

Discussion on Biosafety and Biosecurity provisions Import, Export, Transit controls

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BIOSAFETY AND BIOSECURITY

Biosafety - Measures to help prevent unintentional exposure or accidental release of pathogens

Biosecurity - Measures to help prevent unauthorized access, loss, theft, misuse, diversion or intentional release of pathogens

- Controlled (or select) agent lists
- Establishing a licensing system
- Notification of loss, theft or release
- Comprehensive record-keeping
- Biosafety and biosecurity compliance
- Secure transportation

Controlled (or select) agent lists (Sec.9)

Option 1

(1) The National Authority shall establish and maintain a list of biological agents and toxins that pose a severe threat to public health and safety and national security, based on the following criteria –

- (a) effect of exposure on human, animal, or plant health, or on animal or plant products;
- (b) degree of contagiousness and method of transmission;
- (c) availability and effectiveness of pharmacotherapies and immunisations; and
- (d) other criteria deemed appropriate, if any, provided that the National Authority shall publicly disclose and explain the use of any such criteria.

(2) The controlled agents and toxins list shall be included in the regulations, and shall be periodically reviewed and modified as necessary by the National Authority.

Controlled (or select) agent lists (Sec.9)

Option 2

The National Authority shall establish and maintain a list of biological agents and toxins, based on the World Health Organization's classification of infective micro-organisms by risk group. This list, and the guidelines used to establish it, shall be included in the regulations, and shall be periodically reviewed and modified as necessary by the National Authority.

Laboratory Biosafety Manual (Third Edition), World Health Organization, 2004. The guidelines are:

Risk Group 1 (no or low individual and community risk): A micro-organism that is unlikely to cause human or animal disease.

Risk Group 2 (moderate individual risk, low community risk): A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.

Risk Group 3 (high individual risk, low community risk): A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.

Risk Group 4 (high individual and community risk): A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.

Establishing a licensing system (Sec.11)

Licensing

- (1) Every individual or entity that develops, acquires, manufactures, possesses, stores, transports, transfers or uses controlled agents or toxins shall be in possession of a license from the National Authority. The regulations shall require that individuals and entities obtaining a license have a lawful purpose to develop, acquire, manufacture, possess, store, transport, transfer or use such controlled agents or toxins.
- (2) A license granted shall list each controlled agent or toxin that an individual or entity is authorised to develop, acquire, manufacture, possess, store, transport, transfer or use.
- (3) The regulations shall provide for revocation of a license by the National Authority in appropriate cases, including any violation of the law.
- (4) A license shall not be granted by the National Authority to those prohibited individuals and entities listed in the regulations.

Exemptions from urgent licensing

An exemption from a license shall only be granted by the National Authority for public health or agricultural emergencies, evidentiary purposes, or for products licensed under food, drug, cosmetics, insecticide or similar laws.

Notification of loss, theft or release (Sec.11.11)

Individuals and entities licensed shall immediately notify the national authority, the law enforcement agency and the Biological Emergency Response and Investigation Support System (BERISS) of the theft, loss or release of controlled agents or toxins. Licensed entities may establish procedures for the notification of theft, loss or release by their notified facilities.

Comprehensive record-keeping (Sec.11.10)

The National Authority shall maintain an accurate and current record of all licensed individuals and entities and notified facilities, including the names and locations of the licensed individuals and entities and notified facilities, and information on the controlled agents or toxins each individual or entity is licensed to develop, acquire, manufacture, possess, store, transport, transfer or use.

Biosafety and biosecurity compliance (Sec.11.9)

(1) Every entity seeking a license shall, as a condition of approval, confirm that its notified facilities comply with the biosecurity regulations, to prevent access to controlled agents or toxins by unlicensed individuals. The regulations shall specify physical protection measures, including physical and personnel security plans, for facilities where controlled agents or toxins are developed, acquired, manufactured, possessed, stored, transported, transferred or used. The regulations shall require personnel security background checks to ensure the reliability of individuals working in facilities where controlled agents or toxins are developed, acquired, manufactured, possessed, stored, transported, transferred or used. Requirements for physical and personnel security shall be commensurate with the risk the controlled agents and toxins pose to public health and safety.

