

食品安全檢驗與動植物防疫檢疫措施協定叢書（十一）

# 外來生物防治物輸入及 釋放行爲守則

國際植物防疫檢疫措施標準第三號，一九九六年

## CODE OF CONDUCT FOR THE IMPORT AND RELEASE OF EXOTIC BIOLOGICAL CONTROL AGENTS

INTERNATIONAL STANDARDS FOR  
PHYTOSANITARY MEASURES  
(ISPM Pub. No.3, 1996)

農委會動植物防疫檢疫局 印行

# 序

食品安全檢驗與動植物防疫檢疫 (Sanitary and Phytosanitary, SPS) 是國際間通行的重要措施，目的在避免或減少因農產品貿易流通而導致外來動植物疫病蟲害之入侵、立足或蔓延，及防範食品、飲料或飼料中之添加物、污染物等的潛在風險，以保護境內國民及動植物的生命或健康，及維護自然生態環境。

為避免 SPS 措施對國際農產品貿易造成限制性的影響，世界貿易組織 (WTO) 在商品貿易理事會下設有「食品安全檢驗與動植物防疫檢疫措施委員會」，依據「食品安全檢驗與動植物防疫檢疫措施協定」鼓勵會員採用包括國際食品標準委員會 (Codex)、世界動物衛生組織 (OIE) 及國際植物保護公約 (IPPC) 等三個國際組織所制訂之國際標準、準則或建議，以達到調和措施減少非關稅貿易障礙之目標。

本局為使我國政府機關、相關機構、產學各界及全國的農友瞭解此一重要協定及相關國際規範，特規劃出版中文譯本之「食品安全檢驗與動植物防疫檢疫措施協定叢書」，繼九十年十二月出版「食品安全檢驗與動植物防疫檢疫措施協定」及「國際植物保護公約」二單行本後，接續出版國際植物保護公約秘書處編定

之「國際植物防疫檢疫措施標準」系列（International Standards for Phytosanitary Measures，ISPM），期使相關人員充分認識植物防疫檢疫措施之國際標準，俾運用有利之協定條文及國際標準，維護國內之農業生產安全，並在與貿易對手國家諮商中保障我國應有的權益。

出版本叢書系列由本局同仁策劃編譯工作，並邀請國立台灣大學昆蟲系教授陳秋男及相關領域專家參與譯稿作業。舉凡名詞翻譯、文句潤飾、譯詞統一及語氣之流暢等，均係參與人員字斟句酌、集思廣益的成果，而叢書之設計與編印，亦蒙相關人員之辛勤付出，始得出版問世，在此一併致謝。

本局施政目標之一為建立符合國際規範之動植物防疫檢疫及農產品衛生安全之檢驗體系，本叢書之出版，期能增進與提昇相關工作之效能及水準，促進目標之達成。

農委會動植物防疫檢疫局 局長

江益男 謹誌

二〇〇三年十月

# CONTENT

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<i>Endorsement</i> .....	6
<i>Review and amendment</i> .....	8
<i>Distribution</i> .....	10

## **INTRODUCTION**

SCOPE.....	12
REFERENCES.....	12
DEFINITIONS AND ABBREVIATIONS.....	18
OUTLINE OF THE CODE.....	30

## **CODE OF CONDUCT FOR THE IMPORT AND RELEASE OF EXOTIC BIOLOGICAL CONTROL AGENTS**

1. Objectives of the Code.....	34
2. Designation of authority responsible.....	38
3. Responsibilities of authorities prior to import.....	40
4. Responsibilities of importer prior to import .....	50
5. Responsibilities of exporter prior to export.....	54
6. Responsibilities of authorities upon import.....	60
7. Responsibilities of authorities before and upon release.....	62
8. Responsibilities of importer after import and release.....	64
9. Observance of the Code.....	66

# 目錄

批准 .....	7
審查及修訂.....	9
分發.....	11

## 序言

範圍.....	13
參考文獻.....	13
定義及縮寫.....	19
守則綱要.....	31

## 外來生物防治物輸入及釋放行爲守則

1. 守則宗旨.....	35
2. 主管當局之指定.....	39
3. 輸入前主管當局之責任.....	41
4. 輸入前輸入者之責任 .....	51
5. 輸出前輸出者之責任.....	55
6. 輸入時主管當局之責任.....	61
7. 釋放前及釋放時主管當局之責任.....	63
8. 輸入及釋放後輸入者之責任.....	65
9. 守則之遵守.....	67

## *Endorsement*

International standards for phytosanitary measures are prepared by the Secretariat of the International Plant Protection Convention as part of the United Nations Food and Agriculture Organization's global programme of policy and technical assistance in plant quarantine. This programme makes available to FAO Members and other interested parties these standards, guidelines and recommendations to achieve international harmonization of phytosanitary measures, with the aim to facilitate trade and avoid the use of unjustifiable measures as barriers to trade.

The following standard was endorsed by the 28th Session of the FAO Conference in November 1995.

Jacques Diouf  
Director-General  
Food and Agriculture Organization of the United Nations

## 批准

國際植物防疫檢疫措施標準為國際植物保護公約秘書處所編定，作為聯合國糧農組織的全球性植物防疫檢疫政策及技術協助計畫之一部份。該計畫提供糧農組織會員及其他有關團體這些標準、準則及建議，以達到植物防疫檢疫措施的國際調和，俾促進貿易及避免採用無理措施作為貿易障礙。

本標準業於1995年11月經糧農組織大會第二十八屆會議批准。

Jacques Diouf

秘書長

聯合國糧農組織

## *Review and amendment*

International standards for phytosanitary measures are subject to periodic review and amendment. The next review date for this standard is 2001, or such other date as may be agreed upon by the Commission on Phytosanitary Measures.

Standards will be updated and republished as necessary. Standard holders should ensure that the current edition of this standard is being used.



## 審查及修訂

國際植物防疫檢疫措施標準接受定期審查及修訂。本標準下次審查日期為 2001 年或經由植物防疫檢疫措施委員會同意之其他日期。本標準於必要時將予更新及再版。本標準之持有者應確定係使用標準的現行版本。

## *Distribution*

International standards for phytosanitary measures are distributed by the Secretariat of the International Plant Protection Convention to all FAO Members, plus the Executive/Technical Secretariats of the Regional Plant Protection Organizations:

- Asia and Pacific Plant Protection Commission
- Caribbean Plant Protection Commission
- Comité Regional de Sanidad Vegetal para el Cono Sur
- Comunidad Andina
- European and Mediterranean Plant Protection Organization
- InterAfrican Phytosanitary Council
- North American Plant Protection Organization
- Organismo Internacional Regional de Sanidad Agropecuaria
- Pacific Plant Protection Organization.

