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FOOD SAFETY AND SECURITY ACT 2025

FOOD SAFETY AND SECURITY (FSSA AUTHORISATIONS — ADMINISTRATION) REGULATIONS 2025

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In exercise of the powers conferred by sections 307 and 308 of the Food Safety and Security Act 2025, the Singapore Food Agency, with the approval of the Minister for Sustainability and the Environment, makes the following Regulations:

Citation and commencement

1. These Regulations are the Food Safety and Security (FSSA Authorisations — Administration) Regulations 2025 and come into operation on 28 November 2025.

Definitions

2.—(1) In these Regulations —

"applicant" means the person who makes an application, or on whose behalf an application is made, to the Agency for an FSSA authorisation to be granted to the person; "application" means an application for an FSSA authorisation; "contact address" means the address of —

- (a) for a partnership (other than a limited liability partnership) the partnership's principal place of business in Singapore or elsewhere;
- (b) for a body corporate the body corporate's registered office or principal office in Singapore or elsewhere;
- (c) for an unincorporated association the unincorporated association's principal office in Singapore or elsewhere;
- (d) for an individual carrying on business as a sole proprietor the principal place of business in Singapore or elsewhere; or
- (e) for any other individual the individual's place of residence or workplace in Singapore;

"FSSA authorisation" means a pre-market approval with respect to a novel food or a genetically modified food;

"identity particulars" means —

- (a) for an individual
 - (i) the full name of the individual;
 - (ii) the number of the individual's identity card, or of the individual's passport or work pass if he or she is not a citizen of Singapore; and
 - (iii) the nationality of the individual; or
- (b) for an entity
 - (i) the full name of the entity;
 - (ii) the country where the entity was incorporated or otherwise formed; and
 - (iii) the Unique Entity Number (UEN) of the entity, where available;

- "intellectual property right" means a right conferred by any patent, copyright, trade mark, registered design, geographical indication or the grant of protection of a plant variety.
- (2) Where the time specified by these Regulations for doing any act expires on a Saturday, Sunday or public holiday, the act is on time if done on the next following day that is not a Saturday, Sunday or public holiday.

How to apply

- **3.** An application for an FSSA authorisation must be made in a form approved by the Agency and be made in one of the following ways:
 - (a) by sending an email to the email address at authorisation@sfa.gov.sg;
 - (b) in the case of a malfunction or failure of the email address in paragraph (a) or other exceptional circumstances by sending by post to the Agency at the National Centre for Food Science, situated at 7 International Business Park, Singapore 609919.

Who to apply

- **4.**—(1) Except as provided in paragraph (2), an application for an FSSA authorisation has to be made by the person
 - (a) who owns an intellectual property right associated with the novel food or genetically modified food which is the subject of the application; or
 - (b) who holds a licence from the owner of an intellectual property right mentioned in sub-paragraph (a), conferring on the licensee, or on the licensee and persons authorised by the licensee, any right to supply in Singapore the novel food or genetically modified food which is the subject of the application, that the owner would, but for the licence, have the exclusive right to do.
- (2) An application for an FSSA authorisation may also be made on behalf of the person mentioned in paragraph (1) by the person's agent.

When to apply

- 5.—(1) Subject to paragraph (2), an application for an FSSA authorisation with respect to a novel food or a genetically modified food must be made at least 9 months before the date the supply in Singapore of the novel food or genetically modified food is proposed to start.
- (2) The Agency may accept and consider an application for an FSSA authorisation that is made in a shorter time than is specified in paragraph (1) in any case where the Agency is reasonably satisfied that an earlier application could not have been made.

