Determination of Risk Group and Containment Level

Pathogen Name:

Risk Group Assessment

Risk Factors

1. Pathogenicity/Virulence

Level 1 - unlikely to cause disease
- low individual and community risk

Level 2 - mild or moderate disease/ moderate individual risk, low community risk
- any pathogen that can cause disease but, under normal circumstances, is unlikely to be a serious hazard to healthy laboratory workers, the community, livestock, or the environment

Level 3 - serious livestock, poultry or wildlife disease / high individual risk, low community risk
- any pathogen that usually causes serious disease or can result in serious economic consequences but does not ordinarily spread by casual contact from one individual to another

Level 4 - severe livestock, poultry or wildlife disease / high individual risk, high community risk
- also causes human disease
- any pathogen that usually produces very serious and often fatal disease, often untreatable, and may be readily transmitted from one individual to another, or from animal to human or vice-versa, directly or indirectly, or by casual contact.

Comments:

2. Infectious dose

Level 1 - not applicable (not known to cause disease)
Level 2 - variable or high (1000-5000 organisms or greater)
Level 3 - medium (10-1000 organisms)
Level 4 - high (1-10 organisms)

Comments:

3. Mode of Transmission/Route of Infection

Level 1 - not applicable (not known to cause disease)
Level 2 - primary exposure hazards are through ingestion. inoculation and mucous membrane route (not generally through the airborne route)
Level 3 - may be transmitted through airborne route: direct contact: vectors
Level 4 - readily transmitted. potential for aerosol transmission

Comments:

4. Ability to Spread/Transmission/Communicability

Level 1 - not applicable (not known to cause disease)

Level 2 - geographical risk of spread if released from the laboratory is limited
- direct animal to animal or human to human transmission is relatively limited
- very limited or no transmission between different animal species

Level 3 - geographical risk of spread if released from the laboratory is moderate
- direct animal to animal or human to human transmission occurs relatively easily
- transmission between different animal species may readily occur

Level 4 - geographical risk of spread if released from the laboratory is widespread
- direct animal to animal or human to human transmission occurs very easily
- transmission between different animal species may occur very readily
- transmission from animal to human or vice-versa may occur readily, directly or indirectly, or by casual contact

Comments:

5. Survival in the environment (*Related to "Ability to Spread" above)

Level 1 -Not applicable
Level 2 - short term survival (days); can survive under ideal conditions
Level 3 - resistant (days to months)
Level 4 - highly resistant (months to years) e.g. spores

Agents that can survive outside the host present a higher risk.

Questions to ask:
- is it stable outside the host?
- can it survive for long periods of time outside the host. i.e. on laboratory equipment or surfaces?
- can it survive harsh environmental conditions?
- can it survive in laboratory effluent?

Comments:

6. Host Range

Level 1 - not applicable (not known to cause disease)
Level 2 - infects a limited number of species
Level 3 - infects multiple species
Level 4 - infects many species of animals and humans

Points to consider:
- is the organism zoonotic. or does it infect only animals or humans?
- are the host species present in Canada?
- are the host species economically important in Canada?

Comments:

7. Endemicity

Level 1 - enzootic
Level 2 - generally enzootic (some low-risk exotics or reportable diseases)
Level 3 - exotic or enzootic but subject to official control
Level 4 - exotic

Comments:

8. Economic aspects of introduction and/or release into the environment or the Canadian public

Level 1 - no economic and/or clinical significance
Level 2 - limited economic and/or clinical significance
Level 3 - severe economic and/or clinical significance
Level 4 - extremely severe economic and/or clinical significance

Comments:

9. Availability of prophylactic and therapeutic treatments.

Level 1 - not applicable (not known to cause disease)
Level 2 - effective treatment and preventive measures are available
Level 3 - prophylactic and/or therapeutic treatments may or may not be readily available (or of limited benefit)
Level 4 - prophylactic and/or therapeutic treatments are not usually available

Questions to ask:
- are antibiotics or antivirals available to treat the disease?
- are there effective vaccines available?

