ]  high risk of spreading/establishment of the accidentally released biological agent(s) in the environment or community. Is there a risk of spreading to another country due to the incident [ ] Yes |[ ]  No |[ ]  UnknownPlease briefly substantiate your choice for the risk of spreading (taking into account the containment measures already taken to contain the biological risk(s) of the incident):SEVERITY OF INCIDENT:Please estimate the (possible) severity of the bio-incident[ ] Negligible | [ ] Low | [ ] Moderate |[ ] High *Please substantiate your choice if deviating from the straightforward estimation*[[2]](#footnote-2)*:*  |
| **NOTIFICATION:***(A) Please indicate which people have been notified about the bio-incident and are involved in the evaluation:*[ ] Biosafety advisor |[ ] Occupational health practitioner| [ ] Prevention advisor |[ ] Other: *(please specify)**(B) Please indicate which authorities have already been informed about the incident according to the legal notification requirements, see* [*the online bio-incident notification tool*](https://limesurvey.wiv-isp.be/index.php?sid=48368&newtest=Y&lang=en)*.*[ ]  The regional offices of the Belgian Federal Public Service Employment, Labour and Social Dialogue (tww@werk.belgie.be) ;[ ]  The regional competent authorities for notifiable human infectious diseases[[3]](#footnote-3) ;[ ]  SBB (contained.use@sciensano.be ; 02/642 52 93) ;[ ]  The regional CU competent authority[[4]](#footnote-4) ;[ ]  Crisis Centre (IBZ) of the Federal Public Service of Internal Affairs[[5]](#footnote-5) (02/506 47 11) ;[ ]  Crisis prevention and management service of the Federal Agency for the Safety of the Food Chain (ccc@favv.be ; 02/208.82.83) [ ]  Other: (please specify) |

***If further assistance or feedback is required, please provide contact details (facultative):***

Name: Institute/company:

Email : Phone number:

***For immediate assistance in assessing the incident, completing or submitting the Incident Report, please call or email the Service Biosafety and Biotechnology (SBB) of Sciensano at 0032 2 642 52 93 or*** ***Contained.use@sciensano.be******.***

***Please indicate if a lesson learnt on this incident may be published on our website (www.biosafety.be) with respect for your privacy and confidentiality.*** [ ] Yes |[ ]  No

1. Surveillance is the monitoring of the presence or absence of specific substances of interest in medical sample(s) indicating an exposure to the biological agent of interest (e.g. Mycobacterium, HIV,…) with the aim to detect a (latent) infection or exposure. [↑](#footnote-ref-1)
2. An objective straightforward estimation of the seriousness of the incident can be made by multiplying the maximum risk class of the involved organism(s) with the maximal probability of spreading in the environment (1 if negligible, 2 if low, 3 if moderate and 4 if high), where with a value between 1-2 the severity is considered as negligible, 3-5 as low, 6-9 as average and above 9 as high. Please note that this method is straightforward based on a limited number of parameters. Deviations are possible. Please substantiate every deviation. [↑](#footnote-ref-2)
3. Flemish Region: <http://www.zorg-en-gezondheid.be/meldingsplichtigeinfectieziekten/>**;**

Brussels-Capital Region: <http://www.ccc-ggc.irisnet.be/fr/politique-de-la-sante/maladies-transmissibles>**(FRENCH) ;**

<http://www.ccc-ggc.irisnet.be/nl/gezondheidszorg/besmettelijke-ziekten>**(DUTCH) ;**

Walloon Region:<http://sante.wallonie.be/?q=transfert-competences-sante/surveillance-declaration-maladies-infectieuses> [↑](#footnote-ref-3)
4. Flemish region: GOP.omgeving@vlaanderen.be ; 02 / 553 79 97 ; Brussels-Capital Region: BIM/IBGE 02 / 755 75 11 ; Walloon region: DGARNE 081 / 33 61 29 [↑](#footnote-ref-4)
5. [Crisiscentrum](https://crisiscentrum.be/nl/risicobeheer) | [le Centre de Crise](https://crisiscentrum.be/fr/gestion-des-risques) | [Krisenzzentrum](https://crisiscentrum.be/de/attentate-2203) ; <https://www.biosecurite.be/content/utilisation-confinee-de-mgms-plans-durgence-et-dintervention> (FR) or <https://www.bioveiligheid.be/content/ingeperkt-gebruik-van-ggms-bijzondere-rampenplannen-voor-hulpverlening> (NL) [↑](#footnote-ref-5)