
	TITLE: STANDARD OPERATING PROCEDURE FOR OPERATIONAL OF RAW-UNCLEAN EDIBLE-BIRDNEST PRIMARY PROCESSING ESTABLISHMENT EXPORT TO CHINA	EFFECTIVE DATE: 29 May 2018
	Document No: SOPRUCEBN-2	Revision No.: 00



**Standard Operating Procedure
For Operational of
Raw-unclean Edible-birdnest
Primary Processing Establishment
Export to China**

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**Standard Operating Procedure for
Operational Raw-unclean Edible-birdnest Primary Processing Establishment
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SECTION 1: GENERAL

1.1 Scope

This Standard Operating Procedure (SOP) prescribes requirements of raw-unclean EBN primary processing establishment which may include but not limited to sorting, pre-cleaning, heating, water spraying, drying, weighing, packing and labelling activities; specification of raw-unclean EBN which determines the quality and physical requirements of raw-unclean EBN to be exported to China.

1.2 Normative references

The following normative references are indispensable for the application of this standard. For dated references, only the edition cited applies. For undated references, the latest edition of the normative reference (including any amendments) applies.


SIRIM/DVS 3:2015 Code of Veterinary Practice: Specification for Raw-Unclean Edible-Birdnest (EBN)

1.3 Terms and definitions

For the purposes of this standard operating procedure, the following terms, definitions and abbreviations apply.

1.3.1 certified edible-nest swiftlet bird house

Edible-nest swiftlet bird house which is registered building with ID number assigned by DVS Malaysia where the raw-unclean EBN are received or harvested and the bird house is comply with Malaysia certification scheme by Department of Veterinary Services (DVS).

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1.3.2 certified primary processing establishment

Primary processing establishment which is certified by DVS Malaysia to be in compliance with hygienic requirement stated in “Standard Operating Procedure For Operational of Raw-Unclean Edible-birdnest Primary Processing Establishment Export to China”.

1.3.3 collecting centre

A registered building where the Raw-unclean EBN from edible-nest swiftlet premises are received, and may include but not limited to sorting, pre-cleaning, drying, weighing, packing and labelling activities is carried out for the production of quality and safe raw-unclean EBN.

1.3.4 contaminant

Any biological or chemical agent, foreign matter or other substances, not intentionally or otherwise added to raw-unclean EBN.

1.3.5 edible-birdnest (EBN)

Nest produced by the Edible-nest Swiftlet from their salivary glands which is consumed or used by humans.

1.3.6 finished products


An output from primary processing establishment has been recognized as raw-unclean EBN which may gone through processes which may include but not limited to sorting, pre-cleaning, trimming, heating, water spraying, drying, weighing and packing without any cleaning process.

1.3.7 primary processing establishment

A registered building where the raw-unclean EBN from ranches are received, and may include but not limited to sorting, pre-cleaning, heating, water spraying, drying, weighing, packing and labelling activities is carried out for the production of quality and safe raw-unclean EBN.

1.3.8 primary process

Which may include but not limited to sorting, pre-cleaning, trimming, heating, water spraying, drying, weighing and packing but without any cleaning process.

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SECTION 2: PRIMARY PROCESSING ESTABLISHMENT

2.1 Design and facilities


2.1.1 Registration and certification

The primary processing establishment shall be registered and certified comply with Malaysia certification scheme by Department of Veterinary Services Malaysia as the regulatory authority. The registration and certification of the primary processing establishment shall refer to *SOPRUCEBN-1 Standard Operating Procedure For Registration and Traceability for Raw-Unclean Edible-Birdnest Export to China*, *SOPRUCEBN-3B Standard Operating Procedure DVS Certification Scheme: GVHP for Operational of Raw-Unclean Edible-Birdnest Primary Processing Establishment Export to China*, and *SOPRUCEBN-3C Standard Operating Procedure DVS Certification Scheme: VHM for Operational of Raw-Unclean Edible-Birdnest Primary Processing Establishment Export to China*.

