Guideline of the Biosecurity Plan for the Export of Animal Products

to New Zealand

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1. Purpose

To prevent the importation of animal products that have not been properly treated into New Zealand from threatening the local ecology and economy, also to ensure that animal products exported to New Zealand maintain wholesome and safe, the competent authority of the third country which intends to export processed animal products into New Zealand is required by Ministry of Primary Industries (hereinafter referred to as MPI) to submit an Official Biosecurity Programme (hereinafter referred to as OBP). Meanwhile, food business operators (hereinafter referred to as the FBOs) that export animal products shall also establish and implement a Biosecurity Plan (hereinafter referred to as BP).

2. Applicable Subjects

- (1) Competent health authority: Taiwan Food and Drug Administration (hereinafter referred to as the TFDA), Ministry of Health and Welfare and local (city/county) health bureaus.
- (2) FBOs that intend to export animal products to New Zealand.

3. Scope of Application

Processed and heat-treated meat products and raw materials thereof that are exported to New Zealand.

4. Biosecurity Plan of FBOs

(1) All FBOs that intends to export animal products to New Zealand shall comply with the Act Governing Food Safety and Sanitation

and the related regulations as well as Import Health Standards of New Zealand. The relevant regulations shall be subjected to the latest version of announcements on the websites:

TFDA (http://www.fda.gov.tw/TC/law.aspx?cid=62)
MPI (https://www.mpi.govt.nz/).

- (2) In accordance with paragraph 1 of Article 15 of the Act Governing Food Safety and Sanitation, foods or food additives with any of the following circumstances shall not be manufactured, processed, prepared, packaged, transported, stored, sold, imported, exported, presented as a gift or publicly displayed:
 - a. those have deteriorated or rotten;
 - b. those are unripe and thus harmful to human health;
 - c. those are toxic or contain substances or foreign materials that are harmful to human health;
 - d. those are contaminated by pathogens, or have been established by an epidemiological survey to be a cause of food poisoning;
 - e. those exceeded the pesticide or veterinary drugs residue limit;
 - f. those have been contaminated by atomic dust or radioactive, and its content exceeds the safety limit;
 - g. those are adulterated or counterfeited;
 - h. those are expired;
 - i. those have never been provided for human consumption and never been proven to be harmless to human health; or
 - j. those contain food additives that are not permitted by the central competent authority.
- (3) Raw materials of processed and heat-treated meat products that are exported to New Zealand shall be obtained from eligible countries with approved exporting systems by MPI and exported to New Zealand after proper processing:

- a. Bovine meat: Raw materials shall be obtained from New Zealand, Australia, USA, Canada, Japan, and European Unions (Must be a member country approved to import into Taiwan). Raw materials shall also be subjected to New Zealand Import Health Standard of Animal Products that have Undergone Third Country Processing. The aforementioned countries shall be subjected to the latest version of New Zealand's announcements.
- b. Swine meat: Raw materials shall be obtained from New Zealand, Australia, USA, Canada, and European Unions (Must be a member country approved to import into Taiwan). Raw materials shall also be subjected to New Zealand Import Health Standard of Animal Products that have Undergone Third Country Processing.
- (4) A FBO that exports processed and heat-treated meat products to New Zealand shall ensure that the animal product and its manufacturing process comply with standards and regulations of both Taiwan and New Zealand. All FBOs shall also meet the following requirements:
 - a. FBOs shall establish a manufacturing flow chart from raw materials acceptance to end product transportation.
 - b. FBOs shall establish process management and quality control procedures which contain a contingency plan in the event of cross-contamination risk.
 - e.g., FBOs shall have a contingency plan in response to the suspension of manufacturing such as the processing facility is polluted, or unqualified raw materials are misused in food, or accidents occur like fire, or power failure etc. circumstances happened, the FBO should launch the contingency plan to prevent non-compliant products from entering the market or

- being exported to New Zealand by implementing corresponding measures such as the disposal of raw materials, semi-finished products and finished products, or the cleaning and disinfection of the production line.
- c. Ensure the integrity of product separation to prevent crosscontamination or mixture between the animal products intended to be exported to New Zealand and those that are not.
- d. Employees, operation site, sanitary management of facility, warehouse management, transportation management, and quality assurance system of a food business shall all comply with Regulations on Good Hygiene Practice for Food (hereinafter referred to as GHP) in Taiwan:
 - (a) Process management and quality control in the food manufacturers shall meet the requirements in the Process Management and Quality Control Guidelines in Table 3. Raw materials and ingredients shall conform to the Act Governing Food Safety and Sanitation and related regulations.
 - (b) To ensure food safety and to prevent cross-contamination, FBOs shall comply with requirements on warehouse control in Article 6 and configuration and space at a food operation site in Article 14 of GHP. Besides, FBOs shall meet the following requirements:
 - i Sites of different operating natures shall be set up separately or be partition from one another effectively and remain clean.
 - ii There shall be sufficient room to place operating equipment and food utensils, food containers, and packaging, set up sanitary facilities, and store raw materials and packaging materials.

- iii Warehouses for raw materials and packaging materials, semi-finished products and finished products shall be set up separately or be adequately partition from one another and be given sufficient room to facilitate transport.
- iv Items inside the warehouse shall be classified and placed on pallets, shelves or other effective measures shall be adopted. The items may not be placed directly on the floor and shall be kept clean and well ventilated.
- v Warehouse operations shall be based on the principle of the priority use for the less shelf life mains and be precisely recorded.
- vi When it is necessary to control the temperature or humidity during storage, the control method and criteria shall be established and precisely recorded.
- vii The warehouse shall be periodically inspected with precise records kept. Any abnormality shall be handled immediately to ensure the quality and sanitation status of raw materials and packaging materials, semi-finished products, and finished products.
- viii For items or packaging materials likely to contaminate raw materials and packaging materials, semi-finished products, or finished products, it should be measured to prevent cross-contamination. When prevention against cross-contamination is impossible, they may not be kept together with raw materials and packaging materials, semi-finished products, or finished products.
- (c) In accordance with Article 7 of GHP, transport vehicles shall be kept clean and sanitary. When products are to stack up, they shall be kept steady with air circulation maintained.

- Meanwhile, there should be measures to prevent crosscontamination.
- e. FBOs shall develop a food safety control system in the processing facility based on the principles of Hazard Analysis and Critical Control Points (hereinafter referred to as HACCP).
 - (a) The food safety control system refers to use a system that identifies, evaluates and controls food safety hazards, which is the principle of HACCP, to manage the inspection and acceptance of raw materials and materials, processing, manufacture, storage and transportation.
 - (b) The food safety control system consists of the following items:
 - i Establish a HACCP team
 - ii Conduct a hazard analysis.
 - iii Determine the Critical Control Points (CCPs).
 - iv Establish critical limits.
 - v Establish and implement a monitoring plan.
 - vi Establish and implement corrective actions.
 - vii Confirm the effectiveness of the system implementation.
 - viii Establish documents and records of the system implementation.
 - (c) The system mentioned above shall include control measures to prevent cross-contamination during processing and to identify potential pathways by which cross-contamination occurs in the process.
- f. Establish traceability system of food products
 - (a) In accordance with paragraph 1 in Article 9 of the Act Governing Food Safety and Sanitation, food businesses shall retain the related source documents of the raw

- materials, semi-products and end products.
- (b) Food plants shall establish related standard operating procedures and keep records of related treatments for at least five years by Articles 12 and 13 of GHP.
- (c) In accordance with point 1 and point 19 in Table 3 of GHP, raw materials and packaging materials shall have related data or records for tracing their sources. For the sale of each batch of finished products, there shall be related documents or records available.
- (d) Information of products exported to New Zealand shall be traceable to all manufacturing processes and transportation until the products are imported into New Zealand. The relevant information includes ingredients, employees, control limits (duration of the process, temperature, and so on), date of manufacture, and temperature or humidity during manufacturing or storage.

5. Training

- (1) FBOs shall initiate the programme for education and training which includes relevant regulations on exporting animal products to New Zealand and implementation of the BP.
- (2) New employees shall be properly trained before the first day on the job.
- (3) All in-service employees, including on-site operators, shall receive training on the implementation of the BP and fully understand the content.

6. Food defence and food fraud prevention

(1) Food that is adulterated or counterfeited shall not be manufactured by point 7 in paragraph 1 of article 15 of the Act Governing Food Safety and Sanitation. FBOs shall ensure

products free from pollution and alteration by chapter 1 to chapter 3 of GHP.

- (2) FBOs shall establish food protection measures.
- (3) Explain in detail how food processing facility prevents substitution of products intended-to-export to New Zealand from those not for New Zealand.

7. Product Recall

Food businesses shall establish product recall management plans with regard to elaborate on procedures of product recall and notification to the local (city/county) health bureaus and procedures of product recalls resulting from customer complaints.

8. FBOs shall establish and implement a BP according to Clause 4. to 7. of this guideline with precise records kept. "Self-checklist for the BP for the export of animal products to New Zealand" in the annex is for FBOs to assess and confirm the relevant documents and procedures that shall be established.

9. Official Controls of the Competent Authority

(1) Official Biosecurity Programme (OBP)

The competent authority in Taiwan shall ensure those FBOs which intend to export heat-treated meat products to New Zealand implement the BP and comply with relevant regulations of New Zealand with precise records kept. The competent authority shall also ensure that the following requirements are met:

- a. The BP is established by a FBO.
- b. Quality assurance management systems of the processing facility [e.g., GHP and HACCP].
- c. The integrity of product separation from all other products not eligible for export to New Zealand.

- d. Meat raw materials are originated from countries authorized by New Zealand.
- e. Measures on prevention of product substitution.
- f. Product traceability.
- g. The programme for education and training all persons involved in the operation of the processing facility
- (2) When a FBO is inspected by the competent authority and found to be inconsistent with New Zealand regulations, the competent authority may impose the following measures:
 - a. Notify the certificate-issuing authority (hereinafter referred to as the issuing authority) which issues quarantine certificates for the export of animal products to New Zealand to suspend export certification applications for the non-compliant products with the same batch number.
 - b. The relevant FBOs are requested to correct within a prescribed period on the non-conforming items found in the inspection. The follow-up checks when expired confirms that the correction is completed, and the issuing authority is notified to restore the management mechanism.
 - c. If the correction is not completed after the deadline, the issuing authority may be notified to suspend the quarantine certificate application for all items of the product. Only when the follow-up checks of the competent authority confirm that the correction is completed, the issuing authority is notified to restore issuing procedures.
 - d. The health authority may adjust the intensity and frequency of the official control measures by the severity of non-compliance or the circumstances of non-compliance over the years of the FBOs.

10. Reference

- (1) Import health standards (IHS)

 (https://www.mpi.govt.nz/legal/compliance-requirements/ihsimport-health-standards/)
- (2) Import Health Standard: Animal Products that have Undergone Third Country Processing, Ministry of Primary Industries, New Zealand (2018)

 (https://www.mpi.govt.nz/dmsdocument/1158-Animal-products-that-have-undergone-third-country-processing-Import-Health-Standard)
- (3) Animal Products that have Undergone Third Country Processing (Guidance Document), Ministry of Primary Industries, New Zealand (2019)

 (https://www.mpi.govt.nz/dmsdocument/1159-Animal-products-that-have-undergone-third-country-processing-Import-Health-Standard-Guidance-Document)
- (4) Import Health Standard: Specified Animal Products, Ministry of Primary Industries, New Zealand (2020) (https://www.mpi.govt.nz/dmsdocument/41067-Specified-Animal-Products-Import-Health-Standard)
- (5) General Principles of Food Hygiene, Codex Alimentarius Commission (CXC 1-1969) (http://www.fao.org/fao-who-codexalimentarius/codex-texts/codes-of-practice/en/)

ANNEX - Self-checklist for the Biosecurity Plan for animal products export to New Zealand

Date:

Name of Food Business		Jnified Business No.	
Business Owner			
Business Registration Address			
Location of Processing Facility	☐Same as above; ☐Current address:		
Food Business Registration Number			
Facility Registration Number			
Contact Person/ Phone Number	/		
Contact E-mail			
	☐ Heat-treated meat products containing	g bovine meat	
Product category for New Zealand exportation and	Country of origin of bovine meat: New Zealand Australia U EU(SA □ Canac pan	da
the sourcing countries of raw materials (multiple	☐ Heat-treated meat products containing	g swine meat	
choice)	Country of origin of swine meat: New Zealand Australia U EU (SA □ Canao	da

Requirements for animal products export to New Zealand	Current status of food business and list of confirmation
1. English label shall be used on the exported food and shall meet the labelling requirements in New Zealand.	1. We have confirmed that product labelling meets the requirements in New Zealand.
2. Food businesses shall establish respective and separate Biosecurity Plan (BP) for New Zealand exportation. Output Description:	2. We have established a respective and separate BP for New Zealand exportation. Yes NO, because:

Requirements for animal products export to New Zealand	Current status of food business and list of
3. Management and implementation of BP.	confirmation 3. We have built a team or similar group of the BP management. Members of the BP team:
	Name:Title: In charge of
	Name:Title:
	Name:Title: In charge of
	(Extendable when insufficient space)

Food businesses shall establish respective Biosecurity Plan for New Zealand exportation. The plan shall contain at least the following information:

Description of Biosecurity Plan		
1. The manufacturing process of the product complies with Taiwan GHP.		
Contents to be confirmed:		
(1) We have established an internal management system based on GHP.		
Description of the BP is as follows:		
(2) We are certified by the following food safety certification systems:		
(3) Relevant certificates.		

2. The food business has established a HACCP plan, implemented hazard analysis, identifying all potential pathways of cross-contamination in factories and their control points, established control limits, correction measures, validations and records.

Contents to be confirmed:

(1) All of our products for New Zealand exportation are managed based on HACCP principles, and we performed physical, chemical and biological hazard analysis concerning all steps in the processing flow chart, listing all potential hazards as well as establishing control points, critical control points, control limits, correction measures, validations, and records. Description of the BP is as follows:

3. The	food business has established manufacturing flow charts of all animal	
prod	products for New Zealand exportation from raw materials reception to end	
prod	product transportation.	
Cont	ents to be confirmed:	
(1)	We have established manufacturing flow charts of all animal products	
	for New Zealand exportation from raw materials acceptance to end	
	product transportation. Description of the BP is as follows:	
(2)	Manufacturing flow charts of animal products intended to export to	
	New Zealand is attached:	

4. The food business has established process management and quality con	trol
procedures which contain a contingency plan in the event of cro)SS-
contamination risk.	
Contents to be confirmed:	
(1) Description of the contingency plan in BP for the event of a chang	e in
the risk of cross-contamination is as follows:	
(e.g., When raw materials of animal origin are accident	ally
contaminated by microorganisms or pathogens, the food process	ing
facility shall take measures of emergency response.)	
(2) The methods and frequency of identification of cross-contaminate	ion
risk are:	

5.	Ens	ure the integrity of production line separation from all other production
	lines not eligible for New Zealand exportation.	
	Con	tents to be confirmed:
	(1)	The method of production line separation from all other production
		lines not eligible for exporting to New Zealand is:
		(e.g., With time separation, the production of products for New Zealand
		exportation is before those that are not for New Zealand within the
		same production line. With space separation, the production lines for
		New Zealand exportation is fully separated from those that are not,
		without shared equipment.)
	(2)	Supporting documents of procurement are attached:

	6.	Info	ermation of products exported to New Zealand is traceable to all	
		manufacturing processes and transportations until products are imported		
		into New Zealand.		
		Con	tents to be confirmed:	
		(1)	Description on methods of traceability in BP is:	
		(2)	The recording method for purchasing and shipping is:	
		(3)	The recording method for all manufacturing processes is:	
		(4)	Relevant supporting documents are attached.	
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7. The food business has established implement an education and training programme for employees which includes relevant regulations on animal products for New Zealand exportation and the BP.

Contents to be confirmed:

- (1) The establishment and implementation of an education and training programme for employees which includes relevant regulations on animal products for New Zealand exportation and the BP is explicitly required in our BP. The outline of the programme is:
- (2) The number of employees of our business is:
- (3) The number of participants in the programme is:
- (4) Relevant supporting documents are attached.

8.	The food business has established a food defence and food fraud plan which	
	specifies in details how food processing facility prevents substitution of	
	products for New Zealand exportation from those are not.	
	Contents to be confirmed:	
	(1)	The prevention methods of substitution from products not for New
		Zealand exportation to those are for New Zealand exportation as
		follow:
		(e.g., Use unique recognizable marks, such as batch numbers, text,
		images, etc., on products exported to New Zealand)
	(2)	The methods to prevent non-compliant products from exporting to
		New Zealand are:

9.	The	food business has established a product recall plan which describing
	the procedure of product recall and notification to the local (city/county)	
	health bureaus, and the procedure of the product recalls resulting from	
	cust	omer complaints.
	Con	tents to be confirmed:
	(1)	Description on the procedures of the product recall in the BP are:
	(2)	The notification procedures for product recall and notification objects
		are: