

**BIO-SECURITY ASSURANCE ARRANGEMENT (BSAA)
(FOR IMPORTATION OF PLANTS, SEEDS, GENETICALLY MODIFIED PLANT
MATERIALS, INSECTS, WORMS & MICROORGANISMS)**

GUIDELINES

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AVA Bio-Security Assurance Arrangement for the Import of Plants, Seeds, Genetically Modified Plant Materials, Insects & Microorganisms

Introduction

The Bio-Security Assurance Arrangement (BSAA) is a special service provided by the Agri-food and Veterinary Authority (AVA) to all institutions, companies and organizations that regularly import plants, seeds, genetically modified plant materials, insects, worms and microorganisms into the country.

Under the BSAA, the institutions, companies or organizations play a more responsible role by implementing a documented AVA approved system to minimize the various risks involved during the introduction and use of the introduced plants, insects and microorganisms. AVA will ensure that the implemented system complies with the documented standards through periodic audits.

Who Can Apply

Bio-Security Arrangements with AVA are available to all institutions, companies and organizations. The prerequisites are:-

- 1) The establishment has the facilities/equipments & the staffs have the expertise to operate upon agreed procedures and are able to consistently meet the requirements set by AVA.
- 2) The organization can document in their Bio-Security Assurance (BSAA) manual, its management controls, policies, procedures, allocation of responsibilities and record keeping for the purpose of maintaining assured qualities.
- 3) The organization is capable of complying with the procedures set down in its manual.

What are the benefits?

(A) For the Organization

- 1) A more orderly and transparent coordinated approach in achieving service of consistent qualities.
- 2) Increased flexibility as inspections no longer have to be done by AVA inspectors on the consignment immediately on arrival. The organization has more flexibility in organizing shipment schedules.
- 3) A sense of direction and purpose for employees. Jobs are well documented and understood.
- 4) Cost savings in terms of financial, resources as well as opportunities. This will depend on the volume of shipments per year.

(B) **For AVA**

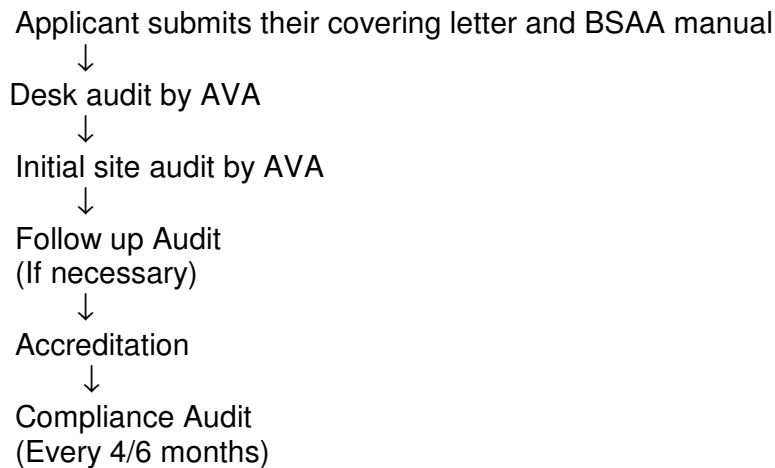
- 1) Savings in manpower & resources.
- 2) Assurance of a more complete & effective means of compliance with requirements.

How to Apply

The organization have to present a covering letter indicating its interests and reasons to apply for BSAA, accompanied by a BSA manual to the Head/Plant Regulatory Branch, AVA. The covering letter should indicate the contact person for the BSA arrangement within the organization.

Procedure Involved

The process can be represented by the flowchart as follows:



Others

All information and data submitted in the BSA manual to AVA will be treated as “**Confidential**”.