## 分發

國際植物防疫檢疫措施標準由國際植物保護公約秘書處分發給糧農組織所有成員，及下列區域性植物保護組織的執行/技術秘書處：

- 亞洲及太平洋區域植物保護委員會
- 加勒比海地區植物保護委員會
- 南錐體區域植物保護委員會
- 安第斯共同體
- 歐洲及地中海區域植物保護組織
- 非洲植物檢疫理事會
- 北美洲植物保護組織
- 區域國際農業衛生組織
- 太平洋植物保護組織

# INTRODUCTION

## *Scope*

This standard describes the Code of Conduct for the Import and Release of Exotic Biological Control Agents. It lists the responsibilities of the authorities of governments, and the responsibilities of the exporters and importers of biological control agents.

The Code addresses the importation of exotic biological control agents capable of selfreplication (parasitoids, predators, parasites, phytophagous arthropods and pathogens) for research and/or release into the environment including those packaged or formulated as commercial products.

Governments that are already fulfilling the objectives of this Code by regulation or other equivalent means may consider adapting their existing systems in the light of this Code.

## *References*

- Anon, 1988. New organisms in New Zealand. Procedures and legislation for the importation of new organisms into New Zealand and the development, field testing and release of genetically modified organisms. A discussion document. Ministry for the Environment, Wellington, New Zealand, 59 p.

# 序言

## 範圍

本標準說明外來生物防治物輸入及釋放行為守則，其內容列出政府主管當局之責任及生物防治物輸出者與輸入者之責任。

本守則針對能自行複製之外來生物防治物（類寄生昆蟲、捕食性天敵、寄生生物、植食性節肢動物及病原）供作為研究及/或田間釋放用之輸入，包括包裝或配製之商業產品。

若政府業已訂定符合本守則目的之相關法規或其他同等措施，則可考慮依照本守則修訂其既有體制。

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- EEC, 1991. Official Journal of the European Communities: Council Directive of 15 July 1991.
- *Glossary of phytosanitary terms*, 1997. ISPM Pub. No. 5, FAO, Rome.<sup>1</sup>
- *Guidelines for pest risk analysis*, 1996. ISPM Pub. No. 2, FAO, Rome.
- *Guidelines on the registration of biological pest control agents*, 1988. FAO, Rome.
- *International code of conduct on the distribution and use of pesticides (Amended version)*, 1990. FAO, Rome.
- *International Plant Protection Convention*, 1992. FAO, Rome.
- Laird, M., Lacey, L.A. & Davidson, E.W. (eds.), 1990. *Safety of microbial insecticides*. CRC Press, Boca Raton, Florida, 259 p.
- Leppla, N.C. & Ashley, T.R. 1978. *Facilities for insect research and production*. USDA Technical Bulletin, No. 1576, 86 p.

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<sup>1</sup> The terms and definitions published in 1996 in this standard conform to this edition of the *lossary of phytosanitary terms*.

- Coulson, J.R. & Soper, R.S., 1989. Protocols for the introduction of biological control agents in the U.S. pp. 1-35. *In Plant Protection and Quarantine vol III, Special Topics*. R.P. Kahn (ed.), CRC Press, Boca Raton, Florida.
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- WHO, 1981. Mammalian safety of microbial agents for vector control: a WHO memorandum. *Bulletin of the World Health Organization*, 59: 857-863.



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- WHO, 1981. Mammalian safety of microbial agents for vector control: a WHO memorandum. *Bulletin of the World Health Organization*, 59: 857-863.

## *Definitions and abbreviations*

<b>Antagonist</b>	An organism (usually pathogen) which does no significant damage to the host but its colonization of the host protects the host from significant subsequent damage by a pest.
<b>Area</b>	An officially defined country, part of a country or all or parts of several countries.
<b>Authority</b>	The National Plant Protection Organization, or other entity or person officially designated by the government to deal with matters arising from the responsibilities set forth in the Code.
<b>Biological control</b> (Biocontrol)	Pest control strategy making use of living natural enemies, antagonists or competitors and other self-replicating biotic entities.
<b>Biological control agent</b>	A natural enemy, antagonist or competitor, and other self-replicating biotic entity, used for pest control.

## 定義和縮寫

- 拮抗生物** 對其寄主不造成顯著損害，但當其在寄主上殖居則可保護其寄主免於隨後遭受某一有害生物顯著損害之生物體（通常為病原）。
- 地區** 官方界定的一個國家的全部、一個國家的部分或數個國家之全部或部分。
- 當局** 政府正式指定負責處理本守則規定責任所產生事項之國家植物保護機關或其他機構或人員。
- 生物防治** 利用活的天敵、拮抗生物或競爭性生物及可自行複製的生物體之有害生物防治的策略。
- 生物防治物** 用於防治有害生物之天敵、拮抗生物或競爭性生物，及其他可自行複製的生物體。

<b>Biological pesticide</b> (Biopesticide)	A generic term, not specifically definable, but generally applied to a biological control agent, usually a pathogen, formulated and applied in a manner similar to a chemical pesticide, and normally used for the rapid reduction of a pest population for short-term pest control.
<b>Classical biological control</b>	The intentional introduction and permanent establishment of an exotic biological agent for longterm pest control.
<b>Competitor</b>	An organism which competes with pests for essential elements (e.g. food, shelter) in the environment.
<b>Ecoarea</b>	An area with similar fauna, flora and climate and hence similar concerns about the introduction of biological control agents.
<b>Ecosystem</b>	A complex of organisms and their environment, interacting as a defined ecological unit (natural or modified by human activity, e.g. agroecosystem), irrespective of political boundaries.

- 生物農藥** 一無特定定義之普通用語，但一般指一生物防治物，通常為病原，其配製與使用方式類似一化學農藥，且通常用於短期性之有害生物防治，以快速降低有害生物族群。
- 古典生物防治** 刻意引進某種外來生物體，並使其永久立足以進行長期性的有害生物防治。
- 競爭性生物** 與有害生物競爭環境中重要元素的一種生物。
- 生態區** 具有相似動物相、植物相及氣候而對引進生物防治物之關心也相似的地區。
- 生態系** 生物體與其環境所構成的複合體，經相互作用而成一界定清楚的生態單元(自然的或經人類活動變更過的，如農業生態系)，其與政治界線無關。

**Establishment** (of a biological control agent) The perpetuation, for the foreseeable future, of a biological control agent within an area after entry.

**Exotic** Not native to a particular country, ecosystem or ecoarea (applied to organisms intentionally or accidentally introduced as a result of human activities). As this Code is directed at the introduction of biological control agents from one country to another, the term “exotic” is used for organisms not native to a country.

**Import permit** (of a biological control agent) An official document authorizing importation (of a biological control agent) in accordance with specified requirements.

**Introduction** (of a biological control agent) The release of a biological control agent into an ecosystem where it did not exist previously (see also “establishment”).

**Inundative release** The release of overwhelming numbers of a massproduced, invertebrate biological control agent in the expectation of achieving a rapid reduction of a pest population without necessarily achieving continuing impact.

**立足（生物防治物）** 一生物防治物在進入某一地區後在可預見之未來能持續生存。

**外來的** 非某一特別國家、生態系、生態區原有的(用於指因人類活動而有意或意外引進的生物體)，鑒於本守則係針對生物防治物自一個國家引進至另一個國家，則”外來的”一詞用於非一個國家原有的生物體。

**輸入許可證（生物防治物）** 依據特定條件核准某一生物防治物輸入之官方文件。

**傳入（生物防治物）** 釋放某一生物防治物於其原先並不存在之生態系中(亦見”立足”)。

**淹沒式釋放** 以壓倒性數量釋放大量繁殖的無脊椎生物防治物，以期迅速降低有害生物族群但不一定產生持續影響。

<b>IPPC</b>	International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended.
<b>Legislation</b>	Any act, law, regulation, guideline or other administrative order promulgated by a government.
<b>Micro-organism</b>	A protozoan, fungus, bacterium, virus or other microscopic self-replicating biotic entity.
<b>National Plant Protection Organization (NPPO)</b>	Official service established by a government to discharge the functions specified by the IPPC.
<b>Natural enemy</b>	An organism which lives at the expense of another organism and which may help to limit the population of its host. This includes parasitoids, parasites, predators and pathogens.
<b>Naturally occurring</b>	A component of an ecosystem or a selection from a wild population, not altered by artificial means.



- IPPC** 係指1951年存檔位於羅馬糧農組織及其後修正的International Plant Protection Convention國際植物保護公約的英文縮寫。
- 法規** 政府公布的法令、法律、規定、準則或其他行政命令。
- 微生物** 原生動物、真菌、細菌、病毒或其他自行複製的微小生物體。
- 國家植物保護機關** 政府為執行國際植物保護公約規定的職責所設立的官方機關。
- 天敵** 靠犧牲另一個生物體而生存並可能有助於限制其寄主的族群的一種生物，包括類寄生物、寄生物、捕食性生物及病原體。
- 自然發生** 未經人為手段改變的生態系的一個組成成分或自一野生族群選出的品種。

<b>Organism</b>	Biotic entity capable of reproduction or replication; vertebrate or invertebrate animals, plants and micro-organisms.
<b>Parasite</b>	An organism which lives on or in a larger organism, feeding upon it.
<b>Parasitoid</b>	An insect parasitic only in its immature stages, killing its host in the process of its development, and free living as an adult.
<b>Pathogen</b>	Micro-organism causing disease.
<b>Pest</b>	Any species, strain or biotype of plant, animal, or pathogenic agent, injurious to plants or plant products.
<b>Predator</b>	A natural enemy that preys and feeds on other animal organisms, more than one of which are killed during its lifetime.
<b>Quarantine</b> (of a biological control agent)	Official confinement of biological control agents subject to phytosanitary regulations for observation and research, or for further inspection and/or testing.

- 生物體** 能繁殖或複製的生物體，脊椎或無脊椎動物、植物及微生物。
- 寄生物** 生活在較大的生物體上或體內取食之生物。
- 類寄生物** 一種僅在幼蟲期為寄生性，在發育過程中殺死其寄主，而成蟲為自由生活的昆蟲。
- 病原菌** 造成疾病的微生物。
- 有害生物** 對植物或植物產品有害的植物、動物或病原體之任何種、品系或生物型。
- 捕食性生物** 捕食其他動物，在其一生中殺死一隻以上生物的天敵。
- 檢疫(生物防治物的)** 依據植物檢疫法規對生物防治物採取官方管制，以便觀察和研究，或進一步檢查及/或檢測。

**Release** (into the environment)

Intentional liberation of an organism into the environment (see also “introduction” and “establishment”).

**Specificity**

A measure of the host range of a biological control agent on a scale ranging from an extreme specialist only able to complete development on a single species or strain of its host (monophagous) to a generalist with many hosts ranging over several groups of organisms (polyphagous).

**釋放** (至環境中) 刻意釋放某一生物至環境中 (亦見“傳入”及“立足”)。

**專一性** 生物防治物寄主範圍之量度，幅度從僅能在單一寄主物種或品系完成生長過程之極端專食者 (單食性)，至有許多種類的寄主之通食者 (雜食者)。

## *Outline of the code*

The Code is concerned with the importation of exotic biological control agents capable of self-replication (e.g. parasitoids, predators, parasites, phytophagous arthropods and pathogens) for research, and field release of control agents used in biological control and those used as biological pesticides. Currently used formulations of live pathogens are included because they possess the potential for multiplication and persistence in the environment. Naturally occurring strains (genetically, if not morphologically distinct entities) of natural enemies may show notable differences in specificity and infectivity, for example strains of *Bacillus thuringiensis* (Bt), and if exotic, fall within the terms of reference of this Code.

It is recognized that it may often be difficult to know whether the agent in a biological pesticide is exotic or not. For that reason many biological pesticides may have to be treated as though they were exotic.

The Code does not deal with other pest control techniques, that are also sometimes referred to as “biological controls”, notably, autocidal methods, resistant host plants, as well as behaviour-modifying chemicals and other novel biological products. For toxic products of microbes used as pesticides which cannot reproduce and which are similar to conventional chemical pesticides, refer to the FAO International Code of Conduct on the Distribution and Use of Pesticides here they are covered in detail.

## 本守則綱要

本守則係有關具有自行複製能力之外來生物防治物(如類寄生物、捕食性生物、寄生物、草食性節肢動物和病原菌)之輸入，以供研究，以及用於生物防治及做生物農藥之防治物之田間釋放。目前使用之活病原菌製劑包括在內，因為其具有在環境中繁殖及持續生存的潛力。自然發生之天敵品系(遺傳上的若非形態上特異的個體)可能在專一性或感染性上有顯著差異，例如蘇力菌(Bt)品係若是外來的即屬本守則適用範圍。

一般都承認要確認一種生物農藥中之生物是否為外來的是困難的。基此，很多生物農藥可能不得已被當作外來種來處理。

本守則不涉及其他有害生物防治技術，這些技術有時亦被稱為生物防治，特別如自殺法、抗性寄主植物，及改變行為之化學品和其他新穎的生物產品。關於用微生物所產生之有毒物質來作農藥，因其無法複製，且與傳統化學農藥相似，請參考對此有詳細規定之糧農組織的《國際農藥配銷及使用之行為守則》。

Procedures governing the handling and release into the environment of strains of organisms created artificially by genetic engineering are currently being examined by various international organizations and by national programmes. If required this Code could be applied to these organisms.

It is possible that this Code, after due evaluation, could also be applied to the introduction of exotic biological agents to control pests affecting human or animal health or the conservation of natural habitats.

Thus the Code deals with:

- the import of exotic biological control agents for research,
- the import and release of exotic biological control agents for biocontrol,
- the import and release of exotic biological control agents for use as biological pesticides where those products incorporate organisms which can multiply.

It does this by:

- identifying the three main groups involved in importing and releasing biological control agents: authorities (as the organizations representing government); exporters and importers;
- describing three responsibility phases of the process of import and release: the responsibilities of those involved before export; those before and upon importation; and those after importation.



以遺傳工程創造的人工生物品種其處理及釋放於環境中之程序，目前正由各國國際組織及國家計畫審議中，如有必要，本守則可適用於那些生物體。

本守則經適當評估亦可適用於引進外來生物體，以防治對人類或動物健康或自然棲境保育有影響之有害生物。

因此本守則處理：

- 研究用外來生物防治物之輸入。
- 生物防治用外來生物防治物之輸入及釋放。
- 作為生物農藥用之外來生物防治物之輸入及釋放，這些農藥含有能夠繁殖之生物體。

本守則以下列方式實施：

- 確定涉及輸入及釋放生物防治物之三大類：當局(代表政府的機關)；輸出者及輸入者。
- 描述輸入及釋放過程中之三個責任階段：輸出前所涉者的責任；輸入前及輸入時之責任；及輸入後之責任。

# **CODE OF CONDUCT FOR THE IMPORT AND RELEASE OF EXOTIC BIOLOGICAL CONTROL AGENTS**

## **1. Objectives of the Code**

1.1 The objectives of the Code are to:

- facilitate the safe import, export and release of exotic biological control agents by introducing procedures of an internationally acceptable level for all public and private entities involved, particularly where national legislation to regulate their use does not exist or is inadequate;
- describe the shared responsibility of the many segments of society involved and the need for cooperation between importing and exporting countries so that:
  - benefits to be derived are achieved without significant adverse effects,
  - practices which ensure efficient and safe use while minimizing health and environmental concerns due to improper handling or use are promoted.

Standards are described that:

- encourage responsible and generally accepted trade practices,

# 外來生物防治物輸入及釋放行為守則

## 1. 守則宗旨

### 1.1 本守則宗旨是：

- 為便利外來生物防治物之安全輸入、輸出及釋放，提出國際可接受之程序，供所有有關之公共及私人團體有所依循，尤其供規範其使用之國家法律不存在或不周延之國家參考。
- 說明所涉及之許多社會部門應分擔的責任，及輸入國和輸出國間合作之必要性以達成：
  - 獲得衍生利益而不致引起顯著不利影響。
  - 促進確保有效且安全的利用，同時降低因不當的處理或使用而導致健康及環境問題的方法。

### 標準：

- 鼓勵負責任的及普被接受之貿易措施。

- assist countries to design regulations to control the suitability and quality of imported exotic biological control agents and to address the safe handling, assessment and use of such products;
- promote the safe use of biological control agents for the improvement of agriculture, and human, animal and plant health;
- allow all those involved in the import or release of exotic biological control agents to determine if, in the context of the International Plant Protection Convention and other relevant conventions and legislation, their proposed actions and the actions of others constitute acceptable practices.

1.2 Responsibilities are outlined for the entities which are addressed by this Code, including governments, individually or in regional groupings; international organizations; research institutes; industry, including producers, trade associations, and distributors; users; and public-sector organizations such as environmental groups, consumer groups and trade unions. All references in this Code to a government or governments shall be deemed to apply equally to regional groupings of governments for matters falling within their areas of competence.

- 幫助各國制訂法規，以控制輸入外來生物防治物的適宜性及品質，並強調這些產品的安全處理、評估及使用。
- 促進生物防治物的安全利用，以改善農業及人類、動物和植物的健康。
- 由所有涉及輸入或釋放外來生物防治物的人員，依據國際植物保護公約及其他有關公約及法律，來決定其擬議採取之行動及他人的行動是否為可接受的方法。

1.2 本守則概述相關實體之責任，包括各別的或屬區域集團之政府、國際組織、研究機構、產業界，包括生產者、貿易協會及經銷者、使用者、及公共部門組織如環境團體、消費者團體及貿易公會。本守則有關某一或某些政府之所有事項，就屬於其職權範圍者，均應被視為適用於區域性集團之政府。

## **2. Designation of authority responsible**

2.1 Governments should designate the competent authority empowered (normally the National Plant Protection Organization) to regulate or otherwise control and, where appropriate, issue permits for the importation and release of biological control agents. The authority may exercise its powers by using an internationally accepted standard (such as this Code) for guidance or by applying national legislation (which should be aligned with this Code). Importations of biological control agents should only be carried out with the consent of the authority.

2.2 The authority needs to:

2.2.1 Consider the legislation and regulations for the import and release of biological control agents.

2.2.2 Establish procedures for the assessment of the dossiers specified in section 4 and for establishing conditions appropriate to the assessed risk for the importation of biological control agents either with confinement in quarantine or directly to the importing agent without such requirement.

2.2.3 Maintain appropriate communication with and advise affected parties, including, where appropriate, other authorities on:

## 2. 主管當局之指定

2.1 政府應指定經授權之主管當局（通常為國家植物保護機關）管理或控制，並於適當時核發生物防治物輸入及釋放許可證。該主管當局可用國際接受的標準（如本守則）作為指導或引用國家法規（應與本守則一致）以行使其權力。生物防治物應經主管機關同意始可輸入。

### 2.2 主管當局必須：

2.2.1 考量生物防治物輸入及釋放之法律及規定。

2.2.2 建立程序，以評估第 4 節規定之文件，並為訂立與評估風險相當之條件，俾輸入生物防治物時需隔離檢疫，或無此要求而可直接交給輸入者。

2.2.3 與所涉各方，適當時包括其他政府單位，保持適當聯繫並對下列事項提供諮詢：

- despatch and handling procedures,
- release and evaluation of agents,
- distribution, trade and advertising factors,
- labelling, packaging and storage,
- information exchange, and
- occurrence of unexpected and/or deleterious incidents, including remedial action taken.

### **3. Responsibilities of authorities prior to import**

#### 3.1 The authority of an importing country should:

- 3.1.1 Endeavour to promote compliance with the Code or use specific powers or introduce necessary legislation to regulate the import, distribution and release of biological control agents in their countries, and make provision for effective enforcement.
- 3.1.2 Evaluate the dossiers specified in section 4 on the pest and the candidate biocontrol agent supplied by the importer in relation to the degree of acceptable risk and establish conditions for importation, containment or release appropriate to the assessed risk.



- 分發和處理程序。
- 生物防治物之釋放及評價。
- 配送、貿易及廣告因素。
- 標示、包裝及貯存。
- 資訊交換。
- 未預料到的及 / 或有害事件的發生，包括採取的補救行動。

### 3. 輸入前主管當局之責任

#### 3.1 輸入國之主管當局應：

- 3.1.1 努力促使遵守本守則，或以特別的權力或必要立法來管制生物防治物在其國家之輸入、分發及釋放，並制定法規以有效實施。
- 3.1.2 評價輸入者提供的第4節規定的有關有害生物及其候選生物防治物之文件，其可接受之風險程度，並根據評估之風險建立輸入、隔離或釋放之條件。

3.1.3 Issue regulations and/or import permits stating conditions to be fulfilled by the exporter and importer. As appropriate, these should include the:

- requirements to ensure authoritative identification of the agent,
- specified source of the biocontrol agent,
- precautions to be taken against inclusion of natural enemies of the agent,
- measures required for the exclusion of contaminants (especially quarantine pests),
- nature of the packaging to provide appropriate security,
- measures to allow inspection without escape of contents,
- point of entry,
- person or organization to receive the consignment,
- conditions under which the package may be opened,
- facilities in which the biological control agent may be held.

3.1.3 發布法規及/或核發輸入許可證，敘明輸出者與輸入者應履行之條件，適當時，這些條件應包含：

- 確保對生物防治物作權威性鑑定之要求。
- 生物防治物之指定來源。
- 採取預防措施，以防止帶入生物防治物之天敵。
- 排除沾染物（尤其是檢疫有害生物）所需之措施。
- 提供適當安全性之包裝方式。
- 允許進行檢查又不致使內容物外洩之措施。
- 輸入口岸。
- 收貨人或組織。
- 包裹開封之條件。
- 生物防治物保存設施。

- 3.1.4 Ensure that procedures are available for the full documentation of the importation (identity, origins), release (numbers/quantities, dates, localities), impact of each particular biological control agent in each country and any other data relevant to assessing the outcome, and make records are available to the scientific community and the public, as may be appropriate, while protecting any proprietary rights to the data.
- 3.1.5 If appropriate, ensure entry and where required, processing through quarantine facilities or consider where a country does not have secure quarantine facilities, the importation through an accredited intermediate quarantine station in a third country.
- 3.1.6 Ensure the deposition in appropriate collections of authoritatively identified voucher specimens of the pest (s) and imported biological control agent where they will be available for reference and study.
- 3.1.7 Consider the necessity to require culturing of imported control agents in quarantine before release. Culturing for one generation can help in ensuring purity of the culture, authoritative identification, freedom from hyperparasites and pathogens or associated pests. This is especially advisable when wild collected agents are involved.

- 3.1.4 確保有程序以完整記錄輸入(特徵及來源)、釋放(次數/數量、日期及地點)，及每一特定生物防治物在各國之影響及其他有關結果評估之資料；並在保護數據之財產權時，讓科學界及社會大眾，如若適當，能取得這些紀錄。
- 3.1.5 在適當情況下，確保入境，並於需要時經過檢疫設施進行處理，或考量若一國無安全檢疫設施時，透過第三國經認證之中繼檢疫站輸入。
- 3.1.6 確保在適當的收集中心保存經權威鑑定過之有害生物及輸入生物防治物之存證標本，以供參考及研究。
- 3.1.7 考慮在釋放之前要求輸入之生物防治物在檢疫設施中培養的必要性。經培養一世代有助確保其純度、權威性的鑑定、無超寄生物及病原感染或伴隨的有害生物。當涉及的是野外採集之生物防治物尤宜採行。

- 3.1.8 Decide if after a first import, further imports of the same biological control agent can be exempted from some or all of the requirements for import.
- 3.1.9 Maintain appropriate communication with and advise affected parties, including, where appropriate, other authorities on:
- despatch and handling procedures,
  - release and evaluation of agents,
  - distribution, trade and advertising factors,
  - labelling, packaging and storage,
  - information exchange, and
  - occurrence of unexpected and/or deleterious incidents, including remedial action to be taken.
- 3.1.10 Ensure, in the case of repeat imports of a biological control agent for use in biocontrol or as a biopesticide, that documentation of the certification system permitting entry and release is such that only imports of at least equivalent standard to the approved import are released.

