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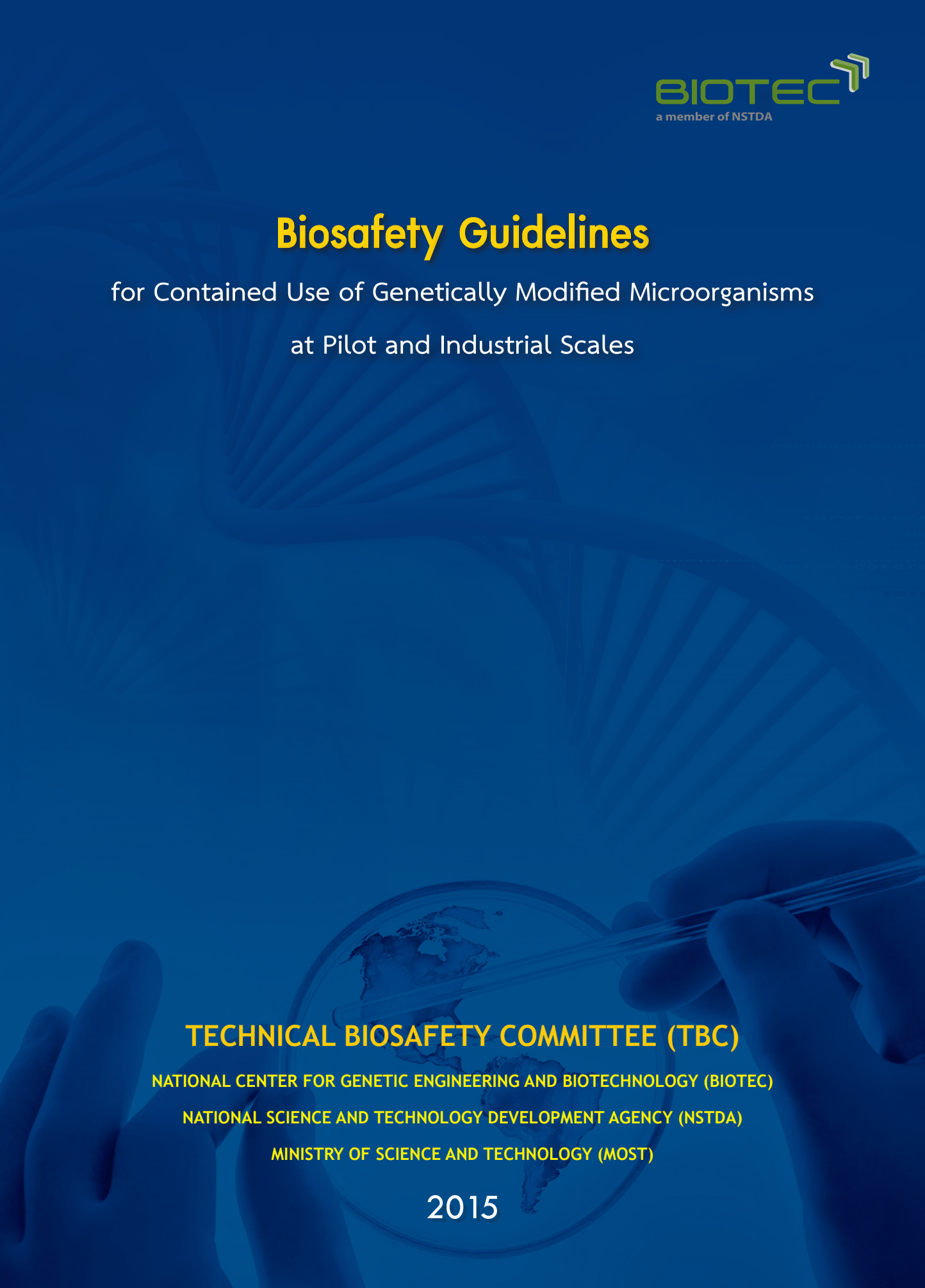
Biosafety Guidelines

for Contained Use of Genetically Modified Microorganisms at Pilot and Industrial Scales



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Technical Biosafety Committee
National Center for Genetic Engineering and Biotechnology
National Science and Technology Development Agency (NSTDA)

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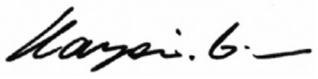
Preface

Genetically Modified Microorganisms (GMMs) were first used in B.E. 2525 to produce insulin in industrial medicine. Currently, GMMs are used in various industries, such as the food, pharmaceutical and bioplastic industries, to manufacture a number of important consumer products. To ensure operator and environmental safety, the Technical Biosafety Committee (TBC) of the National Center for Genetic Engineering and Biotechnology (BIOTEC), the National Science and Technology Development Agency (NSTDA), has prepared guidelines for GMM work, publishing "Biosafety Guidelines for Contained Use of Genetically Modified Microorganisms at Pilot and Industrial Scales" in B.E. 2547. The guidelines have been updated every two years to take into account the latest information and technology. In B.E. 2558, GMM waste management guidelines were added to facilitate operator work, the list of microorganisms/agents was updated to conform to lists of national and international organizations, and an English version was prepared for foreign organizations/institutions involved in GMM work at pilot and industrial scales in Thailand.

The principle and scope of these guidelines cover the use of GMMs in containment at pilot and industrial scales according to GMM classification, together with suggested containment levels, GMM waste management, transport, possession, emergency plans and the responsibilities of personnel associated with GMM work.

The committee acknowledges the Biosafety Sub-Committee on Microorganisms and the Organizing Committee on Biosafety Guidelines for Contained Use of Genetically Modified Microorganism (English version) for their cooperation and revision of these guidelines, and Ajinomoto Co., Ltd. for supporting the preliminary translation.

Finally, the committee hopes that these guidelines will be helpful in promoting safe GMM work at pilot and industrial scales. Suggestions and comments on the guidelines are most welcome.



(Dr. Kanyawim Kirtikara)
Executive Director
National Center for Genetic Engineering and Biotechnology
Chair
Technical Biosafety Committee

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Definitions

Bacteriophage: An obligate intracellular virus that multiplies inside bacteria.

Biosafety level: The level of biosafety of work using GMMs by implementation of a containment level. In some countries, biosafety level is equivalent to 'containment level'.

Closed system: A system which separates GMMs from the environment during the culturing process, such as a bioreactor or biological safety cabinet (tissue culture hood). It also includes production processes utilizing equipment connected in a closed system, such as inoculation of GMMs into a bioreactor, and downstream processes for product purification, as well as systems where equipment are not connected but are set up within a safety enclosure. A closed system used for GMM activities at pilot and industrial scales should be routinely checked.

Contained use: The use of GMMs in a restricted area, isolated from the outside environment through the provision of tools and equipment, working space and working protocols for the purpose of research or industrial production.

Containment and containment level: Control of GMMs to a restricted area, isolated from the outside environment through the provision of tools and equipment, working space and working protocols to facilitate research or industrial production. There are 4 containment levels which have been classified according to degree of risk in terms of human pathogenicity and potential hazard to the environment.

Controlled area: An area for conducting GMM work such as inoculation and propagation of GMMs in a bioreactor, sampling or transport of GMMs, and downstream processes such as the purification of GMM products.

Donor organism: A living organism that is the origin of the DNA or gene inserted into a host cell for a desired phenotype.

Genetic modification technique:

1. The use of recombinant DNA technology to ligate DNA fragments or heterologous genes of interest with vectors followed by transformation into host cells by methods such as electroporation to enable such host cells to exhibit desired phenotypes. Plasmids and viruses are examples of the vectors used.

2. Introduction of DNA fragments or genes of interest into host cells via micro-injection, macro-injection or micro-encapsulation.

3. Cell or protoplast fusion and hybridization techniques between different cell types with different genetic materials, which produce heterologous genes in microorganisms/agents in a manner which cannot occur in nature.

Genetically Modified Microorganism (GMM): A microorganism/agent whose genes or genetic material have been modified from its original counterpart in a manner that cannot occur in nature through genetic modification techniques for expression of desired phenotypes such as enzyme production. They include progeny of such microorganisms, which have inherited the modified genetic material.

Genetically Modified Organism (GMO): An organism whose genetic material has been altered using modern biotechnology.

Good Industrial Large Scale Practice (GILSP): Application of good microbiological practice in the use of harmless microorganisms/agents in industry. Such microorganisms/agents include non-pathogenic microorganisms/agents and GMMs that have a long history of safe use in industry or limited survival in the natural environment. Viruses, phages or plasmids that may cause disease are not used.

HEPA filter: A high efficiency particulate air filter which can prevent the passage of small particles under 0.3 micrometers (μm) in size at 99.97% efficiency. Microorganisms cannot pass through this type of filter.

Host or recipient cells: A cell that has incorporated modified DNA fragments or genes for expression of desired phenotypes.

Inserted DNA: Heterologous DNA or gene that is introduced into a host cell by a vector or other genetic modification techniques to create desired phenotypes.

Institutional Biosafety Committee (IBC): A committee commissioned by an institution or organization to provide advice and monitor work or projects related to modern biotechnology or genetic engineering according to biosafety guidelines.

LD_{50}: The amount of a chemical or biochemical substance that causes death among 50% of test animals.

Microbial inactivation: The inactivation of GMMs from materials, equipment, tools, bioreactors and surfaces which may be contaminated with GMMs by using an appropriate procedure, such as heating or chemical treatment, in a manner that is not harmful to humans or the environment.

Microorganism: A small living cell or particle that is able to reproduce and transfer genetic material. It includes bacteria, yeasts, molds, viruses, viroids, cultivated plant cells and cultivated animal cells.

Operator: A person involved in GMM work within an organization/institution.

Organization and institution: An organization where GMMs are used for commercial purposes at pilot and industrial scales, such as state enterprises, independent research institutes, factories and private companies.

Owner or **authorized representative:** A person who is the head or designated representative of an organization and institute.

Primary containment equipment: Equipment that is designed to provide containment or eliminate exposure to biohazardous materials, such as a biosafety cabinet or an isolater.

Recombinant DNA molecule:

1. Molecules constructed outside living cells by joining natural or synthetic DNA fragments to DNA molecules that can replicate in a living cell, or
2. Molecules that result from the replication of those described above.

Risk assessment: An analytical process used for assessing risks posed to the environment or human health by GMM-related activities. Risks include direct and indirect risks, and those with immediate, delayed or downstream effects.

Technical Biosafety Committee (TBC): A committee whose main responsibilities are :

1. To provide technical consultation to any work or project related to modern biotechnology or genetic engineering according to biosafety guidelines;
2. To identify risk categories for activities that are not clearly classified;
3. To coordinate with agencies responsible for monitoring GMOs; and
4. To enhance the efficiency of IBCs at the national level.

The use of Genetically Modified Microorganisms (GMMs) in pilot plants and the industry: Includes the production of GMMs at a substantial scale (more than 10 liters) to produce biological substances in contained conditions with no intention to release GMMs into the environment.

Vector: DNA capable of self-replication in a living organism, used for introducing DNA or genes of interest into a host cell by ligation to such DNA. Examples include plasmids and viruses.

Viroid: An infectious agent affecting living cells, smaller than a virus and consisting only of nucleic acid without a protein coat.

Virus: A very small agent that cannot reproduce by itself but must replicate inside a living cell. One of its prominent characteristics is that it consists of either DNA or RNA but not both. Most antibacterials and antifungals have no effect on viruses even when used at concentrations that normally inhibit the growth of bacteria or fungi.

Abbreviations

BIOTEC	National Center for Genetic Engineering and Biotechnology
FDA	Food and Drug Administration
GILSP	Good Industrial Large Scale Practice
GMM	Genetically Modified Microorganism
GMO	Genetically Modified Organism
IBC	Institutional Biosafety Committee
MOPH	Ministry of Public Health
NIH	National Institute of Health of Thailand
OECD	The Organisation for Economic Co-operation and Development
ONEP	Office of Natural Resources and Environmental Policy and Planning
TBC	Technical Biosafety Committee

Chapter 1
Introduction

Modern biotechnology has made great strides, particularly in the field of recombinant DNA technology where genetic modification techniques or genetic engineering are employed to modify or introduce DNA fragments or genes that carry desired characteristics to living organisms such as microorganisms/agents, plant cells and animal cells. Living organisms derived from such genetic modifications carry desired phenotypes for use in various sectors such as public health, agriculture, industry and the environment.

Over the past 40 years, recombinant DNA technology has been extensively exploited in various industries such as the pharmaceutical and medical supply industries for human and animal uses. This is exemplified by the production of insulin for treatment of diabetes by microorganisms/agents genetically modified to be capable of producing human insulin and the production of human growth hormones by genetically modified microorganisms/agents to cure growth hormone deficiency in children. Recombinant DNA technology also allows the production of biological substances such as penicillin, vitamin B2 and bioremediation agents in greater amounts, at higher quality and lower costs. Additionally, recombinant DNA technology has lead to the development of drugs and vaccines for disease treatment and prevention as well as disease diagnostics, and may enable the medical industry to produce biological substances for treatment of currently untreatable diseases such as cancers and some infectious diseases. The food industry also benefits from such technology, as seen in the production of food and food-related substances such as enzymes, amino acids, chemicals and food additives. As far as the agricultural sector is concerned, desired characteristics of plants and animals can be augmented using this technology; genetically modified plants can be generated to control insect pests, survive in defined environmental conditions such as in cold or dry weather, or fortified to provide improved nutrition, while genetic engineering of economically important livestock may enhance growth and immunity to diseases.

In order to promote the application of GMMs for industrial use in both developed and developing countries, international bodies such as the Organization for Economic Cooperation and Development (OECD) established guidelines for industrial applications of GMMs in 1986, followed by a revision in 1992. These guidelines, designed to ensure human and environmental safety in conjunction with

GMM use, have been adopted with certain degrees of modification in a number of countries based upon the underlying principles that microorganisms/agents have been used in the food and pharmaceutical industries for a long time and that associated industrial procedures are safe given clear guidelines on microorganism/agent containment as well as specially designed equipment to prevent their release into the environment.

In general, GMMs are not radically different from their parental strains except for modification for desired characteristics. Following the Good Industrial Large Scale Practice (GILSP) that has been mandatory for assessing use of unmodified microorganisms/agents in industry, GMMs which have passed the safety assessment can be eligible for use at industrial scales. GMMs currently used in industry are mostly classified at the GILSP safety level. OECD has suggested that countries formulate domestic guidelines for assessing GMM industrial application by taking into account harmful effects they may cause to humans and the environment, and has supported the application of safe GMMs at pilot and industrial scales. In cases where GMMs are assessed to have potential risks to humans and the environment, stringent safety controls through the implementation of higher containment levels and higher safety levels for working procedures are required.

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Chapter 2
Scope and Principles

The objective of these guidelines is to provide guidance for contained use of GMMs at pilot and industrial scales to ensure safety to operators, the community, and the environment. The scope and principles of the guidelines are as follows:

1. These guidelines for organizations such as state enterprises, private and government research institutes, industrial factories, and private companies, where GMMs are cultivated or used to commercially produce biological substances for various industries with no intent to release GMMs into the environment.

2. GMMs in these working guidelines are microorganisms/agents whose genes or genetic material have been modified from its original counterpart in a manner that cannot occur in nature through genetic modification techniques for expression of desired phenotypes such as enzyme production. They include progeny of such microorganisms, which have inherited the modified genetic material.

3. Genetic modification techniques referred to in these working guidelines are:

3.1 The use of recombinant DNA technology to ligate DNA fragments or heterologous genes of interest with vectors followed by transformation into host cells by methods such as electroporation to enable such host cells to exhibit desired phenotypes. Plasmids and viruses are examples of vectors used.

3.2 Introduction of DNA fragments or genes of interest into host cells via micro-injection, macro-injection and micro-encapsulation.

3.3 Cell or protoplast fusion and hybridization techniques between different cell types with different genetic materials to generate heterologous genes in microorganisms/agents in a manner that cannot occur in nature.

4. Any work using GMMs in pilot plants and industry must undergo safety assessments to ensure safety to operators, the community and the environment. These guidelines classify the use of GMMs at pilot and industrial scales into 4 classes according to the work safety level and level of risk from GMMs. Once GMM activities are classified, appropriate containment and biosafety levels can be adopted as protective measures to prevent release or exposure of GMMs to operators and the environment.

5. The safety or risk assessment of GMM activities at pilot and industrial scales is based upon scientific information regarding GMMs, host cells, vectors, genes or DNA of interest, method of genetic modification and other factors related to

pathogenicity, allergy, and other diseases in humans as well as negative impact on the environment. Therefore, risk assessment must be conducted by a biosafety committee empowered by an organization or institution.

6. The owner or authorized representative is required to submit an application for permission to use GMMs at pilot and industrial scales to the authorities (will be announced later), and approval must be obtained prior to operation commencement. This process can be initiated by the owner or authorized representative along with the new plant approval or permit renewal process. More information for approval processes is decribed in Chapter 5.

7. Some techniques may result in some form of genetic modification to microorganisms/agents, but some of these genetically-altered microorganisms/agents are technically not considered GMMs, and thus are not covered by these guidelines (see list of non-GMMs in Appendix 1).

Chapter 3
Classification of GMM Work at Pilot and Industrial Scales

GMM practices at pilot and industrial scales are classified according to the degree of safety and level of risk from the use of GMMs. Following OECD, 1992, GMM work is classified into 4 classes as:

GILSP Work using GMMs classified as safe and implementing good industrial large scale practice.

Class 1 Work using GMMs classified as safe but does not fulfill GILSP conditions.

Class 2 Work using GMMs that may pose low risks to operators, the community or the environment.

Class 3 Work using GMMs that may pose risks to operators, the community or the environment.

3.1 GILSP

Work in this category involves the use of GMMs that do not cause any harm and adopts good industrial large scale practice. GMMs used must be non-pathogenic, must not involve any viral DNA, bacteriophage or plasmid that may cause disease, and must be derived from microorganisms that have a long history of safe use in industry or have limited survival in the natural environment (Appendix 2). GMMs in this category are those classified in Risk Group 1 (Appendix 4) or class 1 in the biosafety guidelines for laboratory practice. Examples include work using TBC safety-approved host nd vector systems (Appendix 3) such as the *Escherichia coli* K-12, *Saccharomyces cerevisiae, Bacillus subtilis* or *Bacillus licheniformis* host-vector systems.

3.2 Class 1

Work in this category involves the use of GMMs that do not cause any harm but do not fulfill the GILSP conditions above. It requires the minimum of large-scale containment level 1 (LS1).

Work in this class:

1. Work using GMMs classified in Risk Group 1 (Appendix 4) that does not fulfill GILSP conditions (Appendix 2).

2. Work using GMMs classified as class 1 in the biosafety guidelines for laboratory practice that does not fulfill GILSP conditions.

3.3 Class 2

Work in this category involves the use of GMMs that have low potential to cause harm to operators, the community or the environment. It requires a minimum of large-scale containment level 2 (LS2).

Work in this class:

1. Work using GMMs classified in Risk Group 2 (Appendix 4).

2. Work using GMMs from safety-approved host/vector systems (Appendix 3) which contain DNA or genes of interest that:

   - may cause or be involved in the development of diseases, cancer, toxicity, adverse effects on growth or cell division, or other pathological effects on humans, animals or plants; or
   - are uncharacterized DNA/genes with unclear function.

3.4 Class 3

Work in this category involves the use of GMMs that are potentially harmful to human health, the community or the environment. GMMs that fall into this class may cause disease but not disease epidemics, and such diseases can be prevented and treated. This class also includes work with an unidentified level of risk. It requires a minimum of large-scale containment level 3 (LS3).

Work in this class:

1. Work using toxin-producing GMMs, including GMMs with DNA that control toxin production or produce toxins possessing an LD_{50} of less than 100 ng/kg (Appendix 5), or work involving genes producing toxins with an LD_{50} less than 100 ng/kg, or work involving DNA from GMMs that produce unidentified toxins.

2. Work using GMMs that include viral vectors which can infect human cells, and work involving modified DNA with the ability to produce growth-controlling substances or toxic substances to human cells.

3. Work using GMMs that include vectors or hosts from microorganisms/ agents in Risk Group 3, which have potential to cause disease in humans or certain diseases in plants or animals.

4. Work using GMMs that include whole viral genomes or viroids, or genetic materials which can infect humans, animals or plants.

5. Work using GMMs involving ligation between whole viral genomes, viroids and complementary fragments that can cause infection or are important to the development of disease. It also includes work involving infection of host cells or increasing microbial virulence or infectivity.

6. Work using GMMs with multiple antimicrobial resistance genes, where those antibiotics are still used for treatment of infectious diseases in humans, animals or in agriculture. These antibiotic resistance genes must be identified as to whether they can be naturally transferred to other microorganisms/agents or not.

Remarks: 1) Genetically modified microorganisms/agents accepted as safe are classified as GILSP.

2) Safe hosts/vectors expressing virulence genes will be considered on a case-by-case basis.

Table 3.1: Summary of GMM work at pilot and industrial scales

Class	Risk Group*	Description	Containment	Examples
GILSP	1	Use of GMMs that have been classified as safe	GILSP	Bacteria - *Bacillus subtilis* - *Bacillus megaterium* - *Streptococcus thermophilus* Yeast - *Saccharomyces cerevisiae*** - *Schizosaccharomyces pombe*
Class 1	1	Use of GMMs that have been classified as safe but not fulfilling GILSP conditions	LS1	Bacteria - *Bacillus licheniformis* non-spore forming Virus - Adeno-Associated Virus (AAV) Types 1-4
Class 2	2	Use of GMMs that may pose low risks to operators, community or the environment	LS2	Bacteria - *Clostridium botulinum* - *Corynebacterium diphtheriae* - *Staphylococcus aureus* - *Vibrio cholerae*
Class 3	3	Use of GMMs that may pose risks to operators, community or the environment, and may cause disease that can be prevented and treated and do not cause epidemics	LS3	Bacteria - *Mycobacterium tuberculosis* - *Yersinia pestis* Rickettsia - *Rickettsia akari*

* Risk Group of microorganisms/agents according to NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2013).

** Use of *Saccharomyces cerevisiae* subtype *boulardii* is prohibited as it presents a danger to susceptible people, including patients with central venous catheters.

Chapter 4
GMM Containment Levels for Pilot and Industrial Uses

Containment is defined as the control of GMMs in a restricted facility with the aim of preventing their spread into the external environment. There are two types of containment: biological containment and physical containment. **Biological containment** prevents GMMs from surviving or transferring its genetic materials outside a bioreactor, whereas **physical containment** requires a suitable design and installation of facilities, equipment and working areas, as well as a working protocol to prevent the release of GMMs into the environment. Safety of pilot and industrial applications of GMMs can be achieved by implementing appropriate containment measures.

In these guidelines, four containment levels are identified according to degree of safety and risk associated with the GMMs and other criteria such as the amount of GMM in the production process and the purification process, which may alter the level of containment. A combination of containment levels can be adopted within a single working environment depending on safety assessment results. For instance, in a facility operating at containment level 1, it is also possible to incorporate containment level 2 measures for all or specific parts of the work according to other safety considerations to ensure the safety of operators or personnel. The control of GMM biosafety or containment in industry is largely identical to that implemented in laboratories, although more stringent practices and a higher degree of caution are required since the working volume of GMMs at pilot and industrial scales is higher, and adverse effects on humans and the environment would accordingly be more severe.

The regulations applied to all classes using GMMs are listed as follows (also see Appendix 6):

1. Working procedures must be clearly described.

2. Equipment and tools used for GMM work must be regularly inspected, according to GMM classification.

3. Inspection of contamination or release of GMMs both in the contained working areas or the surrounding environment is required.

4. Inactivation/eradication of GMMs and culture fluid before being released into the environment must be done using appropriate methods.

5. Emergency plans must be followed in case of extensive spillage or release of GMMs.

6. Training must be provided for operators or people involved for an understanding of work and safety practices, and proper emergency drills must be conducted regularly.

7. An IBC must be established to coordinate GMM work.

Containment in these guidelines is divided into four levels (see Appendix 7), as follows:

4.1 Good Industrial large Scale Practice (GILSP) Containment

GILSP containment refers to containment applicable to GILSP work at pilot and industrial scales. This containment exercises the lowest level of biosafety control conforming to the general practices outlined above and in Appendix 6. GILSP GMMs are considered safe and therefore are not subject to containment in a closed facility. However, precautions must be taken to prevent direct contact with GMMs or spillage. Sampling, inoculation or transport from one system to another must be conducted with care to prevent contamination or exposure to operators. GMMs and culture fluid must be inactivated before being discharged from the system. Health surveillance is not required for this class of containment.

4.2 Large-scale Containment Level 1 (LS1)

Large-scale containment level 1 refers to the containment applicable to class 1 GMM work. This containment level follows the general practices in Appendix 6 and additional requirements as follows:

1. Facility layout, working area and working protocols must be well planned.

2. GMMs must be contained in a closed system (such as a reactor) or appropriate containment equipment (such as a biosafety cabinet). Released GMMs, if any, must be so minimal that they do not cause harm to operators.

3. Transport of GMMs during working procedures, including sampling and inoculation, must be carried out with considerable caution, and aerosols released during transport must be minimized.

4. Reactors or equipment must be designed to minimize exhaust gas/aerosols. Exhaust gas from a closed facility must be emitted through a high quality filter of at least HEPA standard. Equally effective methods for GMM neutralization, such as incineration or chemical treatment, can be used to minimize release of GMMs.

5. After operation, reactors or equipment must be sterilized before being opened, washed or next use. Routine validation of sterilization process is required.

6. Incidents of spillage or contamination must be reported to the biosafety officer and other responsible persons, including the owner or authorized representative (such as project or institution directors). Medical treatment as well as case follow-ups and therapy details of patients affected by spillage or contamination must be recorded.

7. Operators' health surveillance must be implemented.

8. Emergency plans must be followed in case of extensive spillage or release of GMMs.

9. GMMs in waste must be neutralized before being released into the environment.

4.3 Large-scale Containment Level 2 (LS2)

Large-scale containment level 2 refers to containment applicable to class 2. This containment level follows the general practices in Appendix 6 and large-scale containment level 1 practices, with additional requirements as follows:

1. Equipment in direct contact with GMMs must be specially designed to allow sterilization by heat or chemicals, inactivating GMMs before opening or cleaning.

2. Equipment such as rotating seals or other mechanical devices used in GMM culture processes in a closed system must be properly sealed to prevent release, or placed where exhaust gas can be released through a high quality filter of at least HEPA standard. Equally effective neutralization methods can be also implemented and must be routinely tested.

3. Bioreactors and other equipment in the closed system must be equipped with sensors to monitor containment.

4. Closure monitoring of closed systems must be implemented to ensure no release of GMMs.

5. Closure integrity must be validated against host organisms.

6. Closed system equipment for use with GMMs must be used for this purpose only. Records must be kept for all use of such equipment, including use in research, system testing and production, as well as their maintenance.

7. Ventilation in gas exhaust areas must be maintained using high quality filters of at least HEPA standard or an equivalent process and must be tested on a regular basis.

8. Only pertinent operators may have access to contained areas.

9. Safety plans and emergency training must be provided for pertinent operators so that they manage emergency situations such as GMM spillage or contamination. Emergency protocols must be posted in working areas.

10. Emergency equipment and tools must be located in working areas and routinely checked to ensure that they are in good condition at all times.

11. Signs displaying containment levels must be posted in the contained areas and on equipment for GMM use. Incidence of spillage or release of GMMs must be reported to the IBC and TBC immediately.

4.4 Large-scale Containment Level 3 (LS3)

Large-scale containment level 3 refers to containment applicable to class 3. This containment level follows the general practices in Appendix 6 and large-scale containment level 1 and large-scale containment level 2 practices, with additional requirements as follows:

1. Any work related to the use of GMMs in culture media must be performed in a closed system or in approrpiate containment equipment (such as a level 3 biosafety cabinet). Activities that involve the use of less than 10 liters of GMMs can be conducted outside the closed system but must be maintained within physical containment conditions identified in Appendix G-II-C of by the NIH guidelines (2013).

2. GMMs must not be released from closed systems or basic containment equipment unless the sterilization process has been validated. Validation of sterilization here refers to validation of the sterilization efficacy of host or recipient cells. Culture media containing the end products of GMMs or viral vectors may be removed from the closed system or basic containment equipment, whether for laboratory analysis, use in other processes or for packaging, only by employing closed system techniques.

3. Closed systems for propagating GMMs must be specially designed to prevent overflow of culture medium during cultivation.

4. Contained areas must be designed to have good control of air circulation, allowing air to flow from less contaminated to more contaminated areas. Systems should be developed to prevent reverse air flow and alarms should activate if reverse air flow occurs. Air from restricted areas must not be used in other working areas. Exhaust gas/air shall pass through a HEPA filter or an equivalent filtration or inactivation method prior to discharge from the system in order to remove GMMs.

5. Restricted areas must be accessed through separate entrances and be equipped with double-doored spaces such as air locks or partitions separating the restricted areas from other areas.