Comments:

10. Vectors

Level 1 - not applicable (not known to cause disease)
Level 2 - do not depend on vectors or intermediate hosts for transmission
Level 3 - may depend on vectors or intermediate hosts for transmission
Level 4 - may depend on vectors or intermediate hosts for transmission

Questions to ask:
- is vector present in Canada?
- is intermediate host present in Canada?
- does climate or other environmental factors lower chance of survival?
- can the pathogen survive in surrogate or alternate vectors? (Usually difficult to answer this question)

Comments:

11. Recombinants

Risk group assessment for recombinant organisms will require the reseacher to take into consideration the effect of the modification on all of the previous 10 risk factors. As per the NIH guidelines. there are standard risk group assessment based on the modification, however. for the most part a comprehensive look at the effect of the modification is required. This risk factor assignment can be more subjective, however,

Level 1 - the recombinant is a risk group 1 organism: the modifications have not changed the risk

Level 2 - the recombinant is a risk group 2 organism: the modifications have not changed the risk
- DNA from risk group 2 or 3 organisms is transferred into risk group 1 organisms: but not the whole genome
- DNA from risk group 4 organism is transferred into risk group 1 organism (only after demonstration of a totally and irreversibly defective fraction of the organisms genome is present in the recombinant*)
- the recombinant is a risk group 3 or 4 organism, however, the modification has resulted in proven attenuation

Level 3 - the recombinant is a risk group 3 organism: the modifications have not changed the risk
- the recombinant is based on a risk group 2 organism, however, the modifications have increased the risk

Level 4 - the recombinant is a risk group 4 organism; the modifications have not changed the risk
- DNA from risk group 4 organism is transferred into risk group 1 organism in absence of demonstration of lack of virulence or pathogenicity

Questions to ask:

- Does the inserted material increase virulence or decrease the effectiveness of anti-infective agents?
- Does the inserted gene encode a known toxin or a relatively uncharacterized toxin?
- Does the modification have the potential to alter the host range or cell tropism of the virus?
- Does the modification have the potential to increase the replication capacity of the virus?
- Does the inserted gene encode a known oncogene?
- Does the inserted gene have the potential for altering the cell cycle?
- Does the viral DNA integrate into the host genome?
- What is the probability of generating replication-competent viruses?
- If the modification has resulted in a form of attenuation, how extensively has this strain been utilized without incident and/or has the attenuation been proven in animal models?
- Does the modification have an effect of increasing or decreasing the efficacy of available treatment or prophylaxis?

Comments:

Matrix for Assessment of Risk Group

Risk Factors	Group 1	Group 2	Group 3	Group 4
Pathogenicity/Virulence				
Infectious Dose				
Mode of Transmission/ Route of Infection				
Ability to Spread				
Survival in the Environment				
Host Range - zoonotic? _____ (Yes/No)				
Endemicity				
Economic Consequences				
Availability of Prophylactic and Therapeutic Treatments				
Vectors				
Recombinant/modifications				

Decision (Risk Group):_____

Date Completed: _____

Performed by: _____

Comments:

References:

Containment Level Assessment

Generally the containment level assessment falls in line with the risk group assessment. For example, risk group 2 pathogens are used in a containment level (CL) 2 laboratory. However, certain work practices or research objectives can affect the risk of working with the organism. For example:

- HIV is a risk group 3 pathogen, however, diagnostic work can be safely performed in a CL2 laboratory with additional CL3 operational protocols.
- a 3rd generation lentiviral vector is fairly benign and can be utilized at CL2, however, dependent on the inserted gene, work with the vector may have to take place at CL2 with CL3 operational protocols or CL3.
- in vivo work with an attenuated strain of an organism may have to take place at CL3 dependent on the mechanism of attenuation (LCMV - neurotropic?)

This is not to be considered a job hazard analysis for routine CL assessment for permit application and request for advice, therefore, we will not consider the following although they can be given consideration by the employer:

- Health status of the individual performing the work (immune compromised, pregnant, inherited genetic factors, etc.)
- Skills and experience of the individual performing the work (i.e. Is this a new procedure?)
- Will repetitive and boring procedures be used?
- A detailed review of the task from initiation to completion.

Questions to Ask for CL assessment:

- Work Objectives
  - For example, is the work in vitro, in vivo or large scale?
  - If in vivo, what type of animals will be used and what risk may be associated with that specific animal?
  - Doe s the project involve modifications of the wild type pathogen which may affect host range, virulence, pathogenicity or any other risk factors?
- If the work is not large scale, is there an increased concentration of the pathogen?
- Will a large volume of aerosols be produced?
- Will needles or sharps be used?
- Origin of pathogens, i.e., indigenous, exotic?

All of these factors must be considered for CL assessment and the answers to each question will outline what physical and operational requirements are needed to ensure safety of the worker and the environment. For each question, list whether CL 1,2 3 or 4 physical and/or operational requirements apply and at the end you will have either a straight answer for CL or a combination of one CL for physical and another for operational requirements: a CL assessment is the result of these conclusions.

Questions and Answers

Containment Level Assessment: _____

Date Completed: _____

Performed by: _____

Comments:

References: