**Completed By:** Click here to enter text. **Date Completed:** Click here to enter a date.

1. **Bioagent/Microorganism Category**

[ ] **Bacteria/chlamydia/ Ricketssia** [ ]  **Mycoplasm**

[ ] **Virus** [ ]  **Prion**

[ ] **Parasite** [ ]  **Other: Specify Click here to enter text.**

1. **Species Name:Click here to enter text. Strain Name: Click here to enter text.**
2. **Is a PHAC or CFIA MSDS/PSDS available for the biological agent(s)?** [ ]  **Yes** [ ]  **No**

**According to MSDS/PDS what is the Risk Group** [ ]  **1** [ ]  **2**  [ ]  **3**

***If PDS is available stop here, if not identify below how Risk Group was determined:***

[ ] Human Pathogens and Toxins Act Schedules 2-4

[ ] Risk Group definitions found in the PHAC Laboratory Biosafety Guidelines (3rd Edition)

[ ] PI independent summary of Risk Factor Analysis as per Table below (based on PHAC LBG3rd classification criteria)

[ ] ATCC or other vendor information

[ ] American Biological Safety Association

[ ] Tables 1 and 2 on following pages

[ ] Published article: specify

[ ] Other: Click here to enter text.

1. **Host Range**

[ ] **Human** [ ]  **Non-Human Primate** [ ] **Plant** [ ] **Animal, specify all**

:Click here to enter text.

1. **Bioagent is**

[ ] wild type **OR**  select from one of the options below:

[ ] attenuated [ ] replication incompetent – if yes to either provide supporting evidence

[ ] antibiotic resistance If yes, describe: Click here to enter text.

[ ] Other: describe the variation:

1. **Are toxins actively secreted?** [ ] **Yes** [ ] **No** [ ] **Don’t Know**

If yes, what is the LD50?Click here to enter text.

1. **Micro-organism obtained From**

[ ] Commercial source: *e.g. ATCC* Company Name Click here to enter text.

[ ] Catalogue Number: Click here to enter text.

[ ] Other Source: *e.g. Dr. X at U of YZ, clinical isolate:*Click here to enter text.

If a reliable source (example: PDS or vendor information) is not available, use Tables 1 and 2 below to document your risk assessment. In Table 1, enter a value from 1 – 4 for each category. The values can be determined using the definitions in Table 2. When done, divide the category by 10 and round to the nearest whole number.

If you are unsure how to rate each item, please take the pathogen risk assessment e-learning module located at the [PHAC website](https://training-formation.phac-aspc.gc.ca/). The training is only available after you have signed up for a free account. The e-learning course is also free.

Table 1: Risk Group Summary Table (Choose a risk group for each category – Note these are drop down lists). For the overall risk group, add all values, divide by 10, and round to the nearest whole number.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Risk Factor** | **Risk Group** | **Risk Factor** | **Risk Group** | **Risk Factor** | **Risk Group** |
| **Pathogenicity** |  | **Infectious Dose** |  | **Endemicity** |  |
| **Virulence** |  | **Host range** |  | **rDNA?** |  |
| **Availability of effective treatment or preventive measures** |  | **Environmental Stability** |  | **Overall Risk Group** |  |
| **Mode of Transmission /Route of Infection** |  | **Economic impact of release into the environment/public** |  |

Table 2: Individual Risk Factor Risk Group definitions

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Risk Factor** | **Risk Group 1** | **Risk Group 2** | **Risk Group 3** | **Risk Group 4** |
| Pathogenicity The ability of a pathogen to cause disease. | Low individual and community risk.* Attack Rate – those exposed are generally not infected
* Population specificity – generally no disease
 | Mild or moderate disease, moderate individual risk, low community risk.* Attack Rate – those exposed may be infected
* Population specificity – will attack only a portion of the population
 | Causes serious disease; high individual risk, low community risk: * Attack Rate – of those exposed, many are infected
* Population specificity – may attack more than one portion of a population
 | Causes severe disease / high individual risk, high community risk,* Attack Rate – of those exposed most are infected
* Population specificity – may not be specific to a population type
 |
| Virulence – the ease with which a pathogen will cause disease | * Mortality Rate – none
* Immediate impact – no disease
* Long term impact – no disease
 | * Mortality Rate – 1% - 10%
* Immediate impact – acute affects may be moderate but do not persist
* Long term impact – maybe be moderate
 | * Mortality Rate – 10% - 50%
* Immediate impact – may have serious affects, which may persist
* Long term affects – may have serious affects
 | * Mortality Rate – 50% – 100%
* Immediate Impact – likely to cause severe affects
* Long term impact – likely to cause severe affects
 |

**Individual Risk Factor Risk Group definitions continued…**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Risk Factor** | **Risk Group 1** | **Risk Group 2** | **Risk Group 3** | **Risk Group 4** |
| Availability of prophylactic and therapeutic treatments | Not applicable (not known to cause disease) | Effective treatment and preventive measures are available | Prophylactic and /or treatments may or may not be readily available (or of limited benefit) | Prophylactic and/or treatments are not usually available |
| Mode of Transmission / Route of Infection | Not applicable (not known to cause disease) | Primary exposure hazards are through ingestion, inoculation and mucous membrane route (not generally through the airborne route) | May be transmitted through airborne route; direct contact; vectors | Readily transmitted through casual and indirect contact with a potential for aerosol transmission |
| Infectious Dose | Not applicable (not known to cause disease) | Variable or high (1,000-5,000 organisms or greater) | Medium (10 –1,000 organisms) | High (1-10 organisms) |
| Host Range | Not applicable (not known to cause disease) | Infects a limited number of species | Infects multiple species | Infects many species of animals |
| Environmental Stability | Not applicable | Short term survival (days); can survive under ideal conditions | Resistant (days to months) | Highly resistant (months to years) e.g. spores |
| Natural distribution of pathogen vs hosts(Endemicity – degree of ) | Endemic / Enzootic | Generally enzootic (some low-risk exotics, or reportable diseases) | Exotic or enzootic but subject to official control | Exotic – pathogens not naturally present in the geographic area. |
| Economic aspects of introduction and/or release into the environment of the Canadian public | No economic and /or clinical significance | Limited economic and/or clinical significance | Severe economic and/or clinical significance | Extremely severe economic and/or clinical significance |
| Recombinants (rDNA – recombinant DNA)  | * The recombinant is a risk group (RG) 1 organism; modifications have not changed the risk
* The recombinant is a RG 2 or 3 organism, however, the modification has resulted in proven attenuation down to a RG 1 level.
 | * The recombinant is a RG 2 organism; modifications have not changed the risk
* DNA from RG 2 or 3 organism is transferred into RG 1 organism: but not the whole genome.
* DNA from RG 4 organism is transferred into RG 1 organism (only after demonstration of a totally and irreversible defective fraction of the organism genome is present in the recombinant.
* The recombinant is a RG 3 or 4 organism, however, the modification has resulted in proven attenuation.
 | The recombinant is a RG 3 organism and the modifications have not changed the risk.The recombinant is based on a RG 2 organism, however, the modifications have increased the risk group to a RG 3 organism;. | The recombinant is a RG 4 organism; modifications have not changed the riskDNA from a RG 4 organism is transferred into a RG 1 organism in with an absence of demonstrations of a lack of virulence or pathogenicity. |