Terms and Conditions of BSAA

1. BSAA manual

Organizations will need to define and describe in detail the assurance activities at various points of the procedure which will ensure that the imported plants, insects and microorganisms are securely under their control and there is no risk of escape or threat to the environment. The emphasis is to ensure that the management system is in place and working. The quality assurance manual is an effective working document for the company and allows AVA to audit the system. The Organization undertakes to comply with its BSA manual, once it has been approved by AVA. AVA must be advised immediately of any changes to the key control procedures and the manual must be amended accordingly. Any significant changes to the management system must be approved by AVA. Two key areas of a quality manual that assures bio-security are **document control** and **process control**. General guidelines and elements that need to be included into the BSA manual are outlined in Appendix 1.

2. Desk Audit

This is the primary step of evaluation of the BSA manual by AVA to determine the adequacy of the management system. Files relating to the past performance of the applicant will be checked for any outstanding matters that could affect the regulatory status of this applicant.

3. Initial Site Audit

If the desk audit shows that the management system as described, seems to be effective with respect to specified objectives, then a site audit of the management system will be arranged and conducted. This involves a major assessment of the entire system to ensure that the procedures documented in the manual are being followed and in practice, are effective. The organization will be advised of the findings and recommendations pertaining to the site audit before membership into the BSA arrangement can be approved.

4. Routine Compliance Evaluation

The objective is to ensure that the company continues to operate its management system in accordance with the arrangement and is able to adjust the management system as requirements change and problems are addressed and corrected. No management system procedure is ever finalized. The BSA arrangement is subjected to re-negotiation and update of manuals whenever necessary. The routine compliance evaluation will be in the frequency of every 4/6 months from the last audit depending on the type of BSAA. It may be necessary to increase the frequency and/or intensity depending on organization performance or changed risk factors.

5. **Fees**

Fees apply for Desk Audit, Site Audit and Routine Compliance Evaluation. Note that these fees may be amended from time to time. A schedule of current fees is available from the Plant Health Section, Sembawang Research Station.

6. **Suspension or Closure of Service**

AVA may suspend or close the BSA arrangement if the organization makes or presents any declaration, statement, representation or document which is false for the purpose of seeking approval for the BSA arrangement or if the management performance falls below AVA requirements. Organizations are, of course, at liberty, to terminate the BSA arrangement with AVA by giving notice in writing, if the service is found not useful to them.

Primary Guidelines for the Preparation of BSA Manual

The Bio-Security Assurance (BSA) manual is a document prepared by the organization to describe its management system which operates at that establishment. It is a compilation of policies, procedures, controls and documentation encompassed by the quality assurance system. The manual must be prepared in such a way that it is easily understood, concise and usable. To achieve this, the following are recommended.

1. Cross-referenced thoroughly, particularly where recorded sheets or logs are concerned.
2. Identify recording sheets or logs by title and form or document number, both of which should be quoted whenever the form is referred to in a manual.
3. Clearly labelled flow charts, diagrams, tables and checklists for easy reference.
4. All section should be written together, rather than scatter references throughout a manual.
5. Use tables, diagrams and other forms to make instructions easily understandable wherever possible.

To facilitate amendments, all manuals should:

1. Be prepared in loose leaf with a table of content.
2. Have a number and date on each page.
3. Include a Table of content.

Documenting a Quality System Under the Bio-Security Assurance Arrangement (BSAA)

Management Responsibility

1. Quality Policy Statement

AVA would expect an applicant company for the BSA arrangement to have a strong commitment to quality, which is clearly evident to its staff. A statement describing the aims of the organization in this regard, signed by the Managing Director, should therefore be included in the manual.

2. Declaration by Chief Executive

This is a mandatory statement signed by the Senior Executive of the organization responsible for management assurance, to formalize the BSA arrangement with AVA and to endorse the procedures outlined in the manual. A specimen declaration is provided in Appendix 2.

3. Management Review and Internal Audit of Bio-Security Assurance Arrangement

The company's management assurance system should be reviewed internally on a regular basis. The aim is to review the efficiency of procedures and confirm that it is maintained at or above the agreed level. The plan should state the frequency, method and who is responsible for such reviews. The results of such reviews must be documented and made available to AVA on request.

Organization

4. Personnel

4.1 Organization Chart

It is recommended that an organizational chart of the senior management and involved those in the quality assurance process be documented. The company shall appoint a Management Representative (MR) responsible for all matters affecting the BSAA.

4.2 Duty Statements

Duty statements should include positions of the staffs responsible for the processing operations of the BSA arrangement.

Bio-security Assurance Arrangement

5. Good Management Practice

A good management practice for the maintenance and culture of imported microbial cultures/ plants/ insects should consist of the following:

5.1. Quality control checkups

These include inspection on arrival, specification of imports and arrangement and agreement with the supplier(s).

5.2. Transport procedures

This procedure includes transportation of microbial cultures/nematodes and other controlled items from the point of entry to the designated place and within the establishment. All samples are to be kept in secured and closed containers so that escape or any case of any mechanical damage is avoided.

5.3. Process control

This is a system approach for minimizing the risk of escape of the microorganisms/nematodes with emphasis on preventive action. The flow chart and layout of facilities should be drawn so that critical points of escape and their control could be identified which are potential hazards.

5.4. Hazard audit tables

This table helps to ensure corrective action for every potential risk. Please see item 6.

5.5. Consignment identity & traceability

This will ensure that any missing microbial cultures/nematodes and other controlled items can be traced.

5.6. Rejection of imported consignments

There should be procedures for the rejection and destroy of items which do not meet the import specifications.

5.7. House Keeping

Good house keeping is essential to maintain insects/microbial cultures/nematodes and to prevent their escape. Preventive maintenance of the facilities at regular intervals is required.

5.8. Waste disposal

Procedures for the disposal of microbial cultures/dead insects and other materials have to be documented.

5.9. Dis-infection procedure

The type of disinfectant, its concentration and methods need to be standardized and documented.

5.10. Documentation & Records

To facilitate the audit of the system, all proper records have to be kept and filed systematically.

5.11. Personnel

Duties and responsibilities of all the personnel involved should be documented. Adequate training and facilities should be available for updating the person's knowledge.

5.12. Audit

Regular audit of the management system by an internal audit team and an external audit team such as AVA will help in the smooth running of the system.

5.13. Management commitment

The declaration in the Bio-Security Assurance Arrangement Manual will bind the management for any lapse on their part.

6. HAZARD AUDIT TABLE

6.1. Critical Operation

The procedure or operation which may lead to potential risk

6.2. Potential Risk

The outcome if anything goes wrong with this procedure or operation

6.3. Critical control points

The points to be critically monitored or controlled in a process to ensure that the risk is minimised.

6.4. Monitoring procedure

Inspection or monitoring setups to ensure that the procedures are carried out correctly or supervision is there to ensure the procedures are adhered to.

6.5. Recording and their frequency

Record the monitoring procedure and frequencies in a sheet or chart.

6.6. Specification

Specification for this operation or procedure. It can be a time or a condition specification.

6.7. Person responsible

The person who would be responsible to ensure that this operation or procedure is carried out according to the specification or procedure.

6.8. Corrective action

Person who responsible for correcting the situation if the product is found to be outside the specification.

Declaration by Chief Executive

I _____(name) being the Owner/Manager/Director*
of the registered company/organisation _____(name)

hereby declare to all staff concerned and to Agri-Food and Veterinary Authority (AVA) that I undertake, on behalf of the organization to:

- a) ensure compliance with the Terms and Conditions of the Bio-security Assurance (BSA) arrangement.
- b) comply with the policies, procedures and specifications set out in this manual which defines the quality system in operation .
- c) grant entry to the premises at any time to persons who are AVA authorized officers for the purpose of the BSA arrangement.

I understand that being committed to this BSA arrangement is essential to the successful maintenance of the arrangement and I will endeavor to ensure that all personnel in the system understand their objectives and responsibilities.

Signed _____

Dated _____

* delete whichever not applicable