2.1.2 Design and layout of establishment

2.1.2.1 The design and layout of the establishment are listed below:

- a) The establishment shall be designed to provide adequate space and minimise contamination.
- b) The flow of the activities during processing shall be unidirectional.
- c) The design shall provide appropriate temperature conditions for the process and storage of the product.
- d) There shall be a clear separation before and after the pre-clean production area.
- e) The buildings and facilities shall be designed to prevent the entrance and harbouring of pests as well as minimise the entry of environmental contamination such as smoke, dust, etc.
- f) Sites where activities such as sorting, pre-cleaning, heating, water spraying, drying, weighing, packing and labelling of raw-unclean EBN shall be kept tidy accordingly.
- g) Areas where raw-unclean EBN that has undergone pre-cleaning which may include but not limited to sorting, heating, water spraying, drying, weighing, packing and labelling, shall have:
 - i) adequate ventilation shall be provided; windows and other openings shall be fitted with screens or netting, so constructed and kept as to enable them to be cleaned as and when necessary;
 - ii) potable water and wastewater pipes shall be separated in order to avoid back flow and cross contamination.

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2.1.2.2 An example of a primary processing establishment layout is as shown in Annex A.

2.1.3 Equipment

2.1.3.1 All utensils and equipment used in the raw-unclean EBN pre-clean activities shall be made of durable, impervious material, non-corrosive, non-toxic, non-carcinogenic and also facilitate cleaning and disinfection.

2.1.3.2 All utensils and equipment used in the preparation of raw-unclean EBN activities shall be cleaned and disinfected as necessary during each working day and at the end of each shift or each working day and before being used again if they have been contaminated.

2.1.4 Facilities

2.1.4.1 Water supply

Sufficient potable water supply from an approved source shall be available for use.

2.1.4.2 Drainage and waste disposal

Adequate drainage and waste disposal systems and facilities shall be provided. They shall be designed and constructed separately so as to avoid contaminating EBN or potable water supply.


2.1.4.3 Material for cleaning of establishment and equipment

Appropriate cleaning agent and equipment shall be provided as listed below:

- a) proper tools, suitably designated, shall be provided for cleaning of utensils and equipment;
- b) all chemicals, shall be of approved by the relevant authorities for use in the establishment, in such a manner as not to affect the quality of raw-unclean EBN intended for use; and
- c) detergents and disinfectants used shall not affect the wholesomeness of raw-unclean EBN intended for use.

2.1.4.4 Personnel hygiene facilities

Personnel hygiene facilities shall be available to ensure that an appropriate degree of personal hygiene can be maintained and to avoid contaminating raw-unclean EBN source. Where appropriate, facilities shall include:

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- a) hand-washing facilities shall be adequate, easily accessible, hands-free operated and be furnished with running water and hand wash liquid-soap;
- b) changing room which suitably located and adequately designed for workers from before and after the pre-clean production area; and
- c) lavatories facilities shall be well maintained in a good and sanitary condition at all times.

2.1.4.5 Ventilation and air quality

Ventilation systems shall be designed and constructed so that air does not contaminate the raw-unclean EBN.

2.1.4.6 Lighting

Adequate natural or artificial lighting shall be made available, where distortion of colours is avoided and the intensity shall range from 200 lux to 240 lux. Lighting fixtures shall be protected to ensure that EBN is not contaminated by breakages.


2.2 Storage

2.2.1 Where necessary, control measures shall be in place. Adequate facilities for storage of raw-unclean EBN, raw-unclean EBN after pre-clean, packaging materials and chemical such as cleaning material and hazardous substances shall be provided separately.

2.2.2 Raw-unclean EBN shall be stored at least 150 mm from the floor level on racks or shelves or pallets and shall have no contact with the wall in a well-ventilated room.

2.2.5 Hazardous substances shall be stored under lock and key, used only for the intended purpose, dispensed, handled and recorded by authorised personnel.

2.2.6 The storage facilities shall be designed and constructed to permit adequate maintenance and cleaning.

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2.2.7 Quarantine for raw-unclean edible-birdnest (finished products) to be exported to China shall be carried out at the establishment.

2.3 Control of operation

2.3.1 Raw-unclean EBN primary processing establishment operator shall control hazards in accordance with SIRIM/DVS 3:2015 requirements including and not limited to the following:

- a) identify raw materials and the process steps in their operations which are critical to the safety;
- b) implement effective control procedures at those steps;
- c) monitor control procedures to ensure their continuing effectiveness; and
- d) review control procedures periodically and whenever the operations change.

2.3.2 Key aspects of operational control systems

2.3.2.1 Processing area

Raw-unclean EBN before and after pre-clean operational procedure as well as before and after heating procedure shall be carried out in a well-separated area.

2.3.2.2 Contaminant control (biological, chemical, physical)

The establishments and operational procedure shall be planned to prevent any possibilities of cross-contamination between before and after pre-clean raw-unclean EBN; before and after heating raw-unclean EBN.


2.3.2.3 Raw-unclean EBN raw materials

Raw-unclean EBN shall comply with the following:

- a) Raw-unclean EBN to be used in the operational procedure shall be from registered and certified edible-nest swiftlet bird house and/ or registered collecting centre;
- b) All raw-unclean EBN received shall be recorded;

2.3.3 Packaging material

The packaging materials shall be unused material, non-toxic or non-carcinogenic, stored in dry and clean conditions.

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2.3.4 Operational procedure

2.3.4.1 General

Cleanliness shall be maintained throughout the establishments and in particular, the operation of the establishments shall be conducted in such a manner as to ensure that:

- a) operational procedure shall be supervised;
- b) this site shall be used for the purpose of preparation of the product raw-unclean EBN only;
- c) containers used during operational procedure of raw-unclean EBN shall be placed or handled as not to come in direct contact with the floor or grounds which might cause contamination;
- d) all materials and equipment for maintenance and cleaning, when not in use, shall be kept in rooms provided for the purpose;
- f) working table shall be made from non-toxic, non-corrosive impervious and easy-to-clean materials; and
- g) sites for operational procedure of raw-unclean EBN shall be carried out in a well-ventilated and lighting intensity within the range of 200 lux to 240 lux.

2.3.4.2 Sorting

The raw-unclean EBN shall undergo sorting and grading according to *SIRIM/DVS 3:2015*.

2.3.4.3 Pre-cleaning


The raw-unclean EBN shall undergo removal of faeces, soil, feathers (exclude fine feathers) and other gross impurities.

2.3.4.4 Heat treatment

The raw-unclean EBN shall undergo heat treatment and ensure that the product core temperature should not less than 70°C and retained at least 3.5 seconds.

2.3.4.5 Water spraying

When necessary, spraying of potable water on the heat treated raw-unclean EBN shall be done. The quality of the water shall be in accordance to Food Regulation 1985.

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2.3.4.6 Drying

When necessary, drying of the raw-unclean EBN shall be done. The moisture content of the dried raw-unclean EBN shall not be more than 25%.

2.3.4.7 Packaging and weighing

Packaging and weighing shall be done in a clean designated area. Packaging of the finished products shall be comprised of inner and outer layer. The outer packaging shall be disinfected. The inner and outer packing of the products shall be sealed.

2.3.4.6 Labelling


a) The outer packing shall be clearly labelled in both English and Chinese with;

- i) product name;
- ii) weight;
- iii) name and registration number of swiftlet bird houses;
- iv) name, address and registration number of primary processing establishment;
- v) storage conditions;
- vi) production date;
- vii) shelf life; and
- viii) other necessary information.

b) The outer packages shall also be labelled with the texts of **“Exported to the People’s Republic of China”** and **“Only for Further Processing in the Processing Place, Not Allowed for Retail Market”**.

2.3.4.7 Records and documents

Documents and records required by Good Manufacturing Practices (GMP) shall be available. Records shall include but not limited to raw-materials, operational procedure, non-food chemicals, cleaning, traceability, training, monitoring program, verification program, pest control, storage and distribution shall be maintained and made available for auditing purposes. All the records shall be kept and retained for a period that exceeds the shelf-life of the product.