6. Restricted areas must be sealed for high-efficiency GMM decontamination by fumigation or other decontamination methods.

7. Restricted areas must be designed to prevent release of GMMs into areas outside the closed system in case of GMM spillage or leakage from contained areas or basic containment equipment.

8. Change rooms equipped with showers must be provided in restricted areas for use by operators.*

9. Operators must wear laboratory gowns, put on shoe or foot covers, and shower before entering and leaving restricted facilities.

10. Hand washing is required before exiting restricted areas using hand washing appliances controlled by elbows or feet, or any other kind of automatic, no-touch hand washing equipment.*

11. Used uniforms shall be washed properly or destroyed.

12. Persons under 18 years old are strictly prohibited from entering restricted areas.

13. Infrastructure systems including maintenance, sewers, wiring, telephone lines or any other communication systems must be installed using specially designed materials to prevent contamination of GMMs.

* Effluents from handwashing sinks and showers and other contaminated effluents must be inactivated according to risk assessment before discharge.

Chapter 5
Approval Process for Projects with Contained Use of GMMs at Pilot and Industrial Scales

The approval process for the use of GMMs can be initiated by the owner or authorized representative with the authorized organization (will be announced later) along with the new plant approval or permit renewal process. Documents for consideration are as follows:

- Scientific name of microorganism/agent
- Source of microorganism/agent
- Techniques used for GMM development
- History of use
- Purpose(s) of use
- Containment and safety measures for the use of GMMs at industrial scales
- Emergency procedures for spillage or release of GMMs
- Certified documents of responsible person
- Evidence of biosafety training (if any)
- Import permit or license from related agencies such as the Department of Medical Sciences or the Department of Agriculture (if any)

For the use of GMMs, the owner or authorized representative must follow the Biosafety Guidelines for Contained Use of Genetically Modified Microorganisms at Pilot and Industrial Scales. Additionally, the owner or authorized representative must hold safety certificates to confirm the safe use of microorganisms/agents. For the use of class 2 or 3 GMMs, the responsible authority will be announced later and permission for use must be granted case by case.

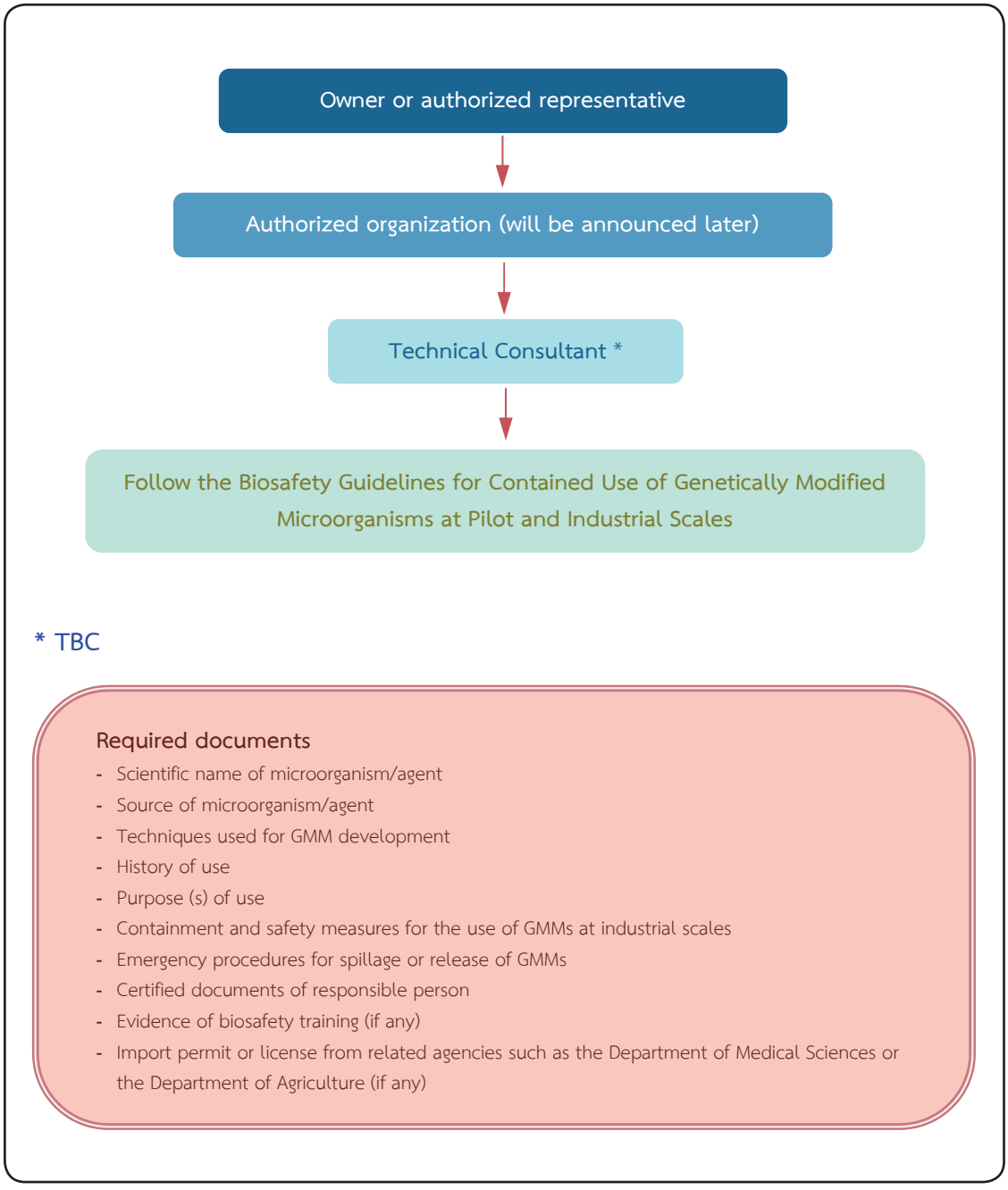


Figure 5.1 The approval process flowchart for projects with contained use of GMMs at pilot and industrial scales

Chapter 6
Risk Assessment for Contained Use of GMMs at Pilot and Industrial Scales

Careful and thorough risk assessment for contained use of GMMs at pilot and industrial scales must be conducted with great consideration for the potential risks posed to humans and the environment from GMM use, working procedures and the amount of GMMs.

6.1 Criteria for risk assessment

1. GMM risk group

Microorganisms/agents are classified into four risk groups according to their relative pathogenicity to humans (Appendix 4) as listed below:

- Risk group 1 consists of microorganisms/agents that are not associated with diseases in healthy adults.
- Risk group 2 consists of microorganisms/agents associated with diseases that are rarely serious and generally controllable through treatment and prevention measures.
- Risk group 3 consists of microorganisms/agents that are associated with serious human diseases but are controllable through treatment and prevention measures (high risk to individual but low risk to the community).
- Risk group 4 consists of microorganisms/agents that cause serious and fatal diseases with no treatment and prevention measures (high risk to both individuals and the community).

2. Risk of harm to humans and the environment

Risk must be assessed from the type of host cell, vector or inserted DNA used; the techniques used for their modification; microorganism/agent pathogenicity, virulence, transmission and degree of survival in the natural environment; working procedures; and the amount of GMMs used.

After risk assessment, the appropriate category of work and containment levesl shall be selected for implementation. The containment level required may be equivalent to the risk group classification of the agent used, or it may be higher or lower as a result of the above assessment. For instance, DNA or genes from microorganisms/agents in risk group 1, which are generally non-pathogenic, may express toxic products, exhibit increased pathogenicity, or induce allergic reactions when introduced into host, therefore necessitating a higher level of containment.

6.2 Required scientific information for risk assessment

The required scientific information for risk assessment of GMM work is summarized below (for class 2 GMMs or higher see details in Appendix 9):

1. GMM information
    - Information regarding host consists of their common name, scientific and strain name including classification level, taxonomy, history of prior genetic modification, pathogenicity, survivability in environment.
    - Information regarding vector and inserted DNA or gene consists of characteristics and history, preparation and ligation method; stability in host cells and mobilisability.
    - Information regarding GMMs consists of expression of inserted DNA or gene, comparison of characteristics with host or recipient cell and survivability in environment
2. Information regarding GMM work requires consideration of the risk to humans and the environment, which is based on GMM propagation conditions, the amounts of GMMs used, and downstream processing and purification.

Chapter 7
Safety Management System for Contained Use of GMMs at Pilot and Industrial Scales

To ensure the safety of work involving contained use of GMMs at pilot and industrial scales, it is necessary to specify the roles and responsibilities of everyone involved in GMM work in the organization, as set forth in the guidelines. Their responsibilities include performing safety assessments, specifying appropriate class and containment levels as well as prevention measures, and reporting possible problems that may affect any aspect of safety. The biosafety officer and specific persons in charge, such as the manufacturing manager, should be designated to manage work safety and an Institute Biosafety Committee (IBC) should be set up to conduct work safety assessments.

Management of work safety regarding contained use of GMMs at pilot and industrial scales is described below.

7.1 Roles and responsibilities of various personnel in the organization/institution

1. Director/Head of the GMM operation unit (manufacturing manager)

This person must clearly understand the Biosafety Guidelines for Contained Use of GMMs at Pilot and Industrial Scales and undertake the following responsibilities:

- Coordinating with operators to facilitate the implementation of control measures for the safest working conditions, according to the guidelines.
- Arranging for biosafety training programs.
- Providing details regarding GMMs, work classification, and working procedures during inspections.
- Ensures that the operators adhere to regulations regarding access to the restricted areas.
- Setting up a system for recording details concerning GMM work, such as
  1) Name of GMMs being used,
  2) Purpose for using GMMs,
  3) Analysis of GMM properties, along with date, time and sampling location,
  4) Storage and transfer of GMMs.
- Arranging for annual health inspections for operators.
- Collaborating with the IBC to review GMM safety measures.

- Setting up a system for recording details concerning inspection of equipment directly exposed to GMMs and other equipment, including sensing tools.
- Organizing training programs on the handling of emergency situations for all personnel. This program shall include information regarding emergency procedures and equipment, chemicals and procedures for emergency reporting to relevant supervisors.

2. Institutional Biosafety Committee (IBC)

The IBC should comprise both technical and academic experts in various fields to make decisions regarding GMM work. Examples of recommended experts include:

- Personnel with the knowledge and skill to assess and examine the safety of GMM work for operators and the environment.
- Biosafety officer (if any).
- Experienced engineer to examine the safety of biological equipment to prevent dissemination of GMMs.
- Owner, director or authorized representatives
- External experts with knowledge, expertise and capacity to provide suggestions on safe GMM use.

Responsibilities of the IBC

- Assessing GMM risks, classifying work and GMM levels, and providing suggestions concerning containment systems and safety measures to ensure compliance with biosafety guidelines prior to commencement of work.
- Providing advice and suggests regarding work safety in matters such as
  1) Working procedures for GMM work,
  2) Training and health surveillance,
  3) Improving work procedures and other essential safety considerations in order to minimise or prevent accidents, and
  4) Other factors necessary for work safety.
- Reviewing reports and related procedures periodically or when necessary.
- Preparing emergency plan for spillage or release of GMMs.

3. Biosafety officer

Biosafety officers should be experts on control of and protection against biohazards, be knowledgeable concerning the Biosafety Guidelines for Contained Use of Genetically Modified GMMs at Pilot and Industrial Scales and/or equivalent Biosafety guidelines, be able to provide advice regarding safety issues, and organize safety training for operators and new personnel. They must also ensure that work procedures in each step follow the working guidelines. The officers will liaise with the IBC and provide relevant information. Substitute officers must be assigned in case the main officers are absent.

4. Operator

Operators should have clear knowledge and understanding about safety issues, carefully implement proper working procedures for occupational safety, and should able to give safety advice to those who are not directly involved in GMM work but need to or are allowed to access the working areas.

7.2 Training for operators

Training program(s) shall be organized for all related operators regarding working procedures prior to actual operation. The following training topics are highly recommended:

1. Knowledge and understanding of safety issues associated with GMMs use.
2. Classification of GMM work according to risk levels.
3. Know-how regarding techniques and devices used to ensure safety to operators and prevent the dissemination of GMMs.
4. Significance of working procedures designed to improve safety for operators and the environment.
5. Working procedures under emergency situations.

7.3 Health surveillance of operators

The owner/director of the organization shall be responsible for monitoring operator health, as follows:

1. Physical examinations for new operators before starting GMM work and for all operators annually.
2. In the case of GMM work classified as class 2 or 3, prevention measures to maximize safety must be implemented prior to operation and specific treatments for diseases caused by GMMs used must be prepared and available.

3. In the case of exposure to GMMs classified as class 2 or 3, intensive medical check-ups by qualified physicians as well as blood tests and follow-ups on symptoms or effects of diseases must be conducted.

4. In the case of work with class 3 GMMs, operator blood samples must be drawn prior to commencing GMM work and kept for at least 10 years after completion of the work to allow monitoring for causes of sickness or disease that may subsequently develop.

Chapter 8
Waste Management of GMMs

According to international guidelines, all contaminated liquid or solid waste must be decontaminated/inactivated by validated means before disposal. The treated waste shall not contain any transferrable gene/DNA to ensure that it will not be disseminated into the environment.

For work classified as GILSP or class 1, inactivation of contaminated materials and waste is required by using validated means. For materials containing GMMs that undergo off-site inactivation, the registered waste contractor hired to remove the waste must hold permit No.101 for factory operation issued by the Department of Industrial Works. Moreover, the details of how waste is treated and disposed by the contractor must be recorded.

For work classified as class 2 or class 3, contaminated materials and waste must be inactivated at the site where contained use activity took place. However, viable GMM cells from class 3 work must be inactivated ***by heat sterilization on-site*** (i.e. materials must not be removed from containment for inactivation). Exhaust gases from class 2 and 3 closed systems must also be treated to prevent the release of viable organisms. Additionally, inactivation of class 3 GMMs in effluents from hand-washing sinks and showers or similar effluents is required.

8.1 Inactivation method(s)

Inactivation method(s) chosen must be appropriate to the GMM risk group and inactivation efficacy must be validated against the organism being used.

Large-scale effluents can be treated by chemical or thermal methods or a combination of both, and possibly combined with pressure. Heat inactivation is generally considered more appropriate for large-scale discharge, with a combination of heat and pressure needed to ensure that all biological agents are destroyed. The combination of heat and chemicals has an advantage in that inactivation requires no pressure and lower temperatures compared to a system based on heat alone. However, appropriate temperature and chemical combinations need to be determined for inactivating the agents used in the facility. Also, chemically inactivated effluents are still required to comply with physical and chemical parameters set down by wastewater regulations (Notification of the Ministry of Industry No.2, B.E. 2539, issued under the Factory Act B.E. 2535, Re: Industrial Effluent Guidelines for Factory Discharge) before release or disposal.

Solid wastes can be treated by autoclaving following the cycle parameters (temperature, time and pressure) in Appendix 10. An approved incineration system can be used as an alternative approach.

8.2 Verification and validation of decontamination/inactivation methods

The chosen method of inactivation (e.g. heat or chemical inactivation) must be verified and validated under working conditions to ensure its effectiveness.

For verification, the appropriate biological indicators (Table 8.1) must be used periodically as a control. The waste treatment method must be tested regularly for efficiency of decontamination and a record of the test results must be kept for 5 years for inspection upon requirement (Regulation of the Office of the Prime Minister on Record Keeping B.E. 2526, Chapter 3: Document storage, lending and destruction).

For validation, the worst-case scenario must be performed using the host cell or equivalent. Conditions to be validated include temperature of heat inactivation, concentration of chemical agents or contact/holding time, density and volume of GMM waste, for each target cell type.

Frequency of validation depends on risk assessment (at least once a year, under normal working conditions). Records of validation such as validation protocol and the results of the validation exercise must be retained by the user and kept for 5 years for inspection by regulatory authorities upon request.

Table 8.1: Examples of biological indicators for verification of heat and chemical inactivation.

Biological indicators		Heat inactivation	Chemical inactivation	Reference
1.	*Bacillus atrophaeus**	✓	✓ (Chlorine dioxide gas, Formaldehyde gas)	* Fleming /Hunt ASM book, 3rd Ed. & BMBL 2007 ** SporeNews, biological indicators newsletter, Volume 10 No.1.
2.	*Bacillus coagulans***	✓	×	
3.	*Bacillus subtilis* var. *niger**	✓	×	
4.	*Clostridium sporogenes***	✓	×	
5.	*Geobacillus (Bacillus) stearothermophilus***	✓	✓ (Hydrogen peroxide vapour)	

8.3 Waste (inactivated/non-inactivated) storage and transport

GMM waste must be collected and stored in secure, closed, and leakproof containers (triple packaged) with status labels and biohazard signs. In the case that the containers must be kept prior to decontamination, access to the storage area must be restricted to authorized personnel only.

GMM waste to be transported must be contained in triple packaged containers labeled with biohazard signs, where the primary and secondary containers must be a secure, closed, and leakproof.

GMMs waste transport:

If waste must be transported, special practices should be developed for transport of infectious materials to designated alternate location(s) within the facility (Notification of the Ministry of Industry on Land Transportation of Hazardous Substances B.E. 2546, and Notification of the Ministry of Industry on Industrial Waste Disposal B.E. 2548). Transportation of untreated waste of GMM class 3 is prohibited.

8.4 Waste disposal

Before final disposal, the presence of viable cells in waste samples shall be monitored by culturing in enriched medium. Negative controls should be used to ensure that any growth observed is verifiably derived from GMMs in liquid waste rather than experimental error. For work in class 2 and class 3, the absence of naked DNA in waste disposal must be periodically validated by transformation into the original host (in the case of GMMs harboring replicative plasmids) or PCR (GMMs with chromosomally integrated genes).

Where DNA is used for preventive or therapeutic medicine, non-functionality of DNA in waste disposal must be assured. This can be achieved either by reducing DNA fragments to non-functional lengths or altering the structure of the DNA.

Moreover, GMM waste management shall comply with the Factory Act B.E. 2535 (C.E. 1992), the Pathogens and Animal Toxins Act B.E. 2525 (C.E. 1982), the Pathogens and Animal Toxins Act (No. 2) B.E. 2544 (C.E. 2001) and currently this act has enforced. Companies that provide waste handling and disposal services must be authorized under the Hazardous Substances Act, B.E. 2535, 2544 and 2551.

8.5 Waste records and labeling

Records of GMM inactivation events (run-time parameters and test results) for the previous 5 years (Regulation of the Office of the Prime Minister on Records Keeping B.E. 2526, Chapter 3: Document storage, lending and destruction) period must be retained by the user, for inspection by authorities upon request. Status labels on the outside of GMM waste containers must provide the following information:

- Type of waste: solid, liquid or sharps
- Amount of waste
- Scientific name, GMM risk group and class of work
- Name(s) of collector(s) and date
- Name of person responsible for waste inactivation

Table 8.2: Waste management requirements

	GILSP/Class 1	Class 2	Class 3
Liquid Waste			
Decontamination • Method	Heat/Chemical inactivation	Heat/Chemical inactivation	Heat sterilization
• Location	On/off-site	On-site	In place
Storage	Segregated, secured, contained, and controlled	Segregated, secured, contained, and controlled	Segregated, secured, contained, and controlled
Transfer	Controlled, and in secure closed container	Strictly controlled, and in secure closed container	Prohibited
Solid Waste			
Decontamination • Method	Incineration Heat/Chemical inactivation	Incineration Heat/Chemical inactivation	Incineration/ Heat sterilization
• Location	On/off-site	On-site	In place
Storage	Container	Container	Container
Transfer	Controlled, and in secure closed container	Strictly controlled, and in secure closed container	Prohibited
Disposal	Landfill	- Landfill - Incinerator	- Landfill - Incinerator
Sharp			
Decontamination	-	Autoclave sterilization	Autoclave sterilization
Storage	Sharps container	Sharps container	Sharps container
Transfer	Controlled, and in secure closed container	Strictly controlled, and in secure closed container	Prohibited
Disposal	Incinerator	Incinerator	Incinerator

Chapter 9
Emergency Plan and Inactivation of Spilled GMMs in Contained Use at Pilot and Industrial Scales

Organizations or institutions that use GMMs at pilot and industrial scales are required to prepare emergency plans and methods of GMMs inactivation in case of spillage as detailed below:

1. Emergency plan(s) for response to accidents must be designed in order to ensure safety to operators and the environment and those plans must be approved by the IBC prior to actual operation.

2. Emergency plan(s) shall include counter measures, standard operating procedures (SOP) and necessary equipment and chemicals. Periodic review of the emergency procedures and validation of equipment are recommended.

3. Emergency incidents must be reported to relevant agencies or units and regulatory authorities (see Appendix 11 for sample incident report form).

4. Incident reports shall include
   - Name of the reporter
   - Place
   - Situation
   - Name of GMM, including its characteristics and the amount spilled, and
   - Other necessary information for assessing the danger posed to operators, the community and the environment

5. In the case of extensive spillage, clearly specify the methods and procedures for GMM inactivation. For instance, drains may be fitted around bioreactors in order to accumulate leaked fluids in a controlled area for chemical or heat inactivation.

6. Emergency incidents shall be reported annually to regulatory authorities and IBC should keep the report(s) for at least 5 years.

Chapter 10
Possession, Transport, Import and Export of GMMs

Possession, transport, import and export of GMMs discussed in this chapter applies to the transfer of GMMs in classes 1–3 only.

For class 1 or class 2 GMMs, the container shall be tight, closed, unbreakable, able to resist pressure and shocks, and designed to prevent content release.

For class 3 GMMs, both the inner and the outer container shall be impermeable to liquids. A liquid-absorbing material capable of absorbing the entire volume of transported liquid shall be placed between the inner and the outer container. If more than one inner container is placed in the same outer container, each inner container shall be wrapped in material that can absorb shocks and liquids. The outer container shall be tight, closed, unbreakable, able to absorb pressure and shocks, and must prevent content release.

10.1 Packaging and Transfer or Transport of GMMs

1. The primary receptacle containing GMMs must be watertight, leakproof and appropriately labeled as to its contents. This primary receptacle is wrapped in enough adsorbent material to absorb all fluid in case of breakage or leakage.

2. A second watertight, leakproof packaging is used to enclose and protect the primary receptacle(s). Several wrapped primary receptacles may be placed in a single secondary packaging. Volume and/or weight limits for packaged infectious substances are included in certain regulatory texts.

3. A third layer protects the secondary packaging from physical damage while in transit. Specimen data forms, letters and other types of information that identify or describe the GMMs and identify the shipper and receiver, and any other documentation required must also be provided according to latest regulations.

4. In the case of transport by parcel post, the outer package shall be made of absorbent material such as thick paper or wood, or material which is not easily broken. Labels shall display common and scientific names of GMMs in English, quantity, day/month/year of production, and production place, and must bear a visible warning of "Danger" together with contact details of the senders for immediate contact in case of loss or destruction during transfer. (See Figures 10.1–10.3)

5. In the case of liquid GMM transport, biological spill kit(s) and absorbent(s) shall be sufficiently available for management of spills.

10.2 Possession, Import and Export

1. Possession, import or export of GMMs shall follow these guidelines and should be under the supervision or guidance of the Biosafety Committee or related agencies. Import of pathogenic bacteria or microorganisms/agents classified as risk group 2 or higher shall comply with the Pathogens and Animal Toxins Act B.E. 2525 (C.E. 1982), the Pathogens and Animal Toxins Act (No. 2) B.E. 2544 (C.E. 2001), and currently this act has enforced for approval by the Department of Medical Sciences, Ministry of Public Health (MOPH). It must also comply with the Biosafety Act (under review) (Appendix 12).

2. Import via international post shall adhere to the guidelines defined by the Universal Postal Union regarding non-infectious and infectious perishable biological substances (NIH 2002).

3. The possession or use of GMMs class 4 is prohibited.

4. For live GMM transport, the container size shall be 2 times larger than the GMM volume. In the case of transportation of GMM classes 2 and 3 in volumes greater than 10 litres, permission must first be granted by the IBC.

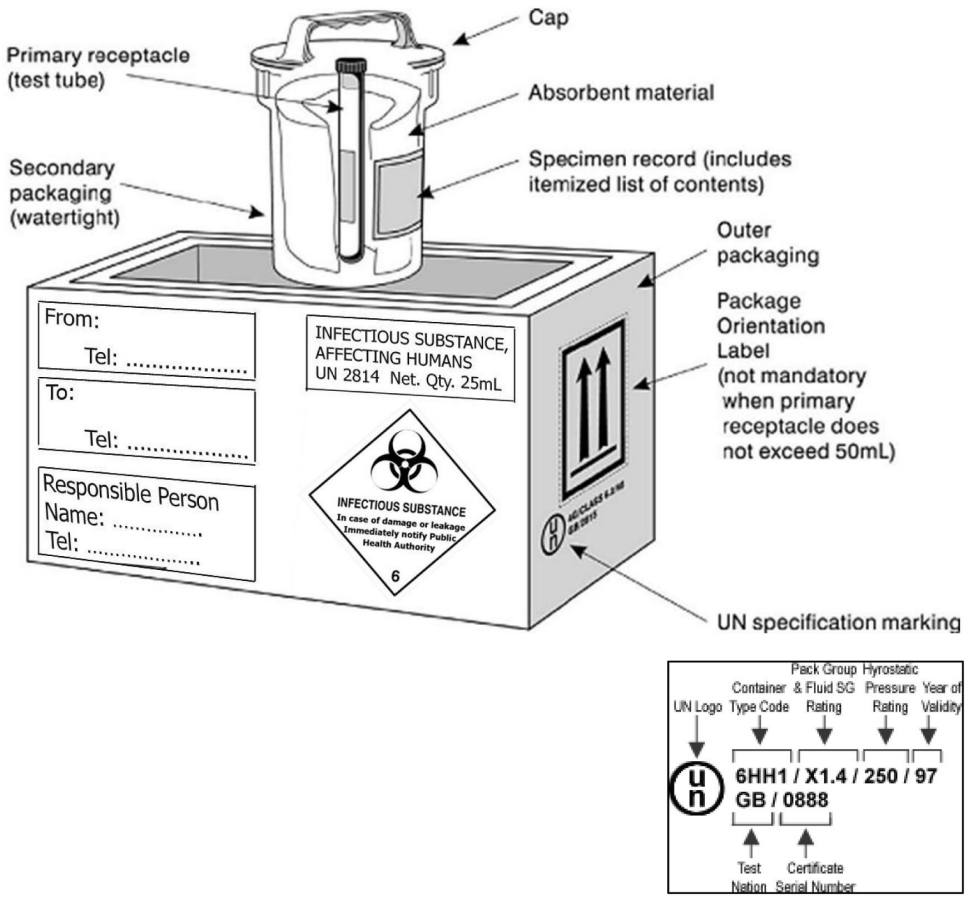


Figure 10.1 Example of the triple packaging system for the packaging and labeling of Category A* infectious substances (modified from: Guidance on Regulations for the Transport of Infectious Substances, World Health Organization, 2013)

* Category A material is an infectious substance that is transported in a form that is capable of causing permanent disability or life-threatening or fatal disease to otherwise healthy humans or animals upon exposure. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. (Source: Biosafety in Microbiological and Biomedical Laboratories 5th Edition, 2009, p.340). A list of infectious substances included in Category A is shown in Appendix 13.

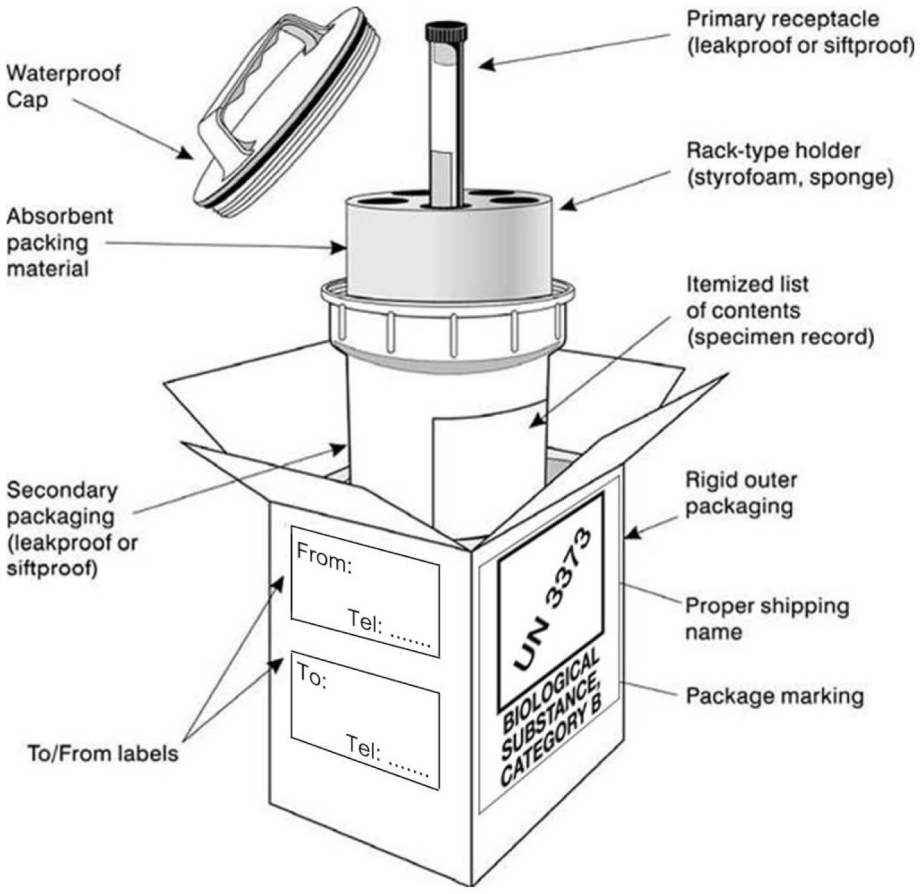


Figure 10.2 Example of the triple packaging system for the packaging and labeling of Category B infectious substances (modified from: Guidance on Regulations for the Transport of Infectious Substances, World Health Organization, 2013)

Figure 10.3 Example of the triple packaging system for GMMs (GILSP/class 1) (courtesy of the BIOTEC Culture Collection (BCC), National Center for Genetic Engineering and Biotechnology (BIOTEC), Thailand)

Appendix 1
Non-Genetically Modified Microorganisms

Microorganisms/agents classified as non-GMMs and therefore excluded from these guidelines are listed below:

1.1 Microorganisms/agents modified by mutagenesis methods that do not involve introduction of non-homologous DNA.

1.2 Microorganisms/agents generated by induction of polyploidism and haploidism.

1.3 Microorganisms/agents generated by prokaryotic cell fusion (including protoplast fusion) without introduction of new genetic material.

1.4 Microorganisms/agents generated by eukaryotic cell fusion (including protoplast fusion) without introduction of new genetic material.

1.5 Microorganisms/agents generated by *in vitro* fertilization

1.6 GILSP and Class 1 microorganisms/agents generated by self-cloning. Applicants must still submit the application form (Appendix 8) to confirm the self-cloning work. (Work with class 2 and 3 microorganisms/agents should follow these guidelines.)

[Self cloning means the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent), whether unaltered or altered by enzymatic or mechanical processes, into cells of the same species or phylogenetically closely related species (species capabable of hybridizing naturally; see Table A1.1). This may include the use of recombinant vectors, with an extended history of safe use in a particular organism, to manipulate and reinsert the nucleic acid sequences, but the vectors shall not consist of any genetic elements other than those designed for vector structure, vector replication, vector maintenance or marker genes.]

1.7 Microorganisms/agents generated by conjugation, transformation, transduction and similar natural processes as shown in Table A1.1

Remark: Classification of microorganisms/agents into microbial groups in Appendix 1 must be considered on a case-by-case basis by the TBC.

Table A1.1: Examples of microorganisms/agents capable of natural DNA transfer within the same sublist.

Sublist	Name
Sublist A	Genus *Escherichia* Genus *Shigella* Genus *Salmonella* - including *Arizona* Genus *Enterobacter* Genus *Citrobacter* - including *Levinea* Genus *Klebsiella* - including *K. oxytoca* Genus *Erwinia* *Pseudomonas aeruginosa, Pseudomonas putida,* *Pseudomonas fluorescens* and *Pseudomonas mendocina* *Serratia marcescens* *Yersinia enterocolitica*
Sublist B	*Bacillus subtilis* *Bacillus licheniformis* *Bacillus pumilus* *Bacillus globigii* *Bacillus niger* *Bacillus natto* *Bacillus amyloliquefaciens* *Bacillus aterrimus*
Sublist C	*Streptomyces aureofaciens* *Streptomyces rimosus* *Streptomyces coelicolor*
Sublist D	*Streptomyces griseus* *Streptomyces cyaneus* *Streptomyces venezuelae*
Sublist E	One-way transfer of *Streptococcus mutans* or *Streptococcus lactis* DNA into *Streptococcus sanguis*
Sublist F	*Streptococcus sanguis* *Streptococcus pneumoniae* *Enterococcus (Streptococcus) faecalis* *Streptococcus pyogenes* *Streptococcus mutans*

Remark: This list of microorganisms/agents capable of natural DNA transfer within the same sublist may be revised on the basis of scientific evidence.

Appendix 2
Elaboration of criteria for GILSP (Good Industrial Large Scale Practice) GMMs

The classification of GMMs into the GILSP category is based on clear demonstration that the GMMs used are safe and pose no possible hazard to humans. The criteria used to determine safety include the natures of the host cell, vector and inserted DNA/genes, and the GMMs themselves.

2.1 Host

Hosts used for preparation of GILSP GMMs shall meet the requirements stated in 2.1.1–2.1.3 or 2.1.4.

2.1.1 Non-pathogenic

The identity of the host must be established and the taxonomy well understood. The host must be evaluated to determine that it is not pathogenic. The host should not appear in lists of human pathogens of WHO and/or NIH (USA). In cases where uncertainty remains for the potential pathogenicity of an organism or an attenuated strain, further data must be provided to assess its safety and hence its suitability for handling under GILSP conditions. In addition, some organisms that are not found in pathogen lists may produce toxic substances in amounts which require further evaluation.

Examples of hosts that are currently used in GILSP practice are listed below.

- **Bacteria**
  - *Bacillus subtilis*
  - *Corynebacterium flavum*
  - *Escherichia coli* K-12
- **Yeast**
  - *Candida boidinii*
  - *Pichia pastoris*
  - *Saccharomyces cerevisiae*
  - *Trigonopsis variabilis*
- **Fungi**
  - *Aspergillus niger*
  - *Aspergillus oryzae*
- **Cell lines**
  - Chinese hamster ovary cell line
  - *Spodoptera frugiiperda* cell line

2.1.2 No adventitious agents

This is mainly relevant to cell cultures where harmful microorganisms/agents, in particular harmful viruses and mycoplasma, should not be present at detectable levels. Bacterial cultures should not contain unwanted phages.

2.1.3 Extended history of safe use

There should be adequate and documented experience of safe use of the host organism and lack of harm to humans and the environment. Historical and other data on the host, its progenitors or closely related strains may be appropriate for evaluation. Such evidence may be obtained from applications such as production of food, enzyme and antimicrobial agents, including data from discharge practices used with such applications. Laboratory use and/or pilot scale fermentation under conditions of minimal containment could also provide useful data.

2.1.4 Built-in environmental limitations permitting optimal growth in industrial setting but limited survival in the environment

The possibility of adverse effects can be reduced by restrictions on the organism's ability to multiply, disseminate or survive. This can be achieved by using built-in stable biological limitations which, without interfering with growth in the bio-reactor, diminish survivability and prevent adverse consequences to the environment. Examples of organisms with biological limitations include auxotrophic strains, asporogenic strains, and strains with built-in sensitivity to environmental factors such as UV light.

2.2 Vector and Inserted DNA or gene

Vectors and insert DNA/genes in the GILSP category shall meet the requirements below:

2.2.1 Well-characterised and free from known harmful sequences

- Vectors can be characterised by a combination of reference to the literature or various other listings, a knowledge of the derivation and construction of the vector, and subsequent experimental confirmation of the construct. The characterisation should ensure that the vector is free from sequences that may harmful to humans or the environment, such as sequences that enable production of substances which can have harmful effects, such as toxins or factors known to be involved in pathogenicity and/or colonisation.
- Inserted DNA or genes must be identified as to their source, positioning, function, and associated genetic sequences affecting gene activity, such as promoters, terminators and introns. In addition, insert DNA or genes should not harmful to humans or the environment.

2.2.2 As limited in size as possible while maintaining the intended function, and should not be able to maintain itself in the environment.

2.2.3 Should be poorly mobilisable

One consideration arising from the use of vectors to introduce an insert is the rate at which the vector/insert cansubsequently be transferred from the original recipient. For example, the rate of exchange of plasmid vectors can be lowered by the elimination of transfer functions. Other approaches can also be used to reduce the frequency at which the inserted DNA can be transferred from the recipient to other organisms, through means such as stable integration into the chromosome.

2.2.4 Should not transfer any resistance markers to microorganisms/agents not known to acquire them naturally.

Frequently, genes for resistance to a variety of substances (e.g. antibiotics, heavy metals) are introduced into recombinant organisms for selection purposes. Considerations for evaluating a specific resistance gene include the frequency that resistance marker(s) can be transferred from the recombinant organism to other organisms, and whether such acquisition can compromise the use of a therapeutic agent or lead to environmental perturbations. Markers for substances such as antibiotics that are not currently in commercial use should also be evaluated to determine whether the marker exhibits cross-reactivity or linked resistance. Furthermore, whether selection pressure for the resistance marker might exist in nature must also be assessed. For example, environmental selection for an organism carrying a resistance gene may be enhanced if the selecting agent in question is present in adequate concentrations in the environment as a result of antibiotic use in livestock feed or pollution by environmental contaminants such as heavy metals.

2.3 GMMs

2.3.1 Non-pathogenic

The nature and, where appropriate, the source of the inserted genes must be considered. The type of gene product and its function must be examined in the context of the characteristics of the host. If, for instance, the gene product has no known role in pathogenicity and the host is not pathogenic, then the GMM is expected to be non-pathogenic.

2.3.2 As safe in industrial settings as the host organism or with limited survival in, and without adverse consequences to, the environment.

In general, the approach taken should be to consider the nature of the host and to focus on the nature of the inserted genes and the resulting products. Their effects on biological fitness and adaptability, including attributes such as the ability to colonise new niches, should be taken into account. Adverse consequences can be avoided, for example, by using GMMs of limited survival in the environment in relation to the wild-type strain. In some cases, it may be necessary to generate and/or collect data on specific properties, for example, through monitoring of environmental discharges.

GMMs with these characteristics can be classified in the GILSP category, and work with these GMMs can follow Good Microbiological Practice for Pilot and Industrial scales.

However, cases that do not fit these criteria upon risk assessment but have enough data to support an assessment of lowest risk can be considered on a case-by-case basis.

Table A2.1: Suggested criteria for GILSP

Topic	Criteria for evaluation
Host	- Non-pathogenic - No adventitious agents - Extended history of safe use Or - Built-in environmental limitations permitting optimal growth in industrial setting but limited survival without adverse consequences in the environment
Vector/Insert	- Detail of history - Well-characterised and free from known harmful sequences - Limited in size as much as possible to the DNA required to perform the intended function - Should not increase the stability of the construct in the environment (unless that is a requirement of the intended function) - Should be low mability - Should not transfer any resistance markers to microorganisms not known to acquire them naturally
GMMs	- Non-pathogenic - As safe in industrial setting as host organism, or with limited survival in, and without adverse consequences to, the environment

Appendix 3
List of safe host systems

3.1 Safe host/vector systems approved by the TBC

Category	Host	Vector
Bacteria	1. *Agrobacterium radiobacter* *Agrobacterium rhizogenes* — disarmed strains *Agrobacterium tumefaciens* — disarmed strains	1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors 2. None (non-vector systems)
	2. *Bacillus subtilis*	**Host-Vector 1 Systems*** The following plasmids are accepted as the vector components of certified *B. subtilis* systems: pUB110, pC194, pS194, pSA2100, pE194, pT127, pUB112, pC221, pC223, and pAB124. *B. subtilis* strains RUB 331 and BGSC 1S53 have been certified as the host component of Host-Vector 1 systems based on these plasmids **Host-Vector 2 Systems**** The asporogenic mutant derivative of *Bacillus subtilis,* ASB 298, with the following plasmids as the vector component: pUB110, pC194, pS194, pSA2100, pE194, pT127, pUB112, pC221, pC223, and pAB124
	3. *Bacillus* — specified species: asporogenic strains with a reversion frequency of less than 10^{-7} a) *B. amyloliquefaciens* b) *B. licheniformis* c) *B. pumilus* d) *B. subtilis* e) *B. thuringiensis*	1. Non-conjugative plasmids 2. Plasmids and phages whose host ranges does not include *B. cereus, B. anthracis* or other pathogenic strains of *Bacillus* 3. None (non-vector systems)

Category	Host	Vector
	4. *Escherichia coli* (EK2) *(E. coli* K-12 strain chi-1776*)*	**Plasmid Systems** The following plasmids are certified for use: pSC101, pMB9, pBR313, pBR322, pDH24, pBR325, pBR327, pGL101, and pHB1. The following *Escherichia coli/ S.cerevisiae* hybrid plasmids are certified as EK2 vectors when used in *Escherichia coli* chi-1776 or in the sterile yeast strains SHY1, SHY2, SHY3, and SHY4: YIpl, YEp2, YEp4, YIp5, YEp6, YRp7, YEp20, YEp21, YEP24, YIp25, YIp26, YIp27, YIp28, YIp29, YIp30, YIp31, YIp32, and YIp33 **Bacteriophage Systems** The following are certified EK2 systems based on bacteriophage lambda: **Vector** — **Host** λgt *WES*λB' — DP50*sup*F λgt *WES*λB* — DP50*sup*F λgt *ZJ vir*λB' — *Escherichia coli* K-12 λgtALO·λB' — DP50*sup*F Charon 3A — DP50 or DP50*sup*F Charon 4A — DP50 or DP50*sup*F Charon 16A — DP50 or DP50*sup*F Charon 21A — DP50*sup*F Charon 23A — DP50 or DP50*sup*F Charon 24A — DP50 or DP50*sup*F *Escherichia coli* K-12 strains chi-2447 and chi-2281 are certified for use with lambda vectors that are certified for use with strain DP50 or DP50supF provided that the *su*-strain not be used as a propagation host
	5. E*scherichia coli* K-12, *E.coli* B or *E. coli* C or *E. coli* Nissle 1917 - any derivative that does not contain a) generalized transducing phages; or b) genes able to complement the conjugation defect in a non - conjugative plasmid	1. Non-conjugative plasmid 2. Bacteriophage that are lambda, lambdoid, and Fd or F1, such as M13 3. None (non-vector systems)

Category	Host	Vector
	6. *Lactobacillus* *Lactococcus lactis*	1. Non-conjugative plasmids 2. None (non-vector systems)
	7. *Oenococcus oeni* syn. *Leuconostoc oeni*	1. Non-conjugative plasmids 2. None (non-vector systems)
	8. *Pediococcus*	1. Non-conjugative plasmids 2. None (non-vector systems)
	9. *Photobacterium angustum*	1. Non-conjugative plasmids 2. None (non-vector systems)
	10. *Pseudoalteromonas tunicata*	1. Non-conjugative plasmids 2. None (non-vector systems)
	11. *Pseudomonas putida* - strain KT2440	1. Non-conjugative plasmids, including certified plasmids pKT 262, pKT 263, pKT 264 2. None (non-vector systems)
	12. *Rhizobium* (including *Allorhizobium*)	1. Non-conjugative plasmids 2. None (non-vector systems)
	13. *Sphingopyxis alaskensis* syn. *Sphingomonas alaskensis*	1. Non-conjugative plasmids 2. None (non-vector systems)
	14. *Streptococcus thermophilus* *Synechococcus*—specified strains: a) PCC 7002 b) PCC 7942 c) WH 8102	1. Non-conjugative plasmids 2. None (non-vector systems)
	15. *Streptomyces*—specified species: a) *S. aureofaciens* b) *S. coelicolor* c) *S. cyaneus* d) *S. griseus* e) *S. lividans* f) *S. parvulus* g) *S. rimosus* h) *S. venezuelae*	1. Non-conjugative plasmids 2. Certified plasmids: SCP2, SLP1, SLP2, PIJ101 and derivatives 3. Actinophage phi C31 and derivatives 4. None (non-vector systems)
	16. *Synechocystis* species - strain PCC 680316.	1. Non-conjugative plasmids 2. None (non-vector systems)
	17. *Vibrio cholerae* CVD103-HgR	1. Non-conjugative plasmids 2. None (non-vector systems)

Category	Host	Vector
Fungi	1. *Kluyveromyces lactis*	1. all vectors 2. none (non-vector systems)
	2. *Neurospora crassa*	**Host-Vector 1 Systems*** The following specified strains of *Neurospora crassa* which have been modified to prevent aerial dispersion: In1 (inositol-less) strains 37102, 37401, 46316, 64001, and 89601. Csp-1 strain UCLA37 and csp-2 strains FS 590, UCLA101 (these are conidial separation mutants). Eas strain UCLA191 (an "easily wettable" mutant).
	3. *Pichia pastoris*	1. all vectors 2. none (non-vector systems)
	4. *Saccharomyces cerevisiae*	**Host-Vector 2 System**** The following sterile strains of *Saccharomyces cerevisiae*, all of which have the ste-VC9 mutation, SHY1, SHY2, SHY3, and SHY4. The following plasmids are certified for use: YIp1, YEp2, YEp4, YIp5, YEp6, YRp7, YEp20, YEp21, YEp24, YIp25, YIp26, YIp27, YIp28, YIp29, YIp30, YIp31, YIp32, and YIp33.
	5. *Schizosaccharomyces pombe*	1. all vectors 2. none (non-vector systems)
	6. *Trichoderma reesei*	1. all vectors 2. none (non-vector systems)
	7. *Yarrowia lipolytica*	1. all vectors 2. none (non-vector systems)
Slime moulds	1. *Dictyostelium* species	1. *Dictyostelium* shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2 2. none (non-vector systems)

Category	Host	Vector
Tissue culture	Any of the following if they cannot spontaneously generate a whole animal: a) animal or human cell cultures (including packaging cell lines); b) isolated cells, isolated tissues or isolated organs, whether animal or human; c) early non-human mammalian embryos cultured *in vitro*	1. Non-conjugative plasmids 2. Non-viral vectors, or replication-defective viral vectors unable to transduce human cells 3. Baculovirus (*Autographa californica* nuclear polyhedrosis virus), polyhedrin minus 4. None (non-vector systems)
	Either of the following if they are not intended, and are not likely without human intervention, to vegetatively propagate, flower or regenerate into a whole plant: a. plant cell cultures; b. isolated plant tissues or organs	1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors, in *Agrobacterium tumefaciens, Agrobacterium radiobacter* or *Agrobacterium rhizogenes* 2. Non-pathogenic viral vectors 3. None (non-vector systems)

Remark * Host-vector 1 system refers to host cells/vectors that have low rates of survival in the environments.

** Host-vector 2 system refers to host cells/vectors that have very low rates of survival in the environments.

3.2 Microorganisms with Qualified Presumption of Safety (QPS), designated by the European Food Safety Authority (EFSA)

Species		Characteristic*
Gram-positive non-sporulating bacteria		
Bifidobacterium adolescentis *Bifidobacterium bifidum* *Bifidobacterium longum*	*Bifidobacterium animalis* *Bifidobacterium breve*	
Corynebacterium glutamicum *(Brevibacterium lactofermentum)*		Only for amino acid production
Lactobacillus acidophilus *Lactobacillus amylovorus* *Lactobacillus aviaries* *Lactobacillus buchneri* *Lactobacillus coryniformis* *Lactobacillus crispatus* *Lactobacillus delbrueckii* *Lactobacillus fermentum* *Lactobacillus gasseri* *Lactobacillus hilgardii* *Lactobacillus kefiranofaciens* *Lactobacillus mucosae* *Lactobacillus paracasei* *Lactobacillus pentosus* *Lactobacillus pontis* *Lactobacillus rhamnosus* *Lactobacillus salivarius*	*Lactobacillus amylolyticus* *Lactobacillus alimentarius* *Lactobacillus brevis* *Lactobacillus casei* *(Lactobacillus zeae)* *Lactobacillus curvatus* *Lactobacillus farciminis* *Lactobacillus gallinarum* *Lactobacillus helveticus* *Lactobacillus johnsonii* *Lactobacillus kefiri* *Lactobacillus panis* *Lactobacillus paraplantarum* *Lactobacillus plantarum* *Lactobacillus reuteri* *Lactobacillus sakei* *Lactobacillus sanfranciscensis*	
Lactococcus lactis		
Leuconostoc citreum *Leuconostoc mesenteroides*	*Leuconostoc lactis*	
Oenococcus oeni		
Pediococcus acidilactici *Pediococcus pentosaceus*	*Pediococcus dextrinicus*	
Propionibacterium freudenreichii	*Propionibacterium acidipropionici*	
Streptococcus thermophilus		

Species		Characteristic*
Gram-positive non-sporulating bacteria		
Bacillus		
Bacillus amyloliquefaciens	*Bacillus atrophaeus*	Only non-toxic strains
Bacillus clausii	*Bacillus coagulans*	
Bacillus fusiformis	*Bacillus lentus*	
Bacillus licheniformis	*Bacillus megaterium*	
Bacillus mojavensis	*Bacillus pumilus*	
Bacillus subtilis	*Bacillus vallismortis*	
Geobacillus stearothermophilus		

Species		Characteristic
Yeasts		
Debaryomyces hansenii		
Hanseniaspora uvarum		
Kluyveromyces lactis	*Kluyveromyces marxianus*	
Pichia angusta	*Pichia anomala*	Only enzyme production strains
Pichia jadinii		
Saccharomyces bayanus	*Saccharomyces cerevisiae***	
Saccharomyces pastorianus		
Schizosaccharomyces pombe		
Xanthophyllomyces dendrorhous		

Remark * The bacteria listed here refer only to species which are non-resistant to antibiotics, while the yeast listed here refer only to species which are non-resistant to antimycotics.

** Use of *Saccharomyces cerevisiae* subtype *boulardii* is prohibited as it presents a danger to susceptible people, including patients with central venous catheters.

3.3 GILSP hosts/vectors, designated by the Ministry of Economy, Trade and Industry of Japan

Name of host	Vector (original vector)
Aspergillus niger 1208-160	pUC19
Aspergillus niger ND48	pNAN8142f (pUC118) pUC18 pUC118
Aspergillus oryzae	pBR322 pNAG142 (pUC18) pUC19 pUC118 pUC119
Aspergillus phoenicis ND205	pNAN8142f (pUC118)
Bacillus amyloliquefaciens	pUC18
Bacillus licheniformis DN2461	pUB110
Bacillus licheniformis DN2717	pBR322 pUB110
Bacillus subtilis K2A1	pUB110
Bacillus subtilis Marburg 168 derivative	pAM α1 pND10 (pWB705) (pUB110) pTB53 (pTB19) pUB18 (pUB110) pUB110 pWB705 (pUB110)
Brevibacillus choshinensis HPD31 (*Bacillus brevis* HPD31)	pUB110 pNU210 (pUB110)
Brevibacillus choshinensis HPD31-M3 (*Bacillus brevis* HPD31-M3)	pUB110 pHT100 (pHT926)
Brevibacillus choshinensis HPD31-SP3 (*Bacillus brevis* HPD31-SP3)	pNY326 (pUB110) pNCM02 (pUB110/pUC119)
Candida boidinii TK62	pUC18
Corynebacterium ammoniagenes DAF-7	pRI109
Corynebacterium glutamicum	pBY503 pCG116 (pCG11) pPK4 (pHSG298/pHM1519)

Name of host	Vector (original vector)
Escherichia coli B	pHB4 (pBR322)
Escherichia coli BL21	pAT153 (pBR322) pBBR122 pBR322 pET-21a (+) (pBR322) pET-28a (+) (pBR322) pKK388-1 (pBR322) pSE380 (pTrc99A) pTrc99A (pBBR122)
Escherichia coli BL21 (DE3)	pET-23d (+) (pBR322) pGEX-4T2 (pBR322)
Escherichia coli BL21 (DE3) plysS	pET-3a (pBR322)
Escherichia coli DB3.1	pBIN19 (pRK252/pBR322) pSMAH621 (pBR322/pVS1) pSMAB704 (pBR322/pVS1)
Escherichia coli K-12 derivatives	Charomid 9-20 Charomid 9-28 Charomid 9-36 Charomid 9-42 Charomid 9-52 ColE1 M13 phage DNA M13 wild type RF M13KO7 M13mp8 M13mp8 RFI M13mp9 M13mp9 am16 M13mp9 RFI M13mp10 M13mp10 RFI M13mp11 M13mp11 am16 M13mp11 RFI

Name of host	Vector (original vector)
	M13mp18
	M13mp18 RFI
	M13mp19
	M13mp19 RFI
	M13tv18 (M13mp9)
	M13tv19 (M13mp9)
	NM816
	pACYC177
	pACYC184
	pAM α1
	pAS118
	pAT153
	pBluescript
	pBluescript KS (-)
	pBluescript KS (+)
	pBluescript KSN (+) (pBluescript KS (+))
	pBluescript SK (-)
	pBluescript SK (+)
	pBluescript SKN (+)
	pBluescript II SK (-) (pBluescript SK (-))
	pBluescript II SK (+) (pBluescript SK (+))
	pBluescript II SK (+) $\triangle$plac (pBluescript II SK (+))
	pBR322
	pBR327
	pBTPB18 (pKK223-3)
	pCR1000 (pUC19)
	pDR720 (pMB1)
	pERISH7 α (pUC18)
	pGEX-4T-3 (pBR322)
	pHSG298
	pHSG299
	pHSG367 (pUC9)
	pHSG396
	pHSG397

Name of host	Vector (original vector)
	pHSG398
	pHSG399
	pHY300PLK (pACYC177)
	pHY300 ·2PLK (pAM α 1)
	pIN III-ompA1
	pKC16 (pBR322)
	pKH1 (pBR322)
	pKK223-3 (pBR322)
	pKK388-1 (pBR322)
	pLacI (pKK223-3)
	pLacII (pKK223-2/pUC19)
	pLED-M1 (pUC9)
	pMalc2e
	pMalc2e-PNC (pMalc2e)
	pMALp2 (pUC18)
	pMAM2-BSD (pUC18)
	pMW118 (pSC101)
	pMW119 (pSC101)
	pMY12-6 ApR (pBR322)
	pNG16 (pBR322)
	pNT203 (pSC101)
	pNUT4
	pNUT5
	pNUT6
	pNUT7
	pNUT8
	pPT0323 (pBR322)
	pRIT2T
	pSC101
	pSE380 (pTrc99A)
	pSE420Q (pBR322)
	pSTV28
	pSV00CAT
	pSY343

Name of host	Vector (original vector)
	pTBE-PL9 (pBR322) pTK31 (pBR322) pTK32 (pBR322) pTlac (pUC19) pTP8-51 (pBR322) pTrc99A pTRP (pTZ19U) pTrS32 (pBR322) pTV118N (pUC118) pTV119N (pUC119) pTYR (pUC119) pTYR-HSVtk (pUC19) pTYR-SV40 (pUC19) pTYR-T (pUC19) pTZ18U (pUC18) pTZ19U (pUC19) pUC8 pUC13 (pBR322) pUC18 pUC19 pUC118 pUC119 pUC119am16 (pUC119) pUC119N (pUC19) pUCSV-BSD (pUC18) pUTE300K (pUC118) pYN7 (pBR322) pYUK101(pBR322/pSC101) pYUM201(pUC18) slp1S (λ phage, ϕ 80 phage) slp501S-Km (λ phage, ϕ 80 phage) slp501S-Tc(λ phage) λ λ 2001

Name of host	Vector (original vector)
	λ EMBL4 λ gt10 λ gtWES λ NM742 λ NM989 ((gtWES) (NM1070
Escherichia coli HB101	pACYC177 pACYC184 pAT153 (pBR322) pAUR101 pAUR112 pAUR123 pBluescript pBluescript II KS (+) pBR322 pGH55 (pBR322) pHSG367 (pUC9) pHSG396 (pBR322) pHSG644 (pHSG367) pKH1 (pBR322) pKK223-3 (pBR322) pKTN (pBR322) pNT203 (pSC101) pPALS (pTRA415) pRIT2T pSTV28 pSTV29 pSV2bsr (pBR322) pSV2neo pTV119N (pUC18) pTWV228 pTWV229 pUC18 pUC19

Name of host	Vector (original vector)
	pUC118N (pUC18/19) pUC119 pUC119N (pUC19) YEUra3
Escherichia coli Rosetta (DE3) plysS	pET11a (pBR322)
Geobacillus stearothermophilus	pUB110
Hypocrea rufa strain 2 (*Trichoderma viride* strain 2)	pCB-eg3 (pUC119) pPYR4 (LITMUS28)
Komagataella pastoris GS115 (*Pichia pastoris* GS115)	pPIC3.5 (pBR322)
Komagataella pastoris KM71 (*Pichia pastoris* KM71)	pPIC9 (pBR322)
Ogataea minuta NBRC 10746 (*Pichia minuta* NBRC 10746)	pOMEA1 (pUC19) pOMEU1 (pUC19)
Providencia stuartii 164	pBR322
Pseudomonas putida KT2440	pME294 (pVS1)
Pseudomonas putida TE3493	pACYC177
Rhodococcus rhodochorus J-1A	pK4 (pHSG299)
Saccharomyces cerevisiae	pUC19 pBluescript II SK (+) pGLD906-1 (pBR322) pHSG399 pRS403 pRS404 pRS405 pRS406 (pBluescript)
Scytalidium thermophilum MN200-1 (FERM P-15736) (*Humicola insolens*)	pJD01 pUC118
Trigonopsis variabilis KC-103	pTHY83-1

Appendix 4
Classification of human etiologic agents on the basis of hazard

The classification of human etiologic agents on the basis of hazard is based on the potential effect of a biological agent on a healthy human adult and does not account for instances in which an individual may have increased susceptibility to such agents, such as preexisting diseases, medications, compromised immunity, pregnancy or breastfeeding (which may increase exposure of infants to some agents).

4.1 List of microorganisms by NIH risk group classification (2013)

4.1.1 Risk group 1 microorganisms are not associated with disease in healthy adult humans.

Examples:

- *Bacillus subtilis*
- *Bacillus licheniformis* (non-spore forming)
- Adeno-associated virus (AAV – all serotypes)
- recombinant AAV constructs
- *Escherichia coli* K-12 and *E. coli* strains that does not possess a complete lipopolysaccharide and does not carry any active virulence factor (e.g., toxins) or colonization factors and does not carry any genes encoding these factors.

Remark: Microorganisms/agents which not listed in risk groups 2–4 are not automatically or implicitly classified into risk group 1; a risk assessment must be conducted on a case-by-case basis.

4.1.2 Risk group 2 microorganisms are associated with human diseases which are rarely serious and for which preventive or therapeutic interventions are *often* available.

- **Bacterial agents including Chlamydia**
  1) *Acinetobacter baumannii* (formerly *Acinetobacter calcoaceticus*)
  2) *Actinobacillus*
  3) *Actinomyces pyogenes* (formerly *Corynebacterium pyogenes*)
  4) *Aeromonas hydrophila*
  5) *Amycolata autotrophica*

6) *Arcanobacterium haemolyticum* (formerly *Corynebacterium haemolyticum)*
7) *Arizona hinshawii* - all serotypes
8) *Bacillus anthracis*
9) *Bartonella henselae, B. quintana, B. vinsonii*
10) *Bordetella* including *B. pertussis*
11) *Borrelia recurrentis, B. burgdorferi*
12) *Burkholderia* (formerly *Pseudomonas* species) except those listed in risk group 3
13) *Campylobacter coli, C. fetus, C. jejuni*
14) *Chlamydia psittaci, C. trachomatis, C. pneumoniae*
15) *Clostridium botulinum, C. chauvoei, C. haemolyticum, C. histolyticum, C. novyi, C. septicum, C. tetani*
16) *Coxiella burnetii* - specifically the Phase II, Nine Mile strain, plaque purified, clone 4
17) *Corynebacterium diphtheriae, C. pseudotuberculosis, C. renale*
18) *Dermatophilus congolensis*
19) *Edwardsiella tarda*
20) *Erysipelothrix rhusiopathiae*
21) *Escherichia coli* - all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen, including *E. coli* O157:H7
22) *Francisella tularensis* specifically *F. tularensis* spp. *novicida* (aka *F. novicida*), strain Utah 112; *F. tularensis* spp. *holarctica* LVS; *F. tularensis* biovar *tularensis* strain ATCC 6223 (aka strain B38)
23) *Haemophilus ducreyi, H. influenzae*
24) *Helicobacter pylori*
25) *Klebsiella* - all species except *K. oxytoca* (risk group 1)
26) *Legionella* including *L. pneumophila*
27) *Leptospira interrogans* all serotypes
28) *Listeria*
29) *Moraxella*
30) *Mycobacterium* (except those listed in risk group 3) including *M. avium complex, M. asiaticum, M. bovis* BCG vaccine strain, *M. chelonae, M. fortuitum, M. kansasii, M. leprae, M. malmoense, M. marinum, M. paratuberculosis, M. scrofulaceum, M. simiae, M. szulgai, M. ulcerans, M. xenopi*

31) *Mycoplasma,* except *M. mycoides* and *M. agalactiae* which are restricted animal pathogens
32) *Neisseria gonorrhoeae, N. meningitidis*
33) *Nocardia asteroides, N. brasiliensis, N. otitidiscaviarum, N. transvalensis*
34) *Rhodococcus equi*
35) *Salmonella* including *S. enterica* serovars Arizonae, Cholerasuis, Enteritidis, Gallinarum, Pullorum, Meleagridis, Paratyphi types A, B, C, Typhi, Typhimurium and *Salmonella bongori*
36) *Shigella including S. boydii, S. dysenteriae,* type 1, *S. flexneri, S. sonnei*
37) *Sphaerophorus necrophorus*
38) *Staphylococcus aureus*
39) *Streptobacillus moniliformis*
40) *Streptococcus* including *S. pneumoniae, S. pyogenes*
41) *Treponema pallidum, T. carateum*
42) *Vibrio cholerae, V. parahaemolyticus, V. vulnificus*
43) *Yersinia enterocolitica*
44) *Yersinia pestis* specifically $pgm^{(-)}$ strains (lacking the 102 kb pigmentation locus) and $lcr^{(-)}$ strains (lacking the LCR plasmid)

- **Fungal agents**
  1) *Blastomyces dermatitidis*
  2) *Cladosporium bantianum, C. (Xylohypha) trichoides*
  3) *Cryptococcus neoformans*
  4) *Dactylaria galopava (Ochroconis gallopavum)*
  5) *Epidermophyton*
  6) *Exophiala (Wangiella) dermatitidis*
  7) *Fonsecaea pedrosoi*
  8) *Microsporum*
  9) *Paracoccidioides brasiliensis*
  10) *Penicillium marneffei*
  11) *Sporothrix schenckii*
  12) *Trichophyton*

- **Parasitic agents**
  1) *Ancylostoma* human hookworms including *A. duodenale, A. ceylanicum*
  2) *Ascaris* including *A. lumbricoides suum*
  3) *Babesia* including *B. divergens, B. microti*
  4) *Brugia* filaria worms including *B. malayi, B. timori*
  5) *Coccidia*
  6) *Cryptosporidium* including *C. parvum*
  7) *Cysticercus cellulosae* (hydatid cyst, larva of *T. solium*)
  8) *Echinococcus* including *E. granulosis, E. multilocularis, E. vogeli*
  9) *Entamoeba histolytica*
  10) *Enterobius*
  11) *Fasciola* including *F. gigantica, F. hepatica*
  12) *Giardia* including *G. lamblia*
  13) *Heterophyes*
  14) *Hymenolepis* including *H. diminuta, H. nana*
  15) *Isospora*
  16) *Leishmania* including *L. braziliensis, L. donovani, L. ethiopia, L. major, L. mexicana, L. peruvania, L. tropica*
  17) *Loa loa* filaria worms
  18) *Microsporidium*
  19) *Naegleria fowleri*
  20) *Necator* human hookworms including *N. americanus*
  21) *Onchocerca* filaria worms including *O. volvulus*
  22) *Plasmodium* including simian species, *P. cynomologi, P. falciparum, P. malariae, P. ovale, P. vivax*
  23) *Sarcocystis* including *S. suihominis*
  24) *Schistosoma* including *S. haematobium, S. intercalatum, S. japonicum, S. mansoni, S. mekongi*
  25) *Strongyloides* including *S. stercoralis*
  26) *Taenia solium*
  27) *Toxocara* including *T. canis*
  28) *Toxoplasma* including *T. gondii*
  29) *Trichinella spiralis*
  30) *Trypanosoma* including *T. brucei brucei, T. brucei gambiense, T. brucei rhodesiense, T. cruzi*
  31) *Wuchereria bancrofti* filaria worms

- **Viral agents**
  1) Adenoviruses, human - all types
  2) Alphaviruses (Togaviruses) - Group A Arboviruses
     - Chikungunya vaccine strain 181/25
     - Eastern equine encephalomyelitis virus
     - Venezuelan equine encephalomyelitis vaccine strains TC-83 and V3526
     - Western equine encephalomyelitis virus
  3) Arenaviruses
     - Junin virus candid #1 vaccine strain
     - Lymphocytic choriomeningitis virus (non-neurotropic strains)
     - Tacaribe virus complex
     - Other viruses listed in the reference source (See Section V-C, NIH 2013)
  4) Bunyaviruses
     - Bunyamwera virus
     - Rift Valley fever virus vaccine strain MP-12
     - Other viruses as listed in the reference source (See Section V-C, NIH 2013)
  5) Caliciviruses
  6) Coronaviruses
  7) Flaviviruses (Togaviruses) - Group B Arboviruses
     - Dengue virus serotypes 1, 2, 3, and 4
     - Japanese encephalitis virus strain SA 14-14-2
     - Yellow fever virus vaccine strain 17D
     - Other viruses as listed in the reference source (See Section V-C, NIH 2013)
  8) Hepatitis A, B, C, D, and E viruses
  9) Herpesviruses except Herpesvirus simiae (Monkey B virus)
     - Cytomegalovirus
     - Epstein Barr virus
     - *Herpes simplex* types 1 and 2
     - *Herpes zoster*
     - Human herpesvirus types 6 and 7
  10) Orthomyxoviruses
     - Influenza viruses types A, B, and C
     - Other tick-borne orthomyxoviruses as listed in the reference source (See Section V-C, NIH 2013)

11) Papovaviruses
    - All human papilloma viruses
12) Paramyxoviruses
    - Newcastle disease virus
    - Measles virus
    - Mumps virus
    - Parainfluenza viruses types 1, 2, 3, and 4
    - Respiratory syncytial virus
13) Parvoviruses
    - Human parvovirus (B19)
14) Picornaviruses
    - Coxsackie viruses types A and B
    - Echoviruses - all types
    - Polioviruses - all types, wild and attenuated
    - Rhinoviruses - all types
15) Poxviruses - all types except monkeypox virus and restricted poxviruses including alastrim, smallpox and whitepox
16) Reoviruses - all types including coltivirus, human rotavirus, and orbivirus (Colorado tick fever virus)
17) Rhabdoviruses
    - Rabies virus - all strains
    - Vesicular stomatitis virus - laboratory adapted strains including VSV-Indiana, San Juan, and Glasgow
18) Rubivirus (Togaviruses)
    - Rubella virus

4.1.3 Risk group 3 microorganisms are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available.

- **Bacterial agents including Rickettsia**
    1) *Bartonella*
    2) *Brucella* including *B. abortus, B. canis, B. suis*
    3) *Burkholderia (Pseudomonas) mallei, B. pseudomallei*
    4) *Coxiella burnetii* (except the Phase II, Nine Mile strain listed in risk group 2 - Bacterial agent including Chlamydia)

5) *Francisella tularensis* (except those strains listed in risk group 2 - Bacterial agent including Chlamydia)
6) *Mycobacterium bovis* (except the BCG strain in risk group 2 - Bacterial agent including Chlamydia), *M. tuberculosis*
7) *Pasteurella multocida* type B -"buffalo" and other virulent strains
8) *Rickettsia akari, R. australis, R. canada, R. conorii, R. prowazekii, R. rickettsii, R. siberica, R. tsutsugamushi, R. typhi (R. mooseri)*
9) *Yersinia pestis* (except those strains listed in Appendix B-11-A, risk group 2 - Bacterial agent including Chlamydia)

- **Fungal agents**
  1) *Coccidioides immitis* (sporulating cultures, contaminated soil)
  2) *Histoplasma capsulatum, H. capsulatum* var. *Duboisii*

- **Parasitic agents**
  None

- **Viral agents and prions**
  1) Alphaviruses (Togaviruses) - Group A Arboviruses
     - Chikungunya virus (except the vaccine strain 181/25 listed in risk group 2)
     - Semliki Forest virus
     - St. Louis encephalitis virus
     - Venezuelan equine encephalomyelitis virus (except the vaccine strains TC-83 and V3526)
     - Other viruses as listed in the reference source (see section V-C, NIH 2013)
  2) Arenaviruses
     - Flexal
     - Lymphocytic choriomeningitis virus (LCM) (neurotropic strains)
  3) Bunyaviruses
     - Hantaviruses including Hantaan virus
     - Rift Valley fever virus
  4) Coronaviruses
     - SARS-associated coronavirus (SARS-CoV)

5) Flaviviruses - Group B Arboviruses
   - Japanese encephalitis virus (except those strains listed in risk group 2)
   - Yellow fever virus
   - West Nile virus (WNV)
   - Other viruses as listed in the reference source (see section V-C, NIH 2013)
6) Orthomyxoviruses
   - Influenza viruses 1918–1919 H1N1 (1918 H1N1), human H2N2 (1957–1968) and highly pathogenic avian influenza H5N1 strains within the Goose/Guangdong/96-like H5 lineage (HPAI H5N1)
7) Poxviruses
   - Monkeypox virus
8) Prions
   - Transmissible spongioform encephalopathies (TME) agents (Creutzfeldt-Jacob disease and kuru agents)
9) Retroviruses
   - Human immunodeficiency virus (HIV) types 1 and 2
   - Human T cell lymphotropic virus (HTLV) types 1 and 2
   - Simian immunodeficiency virus (SIV)
10) Rhabdoviruses
   - Vesicular stomatitis virus (except those strains listed in risk group 2)

4.1.4 Risk group 4 microorganisms are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available.

- **Bacterial, Fungal and Parasitic agents**

  None

- **Viral agents**
  1) Arenaviruses
     - Guanarito virus
     - Lassa virus
     - Junin virus (except the candid #1 vaccine strain listed in Appendix B-II-D Risk Group2 (RG2) – Viruses, NIH 2013)
     - Machupo virus
     - Sabia

2) Bunyaviruses (Nairovirus)
   - Crimean-Congo hemorrhagic fever virus
3) Filoviruses
   - Ebola virus
   - Marburg virus
4) Flaviruses - Group B Arboviruses
   - Tick-borne encephalitis virus complex including Absetterov, Central European encephalitis, Hanzalova, Hypr, Kumlinge, Kyasanur Forest disease, Omsk hemorrhagic fever, and Russian spring-summer encephalitis viruses
5) Herpesviruses (alpha)
   - Herpesvirus simiae (Herpes B or Monkey B virus)
6) Paramyxoviruses
   - Equine morbillivirus
7) Hemorrhagic fever agents and viruses that are not recorded

Remark: Risk assessment of etiologic agents of reemerging infectious diseases should be based on the proposed activity, experiment, or work.

4.2 List of human and animal pathogens classified by the Department of Medical Sciences, Ministry of Public Health B.E. 2557

4.2.1 Risk group 1

- **Fungal agents**

	Name	Risk Group in	
		human	animal
1)	*Absidia corymbifera*	1	1
2)	*Absidia* spp.	1	1
3)	*Acremonium falciforme*	1	1
4)	*Acremonium kilienese*	1	1
5)	*Acremonium recifei*	1	1
6)	*Acremonium* spp.	1	1
7)	*Apophysomyces elegans*	1	1
8)	*Apophysomyces* spp.	1	1
9)	*Arthrographis kalrae*	1	1

	Name	Risk Group in	
		human	animal
10)	*Arthrographis* spp.	1	1
11)	*Aspergillus niger*	1	1
12)	*Aspergillus oryzae*	1	1
13)	*Aspergillus terreus*	1	1
14)	*Aspergillus* spp.	1	1
15)	*Basidiobolus* spp.	1	1
16)	*Candida krusei*	1	1
17)	*Candida* spp.	1	1
18)	*Chrysosporium inops*	1	1
19)	*Chrysosporium* spp.	1	1
20)	*Cladophialophora arxii*	1	1
21)	*Cladophialophora boppii*	1	1
22)	*Cladophialophora devriesii*	1	1
23)	*Cladophialophora emmonsii*	1	1
24)	*Cladophialophora modesta*	1	1
25)	*Cladophialophora* spp.	1	1
26)	*Conidiobolus incongruus*	1	1
27)	*Conidiobolus* spp.	1	1
28)	*Cryptococcus* spp.	1	1
29)	*Cunninghamella bertholletiae*	1	1
30)	*Cunninghamella* spp.	1	1
31)	*Cylindrocarpon cyanescens*	1	1
32)	*Cylindrocarpon* spp.	1	1
33)	*Emmonsia parva*	1	1
34)	*Emmonsia* spp.	1	1
35)	*Epidermophyton* spp.	1	1
36)	*Exophiala dermatitidis*	1	1
37)	*Exophiala lecanii-cornii*	1	1
38)	*Exophiala spinifera*	1	1
39)	*Exophiala* spp.	1	1
40)	*Fonsecaea* spp.	1	1
41)	*Fusarium verticillioides*	1	1

	Name	Risk Group in	
		human	animal
42)	*Fusarium* spp.	1	1
43)	*Geotrichum capitatum*	1	1
44)	*Geotrichum* spp.	1	1
45)	*Leptosphaeria senegalensis*	1	1
46)	*Leptosphaeria* spp.	1	1
47)	*Madurella* spp.	1	1
48)	*Malassezia furfur*	1	1
49)	*Malassezia* spp.	1	1
50)	*Microsporum ferrugineum*	1	1
51)	*Microsporum gallinae*	1	1
52)	*Microsporum persicolor*	1	1
53)	*Microsporum praecox*	1	1
54)	*Microsporum racemosum*	1	1
55)	*Microsporum* spp.	1	1
56)	*Mortierella wolfii*	1	1
57)	*Mortierella* spp.	1	1
58)	*Neotestudina rosatii*	1	1
59)	*Neotestudina* spp.	1	1
60)	*Ochroconis gallopava*	1	1
61)	*Ochroconis* spp.	1	1
62)	*Penicillium* spp.	1	1
63)	*Phialophora europaea*	1	1
64)	*Phialophora richardsiae*	1	1
65)	*Phialophora* spp.	1	1
66)	*Pneumocystis jirovecii*	1	1
67)	*Pneumocystis* spp.	1	1
68)	*Pseudollescheria boydii*	1	1
69)	*Pseudollescheria* spp.	1	1
70)	*Pyrenochaeta romeroi*	1	1
71)	*Pyrenochaeta* spp.	1	1
72)	*Pythium insidiosum*	1	1
73)	*Pythium* spp.	1	1

	Name	Risk Group in	
		human	animal
74)	*Rhamichlorium mackenzie*	1	1
75)	*Rhamichlorium* spp.	1	1
76)	*Rhinocladiella aquaspersa*	1	1
77)	*Rhinocladiella* spp.	1	1
78)	*Rhinosporidium seeberi*	1	1
79)	*Rhinosporidium* spp.	1	1
80)	*Rhizomucor pusillus*	1	1
81)	*Rhizomucor* spp.	1	1
82)	*Rhizopus azygosporus*	1	1
83)	*Rhizopus microsporus*	1	1
84)	*Rhizopus schipperae*	1	1
85)	*Rhizopus* spp.	1	1
86)	*Saksenaea vasiformis*	1	1
87)	*Saksenaea* spp.	1	1
88)	*Scedosporium prolificans*	1	1
89)	*Scedosporium* spp.	1	1
90)	*Scopulariopsis brevicaulis*	1	1
91)	*Scopulariopsis brumptii*	1	1
92)	*Scopulariopsis* spp.	1	1
93)	*Syncephalastrum racemosum*	1	1
94)	*Syncephalastrum* spp.	1	1
95)	*Trichophyton concentricum*	1	1
96)	*Trichophyton interdigitale*	1	1
97)	*Trichophyton simii*	1	1
98)	*Trichophyton* spp.	1	1
99)	*Trichosporon asahii*	1	1
100)	*Trichosporon beigelii*	1	1
101)	*Trichosporon inkin*	1	1
102)	*Trichosporon mucoides*	1	1
103)	*Trichosporon ovoides*	1	1
104)	*Trichosporon* spp.	1	1

4.2.2 Risk group 2

- **Bacterial agents**

	Name	Risk Group in	
		human	animal
1)	*Abiotrophia adiacens*	2	2
2)	*Abiotrophia defective*	2	2
3)	*Abiotrophia elegans*	2	2
4)	*Abiotrophia* spp.	2	2
5)	*Acetivibrio ethanolgignens*	2	2
6)	*Acholeplasma axanthum*	2	2
7)	*Acholeplasma granularum*	2	2
8)	*Acholeplasma hippikon*	2	2
9)	*Acholeplasma laidlawii*	2	2
10)	*Acholeplasma modicum*	2	2
11)	*Acholeplasma morum*	2	2
12)	*Acholeplasma oculi*	2	2
13)	*Achromobacter denitrificans*	2	2
14)	*Achromobacter piechaudii*	2	2
15)	*Achromobacter xylosoxidans*	2	2
16)	*Acidaminococcus fermentans*	2	2
17)	*Acidaminococcus intestini*	2	2
18)	*Acidovorax* spp.	2	2
19)	*Acinetobacter baumannii*	2	2
20)	*Acinetobacter calcoaceticus*	2	2
21)	*Acinetobacter grimontii*	2	2
22)	*Acinetobacter haemolyticus*	2	2
23)	*Acinetobacter johnsonii*	2	2
24)	*Acinetobacter junii*	2	2
25)	*Acinetobacter lwoffii*	2	2
26)	*Acinetobacter porvus*	2	2
27)	*Acinetobacter schindleri*	2	2
28)	*Acinetobacter ursingii*	2	2
29)	*Acinetobacter* spp.	2	2
30)	*Actinobacillus actinomycetemcomitans*	2	2
31)	*Actinobacillus arthritidis*	2	2

	Name	Risk Group in	
		human	animal
32)	*Actinobacillus capsulatus*	2	2
33)	*Actinobacillus delphinicola*	2	2
34)	*Actinobacillus equuli*	2	2
35)	*Actinobacillus hominis*	2	2
36)	*Actinobacillus lignieresii*	2	2
37)	*Actinobacillus pleuropneumoniae*	2	2
38)	*Actinobacillus rossii*	2	2
39)	*Actinobacillus scotiae*	2	2
40)	*Actinobacillus seminis*	2	2
41)	*Actinobacillus suis*	2	2
42)	*Actinobacillus ureae*	2	2
43)	*Actinobacillus* spp.	2	2
44)	*Actinobaculum massiliae*	2	2
45)	*Actinobaculum massiliense*	2	2
46)	*Actinobaculum schaalii*	2	2
47)	*Actinobaculum suis*	2	2
48)	*Actinobaculum urinale*	2	2
49)	*Actinomadura latina*	2	2
50)	*Actinomadura madurae*	2	2
51)	*Actinomadura pelletieri*	2	2
52)	*Actinomyces bernardiae*	2	2
53)	*Actinomyces bovis*	2	2
54)	*Actinomyces bowdenii*	2	2
55)	*Actinomyces canis*	2	2
56)	*Actinomyces cardiffensis*	2	2
57)	*Actinomyces catuli*	2	2
58)	*Actinomyces dentalis*	2	2
59)	*Actinomyces europaeus*	2	2
60)	*Actinomyces funkei*	2	2
61)	*Actinomyces gerencseriae*	2	2
62)	*Actinomyces graevenitzii*	2	2
63)	*Actinomyces hongkongensis*	2	2

	Name	Risk Group in	
		human	animal
64)	*Actinomyces hordeovulneris*	2	2
65)	*Actinomyces hyovaginalis*	2	2
66)	*Actinomyces israelii*	2	2
67)	*Actinomyces marimammalium*	2	2
68)	*Actinomyces meyeri*	2	2
69)	*Actinomyces naeslundii*	2	2
70)	*Actinomyces neuii*	2	2
71)	*Actinomyces odontolyticus*	2	2
72)	*Actinomyces pyogenes*	2	2
73)	*Actinomyces radicidentis*	2	2
74)	*Actinomyces radingae*	2	2
75)	*Actinomyces suimastitidis*	2	2
76)	*Actinomyces suis*	2	2
77)	*Actinomyces turicensis*	2	2
78)	*Actinomyces vaccimaxillae*	2	2
79)	*Actinomyces viscosus*	2	2
80)	*Actinomyces* spp.	2	2
81)	*Advenella incenata*	2	2
82)	*Aegyptianella pullorum*	2	2
83)	*Aerococcus suis*	2	2
84)	*Aerococcus urinae*	2	2
85)	*Aerococcus viridans*	2	2
86)	*Aeromonas allosaccharophila*	2	2
87)	*Aeromonas caviae*	2	2
88)	*Aeromonas culicicola*	2	2
89)	*Aeromonas enteropelogens*	2	2
90)	*Aeromonas hydrophila*	2	2
91)	*Aeromonas jandaei*	2	2
92)	*Aeromonas punctata*	2	2
93)	*Aeromonas schubertii*	2	2
94)	*Aeromonas sobria*	2	2
95)	*Aeromonas trota*	2	2

	Name	Risk Group in	
		human	animal
96)	*Aeromonas veronii*	2	2
97)	*Afipia broomeae*	2	2
98)	*Afipia clevelandensis*	2	2
99)	*Afipia felis*	2	2
100)	*Afipia* spp.	2	2
101)	*Aggregatibacter actinomycetemcomitans*	2	2
102)	*Aggregatibacter aphrophilus*	2	2
103)	*Aggregatibacter segnis*	2	2
104)	*Alcaligenes denitrificans*	2	2
105)	*Alcaligenes faecalis*	2	2
106)	*Alcaligenes piechaudii*	2	2
107)	*Alcaligenes xylosoxidans*	2	2
108)	*Alcaligenes* spp.	2	2
109)	*Alistipes putredinis*	2	2
110)	*Alloiococcus otitis*	2	2
111)	*Alloprevotella tannerae*	2	2
112)	*Alloscardovia omnicolens*	2	2
113)	*Amycolatopsis kentuckyensis*	2	2
114)	*Amycolatopsis lexingtonensis*	2	2
115)	*Amycolatopsis pretoriensis*	2	2
116)	*Anaerobiospirillum succiniciproducens*	2	2
117)	*Anaerobiospirillum thomasii*	2	2
118)	*Anaerococcus prevotii*	2	2
119)	*Anaerococcus vaginalis*	2	2
120)	*Anaerorhabdus furcosa*	2	2
121)	*Anaerorhabdus furcosus*	2	2
122)	*Anaplasma bovis*	2	2
123)	*Anaplasma caudatum*	2	2
124)	*Anaplasma centrale*	2	2
125)	*Anaplasma marginale*	2	2
126)	*Anaplasma ovis*	2	2
127)	*Anaplasma phagocytophila*	2	2

	Name	Risk Group in	
		human	animal
128)	*Anaplasma phagocytophilum*	2	2
129)	*Anaplasma platys*	2	2
130)	*Aquaspirillum aquaticum*	2	2
131)	*Arachnia propionica*	2	2
132)	*Arcanobacterium bernardiae*	2	2
133)	*Arcanobacterium bialowiezense*	2	2
134)	*Arcanobacterium bonasi*	2	2
135)	*Arcanobacterium haemolyticum*	2	2
136)	*Arcanobacterium phocae*	2	2
137)	*Arcanobacterium pyogenes*	2	2
138)	*Arcobacter butzleri*	2	2
139)	*Arcobacter cryaerophilus*	2	2
140)	*Arthrobacter albus*	2	2
141)	*Arthrobacter cumminsii*	2	2
142)	*Arthrobacter gandavensis*	2	2
143)	*Arthrobacter luteolus*	2	2
144)	*Arthrobacter siderocapsulatus*	2	2
145)	*Arthrobacter woluwensis*	2	2
146)	*Atopobium fossor*	2	2
147)	*Atopobium minutum*	2	2
148)	*Atopobium parvulum*	2	2
149)	*Atopobium rimae*	2	2
150)	*Atopobium vaginae*	2	2
151)	*Aureobacterium resistens*	2	2
152)	*Austwickia chelonae*	2	2
153)	*Avibacterium avium*	2	2
154)	*Avibacterium endocarditis*	2	2
155)	*Avibacterium gallinarum*	2	2
156)	*Avibacterium paragallinarum*	2	2
157)	*Bacillus cereus*	2	2
158)	*Bacillus weihenstephanensis*	2	2
159)	*Bacterionema matruchotii*	2	2

	Name	Risk Group in	
		human	animal
160)	*Bacteroides asaccharolyticus*	2	2
161)	*Bacteroides bivius*	2	2
162)	*Bacteroides buccae*	2	2
163)	*Bacteroides buccalis*	2	2
164)	*Bacteroides caccae*	2	2
165)	*Bacteroides capillosus*	2	2
166)	*Bacteroides capillus*	2	2
167)	*Bacteroides coagulans*	2	2
168)	*Bacteroides corporis*	2	2
169)	*Bacteroides denticola*	2	2
170)	*Bacteroides disiens*	2	2
171)	*Bacteroides distasonis*	2	2
172)	*Bacteroides eggerthii*	2	2
173)	*Bacteroides forsythus*	2	2
174)	*Bacteroides fragilis*	2	2
175)	*Bacteroides furcosus*	2	2
176)	*Bacteroides gingivalis*	2	2
177)	*Bacteroides gracilis*	2	2
178)	*Bacteroides helcogenes*	2	2
179)	*Bacteroides heparinolyticus*	2	2
180)	*Bacteroides intermedius*	2	2
181)	*Bacteroides levii*	2	2
182)	*Bacteroides loescheii*	2	2
183)	*Bacteroides macacae*	2	2
184)	*Bacteroides melaninogenicus*	2	2
185)	*Bacteroides multacidus*	2	2
186)	*Bacteroides nodosus*	2	2
187)	*Bacteroides nordii*	2	2
188)	*Bacteroides ochraceus*	2	2
189)	*Bacteroides oralis*	2	2
190)	*Bacteroides oris*	2	2
191)	*Bacteroides ovatus*	2	2

	Name	Risk Group in	
		human	animal
192)	*Bacteroides pentosaceus*	2	2
193)	*Bacteroides pneumosintes*	2	2
194)	*Bacteroides praeacutus*	2	2
195)	*Bacteroides putredinis*	2	2
196)	*Bacteroides pyogenes*	2	2
197)	*Bacteroides ruminicola*	2	2
198)	*Bacteroides salivosus*	2	2
199)	*Bacteroides salyersiae*	2	2
200)	*Bacteroides splanchnicus*	2	2
201)	*Bacteroides suis*	2	2
202)	*Bacteroides tectum*	2	2
203)	*Bacteroides tectus*	2	2
204)	*Bacteroides thetaiotaomicron*	2	2
205)	*Bacteroides uniformis*	2	2
206)	*Bacteroides ureolyticus*	2	2
207)	*Bacteroides zoogleoformans*	2	2
208)	*Bacteroides* spp.	2	2
209)	*Balneatrix alpica*	2	2
210)	*Bartonella alsatica*	2	2
211)	*Bartonella bacilliformis*	2	2
212)	*Bartonella birtlesii*	2	2
213)	*Bartonella bovis*	2	2
214)	*Bartonella capreoli*	2	2
215)	*Bartonella clarridgeiae*	2	2
216)	*Bartonella doshiae*	2	2
217)	*Bartonella elizabethae*	2	2
218)	*Bartonella grahamii*	2	2
219)	*Bartonella henselae*	2	2
220)	*Bartonella koehlerae*	2	2
221)	*Bartonella peromysci*	2	2
222)	*Bartonella quintana*	2	2
223)	*Bartonella schoenbuchensis*	2	2

	Name	Risk Group in	
		human	animal
224)	*Bartonella schoenbuchii*	2	2
225)	*Bartonella talpae*	2	2
226)	*Bartonella taylorii*	2	2
227)	*Bartonella tribocorum*	2	2
228)	*Bartonella vinsonii*	2	2
229)	*Bartonella weisii*	2	2
230)	*Beneckea alginolytica*	2	2
231)	*Beneckea parahaemolytica*	2	2
232)	*Beneckea splendida*	2	2
233)	*Beneckea vulnifica*	2	2
234)	*Bergeyella zoohelcum*	2	2
235)	*Bibersteinia trehalosi*	2	2
236)	*Bifidobacterium dentium*	2	2
237)	*Bilophila wadsworthia*	2	2
238)	*Bordetella avium*	2	2
239)	*Bordetella bronchiseptica*	2	2
240)	*Bordetella hinzii*	2	2
241)	*Bordetella holmesii*	2	2
242)	*Bordetella parapertussis*	2	2
243)	*Bordetella pertussis*	2	2
244)	*Bordetella trematum*	2	2
245)	*Borrelia afzelii*	2	2
246)	*Borrelia anserina*	2	2
247)	*Borrelia baltazardii*	2	2
248)	*Borrelia brasiliensis*	2	2
249)	*Borrelia burgdorferi*	2	2
250)	*Borrelia caucasica*	2	2
251)	*Borrelia coriaceae*	2	2
252)	*Borrelia crocidurae*	2	2
253)	*Borrelia dugesii*	2	2
254)	*Borrelia duttonii*	2	2
255)	*Borrelia garinii*	2	2

	Name	Risk Group in	
		human	animal
256)	*Borrelia graingeri*	2	2
257)	*Borrelia harveyi*	2	2
258)	*Borrelia hermsii*	2	2
259)	*Borrelia hispanica*	2	2
260)	*Borrelia latyschewii*	2	2
261)	*Borrelia mazzottii*	2	2
262)	*Borrelia parkeri*	2	2
263)	*Borrelia persica*	2	2
264)	*Borrelia recurrentis*	2	2
265)	*Borrelia spielmanii*	2	2
266)	*Borrelia theileri*	2	2
267)	*Borrelia tillae*	2	2
268)	*Borrelia turicatae*	2	2
269)	*Borrelia valaisiana*	2	2
270)	*Borrelia venezuelensis*	2	2
271)	*Borrelia* spp.	2	2
272)	*Brachyspira aalborgi*	2	2
273)	*Brachyspira innocens*	2	2
274)	*Brachyspira intermedia*	2	2
275)	*Brachyspira murdochii*	2	2
276)	*Brachyspira pilosicoli*	2	2
277)	*Brackiella oedipodis*	2	2
278)	*Branhamella catarrhalis*	2	2
279)	*Brevibacterium avium*	2	2
280)	*Brevibacterium mcbrellneri*	2	2
281)	*Brevibacterium paucivorans*	2	2
282)	*Brevibacterium sanguinis*	2	2
283)	*Brevinema andersonii*	2	2
284)	*Brevundimonas diminuta*	2	2
285)	*Brucella ceti*	2	2
286)	*Brucella microti*	2	2
287)	*Brucella pinnipedialis*	2	2

	Name	Risk Group in	
		human	animal
288)	*Bulleidia extructa*	2	2
289)	*Burkholderia ambifaria*	2	2
290)	*Burkholderia arboris*	2	2
291)	*Burkholderia cenocepacia*	2	2
292)	*Burkholderia cepacia*	2	2
293)	*Burkholderia cocovenenans*	2	2
294)	*Burkholderia diffusa*	2	2
295)	*Burkholderia dolosa*	2	2
296)	*Burkholderia gladioli*	2	2
297)	*Burkholderia latens*	2	2
298)	*Burkholderia mallei*	2	2
299)	*Burkholderia metallica*	2	2
300)	*Burkholderia multivorans*	2	2
301)	*Burkholderia oklahomensis*	2	2
302)	*Burkholderia pickettii*	2	2
303)	*Burkholderia seminalis*	2	2
304)	*Burkholderia stabilis*	2	2
305)	*Burkholderia vietnamiensis*	2	2
306)	*Burkholderia pseudomallei*	2	2
307)	B*urkholderia* spp.	2	2
308)	*Calymmatobacterium granulomatis*	2	2
309)	*Campylobacter butzleri*	2	2
310)	*Campylobacter cinaedi*	2	2
311)	*Campylobacter coli*	2	2
312)	*Campylobacter concisus*	2	2
313)	*Campylobacter cryaerophilus*	2	2
314)	*Campylobacter curvus*	2	2
315)	*Campylobacter fennelliae*	2	2
316)	*Campylobacter fetus*	2	2
317)	*Campylobacter gracilis*	2	2
318)	*Campylobacter helveticus*	2	2
319)	*Campylobacter hyoilei*	2	2

	Name	Risk Group in	
		human	animal
320)	*Campylobacter hyointestinalis*	2	2
321)	*Campylobacter jejuni*	2	2
322)	*Campylobacter lari*	2	2
323)	*Campylobacter mucosalis*	2	2
324)	*Campylobacter mustelae*	2	2
325)	*Campylobacter pylori*	2	2
326)	*Campylobacter rectus*	2	2
327)	*Campylobacter sputorum*	2	2
328)	*Campylobacter upsaliensis*	2	2
329)	*Campylobacter ureolyticus*	2	2
330)	*Campylobacter* spp.	2	2
331)	*Capnocytophaga canimorsus*	2	2
332)	*Capnocytophaga cynodegmi*	2	2
333)	*Capnocytophaga gingivalis*	2	2
334)	*Capnocytophaga granulose*	2	2
335)	*Capnocytophaga haemolytica*	2	2
336)	*Capnocytophaga ochracea*	2	2
337)	*Capnocytophaga sputigena*	2	2
338)	*Capsularis zoogleiformans*	2	2
339)	*Capsularis zoogleoformans*	2	2
340)	*Cardiobacterium hominis*	2	2
341)	*Cardiobacterium valvarum*	2	2
342)	*Carnobacterium maltaromaticum*	2	2
343)	*Carnobacterium piscicola*	2	2
344)	*Catonella morbi*	2	2
345)	*Cedecea davisae*	2	2
346)	*Cedecea lapagei*	2	2
347)	*Cedecea neteri*	2	2
348)	*Centipeda periodontii*	2	2
349)	*Cetobacterium ceti*	2	2
350)	*Chlamydia muridarum*	2	2
351)	*Chlamydia pecorum*	2	2

	Name	Risk Group in	
		human	animal
352)	*Chlamydia pneumoniae*	2	2
353)	*Chlamydia suis*	2	2
354)	*Chlamydia trachomatis*	2	2
355)	*Chlamydia* spp.	2	2
356)	*Chlamydophila abortus*	2	2
357)	*Chlamydophila caviae*	2	2
358)	*Chlamydophila felis*	2	2
359)	*Chlamydophila pecorum*	2	2
360)	*Chlamydophila pneumoniae*	2	2
361)	*Chromobacterium violaceum*	2	2
362)	*Chryseobacterium arothri*	2	2
363)	*Chryseobacterium gleum*	2	2
364)	*Chryseobacterium hominis*	2	2
365)	*Chryseobacterium indologenes*	2	2
366)	*Chryseobacterium meningosepticum*	2	2
367)	*Chryseobacterium scophthalmum*	2	2
368)	*Chryseomonas luteola*	2	2
369)	*Chryseomonas polytricha*	2	2
370)	*Citrobacter amalonaticus*	2	2
371)	*Citrobacter braakii*	2	2
372)	*Citrobacter diversus*	2	2
373)	*Citrobacter farmeri*	2	2
374)	*Citrobacter freundii*	2	2
375)	*Citrobacter gillenii*	2	2
376)	*Citrobacter koseri*	2	2
377)	*Citrobacter murliniae*	2	2
378)	*Citrobacter rodentium*	2	2
379)	*Citrobacter sedlakii*	2	2
380)	*Citrobacter werkmanii*	2	2
381)	*Citrobacter youngae*	2	2
382)	*Clostridium absonum*	2	2
383)	*Clostridium aldenense*	2	2

	Name	Risk Group in	
		human	animal
384)	*Clostridium argentinense*	2	2
385)	*Clostridium barati*	2	2
386)	*Clostridium baratii*	2	2
387)	*Clostridium bifermentans*	2	2
388)	*Clostridium botulinum*	2	2
389)	*Clostridium butyricum*	2	2
390)	*Clostridium cadaveris*	2	2
391)	*Clostridium carnis*	2	2
392)	*Clostridium chauvoei*	2	2
393)	*Clostridium citroniae*	2	2
394)	*Clostridium clostridiiforme*	2	2
395)	*Clostridium clostridioforme*	2	2
396)	*Clostridium colinum*	2	2
397)	*Clostridium difficile*	2	2
398)	*Clostridium fallax*	2	2
399)	*Clostridium ghoni*	2	2
400)	*Clostridium ghonii*	2	2
401)	*Clostridium glycolicum*	2	2
402)	*Clostridium haemolyticum*	2	2
403)	*Clostridium hastiforme*	2	2
404)	*Clostridium histolyticum*	2	2
405)	*Clostridium indolis*	2	2
406)	*Clostridium innocuum*	2	2
407)	*Clostridium limosum*	2	2
408)	*Clostridium malenominatum*	2	2
409)	*Clostridium novyi*	2	2
410)	*Clostridium oroticum*	2	2
411)	*Clostridium paraperfringens*	2	2
412)	*Clostridium paraputrificum*	2	2
413)	*Clostridium perenne*	2	2
414)	*Clostridium perfringens*	2	2
415)	*Clostridium piliforme*	2	2

	Name	Risk Group in	
		human	animal
416)	*Clostridium putrificum*	2	2
417)	*Clostridium ramosum*	2	2
418)	*Clostridium sardiniense*	2	2
419)	*Clostridium sardiniensis*	2	2
420)	*Clostridium septicum*	2	2
421)	*Clostridium sordellii*	2	2
422)	*Clostridium sphenoides*	2	2
423)	*Clostridium sporogenes*	2	2
424)	*Clostridium subterminale*	2	2
425)	*Clostridium symbiosum*	2	2
426)	*Clostridium tertium*	2	2
427)	*Clostridium tetani*	2	2
428)	*Clostridium* spp.	2	2
429)	*Clostridium botulinum*	2	2
430)	*Coccidioides immitis*	2	2
431)	*Coenonia anatine*	2	2
432)	*Collinsella aerofaciens*	2	2
433)	*Comamonas aquatica*	2	2
434)	*Comamonas kerstersii*	2	2
435)	*Comamonas terrigena*	2	2
436)	*Corynebacterium accolens*	2	2
437)	*Corynebacterium afermentans*	2	2
438)	*Corynebacterium amycolatum*	2	2
439)	*Corynebacterium argentoratense*	2	2
440)	*Corynebacterium auris*	2	2
441)	*Corynebacterium auriscanis*	2	2
442)	*Corynebacterium beticola*	2	2
443)	*Corynebacterium bovis*	2	2
444)	*Corynebacterium camporealensis*	2	2
445)	*Corynebacterium confusum*	2	2
446)	*Corynebacterium coyleae*	2	2
447)	*Corynebacterium cystitidis*	2	2

	Name	Risk Group in	
		human	animal
448)	*Corynebacterium diphtheriae*	2	2
449)	*Corynebacterium equi*	2	2
450)	*Corynebacterium falsenii*	2	2
451)	*Corynebacterium freneyi*	2	2
452)	*Corynebacterium glucuronolyticum*	2	2
453)	*Corynebacterium hoagii*	2	2
454)	*Corynebacterium imitans*	2	2
455)	*Corynebacterium jeikeium*	2	2
456)	*Corynebacterium macginleyi*	2	2
457)	*Corynebacterium mastitidis*	2	2
458)	*Corynebacterium matruchotii*	2	2
459)	*Corynebacterium minutissimum*	2	2
460)	*Corynebacterium mucifaciens*	2	2
461)	*Corynebacterium mycetoides*	2	2
462)	*Corynebacterium pilosum*	2	2
463)	*Corynebacterium propinquum*	2	2
464)	*Corynebacterium pseudodiphtheriticum*	2	2
465)	*Corynebacterium pseudotuberculosis*	2	2
466)	*Corynebacterium pyogenes*	2	2
467)	*Corynebacterium renale*	2	2
468)	*Corynebacterium resistens*	2	2
469)	*Corynebacterium riegelii*	2	2
470)	*Corynebacterium seminale*	2	2
471)	*Corynebacterium simulans*	2	2
472)	*Corynebacterium striatum*	2	2
473)	*Corynebacterium suicordis*	2	2
474)	*Corynebacterium sundsvallense*	2	2
475)	*Corynebacterium thomssenii*	2	2
476)	*Corynebacterium tuberculostearicum*	2	2
477)	*Corynebacterium ulcerans*	2	2
478)	*Corynebacterium urealyticum*	2	2
479)	*Cowdria ruminantium*	2	2

	Name	Risk Group in	
		human	animal
480)	*Coxiella burnetii*	2	2
481)	*Cronobacter dublinensis*	2	2
482)	*Cronobacter malonaticus*	2	2
483)	*Cronobacter muytjensii*	2	2
484)	*Cronobacter sakazakii*	2	2
485)	*Cronobacter turicensis*	2	2
486)	*Crossiella equi*	2	2
487)	*Cupriavidus pauculus*	2	2
488)	*Dermatophilus chelonae*	2	2
489)	*Dermatophilus congolensis*	2	2
490)	*Desulfomicrobium orale*	2	2
491)	*Dialister invisus*	2	2
492)	*Dialister micraerophilus*	2	2
493)	*Dialister pneumosintes*	2	2
494)	*Dialister propionicifaciens*	2	2
495)	*Dichelobacter nodosus*	2	2
496)	*Dolosigranulum pigrum*	2	2
497)	*Dysgonomonas capnocytophagoides*	2	2
498)	*Edwardsiella anguillimortifera*	2	2
499)	*Edwardsiella ictaluri*	2	2
500)	*Edwardsiella tarda*	2	2
501)	*Eggerthella hongkongensis*	2	2
502)	*Eggerthella lenta*	2	2
503)	*Ehrlichia canis*	2	2
504)	*Ehrlichia chaffeensis*	2	2
505)	*Ehrlichia equi*	2	2
506)	*Ehrlichia ewingii*	2	2
507)	*Ehrlichia muris*	2	2
508)	*Ehrlichia phagocytophila*	2	2
509)	*Ehrlichia risticii*	2	2
510)	*Ehrlichia ruminantium*	2	2
511)	*Ehrlichia sennetsu*	2	2

	Name	Risk Group in	
		human	animal
512)	*Ehrlichia* spp.	2	2
513)	*Eikenella corrodens*	2	2
514)	*Elizabethkingia meningoseptica*	2	2
515)	*Empedobacter brevis*	2	2
516)	*Enterobacter aerogenes*	2	2
517)	*Enterobacter agglomerans*	2	2
518)	*Enterobacter amnigenus*	2	2
519)	*Enterobacter asburiae*	2	2
520)	*Enterobacter cancerogenus*	2	2
521)	*Enterobacter cloacae*	2	2
522)	*Enterobacter cowanii*	2	2
523)	*Enterobacter gergoviae*	2	2
524)	*Enterobacter hormaechei*	2	2
525)	*Enterobacter intermedius*	2	2
526)	*Enterobacter kobei*	2	2
527)	*Enterobacter ludwigii*	2	2
528)	*Enterobacter sakazakii*	2	2
529)	*Enterobacter taylorae*	2	2
530)	*Enterobacter* spp.	2	2
531)	*Enterococcus avium*	2	2
532)	*Enterococcus casseliflavus*	2	2
533)	*Enterococcus dispar*	2	2
534)	*Enterococcus durans*	2	2
535)	*Enterococcus faecalis*	2	2
536)	*Enterococcus faecium*	2	2
537)	*Enterococcus flavescens*	2	2
538)	*Enterococcus gallinarum*	2	2
539)	*Enterococcus hirae*	2	2
540)	*Enterococcus porcinus*	2	2
541)	*Enterococcus pseudoavium*	2	2
542)	*Enterococcus raffinosus*	2	2
543)	*Enterococcus ratti*	2	2

	Name	Risk Group in	
		human	animal
544)	*Enterococcus seriolicida*	2	2
545)	*Enterococcus villorum*	2	2
546)	*Enterococcus* spp.	2	2
547)	*Eperythrozoon coccoides*	2	2
548)	*Eperythrozoon ovis*	2	2
549)	*Eperythrozoon parvum*	2	2
550)	*Eperythrozoon suis*	2	2
551)	*Eperythrozoon wenyonii*	2	2
552)	*Erwinia cancerogena*	2	2
553)	*Erwinia herbicola*	2	2
554)	*Erwinia milletiae*	2	2
555)	*Erysipelothrix rhusiopathiae*	2	2
556)	*Erysipelothrix tonsillarum*	2	2
557)	*Escherichia adecarboxylata*	2	2
558)	*Escherichia albertii*	2	2
559)	*Escherichia coli*	2	2
560)	*Escherichia fergusonii*	2	2
561)	*Escherichia hermannii*	2	2
562)	*Escherichia vulneris*	2	2
563)	*Eubacterium aerofaciens*	2	2
564)	*Eubacterium alactolyticum*	2	2
565)	*Eubacterium brachy*	2	2
566)	*Eubacterium combesii*	2	2
567)	*Eubacterium contortum*	2	2
568)	*Eubacterium exiguum*	2	2
569)	*Eubacterium fossor*	2	2
570)	*Eubacterium infirmum*	2	2
571)	*Eubacterium lentum*	2	2
572)	*Eubacterium limosum*	2	2
573)	*Eubacterium minutum*	2	2
574)	*Eubacterium moniliforme*	2	2
575)	*Eubacterium nitritogenes*	2	2

	Name	Risk Group in	
		human	animal
576)	*Eubacterium nodatum*	2	2
577)	*Eubacterium saphenum*	2	2
578)	*Eubacterium suis*	2	2
579)	*Eubacterium sulci*	2	2
580)	*Eubacterium tarantellae*	2	2
581)	*Eubacterium tardum*	2	2
582)	*Eubacterium tenue*	2	2
583)	*Eubacterium timidum*	2	2
584)	*Eubacterium tortuosum*	2	2
585)	*Eubacterium ventriosum*	2	2
586)	*Eubacterium yurii*	2	2
587)	*Ewingella americana*	2	2
588)	*Facklamia hominis*	2	2
589)	*Facklamia ignava*	2	2
590)	*Facklamia languida*	2	2
591)	*Faecalibacterium prausnitzii*	2	2
592)	*Falcivibrio grandis*	2	2
593)	*Falcivibrio vaginalis*	2	2
594)	*Filifactor alocis*	2	2
595)	*Finegoldia magna*	2	2
596)	*Flavimonas oryzihabitans*	2	2
597)	*Flavobacterium breve*	2	2
598)	*Flavobacterium devorans*	2	2
599)	*Flavobacterium gleum*	2	2
600)	*Flavobacterium indologenes*	2	2
601)	*Flavobacterium meningosepticum*	2	2
602)	*Flavobacterium multivorum*	2	2
603)	*Flavobacterium odoratum*	2	2
604)	*Flavobacterium scophthalmum*	2	2
605)	*Flavobacterium spiritivorum*	2	2
606)	*Flavobacterium thalpophilum*	2	2
607)	*Flavobacterium yabuuchiae*	2	2

	Name	Risk Group in	
		human	animal
608)	*Fluoribacter bozemanae*	2	2
609)	*Fluoribacter dumoffii*	2	2
610)	*Fluoribacter gormanii*	2	2
611)	*Francisella novicida*	2	2
612)	*Francisella philomiragia*	2	2
613)	*Fusobacterium alocis*	2	2
614)	*Fusobacterium canifelinum*	2	2
615)	*Fusobacterium equinum*	2	2
616)	*Fusobacterium gonidiaformans*	2	2
617)	*Fusobacterium mortiferum*	2	2
618)	*Fusobacterium naviforme*	2	2
619)	*Fusobacterium necrogenes*	2	2
620)	*Fusobacterium necrophorum*	2	2
621)	*Fusobacterium nucleatum*	2	2
622)	*Fusobacterium periodonticum*	2	2
623)	*Fusobacterium prausnitzii*	2	2
624)	*Fusobacterium pseudonecrophorum*	2	2
625)	*Fusobacterium russii*	2	2
626)	*Fusobacterium sulci*	2	2
627)	*Fusobacterium ulcerans*	2	2
628)	*Fusobacterium varium*	2	2
629)	*Fusobacterium* spp.	2	2
630)	*Gardnerella vaginalis*	2	2
631)	*Gemella bergeri*	2	2
632)	*Gemella cuniculi*	2	2
633)	*Gemella haemolysans*	2	2
634)	*Gemella morbillorum*	2	2
635)	*Gemella sanguinis*	2	2
636)	*Globicatella anguinis*	2	2
637)	*Globicatella sulfidifaciens*	2	2
638)	*Gordona aichiensis*	2	2
639)	*Gordona bronchialis*	2	2

	Name	Risk Group in	
		human	animal
640)	*Gordona sputi*	2	2
641)	*Gordona terrae*	2	2
642)	*Gordona* spp.	2	2
643)	*Gordonia aichiensis*	2	2
644)	*Gordonia bronchialis*	2	2
645)	*Gordonia otitidis*	2	2
646)	*Gordonia sputi*	2	2
647)	*Gordonia terrae*	2	2
648)	*Grahamella peromysci*	2	2
649)	*Grahamella talpae*	2	2
650)	*Granulicatella adiacens*	2	2
651)	*Granulicatella elegans*	2	2
652)	*Grimontia hollisae*	2	2
653)	*Guggenheimella bovis*	2	2
654)	*Haemobartonella canis*	2	2
655)	*Haemobartonella felis*	2	2
656)	*Haemobartonella muris*	2	2
657)	*Haemophilus actinomycetemcomitans*	2	2
658)	*Haemophilus aegyptius*	2	2
659)	*Haemophilus aphrophilus*	2	2
660)	*Haemophilus avium*	2	2
661)	*Haemophilus ducreyi*	2	2
662)	*Haemophilus equigenitalis*	2	2
663)	*Haemophilus felis*	2	2
664)	*Haemophilus haemoglobinophilus*	2	2
665)	*Haemophilus influenzae*	2	2
666)	*Haemophilus paracuniculus*	2	2
667)	*Haemophilus paragallinarum*	2	2
668)	*Haemophilus parahaemolyticus*	2	2
669)	*Haemophilus parainfluenzae*	2	2
670)	*Haemophilus paraphrohaemolyticus*	2	2
671)	*Haemophilus paraphrophilus*	2	2

	Name	Risk Group in	
		human	animal
672)	*Haemophilus parasuis*	2	2
673)	*Haemophilus piscium*	2	2
674)	*Haemophilus pittmaniae*	2	2
675)	*Haemophilus pleuropneumoniae*	2	2
676)	*Haemophilus vaginalis*	2	2
677)	*Haemophilus* spp.	2	2
678)	*Hafnia alvei*	2	2
679)	*Hallella seregens*	2	2
680)	*Helcococcus kunzii*	2	2
681)	*Helcococcus ovis*	2	2
682)	*Helicobacter acinonychis*	2	2
683)	*Helicobacter aurati*	2	2
684)	*Helicobacter bilis*	2	2
685)	*Helicobacter bizzozeronii*	2	2
686)	*Helicobacter canadensis*	2	2
687)	*Helicobacter canis*	2	2
688)	*Helicobacter cetorum*	2	2
689)	*Helicobacter cholecystus*	2	2
690)	*Helicobacter cinaedi*	2	2
691)	*Helicobacter felis*	2	2
692)	*Helicobacter fennelliae*	2	2
693)	*Helicobacter hepaticus*	2	2
694)	*Helicobacter marmotae*	2	2
695)	*Helicobacter muridarum*	2	2
696)	*Helicobacter mustelae*	2	2
697)	*Helicobacter nemestrinae*	2	2
698)	*Helicobacter pullorum*	2	2
699)	*Helicobacter pylori*	2	2
700)	*Helicobacter rodentium*	2	2
701)	*Helicobacter suis*	2	2
702)	*Helicobacter typhlonius*	2	2
703)	*Histophlus somni*	2	2

	Name	Risk Group in	
		human	animal
704)	*Ignavigranum ruoffiae*	2	2
705)	*Johnsonella ignava*	2	2
706)	*Jonesia denitrificans*	2	2
707)	*Jonquetella anthropi*	2	2
708)	*Kerstersia gyiorum*	2	2
709)	*Kingella denitrificans*	2	2
710)	*Kingella indologenes*	2	2
711)	*Kingella kingae*	2	2
712)	*Kingella oralis*	2	2
713)	*Klebsiella granulomatis*	2	2
714)	*Klebsiella mobilis*	2	2
715)	*Klebsiella ornithinolytica*	2	2
716)	*Klebsiella oxytoca*	2	2
717)	*Klebsiella ozaenae*	2	2
718)	*Klebsiella pneumoniae*	2	2
719)	*Klebsiella rhinoscleromatis*	2	2
720)	*Klebsiella variicola*	2	2
721)	*Klebsiella* spp.	2	2
722)	*Kluyvera ascorbata*	2	2
723)	*Kluyvera cochlea*	2	2
724)	*Kluyvera cryocrescens*	2	2
725)	*Kluyvera intermedia*	2	2
726)	*Koserella trabulsii*	2	2
727)	*Lactobacillus carnis*	2	2
728)	*Lactobacillus casei*	2	2
729)	*Lactobacillus maltaromicus*	2	2
730)	*Lactobacillus minutum*	2	2
731)	*Lactobacillus piscicola*	2	2
732)	*Lactobacillus rhamnosus*	2	2
733)	*Lactobacillus rimae*	2	2
734)	*Lactobacillus uli*	2	2
735)	*Lactococcus garvieae*	2	2

	Name	Risk Group in	
		human	animal
736)	*Laribacter hongkongensis*	2	2
737)	*Lawsonia intracellularis*	2	2
738)	*Leclercia adecarboxylata*	2	2
739)	*Legionella anisa*	2	2
740)	*Legionella birminghamensis*	2	2
741)	*Legionella bozemanae*	2	2
742)	*Legionella bozemanii*	2	2
743)	*Legionella cincinnatiensis*	2	2
744)	*Legionella dumoffii*	2	2
745)	*Legionella feeleii*	2	2
746)	*Legionella gormanii*	2	2
747)	*Legionella hackeliae*	2	2
748)	*Legionella jordanis*	2	2
749)	*Legionella lansingensis*	2	2
750)	*Legionella longbeachae*	2	2
751)	*Legionella maceachernii*	2	2
752)	*Legionella micdadei*	2	2
753)	*Legionella oakridgensis*	2	2
754)	*Legionella pittsburghensis*	2	2
755)	*Legionella pneumophila*	2	2
756)	*Legionella sainthelensi*	2	2
757)	*Legionella tucsonensis*	2	2
758)	*Legionella wadsworthii*	2	2
759)	*Legionella* spp.	2	2
760)	*Leptospira borgpetersenii*	2	2
761)	*Leptospira broomii*	2	2
762)	*Leptospira fainei*	2	2
763)	*Leptospira inadai*	2	2
764)	*Leptospira interrogans*	2	2
765)	*Leptospira kirschneri*	2	2
766)	*Leptospira noguchii*	2	2
767)	*Leptospira santarosai*	2	2

	Name	Risk Group in	
		human	animal
768)	*Leptospira weilii*	2	2
769)	*Leptotrichia buccalis*	2	2
770)	*Leuconostoc mesenteroides*	2	2
771)	*Levinea amalonatica*	2	2
772)	*Levinea malonatica*	2	2
773)	*Listeria denitrificans*	2	2
774)	*Listeria ivanovii*	2	2
775)	*Listeria monocytogenes*	2	2
776)	*Listonella anguillarum*	2	2
777)	*Listonella damsela*	2	2
778)	*Listonella damselae*	2	2
779)	*Macrococcus caseolyticus*	2	2
780)	*Mannheimia granulomatis*	2	2
781)	*Mannheimia haemolytica*	2	2
782)	*Mannheimia varigena*	2	2
783)	*Megasphaera elsdenii*	2	2
784)	*Microbacterium resistens*	2	2
785)	*Micromonas micros*	2	2
786)	*Mitsuokella multacida*	2	2
787)	*Mitsuokella multacidus*	2	2
788)	*Mobiluncus curtisii*	2	2
789)	*Mobiluncus mulieris*	2	2
790)	*Moellerella wisconsensis*	2	2
791)	*Mogibacterium neglectum*	2	2
792)	*Mogibacterium pumilum*	2	2
793)	*Mogibacterium timidum*	2	2
794)	*Mogibacterium vescum*	2	2
795)	*Moraxella anatipestifer*	2	2
796)	*Moraxella atlantae*	2	2
797)	*Moraxella bovis*	2	2
798)	*Moraxella bovoculi*	2	2
799)	*Moraxella catarrhalis*	2	2

	Name	Risk Group in	
		human	animal
800)	*Moraxella equi*	2	2
801)	*Moraxella lacunata*	2	2
802)	*Moraxella nonliquefaciens*	2	2
803)	*Moraxella osloensis*	2	2
804)	*Moraxella ovis*	2	2
805)	*Moraxella phenylpyruvica*	2	2
806)	*Moraxella saccharolytica*	2	2
807)	*Moraxella* spp.	2	2
808)	*Morganella morganii*	2	2
809)	*Morococcus cerebrosus*	2	2
810)	*Moryella indoligenes*	2	2
811)	*Mycobacterium abscessus*	2	2
812)	*Mycobacterium africanum*	2	2
813)	*Mycobacterium arupense*	2	2
814)	*Mycobacterium asiaticum*	2	2
815)	*Mycobacterium aubagnense*	2	2
816)	*Mycobacterium avium*	2	2
817)	*Mycobacterium boenickei*	2	2
818)	*Mycobacterium bolletii*	2	2
819)	*Mycobacterium bovis*	2	2
820)	*Mycobacterium branderi*	2	2
821)	*Mycobacterium brisbanense*	2	2
822)	*Mycobacterium canariasense*	2	2
823)	*Mycobacterium canetti*	2	2
824)	*Mycobacterium caprae*	2	2
825)	*Mycobacterium celatum*	2	2
826)	*Mycobacterium chelonae*	2	2
827)	*Mycobacterium chimaera*	2	2
828)	*Mycobacterium colombiense*	2	2
829)	*Mycobacterium conspicuum*	2	2
830)	*Mycobacterium elephantis*	2	2
831)	*Mycobacterium farcinogenes*	2	2

	Name	Risk Group in	
		human	animal
832)	*Mycobacterium flavescens*	2	2
833)	*Mycobacterium florentinum*	2	2
834)	*Mycobacterium fortuitum*	2	2
835)	*Mycobacterium gastri*	2	2
836)	*Mycobacterium genavense*	2	2
837)	*Mycobacterium goodii*	2	2
838)	*Mycobacterium haemophilum*	2	2
839)	*Mycobacterium heckeshornense*	2	2
840)	*Mycobacterium heidelbergense*	2	2
841)	*Mycobacterium houstonense*	2	2
842)	*Mycobacterium immunogenum*	2	2
843)	*Mycobacterium interjectum*	2	2
844)	*Mycobacterium intermedium*	2	2
845)	*Mycobacterium intracellulare*	2	2
846)	*Mycobacterium kansasii*	2	2
847)	*Mycobacterium kubicae*	2	2
848)	*Mycobacterium lentiflavum*	2	2
849)	*Mycobacterium leprae*	2	2
850)	*Mycobacterium lepraemurium*	2	2
851)	*Mycobacterium mageritense*	2	2
852)	*Mycobacterium malmoense*	2	2
853)	*Mycobacterium marinum*	2	2
854)	*Mycobacterium massiliense*	2	2
855)	*Mycobacterium microti*	2	2
856)	*Mycobacterium monacense*	2	2
857)	*Mycobacterium mucogenicum*	2	2
858)	*Mycobacterium neworleansense*	2	2
859)	*Mycobacterium nonchromogenicum*	2	2
860)	*Mycobacterium novocastrense*	2	2
861)	*Mycobacterium palustre*	2	2
862)	*Mycobacterium parascrofulaceum*	2	2
863)	*Mycobacterium paratuberculosis*	2	2

	Name	Risk Group in	
		human	animal
864)	*Mycobacterium peregrinum*	2	2
865)	*Mycobacterium phocaicum*	2	2
866)	*Mycobacterium pinnipedii*	2	2
867)	*Mycobacterium porcinum*	2	2
868)	*Mycobacterium saskatchewanense*	2	2
869)	*Mycobacterium scrofulaceum*	2	2
870)	*Mycobacterium senegalense*	2	2
871)	*Mycobacterium septicum*	2	2
872)	*Mycobacterium setense*	2	2
873)	*Mycobacterium shimoidei*	2	2
874)	*Mycobacterium simiae*	2	2
875)	*Mycobacterium smegmatis*	2	2
876)	*Mycobacterium szulgai*	2	2
877)	*Mycobacterium triplex*	2	2
878)	*Mycobacterium tuberculosis*	2	2
879)	*Mycobacterium ulcerans*	2	2
880)	*Mycobacterium vaccae*	2	2
881)	*Mycobacterium wolinskyi*	2	2
882)	*Mycobacterium xenopi*	2	2
883)	*Mycobacterium* spp.	2	2
884)	*Mycoplasma adleri*	2	2
885)	*Mycoplasma agalactiae*	2	2
886)	*Mycoplasma agassizii*	2	2
887)	*Mycoplasma alkalescens*	2	2
888)	*Mycoplasma alligatoris*	2	2
889)	*Mycoplasma anatis*	2	2
890)	*Mycoplasma arginini*	2	2
891)	*Mycoplasma arthritidis*	2	2
892)	*Mycoplasma bovigenitalium*	2	2
893)	*Mycoplasma bovirhinis*	2	2
894)	*Mycoplasma bovis*	2	2
895)	*Mycoplasma bovoculi*	2	2

	Name	Risk Group in	
		human	animal
896)	*Mycoplasma buteonis*	2	2
897)	*Mycoplasma californicum*	2	2
898)	*Mycoplasma canadense*	2	2
899)	*Mycoplasma canis*	2	2
900)	*Mycoplasma capricolum*	2	2
901)	*Mycoplasma caviae*	2	2
902)	*Mycoplasma coccoides*	2	2
903)	*Mycoplasma collis*	2	2
904)	*Mycoplasma columbinasale*	2	2
905)	*Mycoplasma conjunctivae*	2	2
906)	*Mycoplasma corogypsi*	2	2
907)	*Mycoplasma crocodyli*	2	2
908)	*Mycoplasma cynos*	2	2
909)	*Mycoplasma dispar*	2	2
910)	*Mycoplasma edwardii*	2	2
911)	*Mycoplasma elephantis*	2	2
912)	*Mycoplasma equigenitalium*	2	2
913)	*Mycoplasma equirhinis*	2	2
914)	*Mycoplasma falconis*	2	2
915)	*Mycoplasma felis*	2	2
916)	*Mycoplasma fermentans*	2	2
917)	*Mycoplasma flocculare*	2	2
918)	*Mycoplasma gallinaceum*	2	2
919)	*Mycoplasma gallinarum*	2	2
920)	*Mycoplasma gallisepticum*	2	2
921)	*Mycoplasma gallopavonis*	2	2
922)	*Mycoplasma gateae*	2	2
923)	*Mycoplasma genitalium*	2	2
924)	*Mycoplasma glycophilum*	2	2
925)	*Mycoplasma gypis*	2	2
926)	*Mycoplasma haemocanis*	2	2
927)	*Mycoplasma haemofelis*	2	2

	Name	Risk Group in	
		human	animal
928)	*Mycoplasma haemomuris*	2	2
929)	*Mycoplasma haemosuis*	2	2
930)	*Mycoplasma hominis*	2	2
931)	*Mycoplasma hyopneumoniae*	2	2
932)	*Mycoplasma hyorhinis*	2	2
933)	*Mycoplasma hyosynoviae*	2	2
934)	*Mycoplasma iguanae*	2	2
935)	*Mycoplasma imitans*	2	2
936)	*Mycoplasma iners*	2	2
937)	*Mycoplasma iowae*	2	2
938)	*Mycoplasma lipofaciens*	2	2
939)	*Mycoplasma maculosum*	2	2
940)	*Mycoplasma meleagridis*	2	2
941)	*Mycoplasma microti*	2	2
942)	*Mycoplasma mobile*	2	2
943)	*Mycoplasma mycoides*	2	2
944)	*Mycoplasma neurolyticum*	2	2
945)	*Mycoplasma ovipneumoniae*	2	2
946)	*Mycoplasma ovis*	2	2
947)	*Mycoplasma penetrans*	2	2
948)	*Mycoplasma phocacerebrale*	2	2
949)	*Mycoplasma phocae*	2	2
950)	*Mycoplasma phocarhinis*	2	2
951)	*Mycoplasma phocicerebrale*	2	2
952)	*Mycoplasma phocidae*	2	2
953)	*Mycoplasma phocirhinis*	2	2
954)	*Mycoplasma pneumoniae*	2	2
955)	*Mycoplasma pullorum*	2	2
956)	*Mycoplasma pulmonis*	2	2
957)	*Mycoplasma putrefaciens*	2	2
958)	*Mycoplasma salivarium*	2	2
959)	*Mycoplasma spumans*	2	2

	Name	Risk Group in	
		human	animal
960)	*Mycoplasma sturni*	2	2
961)	*Mycoplasma subdolum*	2	2
962)	*Mycoplasma suis*	2	2
963)	*Mycoplasma synoviae*	2	2
964)	*Mycoplasma testudineum*	2	2
965)	*Mycoplasma verecundum*	2	2
966)	*Mycoplasma wenyonii*	2	2
967)	*Myroides odoratimimus*	2	2
968)	*Myroides odoratus*	2	2
969)	*Neisseria animaloris*	2	2
970)	*Neisseria bacilliformis*	2	2
971)	*Neisseria elongata*	2	2
972)	*Neisseria flavescens*	2	2
973)	*Neisseria gonorrhoeae*	2	2
974)	*Neisseria iguanae*	2	2
975)	*Neisseria meningitidis*	2	2
976)	*Neisseria mucosa*	2	2
977)	*Neisseria ovis*	2	2
978)	*Neisseria sicca*	2	2
979)	*Neisseria subflava*	2	2
980)	*Neisseria weaveri*	2	2
981)	*Neisseria zoodegmatis*	2	2
982)	*Neorickettsia helminthoeca*	2	2
983)	*Nicoletella semolina*	2	2
984)	*Nocardia abscessus*	2	2
985)	*Nocardia africana*	2	2
986)	*Nocardia aobensis*	2	2
987)	*Nocardia arthritidis*	2	2
988)	*Nocardia asiatica*	2	2
989)	*Nocardia asteroides*	2	2
990)	*Nocardia beijingensis*	2	2
991)	*Nocardia brasiliensis*	2	2

	Name	Risk Group in	
		human	animal
992)	*Nocardia caviae*	2	2
993)	*Nocardia cyriacigeorgica*	2	2
994)	*Nocardia exalbida*	2	2
995)	*Nocardia farcinica*	2	2
996)	*Nocardia ignorata*	2	2
997)	*Nocardia kruczakiae*	2	2
998)	*Nocardia mexicana*	2	2
999)	*Nocardia niigatensis*	2	2
1000)	*Nocardia nova*	2	2
1001)	*Nocardia otitidiscaviarum*	2	2
1002)	*Nocardia paucivorans*	2	2
1003)	*Nocardia pseudobrasiliensis*	2	2
1004)	*Nocardia restricta*	2	2
1005)	*Nocardia terpenica*	2	2
1006)	*Nocardia transvalensis*	2	2
1007)	*Nocardia veterana*	2	2
1008)	*Nocardia yamanashiensis*	2	2
1009)	*Nocardia* spp.	2	2
1010)	*Norcardiopsis alborubida*	2	2
1011)	*Norcardiopsis antarctica*	2	2
1012)	*Nocardiopsis dassonvillei*	2	2
1013)	*Ochrobactrum anthropi*	2	2
1014)	*Ochrobactrum intermedium*	2	2
1015)	*Odoribacter denticanis*	2	2
1016)	*Odoribacter splanchnicus*	2	2
1017)	*Oligella* spp.	2	2
1018)	*Olsenella profusa*	2	2
1019)	*Olsenella uli*	2	2
1020)	*Oribaculum catoniae*	2	2
1021)	*Ornithobacterium rhinotracheale*	2	2
1022)	*Pandoraea apista*	2	2
1023)	*Pandoraea pnomenusa*	2	2

	Name	Risk Group in	
		human	animal
1024)	*Pandoraea pulmonicola*	2	2
1025)	*Pandoraea sputorum*	2	2
1026)	*Pannonibacter phragmitetus*	2	2
1027)	*Pantoea agglomerans*	2	2
1028)	*Parabacteroides distasonis*	2	2
1029)	*Parabacteroides goldsteinii*	2	2
1030)	*Paracoccus yeei*	2	2
1031)	*Paraeggerthella hongkongensis*	2	2
1032)	*Parvimonas micra*	2	2
1033)	*Pasteurella aerogenes*	2	2
1034)	*Pasteurella avium*	2	2
1035)	*Pasteurella bettii*	2	2
1036)	*Pasteurella bettyae*	2	2
1037)	*Pasteurella caballi*	2	2
1038)	*Pasteurella canis*	2	2
1039)	*Pasteurella dagmatis*	2	2
1040)	*Pasteurella gallicida*	2	2
1041)	*Pasteurella gallinarum*	2	2
1042)	*Pasteurella granulomatis*	2	2
1043)	*Pasteurella haemolytica*	2	2
1044)	*Pasteurella lymphangitidis*	2	2
1045)	*Pasteurella mairi*	2	2
1046)	*Pasteurella mairii*	2	2
1047)	*Pasteurella multocida*	2	2
1048)	*Pasteurella pneumotropica*	2	2
1049)	*Pasteurella skyensis*	2	2
1050)	*Pasteurella stomatis*	2	2
1051)	*Pasteurella testudinis*	2	2
1052)	*Pasteurella trehalosi*	2	2
1053)	*Pasteurella ureae*	2	2
1054)	*Pasteurella* spp.	2	2
1055)	*Pelistega europaea*	2	2

	Name	Risk Group in	
		human	animal
1056)	*Peptococcus assacharolyticus*	2	2
1057)	*Peptococcus glycinophilus*	2	2
1058)	*Peptococcus indolicus*	2	2
1059)	*Peptococcus magnus*	2	2
1060)	*Peptococcus niger*	2	2
1061)	*Peptococcus prevotii*	2	2
1062)	*Peptococcus saccharolyticus*	2	2
1063)	*Peptoniphilus asaccharolyticus*	2	2
1064)	*Peptoniphilus harei*	2	2
1065)	*Peptoniphilus indolicus*	2	2
1066)	*Peptoniphilus ivorii*	2	2
1067)	*Peptoniphilus lacrimalis*	2	2
1068)	*Peptostreptococcus anaerobius*	2	2
1069)	*Peptostreptococcus asaccharolyticus*	2	2
1070)	*Peptostreptococcus harei*	2	2
1071)	*Peptostreptococcus indolicus*	2	2
1072)	*Peptostreptococcus ivorii*	2	2
1073)	*Peptostreptococcus lacrimalis*	2	2
1074)	*Peptostreptococcus magnus*	2	2
1075)	*Peptostreptococcus micros*	2	2
1076)	*Peptostreptococcus parvulus*	2	2
1077)	*Peptostreptococcus prevotii*	2	2
1078)	*Peptostreptococcus stomatis*	2	2
1079)	*Peptostreptococcus vaginalis*	2	2
1080)	*Peptostreptococcus* spp.	2	2
1081)	*Photobacterium damselae*	2	2
1082)	*Photobacterium histaminum*	2	2
1083)	*Photorhabdus asymbiotica*	2	2
1084)	*Plesiomonas shigelloides*	2	2
1085)	*Porphyromonas asaccharolytica*	2	2
1086)	*Porphyromonas cangingivalis*	2	2
1087)	*Porphyromonas canoris*	2	2

	Name	Risk Group in	
		human	animal
1088)	*Porphyromonas cansulci*	2	2
1089)	*Porphyromonas catoniae*	2	2
1090)	*Porphyromonas circumdentaria*	2	2
1091)	*Porphyromonas crevioricanis*	2	2
1092)	*Porphyromonas gingivalis*	2	2
1093)	*Porphyromonas gingivicanis*	2	2
1094)	*Porphyromonas gulae*	2	2
1095)	*Porphyromonas levii*	2	2
1096)	*Porphyromonas macacae*	2	2
1097)	*Porphyromonas salivosa*	2	2
1098)	*Porphyromonas somerae*	2	2
1099)	*Porphyromonas uenonis*	2	2
1100)	*Porphyromonas* spp.	2	2
1101)	*Prevotella albensis*	2	2
1102)	*Prevotella baroniae*	2	2
1103)	*Prevotella bergensis*	2	2
1104)	*Prevotella bivia*	2	2
1105)	*Prevotella brevis*	2	2
1106)	*Prevotella bryantii*	2	2
1107)	*Prevotella buccae*	2	2
1108)	*Prevotella buccalis*	2	2
1109)	*Prevotella corporis*	2	2
1110)	*Prevotella denticola*	2	2
1111)	*Prevotella disiens*	2	2
1112)	*Prevotella heparinolytica*	2	2
1113)	*Prevotella intermedia*	2	2
1114)	*Prevotella loescheii*	2	2
1115)	*Prevotella marshii*	2	2
1116)	*Prevotella melaninogenica*	2	2
1117)	*Prevotella multiformis*	2	2
1118)	*Prevotella multisaccharivorax*	2	2
1119)	*Prevotella nanceiensis*	2	2

	Name	Risk Group in	
		human	animal
1120)	*Prevotella nigrescens*	2	2
1121)	*Prevotella oralis*	2	2
1122)	*Prevotella oris*	2	2
1123)	*Prevotella pallens*	2	2
1124)	*Prevotella ruminicola*	2	2
1125)	*Prevotella tannerae*	2	2
1126)	*Prevotella zoogleoformans*	2	2
1127)	*Prevotella* spp.	2	2
1128)	*Propionibacterium acnes*	2	2
1129)	*Propionibacterium australiense*	2	2
1130)	*Propionibacterium avidum*	2	2
1131)	*Propionibacterium granulosum*	2	2
1132)	*Propionibacterium lymphophilum*	2	2
1133)	*Propionibacterium propionicum*	2	2
1134)	*Propionibacterium propionicus*	2	2
1135)	*Propionimibium lymphophilum*	2	2
1136)	*Proteus hauseri*	2	2
1137)	*Proteus inconstans*	2	2
1138)	*Proteus mirabilis*	2	2
1139)	*Proteus morganii*	2	2
1140)	*Proteus penneri*	2	2
1141)	*Proteus rettgeri*	2	2
1142)	*Proteus vulgaris*	2	2
1143)	*Providencia alcalifaciens*	2	2
1144)	*Providencia friedericiana*	2	2
1145)	*Providencia rettgeri*	2	2
1146)	*Providencia rustigianii*	2	2
1147)	*Providencia stuartii*	2	2
1148)	*Providencia* spp.	2	2
1149)	*Pseudoflavonifractor capillosus*	2	2
1150)	*Pseudomonas aeruginosa*	2	2
1151)	*Pseudomonas alcaligenes*	2	2

	Name	Risk Group in	
		human	animal
1152)	*Pseudomonas antimicrobica*	2	2
1153)	*Pseudomonas cepacia*	2	2
1154)	*Pseudomonas cocovenenans*	2	2
1155)	*Pseudomonas diminuta*	2	2
1156)	*Pseudomonas gladioli*	2	2
1157)	*Pseudomonas luteola*	2	2
1158)	*Pseudomonas mallei*	2	2
1159)	*Pseudomonas maltophilia*	2	2
1160)	*Pseudomonas mendocina*	2	2
1161)	*Pseudomonas oryzihabitans*	2	2
1162)	*Pseudomonas otitidis*	2	2
1163)	*Pseudomonas paucimobilis*	2	2
1164)	*Pseudomonas pickettii*	2	2
1165)	*Pseudomonas pseudomallei*	2	2
1166)	*Pseudomonas putida*	2	2
1167)	*Pseudomonas simiae*	2	2
1168)	*Pseudomonas* spp.	2	2
1169)	*Pseudoramibacter alactolyticus*	2	2
1170)	*Psychrobacter phenylpyruvicus*	2	2
1171)	*Psychrobacter pulmonis*	2	2
1172)	*Ralstonia mannitolilytica*	2	2
1173)	*Ralstonia mannitolytica*	2	2
1174)	*Ralstonia paucula*	2	2
1175)	*Ralstonia pickettii*	2	2
1176)	*Raoultella ornithinolytica*	2	2
1177)	*Rhodococcus aichiensis*	2	2
1178)	*Rhodococcus bronchialis*	2	2
1179)	*Rhodococcus chubuensis*	2	2
1180)	*Rhodococcus equi*	2	2
1181)	*Rhodococcus gordoniae*	2	2
1182)	*Rhodococcus obuensis*	2	2
1183)	*Rhodococcus sputi*	2	2

	Name	Risk Group in	
		human	animal
1184)	*Rhodococcus terrae*	2	2
1185)	*Riemerella anatipestifer*	2	2
1186)	*Riemerella columbina*	2	2
1187)	*Rochalimaea elizabethae*	2	2
1188)	*Rochalimaea henselae*	2	2
1189)	*Rochalimaea quintana*	2	2
1190)	*Rochalimaea* spp.	2	2
1191)	*Roseomonas cervicalis*	2	2
1192)	*Roseomonas gilardii*	2	2
1193)	*Roseomonas mucosa*	2	2
1194)	*Rothia dentocariosa*	2	2
1195)	*Rothia mucilaginosa*	2	2
1196)	*Salmonella arizonae*	2	2
1197)	*Salmonella bongori*	2	2
1198)	*Salmonella choleraesuis*	2	2
1199)	*Salmonella enterica*	2	2
1200)	*Salmonella enteritidis*	2	2
1201)	*Salmonella paratyphi*	2	2
1202)	*Salmonella typhi*	2	2
1203)	*Salmonella typhimurium*	2	2
1204)	*Salmonella* spp.	2	2
1205)	*Selenomonas artemidis*	2	2
1206)	*Selenomonas dianae*	2	2
1207)	*Selenomonas flueggei*	2	2
1208)	*Selenomonas infelix*	2	2
1209)	*Selenomonas noxia*	2	2
1210)	*Serpula innocens*	2	2
1211)	*Serpulina innocens*	2	2
1212)	*Serpulina intermedia*	2	2
1213)	*Serpulina murdochii*	2	2
1214)	*Serpulina pilosicoli*	2	2
1215)	*Serpulina* spp.	2	2

	Name	Risk Group in	
		human	animal
1216)	*Serratia grimesii*	2	2
1217)	*Serratia marcescens*	2	2
1218)	*Serratia marinorubra*	2	2
1219)	*Serratia proteamaculans*	2	2
1220)	*Serratia rubidaea*	2	2
1221)	*Serratia* spp.	2	2
1222)	*Shewanella algae*	2	2
1223)	*Shigella boydii*	2	2
1224)	*Shigella dysenteriae*	2	2
1225)	*Shigella flexneri*	2	2
1226)	*Shigella sonnei*	2	2
1227)	*Shigella* spp.	2	2
1228)	*Shuttleworthia satelles*	2	2
1229)	*Simkania negevensis*	2	2
1230)	*Slackia exigua*	2	2
1231)	*Sphaerophorus necrophorus*	2	2
1232)	*Sphingobacterium multivorum*	2	2
1233)	*Sphingobacterium spiritivorum*	2	2
1234)	*Sphingobacterium thalpophilum*	2	2
1235)	*Sphingobacterium faecium*	2	2
1236)	*Sphingomonas parapaucimobilis*	2	2
1237)	*Sphingomonas paucimobilis*	2	2
1238)	*Spiroplasma mirum*	2	2
1239)	*Staphylococcus aureus*	2	2
1240)	*Staphylococcus caprae*	2	2
1241)	*Staphylococcus caseolyticus*	2	2
1242)	*Staphylococcus chromogenes*	2	2
1243)	*Staphylococcus epidermidis*	2	2
1244)	*Staphylococcus felis*	2	2
1245)	*Staphylococcus haemolyticus*	2	2
1246)	*Staphylococcus hominis*	2	2
1247)	*Staphylococcus hyicus*	2	2

	Name	Risk Group in	
		human	animal
1248)	*Staphylococcus intermedius*	2	2
1249)	*Staphylococcus lugdunensis*	2	2
1250)	*Staphylococcus lutrae*	2	2
1251)	*Staphylococcus nepalensis*	2	2
1252)	*Staphylococcus pasteuri*	2	2
1253)	*Staphylococcus pettenkoferi*	2	2
1254)	*Staphylococcus pseudintermedius*	2	2
1255)	*Staphylococcus saccharolyticus*	2	2
1256)	*Staphylococcus saprophyticus*	2	2
1257)	*Staphylococcus schleiferi*	2	2
1258)	*Staphylococcus simiae*	2	2
1259)	*Stenotrophomonas africana*	2	2
1260)	*Stenotrophomonas maltophilia*	2	2
1261)	*Stomatococcus muculaginosa*	2	2
1262)	*Streptobacillus moniliformis*	2	2
1263)	*Streptococcus acidominimus*	2	2
1264)	*Streptococcus adjacens*	2	2
1265)	*Streptococcus agalactiae*	2	2
1266)	*Streptococcus anginosus*	2	2
1267)	*Streptococcus bovis*	2	2
1268)	*Streptococcus canis*	2	2
1269)	*Streptococcus casseliflavus*	2	2
1270)	*Streptococcus constellatus*	2	2
1271)	*Streptococcus defectivus*	2	2
1272)	*Streptococcus dentirousetti*	2	2
1273)	*Streptococcus devriesei*	2	2
1274)	*Streptococcus didelphis*	2	2
1275)	*Streptococcus difficile*	2	2
1276)	*Streptococcus difficilis*	2	2
1277)	*Streptococcus durans*	2	2
1278)	*Streptococcus dysgalactiae*	2	2
1279)	*Streptococcus equi*	2	2

	Name	Risk Group in	
		human	animal
1280)	*Streptococcus equinus*	2	2
1281)	*Streptococcus faecalis*	2	2
1282)	*Streptococcus faecium*	2	2
1283)	*Streptococcus gallinaceus*	2	2
1284)	*Streptococcus gallinarum*	2	2
1285)	*Streptococcus gallolyticus*	2	2
1286)	*Streptococcus garvieae*	2	2
1287)	*Streptococcus gordonii*	2	2
1288)	*Streptococcus ictaluri*	2	2
1289)	*Streptococcus infantarius*	2	2
1290)	*Streptococcus iniae*	2	2
1291)	*Streptococcus intermedius*	2	2
1292)	*Streptococcus lutetiensis*	2	2
1293)	*Streptococcus mitis*	2	2
1294)	*Streptococcus morbillorum*	2	2
1295)	*Streptococcus mutans*	2	2
1296)	*Streptococcus oralis*	2	2
1297)	*Streptococcus ovis*	2	2
1298)	*Streptococcus parasanguinis*	2	2
1299)	*Streptococcus parauberis*	2	2
1300)	*Streptococcus parvulus*	2	2
1301)	*Streptococcus pasteurianus*	2	2
1302)	*Streptococcus phocae*	2	2
1303)	*Streptococcus pluranimalium*	2	2
1304)	*Streptococcus pneumoniae*	2	2
1305)	*Streptococcus porcinus*	2	2
1306)	*Streptococcus pseudopneumoniae*	2	2
1307)	*Streptococcus pseudoporcinus*	2	2
1308)	*Streptococcus pyogenes*	2	2
1309)	*Streptococcus salivarius*	2	2
1310)	*Streptococcus sanguinis*	2	2
1311)	*Streptococcus shiloi*	2	2

	Name	Risk Group in	
		human	animal
1312)	*Streptococcus sinensis*	2	2
1313)	*Streptococcus sobrinus*	2	2
1314)	*Streptococcus suis*	2	2
1315)	*Streptococcus uberis*	2	2
1316)	*Streptococcus* spp.	2	2
1317)	*Streptomyces flavidofuscus*	2	2
1318)	*Streptomyces somaliensis*	2	2
1319)	*Sutterella wadsworthensis*	2	2
1320)	*Suttonella indologenes*	2	2
1321)	*Suttonella ornithocola*	2	2
1322)	*Tannerella forsythensis*	2	2
1323)	*Tannerella forsythia*	2	2
1324)	*Tatlockia maceachernii*	2	2
1325)	*Tatlockia micdadei*	2	2
1326)	*Tatumella ptyseos*	2	2
1327)	*Taylorella equigenitalis*	2	2
1328)	*Tissierella praeacuta*	2	2
1329)	*Treponema amylovorum*	2	2
1330)	*Treponema brennaborense*	2	2
1331)	*Treponema carateum*	2	2
1332)	*Treponema denticola*	2	2
1333)	*Treponema innocens*	2	2
1334)	*Treponema lecithinolyticum*	2	2
1335)	*Treponema maltophilum*	2	2
1336)	*Treponema medium*	2	2
1337)	*Treponema pallidum*	2	2
1338)	*Treponema paraluiscuniculi*	2	2
1339)	*Treponema parvum*	2	2
1340)	*Treponema pectinovorum*	2	2
1341)	*Treponema pertenue*	2	2
1342)	*Treponema putidum*	2	2
1343)	*Treponema socranskii*	2	2

	Name	Risk Group in	
		human	animal
1344)	*Treponema* spp.	2	2
1345)	*Tropheryma whipplei*	2	2
1346)	*Trueperella bernardiae*	2	2
1347)	*Trueperella bialowiezense*	2	2
1348)	*Trueperella bonasi*	2	2
1349)	*Trueperella pyogenes*	2	2
1350)	*Tsukamurella inchonensis*	2	2
1351)	*Tsukamurella pulmonis*	2	2
1352)	*Tsukamurella tyrosinosolvens*	2	2
1353)	*Turicella otitidis*	2	2
1354)	*Ureaplasma diversum*	2	2
1355)	*Ureaplasma gallorale*	2	2
1356)	*Ureaplasma parvum*	2	2
1357)	*Ureaplasma urealyticum*	2	2
1358)	*Uruburuella suis*	2	2
1359)	*Vagococcus fluvialis*	2	2
1360)	*Varibaculum cambriense*	2	2
1361)	*Veillonella alcalescens*	2	2
1362)	*Veillonella parvula*	2	2
1363)	*Vibrio albensis*	2	2
1364)	*Vibrio alginolyticus*	2	2
1365)	*Vibrio anguillarum*	2	2
1366)	*Vibrio cholerae*	2	2
1367)	*Vibrio cincinnatiensis*	2	2
1368)	*Vibrio damsela*	2	2
1369)	*Vibrio fluvialis*	2	2
1370)	*Vibrio furnissii*	2	2
1371)	*Vibrio hollisae*	2	2
1372)	*Vibrio metschnikovii*	2	2
1373)	*Vibrio mimicus*	2	2
1374)	*Vibrio parahaemolyticus*	2	2
1375)	*Vibrio splendidus*	2	2

	Name	Risk Group in	
		human	animal
1376)	*Vibrio vulnificus*	2	2
1377)	*Vibrio* spp.	2	2
1378)	*Volucribacter amazonae*	2	2
1379)	*Volucribacter psittacicida*	2	2
1380)	*Waddlia chondrophila*	2	2
1381)	*Wauteria paucula*	2	2
1382)	*Wautersiella falsenii*	2	2
1383)	*Weeksella zoohelcum*	2	2
1384)	*Wolinella curva*	2	2
1385)	*Wolinella recta*	2	2
1386)	*Xanthomonas maltophilia*	2	2
1387)	*Yersinia aleksiciae*	2	2
1388)	*Yersinia enterocolitica*	2	2
1389)	*Yersinia frederiksenii*	2	2
1390)	*Yersinia intermedia*	2	2
1391)	*Yersinia kristensenii*	2	2
1392)	*Yersinia pseudotuberculosis*	2	2
1393)	*Yersinia similis*	2	2
1394)	*Yersinia* spp.	2	2
1395)	*Yokenella regensburgei*	2	2

- **Fungal agents**

	Name	Risk Group in	
		human	animal
1)	*Ajellomyces capsulatus*	2	2
2)	*Ajellomyces* spp.	2	2
3)	*Aphanomyces invadans*	2	2
4)	*Aphanomyces* spp.	2	2
5)	*Aspergillus flavus*	2	2
6)	*Aspergillus fumigatus*	2	2
7)	*Basidiobolus ranarum*	2	2
8)	*Candida albicans*	2	2
9)	*Candida glabrata*	2	2

	Name	Risk Group in	
		human	animal
10)	*Candida tropicalis*	2	2
11)	*Cladophialophora bontiana*	2	2
12)	*Cladophialophora carrionii*	2	2
13)	*Conidiobolus coronatus*	2	2
14)	*Cryptococcus gattii*	2	2
15)	*Cryptococcus neoformans*	2	2
16)	*Epidermophyton floccosum*	2	2
17)	*Exophiala jeanselmei*	2	2
18)	*Fonsecaea compacta*	2	2
19)	*Fonsecaea pedrosoi*	2	2
20)	*Fusarium oxysporum*	2	2
21)	*Fusarium solani*	2	2
22)	*Histoplasma capsulatum*	2	2
23)	*Histoplasma duboisii*	2	2
24)	*Histoplasma* spp.	2	2
25)	*Madurella grisea*	2	2
26)	*Madurella mycetomatis*	2	2
27)	*Microsporum audouinii*	2	2
28)	*Microsporum canis*	2	2
29)	*Microsporum gypseum*	2	2
30)	*Microsporum nanum*	2	2
31)	*Penicillium marneffei*	2	2
32)	*Phialophora verrucosa*	2	2
33)	*Scedosporium apiospermum*	2	2
34)	*Sporothrix schenckii*	2	2
35)	*Sporothrix* spp.	2	2
36)	*Trichophyton mentagrophytes*	2	2
37)	*Trichophyton rubrum*	2	2
38)	*Trichophyton schoenleinii*	2	2
39)	*Trichophyton tonsurans*	2	2
40)	*Trichophyton verrucosum*	2	2
41)	*Trichophyton violaceum*	2	2

- **Viral agents**

	Name	Risk Group in	
		human	animal
1)	Astrovirus	2	2
2)	Avian encephalomyelitis virus	2	2
3)	Avian leukosis virus	2	2
4)	BK and JC viruses	2	2
5)	Bluetongue virus	2	2
6)	Bocavirus	2	2
7)	Border disease virus	2	2
8)	Bovine diarrhea virus	2	2
9)	Bovine ephemeral virus	2	2
10)	Bovine leukemia virus	2	2
11)	Bovine papillomavirus	2	2
12)	Caliciviridae	2	2
13)	Caprine arthritis encephalitis virus	2	2
14)	Chicken anemia virus	2	2
15)	Chikungunya virus	2	2
16)	Classical swine fever virus	2	2
17)	Cowpox virus	2	2
18)	Coxsackie viruses	2	2
19)	Dengue virus type 1-4	2	2
20)	Duck Tembusu virus (TMUV)	2	2
21)	Duck viral enteritis (Duck plague)	2	2
22)	Duck viral hepatitis	2	2
23)	Echovirus	2	2
24)	Egg drop syndrome 1976 virus	2	2
25)	Enterovirus	2	2
26)	Epizootic haematopoietic necrosis virus	-	2
27)	Foot and mouth disease virus	2	3
28)	Fowl adenovirus	2	2
29)	Fowl pox virus	2	2
30)	Goose hepatitis virus, Muscovy duck parvovirus (Derzsy's disease)	2	2
31)	Hantaviruses (except Hantaan, Seoul and Sin Nombre)	2	4

	Name	Risk Group in	
		human	animal
32)	Hepatitis A virus	2	2
33)	Hepatitis B virus	2	2
34)	Hepatitis C virus	2	2
35)	Hepatitis D (delta)	2	2
36)	Hepatitis D virus	2	2
37)	Hepatitis E virus	2	2
38)	Hepatitis F virus	2	2
39)	Hepatitis G virus (GBV-C)	2	2
40)	Human adenovirus type A, B, C, 0, E, F, G	2	2
41)	Human coronavirus (except SARS coronavirus and MERS coronavirus)	2	2
42)	Human herpesvirus	2	2
43)	Human metapneumonovirus	2	2
44)	Human papillomaviruses	2	-
45)	Human parvovirus	2	2
46)	Human respiratory syncytial virus	2	2
47)	Human rotavirus	2	2
48)	Ranavirus	-	2
49)	Infectious bovine rhinotracheitis virus	2	2
50)	Infectious bronchitis virus	2	2
51)	Infectious bursal disease virus	2	2
52)	Infectious haematopoietic necrosis virus	-	2
53)	Infectious hypodermal and haematopoietic necrosis virus	-	2
54)	Infectious laryngotrachelitis virus	2	2
55)	Infectious myonecrosis virus	-	2
56)	Infectious salmon anaemia virus	-	2
57)	Influenza A virus (low pathogenic strain)	2	2
58)	Influenza virus type B	2	2
59)	Influenza virus type C	2	2
60)	Influenza virus types A-C (excluding type A 1918 Spanish Flu and H2N2 strains)	2	2
61)	Japanese encephalitis virus	2	2
62)	Koi herpesvirus	-	2

	Name	Risk Group in	
		human	animal
63)	Lumpy skin disease virus	2	2
64)	Maedi-visna virus	2	2
65)	Malignant catarrhal fever virus	2	2
66)	Marek ‘s disaese virus	2	2
67)	Measles virus	2	2
68)	Merkel cell polyomavirus	2	-
69)	Molluscum contagiosum virus (MCV)	2	2
70)	Mumps virus	2	2
71)	Murray Valley encephalitis virus	2	2
72)	Newcastle disease virus	2	2
73)	Norovirus	2	2
74)	Parainfluenza virus type 1- 4	2	2
75)	Parvovirus B19	2	2
76)	PCV2	2	2
77)	Peste-des-petits ruminants virus	2	2
78)	Porcine circovirus	2	2
79)	Porcine epidemic diarrhea virus	2	2
80)	Porcine parvovirus	2	2
81)	Porcine reproductive and respiratory syndrome	2	2
82)	Porcine respiratory coronavirus	2	2
83)	Porcine rotavirus	2	2
84)	Porcine transmissible gastroenteritis virus	2	2
85)	Pseudorabies virus	2	2
86)	Rabies virus	2	2
87)	Red sea bream iridovirus	-	2
88)	Respiratory syncytial virus	2	2
89)	Revovirus	2	2
90)	Rhinovirus	2	2
91)	Rinderpest virus	2	2
92)	Rotavirus	2	2
93)	Rubella virus	2	2
94)	Semian virus 40	2	2
95)	Semliki forest virus	2	2

	Name	Risk Group in	
		human	animal
96)	Sendai virus	2	2
97)	Simian immunodeficiency virus	2	2
98)	Sindbis virus	2	2
99)	Spring viraemia of carp virus	-	2
100)	Swine influenza virus	2	2
101)	Swine vesicular disease virus	2	2
102)	Taura syndrome virus	-	2
103)	Torovirus	2	2
104)	Transmissible gastroenteritis (TGE)	2	3
105)	Vacciniavirus	2	2
106)	Vesicular stomatitis virus	2	2
107)	Viral haemorrhagic septicaemia virus	-	2
108)	White spot syndrome virus	-	2
109)	Macrobrachium rosenbergii nodavirus	-	2
110)	Yatapox (Tana and Yaba)	2	2
111)	Yellow head virus	-	2
112)	Zikavirus	2	2

4.2.3 Risk group 3

- **Bacterial agents**

	Name	Risk Group in	
		human	animal
1)	*Bacillus anthracis*	3	3
2)	*Brucella ovis*	3	3
3)	*Brucella* spp.	3	3
4)	*Brucella abortus*	3	3
5)	*Brucella canis*	3	3
6)	*Brucella melitensis*	3	3
7)	*Brucella neotomae*	3	3
8)	*Brucella suis*	3	3
9)	*Chlamydia psittaci*	3	3
10)	*Francisella tularensis*	3	3
11)	*Yersinia pestis*	3	3

- **Fungal agents**

	Name	Risk Group in	
		human	animal
1)	*Ajellomyces dermatitidis*	3	3
2)	*Blastomyces dermatitidis*	3	3
3)	*Blastomyces* spp.	3	3
4)	*Coccidioides immitis*	3	3
5)	*Coccidioides posadasl!*	3	3
6)	*Coccidioides* spp.	3	3
7)	*Paracoccidioides brasiliensis*	3	3
8)	*Paracoccidioides* spp.	3	3

- **Viral agents**

	Name	Risk Group in	
		human	animal
1)	African Hourse Sickness virus	3	2
2)	African swine fever virus	3	2
3)	Akabane virus	3	2
4)	Borna disease virus	3	2
5)	Eastern equine encephalitis virus	3	2
6)	Hantaan virus	3	2
7)	Human immunodeficiency virus type 1 and 2	3	2
8)	Human T-cell leukemia virus type 1 and 2 (T-cell lymphotropic virus type 1 and 2)	3	2
9)	Influenza A virus (Highly pathogenic strain:HS,H7)	3	2
10)	Kunjin virus	3	2
11)	Lymphocytic choriomeningitis virus	3	2
12)	MERS coronavirus	3	2
13)	Nipah virus	3	2
14)	Polio virus type 1-3	3	2
15)	Rift Valley Fever virus	3	2
16)	Seoul virus	3	2
17)	Sin Nombre virus (formerly Muerto Canyon)	3	2
18)	St Louis encephalitis virus	3	2
19)	Venezuelan equine encephalitis virus	3	2

	Name	Risk Group in	
		human	animal
20)	West Nile virus	3	3
21)	Western equine encephalitis virus	3	2
22)	Yellow fever virus	3	3

4.2.4 Risk group 4

- **Viral agents**

	Name	Risk Group in	
		human	animal
1)	Crimean-Congo Haemorrhagic Fever virus	4	2
2)	Ebola virus	4	4
3)	Hendra virus	4	2
4)	Herpes B virus	4	2
5)	Herpesvirus simiae (B virus)	4	2
6)	Influenza A H2N2 + Spanish flu	4	2
7)	Junin virus	4	2
8)	Lassa virus	4	2
9)	Machupo virus	4	2
10)	Marburg virus	4	2
11)	SARS coronavirus	4	2
12)	Tick-borne encephalitis virus	4	2
13)	Variola virus	4	2

4.3 List of microorganisms with differences in risk group classification between the Department of Medical Sciences and NIH guidelines

In order to comply with Thai regulations and practices, the classification of microorganisms/agents used in this guideline is based on the risk group classification by the Department of Medical Sciences. Microorganisms/agents differentially classified by the Department of Medical Sciences and the NIH guidelines are shown below.

Name	Risk Group	
	Department of Medical Sciences	NIH guidelines
Bacterial agents		
1) *Bacillus anthracis*	3	2
2) *Bartonella* spp.	2	3
3) *Burkholderia mallei*	2	3
4) *Burkholderia pseudomallei*	2	3
5) *Chlamydia psittaci*	3	2
6) *Klebsiella oxytoca*	2	1
7) *Mycoplasma agalactiae*	2	3
8) *Mycoplasma mycoides*	2	3
9) *Mycobacterium tuberculosis*	2	3
10) *Pasteurella multocida*	2	3
Fungal agents		
1) *Blastomyces dermatitidis*	3	2
2) *Exophiala dermatitidis*	1	2
3) *Histoplasma capsulatum*	2	3
4) *Paracoccidioides brasiliensis*	3	2
Viral agents and prions		
1) Eastern equine encephalitis virus	3	2
2) Hantaviruses	2	3
3) SARS coronavirus	4	3
4) Semliki forest virus	2	3
5) Western equine encephalomyelitis virus	3	2

4.4 List of plant pathogens according to the Notification of the Ministry of Agriculture and Cooperatives, re: Specification of plant pests as prohibited articles under the Plant Quarantine Act B.E. 2507 (No. 6 and 7) B.E. 2550

- **Bacterial agents**
  1) *Burkholderia caryophylli* (Burkholder) Yabuuchi et al.
  2) *Candidatus* Liberibacter africanus (Jagoueix et al.)
  3) *Candidatus* Liberibacter americanus (Teixeira et al.)
  4) *Clavibacter michiganensis* spp. *michiganensis* (Smith) Davis et al.
  5) Clavibacter *michiganensis* spp. *nebraskensis* (Vidaver & Mandel)Davis et al.
  6) Clavibacter *michiganensis* spp. *sepedonicum* (Spieckermann & Kotthoff) Davis et al.
  7) *Curtobacterium flaccumfaciens* pv. *flaccumfaciens* (Hedges) Collins & Jones
  8) *Curtobacterium flaccumfaciens* pv. *oortii* (Saaltink & Maas Geest.) Collins & Jones
  9) *Erwinia amylovora* (Burrill) Winslow et al.
  10) *Pantoea agglomerans* (Beijerinck) Gavini et al.
  11) *Pantoea ananatis* (Serrano) Mergaert et al.
  12) *Pantoea citrea* Kageyama et al.
  13) *Pseudomonas cichorii* (Swingle) Stapp.
  14) *Pseudomonas corrugata* (ex Scarlett et al.) Roberts & Scarlett
  15) *Pseudomonas fuscovaginae* (ex Tanii et al.) Miyajima et al.
  16) *Pseudomonas glumae* Kurita & Tabei
  17) *Pseudomonas marginalis* pv. *marginalis* (Brown) Stevens
  18) *Pseudomonas putida* (Trevisan) Migula
  19) *Pseudomonas rubrisubalbicans* (Christopher & Edgerton) Krasil'nikov
  20) *Pseudomonas syringae* pv. *atrofaciens* (McCulloch) Young et al.
  21) *Pseudomonas syringae* pv. *coronafaciens* (Elliott) Young et al.
  22) *Pseudomonas syringae* pv. *lachrymans* (Smith & Bryan) Young et al.
  23) *Pseudomonas syringae* pv. *maculicola* (McCulloch) Young et al.
  24) *Pseudomonas syringae* pv. *tomato* (Okabe) Young, Dye & Wilkie
  25) *Pseudomonas syringae* pv. *theae* (Hori) Young et al.
  26) *Pseudomonas viridiflava* (Burkholder) Dowson
  27) *Rhizobium vitis* (Ophel & Kerr) Young et al.
  28) *Xanthomonas arboricola* pv. *celebensis* (Gaumann) Vauterin et al.
  29) *Xanthomonas axonopodis* pv. *citrumelo* (Gabriel et al.) Vauterin et al.

30) *Xanthomonas axonopodis* pv. *vasculorum* (Cobb) Vauterin et al.
31) *Xanthomonas axonopodis* pv. *vitians* (Brown) Vauterin et al.
32) *Xanthomonas campestris* pv. *armoraciae* (McCulloch) Dye
33) *Xanthomonas campestris* pv. *cassavae* (Wiehe & Dowson) Maraite & Weyns
34) *Xanthomonas campestris* pv. *theicola* Uehara, Arai, Nonaka & Sano
35) *Xanthomonas campestris* pv. *zantedeschiae* (Joubert & Truter) Dye
36) *Xanthomonas cucurbitae* (Bryan) Vauterin et al.
37) *Xanthomonas hortorum* pv. *carotae* (Kendrick) Vauterin et al.
38) *Xylella fastidiosa* Wells et al.
39) *Xylophilus ampelinus* (Panagopoulos) Willems et al.

- **Rickettsia**
  1) *Papaya bunchy top* (*Rickettsia* sp.) (Davis et al.)

- **Fungal agents**
  1) *Ascochyta gossypii* (Woronichin) Syd.
  2) *Asperisporium caricae* (Speg.) Maubl.
  3) *Balansia oryzae-sativae* Hashioka
  4) *Botryotinia allii* (Sawada) W.Yamamoto
  5) *Botryotinia fuckeliana* (de Bary) Whetzel
  6) *Botryotinia porri* (JFH Beyma) Whetzel
  7) *Botrytis aclada* Fresen.
  8) *Cephalosporium maydis* Samra, Sabet & Hingorani
  9) *Cercospora elaeidis* Steyaert
  10) *Cercospora zeae-maydis* Tehon & E.Y. Daniels
  11) *Ceratobasidium cereale* Murray & Burpee
  12) *Chalara elegans* Nag Raj & W.B. Kendr.
  13) *Claviceps gigantea* S.F. Fuentes, Isla, Ullstrup & Rodriquez
  14) *Claviceps purpurea* (Fr.) Tul.
  15) *Claviceps sorghi* B.G.P. Kulk., Seshadri & Hegde
  16) *Colletotrichum circinans* (Berk.) Voglino
  17) *Colletotrichum kahawae* J.M. Waller & Bridge
  18) *Crinipellis perniciosa* (Stahel) Singer
  19) *Diaporthe phaseolorum* var. *meridionalis* F.A. Fern.
  20) *Diaporthe vexans* Gratz

21) *Elsinoe australis* Bitancourt & Jenkins
22) *Elsinoe theae* Bitancourt & Jenkins
23) *Fusarium culmorum* (W.G. Sm.) Sacc.
24) *Fusarium graminearum* Schwabe
25) *Fusarium oxysporum* f.sp. *elaeidis* Toovey
26) *Fusarium oxysporum* f.sp. *melonis* (Leach & Currence) Snyder & Hansen
27) *Fusarium oxysporum* f.sp. *lilii* Imle
28) *Fusarium oxysporum* f.sp. *narcissi* Snyder & Hansen
29) *Gibberella xylarioides* R. Heim & Saccas
30) *Guignardia camelliae* (Cooke) E.J.Butler
31) *Haplobasidion musae* M.B.Ellis
32) *Helminthosporium allii* Campanile
33) *Kabatiella zeae* Narita & Y. Hirats.
34) *Microcyclus ulei* (Henn.) Arx
35) *Moniliophthora roreri* (Cif.) H.C. Evans et al.
36) *Monographella nivalis* (Schaffnit) E.Mull.
37) *Mycena citricolor* (Berk. & M.A. Curtis) Sacc.
38) *Mycosphaerella citri* Whiteside
39) *Nectria rigidiuscula* Berk. & Broome
40) *Peronospora dianthicola* Barthelet
41) *Phaeoramularia angolensis* (T. Carvalho & O. Mendes) P.M. Kirk
42) *Phakopsora jatrophicola* (Arthur) Cummins
43) *Phellinus noxius* (Corner) G. Cunn.
44) *Phoma andigena* Turkenst.
45) *Phoma foveata* Foister
46) *Phoma theiocola* Petch
47) *Phoma tracheiphila* (Petri) Kantachveli & Gikachvili
48) *Phomopsis longicolla* Hobbs
49) *Phymatotrichopsis omnivora* (Duggar) Hennebert
50) *Phytophthora boehmeriae* Sawada
51) *Phytophthora capsici* Leonian
52) *Phytophthora citricola* Sawada
53) *Phytophthora cryptogea* Pethybr. & Laff.
54) *Phytophthora hibernalis* Carne
55) *Phytophthora katsurae* W.H. Ko & H.S. Chang

56) *Phytophthora megakarya* Brasier & M.J. Griffin
57) *Phytophthora megasperma* Drechsler
58) *Phytophthora porri* Foister
59) *Plasmodiophora brassicae* Woronin
60) *Pseudocercospora jatrophae* (G.F. Atk.) A.K. Das & Chattopadh.
61) *Puccinia asparagi* DC.
62) *Pyricularia setariae* Y.Nisik.
63) *Rosellinia bunodes* (Berk. & Broome) Sacc.
64) *Rosellinia pepo* Pat.
65) *Sclerospora graminicola* (Sacc.) J. Schrot.
66) *Sclerophthora macrospora* (Sacc.) Thirum., C.G. Shaw & Naras
67) *Sclerotium cepivorum* Berk.
68) *Septoria cucurbitacearum* Sacc.
69) *Septoria helianthi* Ell. & Kellerman
70) *Septoria limonum* Pass.
71) *Sphaceloma manihoticola* Bitanc.& Jenkins
72) *Sphacelotheca cruenta* (J.G. Kuhn) A.A. Potter.
73) *Sphacelotheca reiliana* (J.G. Kuhn) Clinton
74) *Stenocarpella macrospora* (Earle) B.Sutton
75) *Synchytrium endobioticum* (Schilb.) Percival
76) *Spongospora subterranea* f.sp. *subterranea* J.A. Toml.
77) *Thecaphora solani* (Thirum & M.J. O'Brien) Mordue
78) *Tilletia controversa* J. G. Kuhn
79) *Urocystis gladiolicola* Ainsworth
80) *Uromyces gladioli* Henn.
81) *Uromyces musae* Henn.
82) *Verticillium albo-atrum* Reinke & Berthold
83) *Verticillium dahliae* Kleb.

- **Viral agents**
  1) African cassava mosaic virus
  2) African cotton mosaic virus
  3) Alfalfa mosaic virus
  4) Andean potato latent virus
  5) Andean potato mottle virus

6) Arabis mosaic nepovirus
7) Asparagus virus-1
8) Asparagus virus-2
9) Banana bract mosaic virus
10) Barley stripe mosaic virus
11) Cassava American latent virus
12) Cassava brown streak virus
13) Cassava common mosaic virus
14) Cassava green mottle virus
15) Cassava Ivorian bacilliform virus
16) Cassava vein mosaic virus
17) Cassava virus X
18) Celery mosaic virus
19) Citrus leaf rugose virus
20) Citrus leprosis virus
21) Citrus ringspot virus (Citrus psorosis virus complex A,B)
22) Citrus rubbery wood virus
23) Citrus tatter leaf virus
24) Citrus variegation virus
25) Citrus vein enation virus
26) Cacao red mottle virus
27) Cacao swollen shoot virus
28) Cacao vein-clearing virus
29) Cacao yellow mosaic virus
30) Cacao yellow vein banding virus
31) Cocoa necrosis virus
32) Coconut foliar decay virus
33) Coconut wilt disease
34) Coffee ringspot virus
35) Cotton anthocyanosis virus
36) Cotton leaf crumple virus
37) Cotton leaf mosaic virus
38) Cotton leaf mottle virus
39) Cotton stenosis virus
40) Cotton terminal stunt virus

41) Cowpea mild mottle virus
42) Cucumber green mottle mosaic virus
43) East African cassava mosaic virus
44) Grapevine virus A
45) Grapevine virus B
46) Hibiscus chlorotic ringspot virus
47) High plains virus
48) Impatiens necrotic spot virus
49) Impatiens necrotic virus
50) Indian cassava mosaic virus
51) Lettuce necrotic yellow virus
52) Maize chlorotic dwarf virus
53) Maize chlorotic mottle virus
54) Maize dwarf mosaic virus A
55) Maize mosaic virus
56) Maize rayado fino virus
57) Papaya leaf curl virus
58) Papaya mosaic virus
59) Papaya waialua virus
60) Pelargonium chlorotic ring pattern virus
61) Pelargonium line pattern carmovirus
62) Pelargonium ringspot virus
63) Pelargonium vein clearing virus
64) Pelargonium zonate spot virus
65) Pepino mosaic virus
66) Potato black ringspot virus
67) Potato deforming mosaic virus
68) Potato mop-top virus
69) Potato virus S
70) Potato yellow dwarf virus
71) Potato yellow virus
72) Potato yellow vein virus
73) Rice dwarf virus
74) Rice hoja blanca virus
75) Rice stripe virus

76) Rice yellow mottle virus
77) Satsuma dwarf virus
78) Sorghum mosaic virus
79) Squash mosaic virus
80) Sugarcane bacilliform virus
81) Sugarcane streak virus
82) Tobacco rattle virus
83) Tobacco streak virus
84) Tomato aspermy virus
85) Tomato black ring virus
86) Tomato bushy stunt virus
87) Tomato ringspot virus
88) Tomato spotted wilt virus
89) Tulip breaking virus
90) Zantedeschia mosaic virus
91) Zucchini yellow mosaic virus

- **Viroid**
  1) Avocado sunblotch viroid
  2) Chrysanthemum chlorotic mottle viroid
  3) Chrysanthemum stunt viroid
  4) Citrus cachexia viroid
  5) Citrus exocortis viroid
  6) Coconut cadang-cadang viroid
  7) Coconut tinangaja viroid
  8) Columnea latent viroid
  9) Hop stunt viroid
  10) Mexican papita viroid
  11) Peach latent mosaic viroid
  12) Potato spindle tuber viroid
  13) Tomato apical stunt viroid
  14) Tomato chlorotic dwarf viroid
  15) Tomato planta macho viroid

- **Protozoa**
  1) *Nosema bombycis* Naegeli
  2) *Phytomonas staheli* McGhee & McGhee

- **Mycoplasma**
  1) *Spiroplasma citri* Saglio et al.
  2) *Spiroplasma kunkelii* Whitcomb et al.

- **Phytoplasma**
  1) Banana marbling disease
  2) *Cassava frog skin phytoplasma*
  3) *Cassava Witches'Broom*
  4) *Coconut lethal yellows phytoplasma*
  5) *Grapevine flavescence doree phytoplasma*
  6) *Grapevine yellows phytoplasmas* Seemuller et al.
  7) Lime Witches'Broom
  8) *Sugarcane Ramu stunt disease phytoplasma*

Appendix 5
Examples of human toxins

DNA containing genes coding for the biosynthesis of toxic molecules which are lethal to vertebrates at 100 ng to 100 μg/kg body weight shall be classified as class 3. Below are examples of toxins with LD50 of less than 100 ng/kg body weight.

- Abrin
- *Bacillus anthracis* lethal factor
- *Bordetella pertussis* toxin
- *Clostridium botulinum* toxins
- *Clostridium perfringens* epsilon toxin
- *Clostridium tetani* toxin
- *Corynebacterium diphteriae* toxins
- *Escherichia coli* heat labile (LT) enterotoxin and LT-link toxin
- Oxygen-labile haemolysins such as streptolysin O
- *Yersinia (Pasteurella) pestis* murine toxins
- *Pseudomonas aeruginosa* exotoxin A
- Ricin
- *Shigella dysenteriae* toxin
- *Staphylococcus aureus* determinants A, B, and F, alpha and beta toxin, exfoliative toxin
- *Vibrio cholerae* (comma) toxin and toxins neutralised by antiserum monospecific for cholera toxin (e.g. heat-labile toxins of *E. coli, Klebsiella* and other related enterotoxins)
- *Yersinia enterocolitica* heat-stable toxin

Appendix 6
Basic working procedures for contained use of GMMs at pilot and industrial scales for health and environmental safety

For safe use of GMMs, appropriate containment and working procedures must be implemented. In general, biosafety controls and containment implemented with GMMs in industry are largely identical to its counterpart at the laboratory level. However, additional practices and caution are required as industrial working volumes are much larger, with a correspondingly greater impact on humans and the environment in the event of GMM release. Basic regulations for all categories of GMM work are listed below.

6.1 The working procedures shall be clearly described for every step of the process, including good microbiological practices.

6.2 Regular inspection of GMM equipment and tool performance is required. Inspection frequency and methods are based on microorganism/agent classification. For instance, equipment and tools for LS 1 work should be inspected once a week by air and surface sampling at areas where GMMs may leak from containment by microbiological techniques such as swabbing or placement of an open plate.

6.3 GMM monitoring should be conducted in both inner and outer working areas close to work stations, closed system reactors or equipment in direct contact with GMMs by techniques such as air sampling and swabbing techniques. This monitoring is not required for work using GILSP class GMMs.

6.4 Inactivation of GMMs in closed systems such as bioreactors, equipment, tools, and contaminated liquids (For class 3, effluents from hand - washing sinks and showers or similar effluents must be inactivated) including culture liquids and media is required, using suitable methods such as:

- High pressure steam sterilizer/ autoclave
- Chemical agents
- Incineration

These methods shall be validated periodically and the results recorded.

6.5 Emergency plans must be followed in case of extensive spillage or release of GMMs.

6.6 Training must be provided for operators or people involved to promote understanding of work and safety practices. Proper emergency drills must be conducted regularly, and should include methods for handling GMM spillage or release.

6.7 An Institutional Safety Committee (IBC) must be established in the work place, which must liaise with operators and regulatory authorities or the TBC.

6.8 Health surveillance is required through regular medical check-ups. In the case of exposure to GMMs classified as class 2 or 3, intensive medical check-ups by qualified physicians as well as blood tests and follow-ups on symptoms or effects of diseases must be conducted. In the case of work with class 3 GMMs, operator blood samples must be drawn prior to commencing GMM work and kept for at least 10 years after completion of the work to allow monitoring for causes of sickness or disease that may subsequently develop.

Appendix 7
Containment for work using GMMs at pilot and industrial scales (Large-scale Containment Level, LS)

Table A7.1: Levels of safety control and safety protective measures for using GMMs at pilot and industrial scales

Containment and other protective measures	Containment level			
	GILSP	**LS1**	**LS2**	**LS3**
1. GMMs contained in a system which separates the process from the workplace and wider environment (closed system)	Not required	Required	Required	Required
2. Closed systems located within controlled areas	Not required	Not required	Required	Required
3. Entry via airlock	Not required	Not required	Optional	Required
4. Specific measures to adequately ventilate controlled areas in order to minimize air contamination	Not required	Not required	Optional	Required
5. Exhaust and input air flow in controlled areas should pass through HEPA filters	Not required	Not required	Required for exhaust air only	Required
6. Controlled areas maintained at negative air pressure relative to immediate surroundings	Not required	Not required	Optional	Required
7. Controlled areas sealable to permit fumigation	Not required	Not required	Not required	Required
8. Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean				
8.1 Bench	Required	Required	Required	Required
8.2 Floor	-	Required	Required	Required
8.3 Ceiling, Walls	-	-	-	Required

Containment and other protective measures	Containment level			
	GILSP	LS1	LS2	LS3
9. Controlled areas designed to contain spillage of the entire volume of closed systems	Not required	Not required	Optional	Required
10. Control of exhausted gases from closed systems	Minimise release to levels not harmful to humans and the environment	Minimise release	Prevent release	Prevent release
11. Seals designed to minimise or prevent release of GMMs	Minimise release to levels not harmful to humans and the environment	Minimise release	Prevent release	Prevent release
12. Alarm systems to indicate whether any technical safety equipment is out of order	Not required	Not required	Required	Required
13. Reserve power supply provided for technical safety equipment	Not required	Not required	Required	Required
14. Biohazard sign posted	Not required	Optional	Required	Required
15. Decontamination and washing facilities provided for personnel	Required	Required	Required	Required
16. Showers available near the work place	Not required	Not required	Optional	Required
17. Access restricted to assigned personnel only	Not required	Not required	Only for assigned personnel and always close	Only for assigned personnel andalways close

Containment and other protective measures	Containment level			
	GILSP	LS1	LS2	LS3
18. Personnel wear protective clothing	Required	Required	Required	Required, including change of clothing and footwear
19. Personnel shower before leaving controlled areas	Not required	Not required	Not required	Required
20. Inactivation of GMMs in contaminated material and waste, including those in process effluent, before final discharge or disposal	Required, by validated means	Required, by validated means	Required, by validated means	Required, by validated means
21. Release of GMMs during sampling or transfer in and out of contained systems	Reduced	Minimized	Prohibited	Prohibited
22. Inactivation of GMMs in culture fluids before removal from closed systems	Required	Required	Required	Required
23. Inactivation of GMMs in effluents from handwashing sinks and showers before discharge	Not required	Not required	Optional	Required
24. Eradication of genetic materials				
24.1 Without antibiotic resistance markers	Not required	Not required	Required	Required
24.2 With antibiotic resistance markers	Required	Required	Required	Required

Remark: Emergency plans for managing spilled GMMs must be prepared, as described in Chapter 9.

Appendix 8
Application form for contained use of GMMs at pilot and industrial scales

Please clearly provide the requested information for each topic for consideration.

Note: Instructions on how to fill out this form are shown at page 140.

Section I: General information	
1.1	Name of organization/institution/private sector .....
1.2	Name of applicant ..... Position ..... Address ..... Telephone ..... Fax ..... E-mail .....
1.3	Name of contact person ..... Position ..... Address ..... Telephone ..... Fax ..... E-mail .....
1.4	Name of person in charge of work (Principal investigator/Project manager) ..... Position ..... Address ..... Telephone ..... Fax ..... E-mail .....
1.5	Duration of work .....
1.6	Starting date (DD/MM/YYYY) .....
1.7	Production site .....

Section II: Work information			
2.1	Name of work or project		
2.2	Objective(s)		
2.3	Briefly explain work or project		
2.4	Cell density (CFU/litre or CFU/kg for solid state fermentation) ..... Maximum working volume of GMMs (per batch) ..... Estimated working volume (per year)		
2.5	What are the GMM-derived product(s)?		
2.6	Appointed Institutional Biosafety Committee (IBC) ○ Yes ○ No		
2.7	Biosafety officer(s)		
		Name	Records/certificate of biosafety training
	1.		

Section III: Risk assessment for classification of work and containment level		
3.1	GMM	
		Characteristics
	3.1.1 Host or recipient cell	
	3.1.2 Vector	
	3.1.3 Gene transfer / Manipulation method at each step	
	3.1.4 Marker gene(s)	
	3.1.5 Inserted gene(s) or modified gene	
	3.1.6 GMM	
	3.1.7 Restriction map of recombinant DNA	
3.2	Classification of work ○ GILSP ○ class1 ○ class2 ○ class3	
3.3	Containment level ○ GILSP ○ LS1 ○ LS 2 ○ LS 3	
3.4	Production process **(attach flow chart)**	
	○ Upstream process ☐ Solid ☐ Liquid ☐ Other (specify) ..... ☐ Closed system ☐ Open system	
	○ Cell harvesting ☐ Centrifugation ☐ Sedimentation ☐ Filtration ☐ Others (specify)	
	○ Others (specify)	
3.5	Downstream process (specify the total amounts or volume of microorganisms/ agents in each procedure, if possible)	
3.6	GMM inactivation process, verification and validation for inactivation methods (including reference method and document to confirm the death of GMM)	

3.7	Waste treatment method for:
	3.7.1 Inactivate cell ☐ Effluent ..... ☐ Solid waste ..... ☐ Exhausted gas ..... ☐ Disposal .....
	3.7.2 Inactivate DNA ☐ Effluent ..... ☐ Solid waste ..... ☐ Exhausted gas ..... ☐ Disposal .....
3.8	Emergency plan, including countermeasures and standard operating procedure(s) for GMM leakage (attach evidence of practice drills).
3.9	Risk assessment for class 2 and higher (refer to Appendix 9)

Signature of Head of Institutional Biosafety Committee (IBC)

.....

( )

Date .....

Signature of applicant

.....

( )

Position .....

Date .....

Detailed instructions on completing the application form

Section I: General information

1.2 Name of owner or authorized representative.

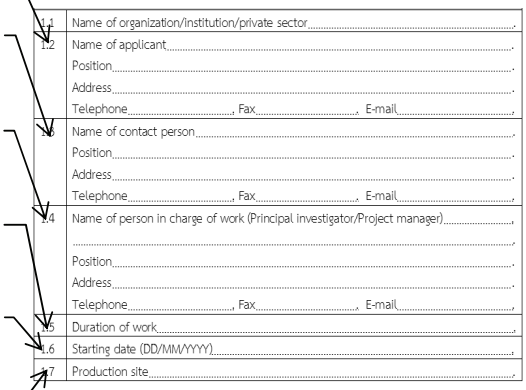
1.3 Name of person to contact for support documents.

1.4 Name of principal investigator/project manager responsible for the production process.

1.5 Specify duration of GMM use at pilot or industrial scale in months and years.

1.6 Date for commencing use of GMMs for production at the pilot or industrial scale.

1.7 Site of pilot plant or factory using GMMs for this project.



Section II: Work information

2.2 Include product information and production level, such as pilot scale for production testing or industrial scale for commerce, etc.

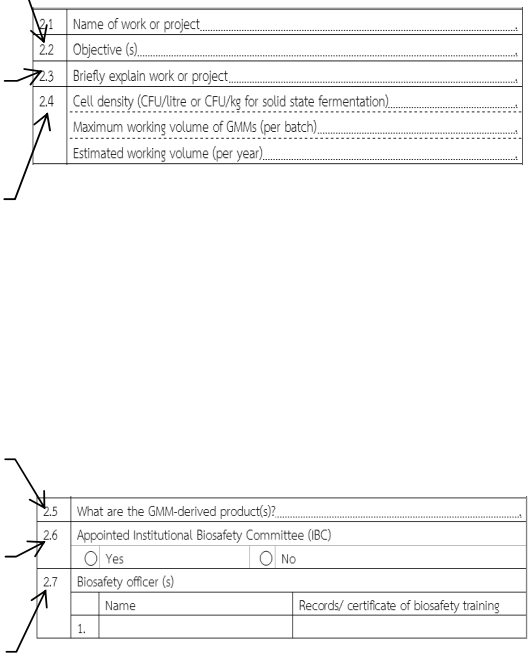
2.3 Describe raw materials, type of GMMs and steps using GMMs. Attach a production flow chart.

2.4 Working volume of GMM
- Cell density of GMM
- For the maximum GMM volume per batch, specify volume per production reactor and CFU/litre
- Total working volume of GMM per year

2.5 List all GMM-derived product(s) and indicate which is the main product.

2.6 Specify the status of the IBC. Attach a copy of the IBC appointment form.

2.7 Identify the biosafety officer or person responsible for biosafety. Attach a copy of a biosafety training record or certificate.



Section III: Risk assessment for classification of work and containment level

3.1.1 Host or recipient cell details, including
- common name, scientific, strain name / source
- pathogenic history
- report or record of industrial use

3.1.2 Vector information, including
- source
- pathogenic history (if any)

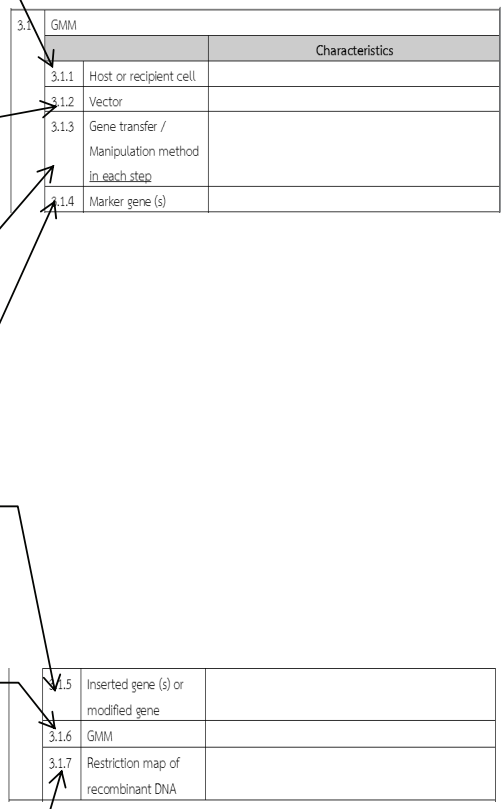
3.1.3 Describe modification methods and the modified genes for all steps of development.

3.1.4 Name of marker genes such as antibiotic resistance genes. For GMMs where marker genes were excised after development, attach evidence to demonstrate that the GMMs are marker free.

3.1.5 Name of inserted or modified genes and details, including
- gene characteristics and expression regulation
- gene source and expression regulation

3.1.6 Name of GMMs and details, including
- product from inserted gene compared with host or recipient
- pathogenicity (for species with no report of pathogenicity, attach supporting document; for strains which may be pathogenic in humans, animals or plants, attach data confirming that the production strain will not be pathogenic in humans, animals or plants, according to Appendix 9).

3.1.7 Restriction map should indicate insert gene ligation site, positions of promoters, terminators, introns, marker gene(s) and modified gene(s), and chromosomal integration site (if any).



3.2 Specify classification of work. Details about each classification can be found in Chapter 3.

3.3 Specify containment level. Details about each level can be found in Chapter 4.

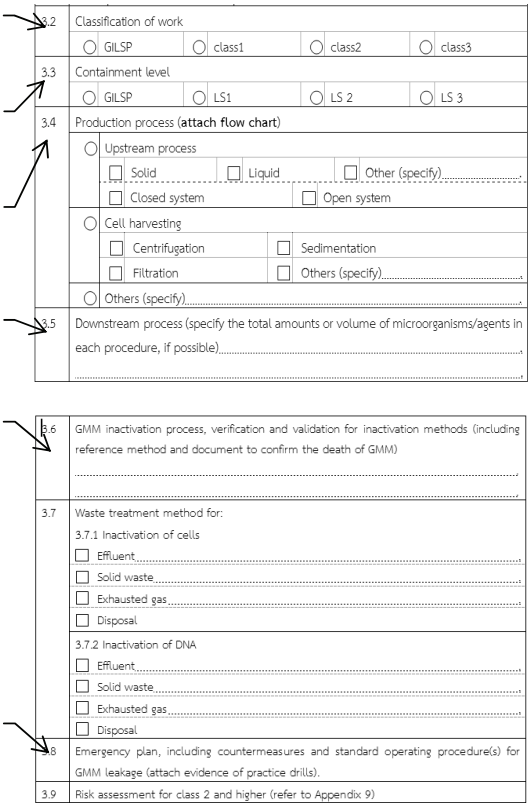
3.4 Specify the GMM production process (more than 1 can be selected). Attach a production process flow chart which related to GMM.

3.5 Specify GMM amounts and volumes. Describe the post-production GMM purification method.

3.6 Describe the post-production GMM inactivation process, including
- GMMs used in production process
- GMMs used at the laboratory level
- instruments and equipment in contact with GMMs

Attach evidence to demonstrate neutralisation of GMMs, such as a graph illustrating the rate of GMM inactivation during neutralisation.

3.8 Describe the emergency plan. Attach a copy of the SOP. SOP information can be found in Chapter 9.



Appendix 9
Criteria for risk assessment of contained use of GMMs at pilot and industrial scales (for class 2 GMMs or higher)

Criteria for risk assessment

Risk assessment of work using GMMs should take into account both the nature of GMMs and the relevant working procedures in order to achieve appropriate levels of containment. Issues to be considered as part of the assessment are:

1. **Formation:** The creation of GMMs, through deliberate or accidental means
2. **Release:** the deliberate or accidental release of GMMs in the workplace and/or into the environment
3. **Proliferation:** reproduction, genetic reconstruction, growth, transport, modification and die-off of GMMs in the environment, including possible transfer of genetic material to other microorganisms/agents
4. **Establishment:** the establishment of GMMs within an ecosystem niche, including possible colonisation of humans or other biota
5. **Effect:** the subsequent occurrence of human or ecological effects due to interaction of the organism with some host or environmental factor

Applicant shall provide a comprehensive description as below, together with the application form for contained use of GMMs at pilot and industrial scales.

9.1 Information related to the GMM

9.1.1 Host or recipient cell

9.1.1.1 General information

a. Common name, scientific and strain name including classification level
b. Nature, characteristics, and guidance for taxonomic identification
c. Reproduction

9.1.1.2 Genetic materials

a. History of prior genetic modification
b. Detection method
c. Factor(s) affecting gene transfer ability and genetic stability

9.1.1.3 Pathogenicity

a. Ability to replicate in humans
b. Pathogenic history
c. Other related information such as associated diseases and virulence factors (route of infection, infective dose, dissemination), antimicrobial-resistance patterns, allergenicity, availability of appropriate therapies and prophylactic measures

9.1.1.4 Survivability in environment, possibility of dissemination or effect on ecosystem, water, air, soil, sand, plants and animals

9.1.1.5 Report or record of industrial application of specified host for GMM work

9.1.2 Vector and inserted DNA or gene

a. Characteristics and history
b. Preparation method of vector, DNA or gene for recombination, sequences of DNA fragment or genes (such as promoters, terminators and introns), and other genetic sequences affecting gene activity
c. Ligation method, orientation of DNA fragment or gene in vector, and gene activity
d. Introduction of DNA fragment or gene and vector into host cell
   - Methods used for DNA introduction and selection of GMM
   - Stability of inserted gene or DNA fragment in host cell
   - Mobilisability of vector and recombinant DNA or potential for transmission of inserted DNA or gene

9.1.3 GMMs

9.1.3.1 Expression of inserted DNA or gene

a. Gene expression
b. Gene product and production rate via the expression of inserted DNA or gene, including reliable measurement methods

9.1.3.2 Comparison of characteristics with host or recipient cell

a. Conditions of survivability and replication
b. Possibility of replication in humans *(ex vivo)* and in the environment (under laboratory conditions)
c. Pathogenicity

d. Other related information such as associated diseases and virulence factors (route of infection, infective dose, dissemination), antimicrobial-resistance patterns, allergenicity, availability of appropriate therapies and prophylactic measures

e. Characteristics which can be changed to cause disease in the case of phage vector use

9.1.3.3 Survivability in environment, if any, the possibility of dissemination, and effect on ecosystem, water, air, soil, sand, plants and animals

9.2 Information related to the work

9.2.1 Biomass and the level of product per unit volume (both per batch and per year)

9.2.2 Conditions of GMM cultivation

9.2.3 Isolation and purification processes and amount of product

9.2.4 Facility design (for contained GMMs)

9.2.5 Waste management (refer to Chapter 8)

Appendix 10
Autoclave parameters for waste treatment

Autoclaving is an example of the heat inactivation method. A range of autoclave cycle parameters are suitable for inactivating microorganisms/agents and a typical cycle would be 121 °C, maintained for 15 minutes. This holding time is required for all parts of the load to reach and remain at the desired temperature. The minimum recommended values for inactivating microorganisms/agents and waste decontamination cycles are shown in Table A10.1.

Table A10.1 Minimum recommended values for inactivating microorganisms/agents and waste decontamination cycles (applied from laboratory scale) by autoclave

Temperature (˚C)	Pressure (bars)	Contact time (minutes)
121	1.15	15
126	1.5	10
134	2.25	3

Appendix 11
Sample incident reporting form

Section I: General information	
1.1	Name of organizations/institutions/private sector ....
1.2	Date of report .....
1.3	Name of reporter..... Address ..... Position ..... Telephone ..... Fax ..... E-mail .....

Section II: Incident report	
2.1	Date of incident .....
2.2	Name of principal investigator/project manager ..... Address ..... Position ..... Telephone ..... Fax ..... E-mail .....
2.3	What was the **nature** of the incident? ○ Personnel exposure ○ Failure to obtain IBC approval ○ Spillage ○ Failure to follow approved containment ○ Loss of containment conditions ○ Others (specify) .....
2.4	Did the Institutional Biosafety Committee (IBC) approve this project? ○ Yes ○ No If yes, please provide : Approval date ..... Approved biosafety level(s) for the project ..... Additional approval requirements .....
2.5	Description of recombinant or synthetic agent or material involved (please indicate strain, attenuation, etc., as relevant) ....

2.6	Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.** • Incident/violation location (e.g. laboratory, vivarium, non-laboratory space) • Personnel involved in the incident/violation, including others present at the incident location; **note: please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)** • Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event • The training received by the individual(s) involved and the date(s) the training was conducted • Institutional or laboratory standard operating procedures (SOPs) for work and whether there was any deviation from these SOPs at the time of the incident/violation • Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation • The personal protective equipment in use at the time of the incident/violation • The occupational health requirements for laboratory personnel involved in the research • Any medical advice/treatment/surveillance provided or recommended after the incident • Any injury or illness associated with the incident • Medical surveillance results (if not available at the time of initial report, please indicate when results will be available) • Equipment failure **Description of incident** (use additional space as necessary): …… …… …… …… ……

2.7 Has the IBC reviewed this incident?

- ○ Yes (please provide a copy the minutes of the IBC meeting in which the incident was reviewed)
- ○ No

2.8 Has a root cause for this incident been identified?

- ○ Yes (please describe) .....
- ○ No

2.9 Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

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Appendix 12
Lists of related laws, regulations and ministry notifications

1. Pathogens and Animal Toxins Act B.E. 2525
2. Pathogens and Animal Toxins Act (No.2) B.E. 2544
3. Ministerial Regulation of the Ministry of Public Health re: Specification of criteria, procedures and conditions for granting permission and permit to manufacture, possess, distribute, import or bring in-transit of pathogens and animal toxins B.E. 2552
4. Ministerial Regulation of the Ministry of Public Health re: Specification on the implementation of the exemption to manufacture, possess, distribute, import or bring in-transit of pathogens and animal toxins B.E. 2552
5. Plant Quarantine Act B.E. 2507
6. Plant Quarantine Act (No.2) B.E. 2542
7. Plant Quarantine Act (No.3) B.E. 2551
8. Notification of the Ministry of Agriculture and Cooperatives re: Specification of plants and carriers from certain sources as prohibited articles, of exceptions and conditions under the Plant Quarantine Act B.E. 2507 (No.5) B.E. 2550
9. Notification of the Ministry of Agriculture and Cooperatives re: Specification of plant pests as prohibited articles under the Plant Quarantine Act B.E. 2507 (No.6 and 7) B.E. 2550
10. Notification of the Department of Agriculture re: Criteria, procedures and conditions for the importation or bringing in-transit of prohibited, restricted and unprohibited articles B.E. 2551
11. Hazardous Substance Act B.E. 2535
12. Hazardous Substance Act. (No.2) B.E. 2544
13. Hazardous Substance Act. (No.3) B.E. 2551
14. Notification of the Ministry of Industry on Land Transportation of Hazardous Substance B.E. 2546, issued under the Hazardous Substance Act. B.E. 2535
15. Factory Act B.E. 2535
16. Notification of the Ministry of Industry No.2, B.E. 2539, issued under the Factory Act B.E. 2535, re: Industrial Effluent standards
17. Notification of the Ministry of Industry re: Disposal of wastes or unusable materials B.E. 2548
18. Regulation of the Office of the Prime Minister on Records Keeping B.E. 2526, Chapter 3 Document storage, lending and destruction

Appendix 13
Examples of infectious substances classified as Category A

The table provided below is an indicative list taken from the 17th edition of the United Nations Model Regulations. In this table, the names in italics indicate bacteria, mycoplasmas, rickettsiae or fungi.

UN Number and Proper Shipping Name	Microorganism
UN 2814 Infectious substance, affecting humans	*Bacillus anthracis* (cultures only)
	Brucella abortus (cultures only)
	Brucella melitensis (cultures only)
	Brucella suis (cultures only)
	Burkholderia mallei (Pseudomonas mallei) glanders (cultures only)
	Burkholderia pseudomallei–Pseudomonas pseudomallei (cultures only)
	Chlamydia psittaci - avian strains (cultures only)
	Clostridium botulinum (cultures only)
	Coccidioides immitis (cultures only)
	Coxiella burnetii (cultures only)
	Crimean-Congo haemorrhagic fever virus
	Dengue virus (cultures only)
	Eastern equine encephalitis virus (cultures only)
	Escherichia coli, verotoxigenic (cultures only)
	Ebola virus
	Flexal virus
	Francisella tularensis (cultures only)
	Guanarito virus
	Hantaan virus
	Hantaviruses causing haemorrhagic fever with renal syndrome
	Hendra virus
	Hepatitis B virus (cultures only)
	Herpes B virus (cultures only)
	Human immunodeficiency virus (cultures only)
	Highly pathogenic avian influenza virus (cultures only)
	Japanese Encephalitis virus (cultures only)
	Junin virus
	Kyasanur Forest disease virus
	Lassa virus
	Machupo virus

UN Number and Proper Shipping Name	Microorganism
	Marburg virus
	Monkeypox virus
	Mycobacterium tuberculosis (cultures only)
	Nipah virus
	Omsk haemorrhagic fever virus
	Poliovirus (cultures only)
	Rabies virus (cultures only)
	Rickettsia prowazekii (cultures only)
	Rickettsia rickettsii (cultures only)
	Rift Valley fever virus (cultures only)
	Russian spring-summer encephalitis virus (cultures only)
	Sabia virus
	Shigella dysenteriae type 1 (cultures only)
	Tick-borne encephalitis virus (cultures only)
	Variola virus
	Venezuelan equine encephalitis virus (cultures only)
	West Nile virus (cultures only)
	Yellow fever virus (cultures only)
	Yersinia pestis (cultures only)
UN 2900 Infectious substance, affecting animals only	African swine fever virus (cultures only)
	Avian paramyxovirus type 1 - Velogenic Newcastle disease virus (cultures only)
	Classical swine fever virus (cultures only)
	Foot and mouth disease virus (cultures only)
	Lumpy skin disease virus (cultures only)
	Mycoplasma mycoides - contagious bovine pleuropneumonia (cultures only)
	Peste des petits ruminants virus (cultures only)
	Rinderpest virus (cultures only)
	Sheep-pox virus (cultures only)
	Goatpox virus (cultures only)
	Swine vesicular disease virus (cultures only)
	Vesicular stomatitis virus (cultures only)

Remark: When the cultures are intended for diagnostic or clinical purposes, they may be classified as infectious substances of Category B for surface transport.

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