What is needed in application: general

- **6.**—(1) For the purposes of section 292(2)(b) and (d) of the Act, every application for an FSSA authorisation must be accompanied by the following, if not waived under regulation 7 or 9:
 - (a) the application fee specified in the First Schedule for the FSSA authorisation;
 - (b) the identity particulars, telephone number, email address and contact address of the applicant;
 - (c) where the application is made by an agent on behalf of the applicant the identity particulars, telephone number, email address and contact address of the agent;
 - (d) the special information specified in the Second Schedule in respect of the subject of the application;
 - (e) documents and other evidence of the information mentioned in sub-paragraphs (b), (c) and (d);
 - (f) any other information that the Agency specifies that it requires to decide the application, and documents and other evidence of that other information.
- (2) An authorised officer may require an applicant for an FSSA authorisation to amend and re-submit any information contained in or accompanying the application for the purpose of assessing the application by the applicant.

Waiver of application requirement

7. Despite anything in these Regulations, an authorised officer may, in any particular case and if satisfied that it is just and equitable, waive any requirement in regulation 5 or 6, as the case may be.

Fees

8. Every fee specified in these Regulations must be paid in full when due unless regulation 9 applies.

Waiver, etc., of fees

- **9.** An authorised officer may in any particular case, and if satisfied that it is just and equitable
 - (a) refund, in whole or part, any fee mentioned in these Regulations that has been paid; or
 - (b) waive or reduce, in whole or part, any fee payable under these Regulations.

FIRST SCHEDULE

Regulation 6(1)

FEES

First column	Second column
Item	Fee
1. Application fee for a pre-market approval for a novel food	\$1,750
2. Application fee for a pre-market approval for a genetically modified food, derived or produced from —	
(a) any genetically modified organism with any genetic modification not covered by any current pre-market approval;	\$880

FIRST SCHEDULE — continued

First column	Second column
Item	Fee
(b) any genetically modified organism with genetic modifications that are derived or originate from 2 or more genetically modified organisms, which are each covered by a current pre-market approval; or	\$440
 (c) any genetically modified organism with genetic modifications that are — (i) a subset of the genetic modifications in another genetically modified organism; and 	\$110
(ii) all covered by any current pre-market approval.	

SECOND SCHEDULE

Regulation 6(1)

SPECIAL INFORMATION REQUIRED FOR PRE-MARKET APPROVAL APPLICATION

- 1. An application for pre-market approval with respect to a novel food or a genetically modified food must contain or be accompanied by the following information:
 - (a) information that identifies the novel food or genetically modified food, including in particular
 - (i) the name of the novel food or genetically modified food, the scientific name of the novel food or genetically modified food and where relevant, information about the part of the organism that it is derived from;
 - (ii) the common name under which the novel food or genetically modified food will be supplied or advertised by the applicant for consumption as food by the general public; and

- (iii) if the food is an extract or is a ground up preparation (such as a powder), the form of the food and any relevant information about its origin, concentration factors, processing methods, or other distinguishing features;
- (b) the proposed use in Singapore of the novel food or genetically modified food, including in particular
 - (i) whether the novel food or genetically modified food is proposed for use as an ingredient in food;
 - (ii) if proposed as an ingredient in food
 - (A) the type of products the novel food or genetically modified food is intended to be used in;
 - (B) how the novel food or genetically modified food is to be used in the products in sub-paragraph (A); and
 - (C) the maximum intended use level of the novel food or genetically modified food in the products in sub-paragraph (A);
 - (iii) whether any special preparation is required before using or consuming the novel food or genetically modified food as a food or an ingredient in food or whether the novel food or genetically modified food is to be consumed raw; and
 - (iv) where appropriate, the conditions for supply in Singapore of the novel food or genetically modified food, including specific conditions for its consumption and handling;
- (c) scientific evidence demonstrating that the novel food or genetically modified food as a food or an ingredient in food does not pose a risk to human health, taking into account the potential for the presence of food safety hazards in the novel food or genetically modified food, including in particular
 - (i) studies which have been carried out, and any other material which is available, to demonstrate that the novel food or genetically modified food as a food or an ingredient in food does not pose a risk to human health; and
 - (ii) where appropriate, the analysis method or methods used in those studies or other material;
- (d) a description of any known adverse effects associated with the use of the novel food or genetically modified food as a food or an ingredient in food, in any foreign country in which it has been used, including —

- (i) details about the nature and extent of those adverse effects;
- (ii) whether the adverse effects are based on observations in human or animal studies accompanied by copies of the referenced studies; and
- (iii) the approximate level of human intake of the novel food or genetically modified food which is associated with any adverse effects:
- (e) the expected level of human intake of the novel food or genetically modified food from its use in Singapore as a food or as an ingredient in food, including
 - (i) how the expected level of human intake compares with the human intake of the novel food or genetically modified food as a food or an ingredient in food in any foreign country or region in which it is being or has been used; and
 - (ii) whether the expected level of human intake of the novel food or genetically modified food as a food or an ingredient in food is likely to exceed levels at which there are known adverse effects;
- (f) whether the safety of the novel food or genetically modified food as a food or an ingredient in food has been assessed by any foreign food authority for use in any foreign country as a food or an ingredient in food and what the foreign countries are and, if available, a copy of the safety report;
- (g) whether the novel food or genetically modified food as a food or an ingredient in food is the subject of any approval, or any pending application or petition for approval, from a foreign food authority for use in any foreign country as a food or an ingredient in food, and what the foreign countries are;
- (h) any prohibition or restriction imposed by any foreign food authority in respect of the novel food or genetically modified food as a food or an ingredient in food, or a declaration that there is no such prohibition or restriction imposed;
- (i) a proposal for labelling the novel food or genetically modified food to inform the consumer about the novel food or genetically modified food;
- (*j*) where appropriate, a proposal for post-market monitoring regarding the human consumption in Singapore of the novel food or genetically modified food or its handling for human consumption in Singapore;

- (k) the date the supply in Singapore of the novel food or genetically modified food is proposed to start.
- 2. In addition, an application for pre-market approval with respect to a novel food must contain or be accompanied by the following information:
 - (a) the description of the novel food, including the detailed composition of the novel food;
 - (b) information about the history (if any) about the use in any foreign country of the novel food as a food or an ingredient in food, including in particular
 - (i) whether the food or ingredient is used by the general population in that foreign country or by a specific sub-population in that foreign country; and
 - (ii) how long has the novel food been used as a food or an ingredient in food;
 - (c) if the novel food has been manufactured, prepared or preserved by a process that has not been previously used in food production for a period of at least 20 years, information about the history (if any) about its manufacturing, preparation or preservation process in any foreign country;
 - (d) whether the novel food as a food or an ingredient in food is recognised worldwide, regionally, or in isolated populations;
 - (e) whether the novel food has been used as a food or an ingredient in food or has been used for other purposes in addition to or instead of such food use (such as in traditional medicine);
 - (f) if the novel food has been used for medicinal purposes in any foreign country
 - (i) information about the therapeutic claims associated with its use;
 - (ii) the typical use levels prescribed; and
 - (iii) how the medicinal use levels relate to the proposed level of intake from food;
 - (g) a comprehensive description of the manufacturing process and information as to whether the method has previously been applied to food, together with a process flow chart that shows the method of production for the novel food;

- (h) whether the novel food is produced from a source that in itself is not normally consumed as part of the human diet and what that source is, or whether the source is new or uncharacterised such that its safety for human consumption has not been established.
- 3. In addition, an application for pre-market approval with respect to a genetically modified food must contain or be accompanied by the following information:
 - (a) the designation of the genetically modified food, including the details of its specification and the transformation event or events used;
 - (b) where applicable, a detailed description of the method of production and manufacturing of the genetically modified food;
 - (c) an analysis, supported by appropriate information and data, showing that the characteristics of the genetically modified food and how those characteristics are different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such;
 - (d) information as to the place where the reference material for the transformation event or events can be accessed.

Made on 19 November 2025.

LIM CHUAN POH

Chairperson,

Singapore Food Agency.

[AG/LEGIS/SL/111D/2025/1]

(To be presented to Parliament under section 316 of the Food Safety and Security Act 2025).