

**Sample Form for Prescribed Document Accompanying
GMOs Intended for Release into Environment**

(Specified forms for documentation are not mandatory. Any documents, such as commercial invoices or import/export manifests, which contain the required information, could satisfy the documentation requirements under the Regulation)

This shipment contains a GMO that is intended for release into environment.

<u>Exporter</u>	<u>Importer</u>
Name: ABC Company Ltd. Address: 12345 ABC Road Cambridge, MA USA Phone: (314) 987-6543	Name: XYZ Company Ltd. Address: 98765 XYZ Road, Sham Shui Po, Hong Kong Phone: (852) 1233-4567

**Person who can provide information relating to the safe handling, storage, transport
or use of the GMO in case of emergency**

Name: Professor David Chan
Address: Equine Protection Laboratory, XYZ University, Iowa, USA
Phone: (210) 123-4567

Identity of the GMO

Common name: Equine strangles vaccine
Scientific name: *Streptococcus equi*
Commercial name^{Note 1}: Equilis StrepE
Approval granted under the Genetically Modified Organisms (Control of Release)
Ordinance^{Note 2}: 20110301-1
Condition attached to the approval^{Note 3}: The GM horse vaccines shall only be administered
by a registered veterinary surgeon.

Traits and Characteristics of the GMO

Transformation event code: TW928
Unique identifier code^{Note 4}: -
Risk class^{Note 5}: EEC Class 1 (according to EU Guideline 2000/54/EC)

Safety Requirements Applicable to the GMO

(a) Applicable existing international instrument^{Note 6}:

UN Recommendations on the Transport of Dangerous Goods - Model Regulations - Sixteenth Revised Edition

Provision 2.9.2 Assignment to Class 9: GMMOs or GMOs which do not meet the definition of toxic substances or infectious substances shall be assigned to UN 3245.

Provision 4.1.4.1 (P904 - Packing Instruction Applicable for UN3245):

The following packagings are authorized:

- (1) Packagings meeting the provisions of 4.1.1.1, 4.1.1.2, 4.1.1.4, 4.1.1.8 and 4.1.3 and so designed that they meet the construction requirements of 6.1.4. Outer packagings constructed of suitable material of adequate strength and designed in relation to the packaging capacity and its intended use shall be used. Where this packing instruction is used for the transport of inner packagings of combination packagings, the packaging shall be designed and constructed to prevent inadvertent discharge during normal conditions of transport.
- (2) Packagings, which need not conform to the packaging test requirements of Part 6, but conforming to the following:
 - (a) An inner packaging comprising:
 - (i) primary receptacle(s) and a secondary packaging, the primary receptacle(s) or the secondary packaging shall be leak-proof for liquids or sift-proof for solids;
 - (ii) for liquids, absorbent material placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in a quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging;
 - (iii) if multiple fragile primary receptacles are placed in a single secondary packaging they shall be individually wrapped or separated to prevent contact between them;
 - (b) An outer packaging which shall be strong enough for its capacity, mass and intended use, and with a smallest external dimension of at least 100 mm.

The GM vaccine is packaged in accordance with the requirements laid down by the UN Recommendations on the Transport of Dangerous Goods above.

(b) Ordinance^{Note 6}:

The Hong Kong Legislation Chapter 138A Pharmacy and Poisons Regulations Section

36(1) states that:

No person shall sell, offer for sale or distribute or possess for the purposes of sale, distribution or other use any pharmaceutical product or substance unless the product or substance is registered with the Board-

- (a) by the manufacturer, if the pharmaceutical product or substance is manufactured in Hong Kong;
- (b) by the importer, if the pharmaceutical product or substance is manufactured outside Hong Kong; or
- (c) by the local branch, subsidiary, representative, agent or distributor of a manufacturer outside Hong Kong.

A copy of the certificate of registration for the GM vaccine issued by the Pharmacy and Poisons Regulations is attached.

(c) Agreement entered into by the importer and exporter of the GMO:

Nil.

Declaration

The transboundary movement of the GMO is in conformity with the requirements of the Cartagena Protocol on Biosafety that are applicable to the exporter.

Signature of the Exporter

Date

Note:

- 1 This information is not required if the GMO's commercial name is not available.
- 2 This information should be provided if the GMO has been approved for release into the environment under section 10 of the Genetically Modified Organisms (Control of Release) Ordinance.
- 3 This information is not required if there is no condition attached to the approval.
- 4 This information is not required if the GMO's unique identifier code is not available.
- 5 This information is not required if the GMO's risk class is not available.
- 6 If there is no such requirement, then provide a statement to that effect.
"safety requirement", in relation to a GMO imported into or exported from Hong Kong, means any requirement for the safe handling, storage, transport or use of the GMO under—
 - (a) any applicable existing international instrument;
 - (b) any Ordinance; or
 - (c) any agreement entered into by the importer and exporter of the GMO.