(2) Every entity seeking a license shall also, as a condition of approval, confirm that its notified facilities comply with the biosafety regulations, to prevent unintentional exposure to controlled agents and toxins, or their accidental release.

Secure transportation (Sec.14)

Transfers by approved carriers only

Internal and international transfers of controlled agents and toxins shall only be undertaken by carriers approved by Ministry of Transportation or the National Authority.

Approved carriers

The Ministry of Transportation or the National Authority shall maintain a roster of carriers approved to transport controlled agents and toxins internally and internationally. The roster shall only include those carriers that have demonstrated that they comply with best practices for packaging and labelling; shipment tracking; and safety and security measures for their personnel, vehicles and facilities.

Transport guidelines

Internal and international transportation of controlled agents and toxins shall be conducted in accordance with the hazardous material transport guidelines and packaging and labelling requirements issued by the Ministry of Transportation and any regulations issued by the National Authority. Every carrier that imports, exports, re-exports, tranships or transits controlled agents or toxins through the national territory shall also comply with all applicable international regulations for the shipment of hazardous materials.

IMPORT, EXPORT, TRANSFER, TRANSIT AND TRANSHIPMENT CONTROLS

- Internal controls through permits
- International transfer controls through permits
- End-use certificates
- Customs/border controls and checks of documentation and detection equipment

Internal transfer controls through permits (Sec.12)

Controlled agents and toxins shall only be transferred within the national territory among individuals and entities (and their notified facilities) licensed.

All proposed transfers of controlled agents or toxins within the national territory are subject to advance notification to the National Authority .

Regulations issued by the National Authority shall specify additional technical and security requirements for transfer, including measures to track controlled agents and toxins and to confirm receipt of the transfer by the transferee, such that strict accountability for controlled agents and toxins is maintained at all times.

International transfer controls through permits (Sec.13)

Import, export, re-export, and transshipment

(1) Every individual or entity that imports, exports, re-exports, or transships any controlled agent or toxin or controlled equipment or technology through the national territory shall be in possession of a permit from the National Authority or the National Import/Export Control Authority.

(2) The National Authority or the National Import/Export Control Authority shall issue regulations establishing the requirements and procedures to obtain a transfers permit for controlled agents or toxins or controlled equipment or technology.

(3) If the National Authority has reason to believe or suspect that an imported, exported, re-exported, or transhipped non-controlled agent or toxin or non-controlled equipment or technology might be used for purposes prohibited, the National Authority may obtain an injunction from appropriate judicial authorities to prevent the import, export, re-export, or transshipment.

International transfer controls through permits

Export procedures

The National Authority or the National Import/Export Control Authority shall adopt procedures to ensure that controlled agents or toxins or controlled equipment or technology are only exported to individuals, entities or facilities in another State that are similarly regulated in respect of controlled agents or toxins or controlled equipment or technology.

Transit

The National Authority or the National Import/Export Control Authority shall issue regulations establishing the requirements and procedures for the transit of controlled agents or toxins or controlled equipment or technology through the national territory.

End-use certificates (Sec.13.5)

The procedures for international transfers shall include a requirement for an end-use certificate which shall contain, at a minimum –

- (a) A statement that the controlled agent or toxin or controlled equipment or technology will only be used for lawful purposes;
- (b) A statement that the controlled agent or toxin or controlled equipment or technology will not be retransferred;
- (c) The type and quantity of controlled agent or toxin, or a description of the controlled equipment or technology, to be transferred;
- (d) The end-use of the controlled agent or toxin or controlled equipment or technology to be transferred; and
- (e) The name(s) and location(s) of the end-user(s) and any intermediaries.

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