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2.3.4.8 Transportation

Raw-unclean EBN product pack shall be transported in suitable containers. The transportation facilities shall be disinfected before and after shipment. The hygiene of the transport shall be monitored. During transportation, the packages of the products shall not be unsealed or replaced.

2.3.4.9 Traceability and recall procedure

Traceability system shall be established ranging from the edible-nest swiftlet bird houses to exportation in order to ensure that products are traceable and could be recalled timely in case of problem. The traceability system shall comply with one step forward and one step back approach. Traceability system shall refer to the Standard Operating Procedure For Registration and Traceability for Raw-Unclean Edible-Birdnest Export to China.

Recall procedure shall be established to ensure effective procedures are in place to deal with any food safety hazard and to enable the effective recall of any implicated lot of the finished products from the market. Recall system shall include written procedures to ensure rapid identification and removal of products from the market in a timely manner.


2.3.5 For the China approved raw-clean EBN processing establishments which intent to process both raw-clean and raw-unclean EBN shall provide evidences and verified to ensure there is clear separation between the raw-unclean and raw-clean EBN; workers flow; process/material flow; traceability system; to ensure there is no cross contamination occur.

2.4 Product safety control procedures

The operational procedure for raw-unclean EBN shall follow safety procedures as follows:

- a) Raw-unclean EBN primary processing establishment operator shall comply with product safety control in accordance with this procedure;
- b) Annual monitoring plan for finished products shall be conducted at least twice per year.
- c) Tests for finished products safety shall include microbiology, toxic substances and sensory tests.

The specification of the raw-unclean edible-birdnest can be referred at Annex B.

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2.5 Maintenance and cleaning

The following requirements shall be maintained:

- a) The establishment, equipment and all other physical facilities of establishment including drains shall be maintained in good and in orderly condition.
- b) Cleaning procedure and maintenance of establishment facilities and equipment shall be recorded.
- c) Cleaning and disinfection schedule shall be drawn up to ensure that all areas appropriately cleaned.

2.6 Pest control

There shall be an effective and continuous programmed for the control of pests.

2.7 Personnel hygiene

Personnel engaged in the handling of raw-unclean EBN shall:

- a) put on proper working attire;
- b) wash and disinfect hands before and after working process;
- c) personnel shall not eat, drink, chew or smoke during sorting, pre-cleaning, heating, water spraying, drying, packing, storing or in any part of the operational procedure;
- d) personnel suffering from or known to be a carrier of a disease transmissible by food shall not work in the establishments, which are liable to cause contamination of raw-unclean EBN; and
- e) personnel shall not handle before pre-clean or after pre-clean raw-unclean EBN, if he or she has any sore, cut or abrasion.



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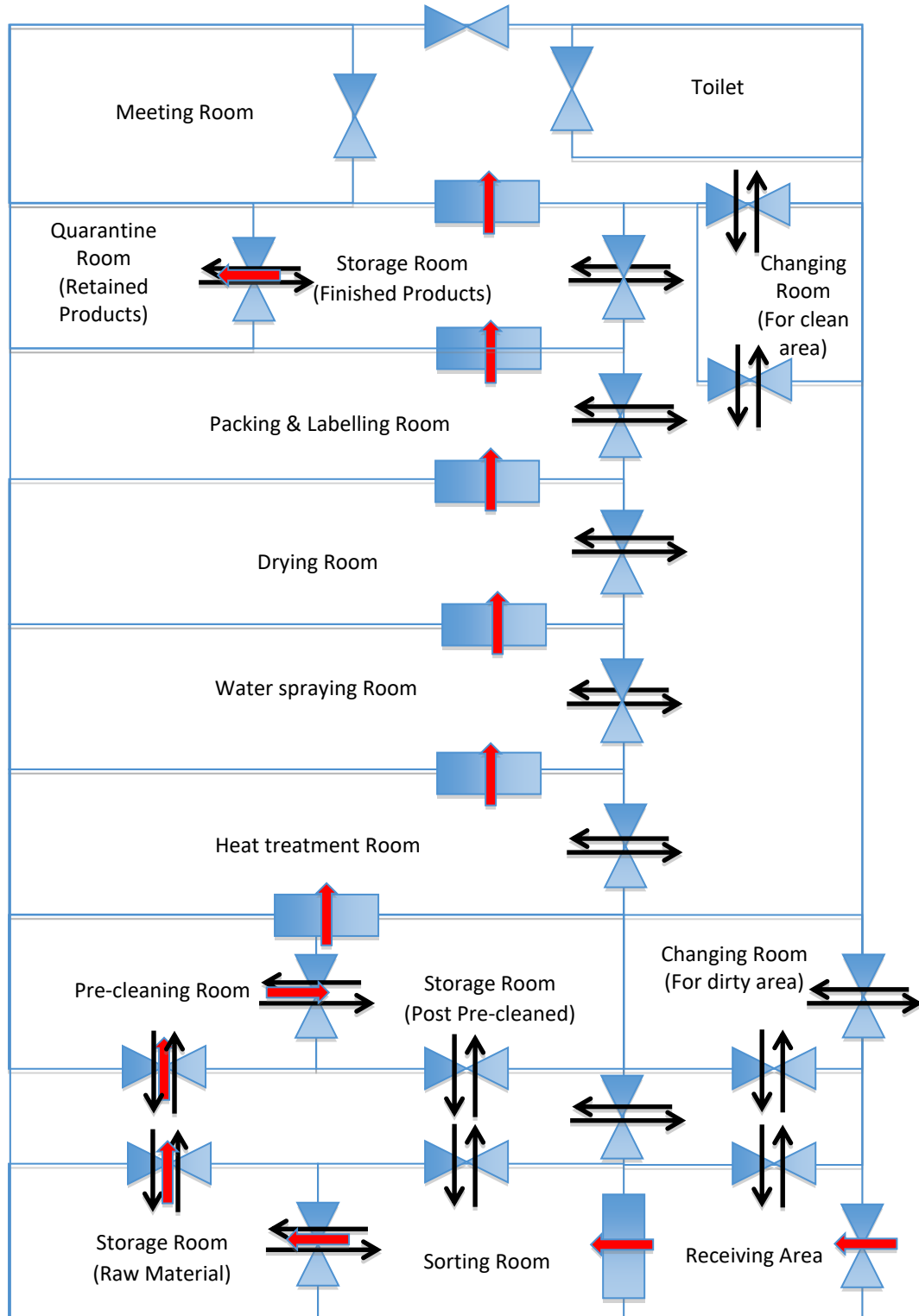
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ANNEX A





EXAMPLE ONLY


LAYOUT OF RAW-UNCLEAN EDIBLE-BIRDNEST PRIMARY PROCESSING ESTABLISHMENT



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Keys:

	Workers flow
	Product flow
	Door
	Passing Box


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ANNEX B

SPECIFICATION FOR RAW-UNCLEAN (RUC) EDIBLE-BIRDNEST (EBN)

The microbiological and physical requirements for RUC EBN:

Category	Parameters	Tolerance Level	Methods of tests
Microbiology	<i>Escherichia coli</i>	$\leq 1.0 \times 10^2$ cfu/g	Bacteriology Analytical Manual (BAM) Method or equivalent method
	<i>Salmonella</i> Enteritidis <i>Salmonella</i> Typhimurium <i>Salmonella</i> Gallinarum	Not detected	
	Coagulative Positive <i>Staphylococcus aureus</i>	$\leq 2.5 \times 10^3$ cfu/g	
	<i>Listeria monocytogenes</i>	Not detected	
Heavy metals	Lead (Pb)	≤ 2 mg/kg	AOAC Atomic Absorption Spectrophotometer (AAS) or Inductively Coupled Plasma Mass Spectrometry (ICP-MS) or equivalent method
	Arsenic (As)	≤ 1 mg/kg	
	Mercury (Hg)	≤ 1 mg/kg	
	Cadmium (Cd)	≤ 1 mg/kg	
Foreign matter	Paint Wood Twig Cement Sand Soil Dead nestling	Reasonably clean	Organoleptic or visual

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