3.1.8 決定是否在第一次輸入後，後續輸入相同生物防治物時，可免除部分或全部輸入規定。

3.1.9 與所涉各方，適當時包括其他政府單位，保持適當聯繫及對下列事項提供諮詢：

- 分發和處理程序。
- 生物防治物之釋放及評價。
- 配送、貿易及廣告因素。
- 標示、包裝及貯存。
- 資訊交換。
- 未預料到的及/或有害事件的發生，包括採取的補救行動。

3.1.10 確保為用於生物防治或作生物農藥而重複輸入一種生物防治物之情況下，簽發核准入境及釋放之證明書時，應僅放行與已核准輸入者至少具有同等標準之輸入品。

3.1.11 Take action to inform and educate local suppliers of biological control agents, farmers, farmer organizations, agricultural workers' unions, and other interested parties on the appropriate use of biological control agents.

3.1.12 Consult with authorities in neighbouring countries within the same ecoarea and with relevant regional organizations to clarify and resolve any potential conflicts of interest that may arise between countries.

3.2 The authority of an exporting country, to the extent possible, should:

3.2.1 Ensure that regulations of the importing country relevant to the Code are followed in the export from their countries of biological control agents.

3.2.2 Follow, where the importing country has no or limited legislation concerning the import of biological control agents, the elements of the Code concerning the export of agents.

3.2.3 Ensure that arrangements are made for the taking and storing of voucher specimens of the exported material.



3.1.11 採取行動以告知及教育生物防治物之地方供應商、農民、農民組織、農業從業公會和其他有興趣者，生物防治物之適當用途。

3.1.12 與相同生態區鄰近國家的當局和相關區域組織磋商，以澄清和解決國家間可能發生之潛在利益衝突。

### 3.2 輸出國的主管當局應盡可能：

3.2.1 確保輸出該國的生物防治物時，遵守輸入國依本守則所訂的法規。

3.2.2 如果輸入國無有關輸入生物防治物之法律或法律有限，則遵守本守則有關輸出生物防治物之條文。

3.2.3 確保對輸出物存證標本之取得與保存作出安排。

#### **4. Responsibilities of importer prior to import**

4.1 At the first importation, the importer of biological control agents for any purpose should prepare dossiers for submission to the authority with information on the pest to be controlled, including:

4.1.1 Accurate identification of the target pest, its world distribution and probable origin,

4.1.2 Assessment of its importance,

4.1.3 Its known natural enemies, antagonists or competitors already present or used in the proposed release area or in other parts of the world.

4.2 At the first importation, the importer of biological control agents for any purpose should prepare dossiers with information on the candidate biological control agent including:

4.2.1 Accurate identification or, where necessary, sufficient characterization of the agent to allow its unambiguous recognition,

4.2.2 A summary of all available information on its origin, distribution, biology, natural enemies and impact in its area of distribution,

## 4. 輸入前輸入者之責任

4.1 在第一次輸入時，不論供任何用途之生物防治物的輸入者，應準備文件，以提供主管當局有關所要防治有害生物之資訊，包括：

4.1.1 標的有害生物之正確鑑定，其在世界之分布及可能之來源。

4.1.2 其重要性之評估。

4.1.3 在擬釋放地區或世界其他地區已經存在或已使用之已知天敵、拮抗生物或競爭性生物。

4.2 在第一次輸入時，不論供任何用途之生物防治物的輸入者，應準備有關候選生物防治物資訊之文件，包括：

4.2.1 正確的鑑定，或必要時，提供其足夠的特徵以供明確的辨識。

4.2.2 所有現有資料的摘要，包括其來源、分布、生物學、天敵和其在分布地區之影響。

4.2.3 An analysis of the host specificity of the biological control agent and any potential hazards posed to non-target hosts,

4.2.4 Natural enemies or contaminants of the candidate agent and procedures required for their elimination from laboratory colonies including, if appropriate, procedures to accurately identify and, if necessary, eliminate from the culture the host upon which the agent was cultured.

4.3 At the first importation, the importer of biological control agents for any purpose should also prepare a dossier for presentation to the authority which identifies potential hazards analyses the risks posed thereby and proposes mitigating procedures with respect to:

- those who may be handling biological control agents under laboratory, production and field conditions,
- human and animal health following introduction.

4.4 The importer of candidate biological control agents proposed for research in quarantine only should include information on the above points, plus the:

- nature of the material proposed for importation,
- security of quarantine (based on a description of the facilities and the qualifications of the staff).

4.2.3 生物防治物寄主專一性和對非寄主標的任何潛在為害之分析。

4.2.4 候選生物防治物之天敵或污染物，及消滅實驗室群落所須之步驟，適當時包含正確鑑定方法及，必要時，從培養體中消滅培養生物防治物之寄主之方法。

4.3 在第一次輸入時，不論供任何用途之生物防治物的輸入者，亦須準備文件提報主管當局說明潛在危害分析其所產生的風險並提出減輕風險之方法：

— 可能在實驗室、生產過程及田間處理生物防治物之人員。

— 引進後的人畜健康。

4.4 候選生物防治物作為檢疫研究用時的輸入，應包括上述幾點資料外應增加：

— 擬輸入材料之性質。

— 檢疫安全性（根據對設施之描述及檢疫人員之資格）。

4.5 The importer of biological control agents for import and release and use as biological pesticides should include in the dossier specified in 4.3 above, an analysis of the risks posed to possible non-target organisms and to the environment generally and should detail available emergency procedures should the biological control agent after release display unexpected adverse properties. The dossier should also contain a report detailing laboratory tests, and/or field observations and any other appropriate data to indicate the known or probable host range of the candidate agent. Testing should be based on recommended procedures and approved by the authority. These tests should relate to the candidate agent only and different procedures should apply to any additives used in formulations of products which contain biological control agents.

## **5. Responsibilities of exporter prior to export**

5.1 Exporters of biological pesticides and other biological control agents for inundative release should:

5.1.1 Take all necessary steps to ensure that exported biological control agents conform to relevant regulations of importing countries, FAO and World Health Organization specifications concerning labelling, packaging and advertising, in particular the International Code of Conduct on Distribution and Use of Pesticides, as applicable, and this Code.

