



2 July 2019

Dear all,

ADVISORY TO FACILITIES THAT IMPORT BIOLOGICAL AGENTS AND/OR TOXINS INCLUDING PROFICIENCY TESTING MATERIALS

In recent months, the Ministry of Health (MOH) has come to know of several incidents related to the importation of proficiency testing (PT) materials, some of which resulted in the importation of such materials without import permit.

2 We would like to take this opportunity to share with all facilities importing biological agents and/or toxins the lessons learnt from these incidents. The following are two examples of the incidents, the key issues and the corrective actions introduced by the affected facilities to prevent recurrence of such incidents.

Summary of Events	Key Issues and Preventive Actions
<p><u>Incident #1</u></p> <p>Laboratories A and B are part of a department with multiple laboratories. Both laboratories A and B subscribed to new PT programmes but forgot to apply for Import Specific Product (ISP) codes for the PT materials. The laboratories failed to inform the PT provider and the declaring agent of the need to apply for import permits and also failed to verify that valid import permits had been secured prior to receiving the imported shipments of PT materials.</p>	<p><u>Key Issues</u></p> <p>A series of lapses by the laboratories, i.e.</p> <ul style="list-style-type: none"> (a) Overlooked the need to apply for ISP code when subscribing to new PT programme; (b) Did not advise PT provider and declaring agent of the need for import permit; and (c) Did not verify that import permit declaration was correctly secured for each shipment. <p><u>Corrective Actions</u></p> <p>Improved the oversight and procedures for procurement and importation of PT materials by:</p> <ul style="list-style-type: none"> a) Including in the department’s manual, standard procedures (SOPs) for application of ISP code and verification that import permit is correctly secured for each imported shipment; and b) Introducing a second layer check to ensure the above SOPs are followed by establishing a departmental-wide register for PT subscriptions, which is overseen by the departmental Quality Team.



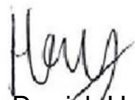
Summary of Events	Key Issues and Preventive Actions
<p><u>Incident #2</u></p> <p>Laboratory C received an unexpected delivery of PT materials from overseas. The laboratory had not been informed by the PT provider to expect shipment delivery. Upon receipt of the shipment, the laboratory discovered that import permit had not been secured for the shipment.</p>	<p><u>Key Issue</u> Lack of proper communication between exporter and importer.</p> <p><u>Corrective Actions</u> a) Reminded the PT provider of regulations governing importation of PT materials into Singapore; and b) Request to be notified in advance for future PT shipments.</p>

3 Please be reminded that:

- a) Under the Biological Agents and Toxins Act (BATA), it is the responsibility of the importer to ensure that import permit is secured for each imported shipment containing biological agents and/or Fifth Schedule toxins, including PT materials. Depending on the biological agent and/or toxin being imported, a contravention of this BATA requirement carries a fine not exceeding \$100,000 and/or an imprisonment term not exceeding 10 years;
- b) The import permit must be applied via the Singapore Customs TradeNet portal. For the importation of PT materials, importers are reminded to obtain ISP codes upon subscription of new PT panels and to use the correct ISP codes for import permit application;
- c) Importers shall request that the exporter (sender) provide advance notice prior to sending shipment(s) of biological agents and/or toxins. This will allow the importer to facilitate and oversee the application for import permit. Importers are encouraged to inform the exporters (senders) of regulatory requirements related to the importation of biological agents and/or toxins into Singapore;
- d) Prior to the importation of any biological agent and/or toxin, where the application for import permit is submitted through a third party agent, the importer shall:
 - i. Advise the declaring agent that import permit is required;
 - ii. Provide relevant information e.g. item description, HS code, ISP code, MOH product code (and Animal and Veterinary Service product code, where applicable) and supporting documents to the declaring agent; and
 - iii. Obtain a copy of the import permit from the declaring agent to verify the accuracy of the declaration submitted for each shipment. Inaccuracies in declaration shall be promptly reported to the relevant controlling authorities.

4 In cases where the choice of the declaring agent was pre-determined by the exporter (sender) and issues related to import permit applications were encountered, e.g. wrong submission, delay in submission, the importer is advised to actively provide feedback to the exporter (sender) about these issues so as to work out an arrangement to prevent recurrence.

5 For clarifications, please contact our officers from MOH Biosafety Branch at [MOH Biosafety@moh.gov.sg](mailto:MOH_Biosafety@moh.gov.sg).

A handwritten signature in black ink, appearing to read 'Heng', written in a cursive style.

Dr Derrick Heng
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