4.5 輸入、釋放及作為生物農藥使用的生物防治物，輸入者應提供包括 4.3 規定之文件，對可能非標的生物及一般環境進行風險分析，並詳細說明若生物防治物釋放後，出現意料之外的不利特性時所應採取之緊急措施。此文件尚需包含一份報告詳細說明實驗室試驗及 / 或田間觀察與其他適當資料，指出本候選生物防治物已知或可能之寄主範圍。試驗應依據建議之程序並經主管當局核准。試驗應僅針對候選之生物防治物，含有生物防治物之產品劑型中的任何添加物，則應採用不同試驗程序。

## 5. 輸出前輸出者之責任

5.1 生物農藥和供淹沒式釋放之其他生物防治物之輸出者應：

5.1.1 採取所有必要步驟以確保輸出之生物防治物符合輸入國、糧農組織及世界衛生組織關於標示、包裝及廣告之相關規定，特別是在適用時，符合《國際農藥配銷及使用行為守則》及本守則。

5.1.2 Ensure that biological control agents used in biological pesticides and for inundative release are evaluated for safety as provided for in section 4.3.

5.1.3 Ensure that all biological pesticides and other biological control agents for inundative release are evaluated for safety to human health and the environment and freedom from contaminating organisms.

5.2 The exporter of biological control agents for any purpose should ensure that:

5.2.1 All conditions specified in the regulations of the importing country or on the import permit are complied with.

5.2.2 Consignments, upon export, are accompanied by appropriate documentation:

- specifying that the contents are in compliance with the legislative provisions of the importing country and the permit provisions for that consignment,
- including information on the identity and recognition, safety, rearing or culture, and handling methods of the agent, and on possible contaminants, their recognition and elimination.



5.1.2 確保生物農藥中所用及供淹沒式釋放之生物防治物，依照第4.3節規定評估其安全性。

5.1.3 確保對所有生物農藥中及用於淹沒式釋放之生物防治物，針對人類健康與環境之安全性及不帶有其他污染生物體進行評估。

5.2 供任何用途生物防治物輸出者應確保：

5.2.1 遵守輸入國法規或輸入許可證上規定的所有條件。

5.2.2 貨品輸出時均隨附適當文件：

— 說明其內容物符合輸入國之法規及該批貨品之許可證規定。

— 包括該生物體之特徵和識別、安全性、飼養或培養及處理方法，可能之污染物、其辨識和消除等資訊。

5.2.3 Packaging be sufficiently robust and consists of inert material secured in such a way that it can be inspected without escape of the contents. Wherever possible, organisms should be transported without their hosts (to reduce quarantine risks) and/or when they are in a dormant, inactive stage that is least likely to escape from packaging.

5.3 The exporter of biological control agents for research or classical biological control should also ensure that:

5.3.1 The import permit and all other documentation required in association with it are available prior to dispatch of the agent.

5.3.2 Packages are properly labelled in the official language of the importing country as to their contents and handling both in transit and on receipt in the receiving country. The information should include instructions to handlers and officials at the point of entry on how the package should be treated to avoid damage to the contents and on action to be taken if the packaging is breached. It should also indicate whether it may be opened for customs inspection or must be sent directly into quarantine before opening.

5.2.3 包裝應牢固，使用惰性材料，確保能夠檢查而又不會洩漏內容物。生物防治物之運輸應盡可能不含其寄主（以減少檢疫風險），及/或在生物防治物處於最不可能洩漏到包裝外之休眠靜止期。

5.3 供研究或傳統生物防治的生物防治物輸出者，亦應確保：

5.3.1 輸入許可和所有其他必備相關文件應於生物防治物付運前備齊。

5.3.2 包裝應以輸入國之官方語言適當標示其內容物，及轉運途中或收貨國收到時之處理方法。此資料應包含在入境口岸時，搬運人員或政府官員如何處理包裝以避免損及內容物，及若包裝有破損時應採取之行動的指導說明。並應指出海關檢查是否可打開包裝或在開包前必須直接送至隔離檢疫區。

5.3.3 Advance notice with full details of routing is provided to the receiver to minimize delays and to alert officials at the point of entry.

## **6. Responsibilities of authorities upon import**

6.1 Authorities should:

6.1.1 Ensure that, where required (see section 3.1.5), all imports of classical biological control agents for research or biological control, after completion of import requirements at the point of entry, are taken directly to the specified quarantine facility for inspection or other required procedure. All dead, diseased or contaminated material, as well as extraneous material and packaging material should be sterilized or destroyed in quarantine.

6.1.2 Ensure that biological control agents for which it is considered necessary (see section 3.1.6) are cultured in quarantine as long as has been specified by the authority.

5.3.3 應事先通知收貨者，詳細的運送路線，以減少延遲及提醒入境口岸的官員注意。

## 6. 輸入時主管當局之責任

### 6.1 主管當局應：

6.1.1 確保必要時（見第 3.1.5 節）所有輸入供研究或生物防治用之傳統生物防治物，應在入境口岸完成輸入手續後，直接送往指定之檢疫設施接受檢查或採取其他必要之程序。所有死亡、罹病或污染材料及外來材料和包裝材料均應在檢疫區消毒或銷毀。

6.1.2 確保生物防治物必要時(見第3.1.6節)，按主管當局規定的時間於檢疫設施中培養。

6.1.3 Allow certain biological control agents to be passed directly for release providing all conditions have been complied with and appropriate documentary evidence is made available (see section 3). In all cases where identification or compliance is to be checked, this should be undertaken in a secure laboratory (i.e. a closed room with facilities for sterilizing or autoclaving extraneous or suspect materials).

## **7. Responsibilities of authorities before and upon release**

7.1 Authorities should:

7.1.1 *If not already agreed under the terms of the import permit:*

Consider for approval for release following critical assessment of the submitted dossier on the agent and the establishment of appropriate conditions to reduce the assessed risk to an acceptable level. Assessments should be made using the types of procedures established in the ISPM *Guidelines for pest risk analysis* (e.g. to assess risks to non-target organisms and to identify risk-mitigating procedures). This may require information from specified additional tests.

6.1.3 允許某些生物防治物於符合所有規定之條件，及備有適當文件證據，得直接通關逕行釋放（見第3節）。在所有情況下若需查驗其特徵及其是否符合規定，則應在安全之實驗室中進行（亦即在密閉並有消毒或高壓蒸氣釜之設施以處理外來或可疑的材料）。

## 7. 主管當局在釋放前及釋放時的責任

### 7.1 主管當局應：

#### 7.1.1 如尚未同意輸入許可證之條件時：

經嚴格評估所繳交有關生物防治物之文件後，考慮批准其釋放，並訂定適當條件以降低評估後之風險至可接受程度。評估時應使用 ISPM《有害生物風險分析準則》規定之各種程序（如評估非標的生物之風險及確定降低風險之程序）。此評估可能需要自特定的額外試驗中獲得資料。

- 7.1.2 Ensure full documentation of novel importations and their release programme as to identities, origins, numbers/quantity released, localities, dates, location of voucher specimens and any other data relevant to assessing the outcome, and maintenance of records of appropriate information with regard to other repeated releases of the same species.
- 7.1.3 Encourage the monitoring of the release of biological control agents in order to assess the impact on the target and non-target organisms.
- 7.1.4 Where problems (i.e. unexpected deleterious incidents) are identified, consider, and where appropriate, ensure corrective action is taken and inform all relevant interested parties.

## **8. Responsibilities of importer after import and release**

### 8.1 The importer should:

- 8.1.1 Ensure that persons involved in distribution of their biological control agents are trained adequately, such that they are capable of providing a user with advice on efficient use.



7.1.2 確保全面記錄新的輸入物及其釋放計畫資料，包括特徵、來源、釋放次數或數量、地點、日期，存證標本之存放地點及其他與評估結果相關之資料，並保存同一物種在其他情況下重複釋放之有關資料之紀錄。

7.1.3 鼓勵對生物防治物釋放之監測，以評估其釋放後對標的及非標的生物之影響。

7.1.4 如果發現問題（如預料之外的危害事件）應考慮及確實採取補救行動並通知所有攸關各方。

## 8. 輸入及釋放後輸入者之責任

### 8.1 輸入者須：

8.1.1 確保參與分發生物防治物之人員受有適當訓練，使能夠就其有效使用提供使用者諮詢。

- 8.1.2 Make information relating to the safety and environmental impact of biological control agents publicly available, and maintain a free and frank exchange of information, not subject to commercial confidentiality, with exporters, authorities other importers and operators of programmes involving biocontrol agents.
- 8.1.3 Consider publication of the results of each first importation and release programme in an international journal. Such publication should include details of the programme and its economic and environmental impact as soon as practicable after the release of the agent.
- 8.1.4 Notify the authorities when problems occur and voluntarily take corrective action and, when requested by authorities, help to find solutions to difficulties.
- 8.1.5 Ensure application of the provisions of Article 11 of the International Code of Conduct on the Distribution and Use of Pesticides with respect to the advertising of commercial preparations of biological control agents for sale to the public.

## **9. Observance of the Code**

- 9.1 This Code should be observed through collaborative action on the part of: governments, individually or in regional groupings;

- 8.1.2 公布有關生物防治物之安全性及其對環境影響之資訊，在不涉及商業機密之下，與其輸出者、主管當局、其他輸入者及涉及生物防治物計畫之執行者，保持自由及坦誠的資訊交換。
- 8.1.3 考慮將每一項首次輸入及釋放計畫之結果發表於國際期刊，此發表內容應包括計畫細節和儘早於釋放後發表生物防治物對經濟及環境的影響。
- 8.1.4 問題發生時通知主管當局，並自動地採取矯正措施，且當主管當局要求時，協助找出解決困難之方法。
- 8.1.5 確保向大眾出售之生物防治物商業產品而做廣告時適用《國際農藥配銷及使用行為守則》第 11 條條款。

## 9. 本守則之遵守

- 9.1 本守則應由下列單位及人員共同遵守：包括各別政府或區域性政府團體、國際組織、研究機構、

international organizations; research institutes; industry, including producers, trade associations, and distributors; users; and other organizations such as environmental groups, consumer groups and trade unions.

- 9.2 The Code should be interpreted so that the requirements of other relevant codes or treaties are respected.
- 9.3 All parties addressed by this Code should observe this Code and promote the principles and ethics expressed, irrespective of other parties' ability to observe the Code.
- 9.4 The parties involved in providing biological control agents should retain an active interest in following their products, keeping up to date with major users and with the occurrence of problems arising in the use of their products.
- 9.5 FAO Members should periodically review the relevance and effectiveness of the Code. The Code should be considered a dynamic text which must be brought up to date as required, taking into account technical, economic and social progress.
- 9.6 Authorities should monitor the observance of the Code and report on progress made to the Director-General of FAO.

產業界包括生產者、貿易協會及分銷商、使用者以及其他組織如環保團體、消費者團體及貿易公會。

- 9.2 本守則之解釋應尊重其他相關的規則或條約之要求。
- 9.3 本守則所規範之所有各方均需遵守本守則，並弘揚其所表達之原則與倫理，不管其他各方是否有能力遵循本守則。
- 9.4 生物防治物之供應方應對其產品之後續、與主要使用者保持最新連繫，及知悉使用其產品後所衍生之問題等保有積極的關切。
- 9.5 糧農組織成員必須定期檢討本守則之適用性及有效性。本守則之條文應被視為動態性者，需要時，應顧及技術、經濟及社會之發展加以更新。
- 9.6 主管當局應監視本守則之遵守情況，並向糧農組織秘書長提出進展報告。

For further information on international standards, guidelines and recommendations concerning phytosanitary measures, and the complete list of current publications, please contact the:

**Secretariat of the International Plant Protection Convention**

By mail: IPPC Secretariat

Plant Protection Service

Food and Agriculture Organization of the United Nations (FAO)

Viale delle Terme di Caracalla

00100 Rome, Italy

Fax: + (39) (06) 57056347

Email: [ippc@fao.org](mailto:ippc@fao.org)

Or visit our WEB site at:

<http://www.fao.org/WAICENT/FaoInfo/Agricult/AGP/AGPP/PQ/Default.htm>

若需更多有關植物防疫檢疫措施之國際標準、  
準則及建議或現有刊物之全部目錄請洽下列單位：

### **國際植物保護公約秘書處**

信件寄往下列住址：

IPPC Secretariat

Plant Protection Service

Food and Agriculture Organization of the United Nations (FAO)

Viale delle Terme di Caracalla

00100 Rome, Italy

FAX: +(39)(06)57056347

Email: [ippc@fao.org](mailto:ippc@fao.org)

WEB site:

<http://www.fao.org/WAICENT/FaoInfo/Agricult/AGP/AGPP/>

[PQ/Default.htm](http://www.fao.org/WAICENT/FaoInfo/Agricult/AGP/AGPP/PQ/Default.htm)

食品安全檢驗與動植物防疫檢疫措施協定叢書 (十一)

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國際植物防疫檢疫措施標準第三號

# 外來生物防治物輸入及釋放行爲守則

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