

Annex II – Draft text & Explanatory note

DEFINED FOOD

EXTRACTED PROVISIONS FROM FSSB VERSION 7.2

Meaning of “defined food”

1.—(1) For the purposes of this Act, food is defined food if the food —

- (a) is, consists of or has as an ingredient a novel food in respect of which no pre-market approval is granted;
- (b) is, consists of or has as an ingredient a genetically modified food in respect of which no pre-market approval is granted; or
- (c) is, consists of or has as an ingredient, in any form (whether whole or in parts and whether fresh, chilled, frozen, dried, smoked, salted or in brine, or as flour) an insect-like species which is not a catalogued insect-like species.

(2) The Agency may, with the approval of the Minister, by order in the *Gazette*, declare an insect-like species as a catalogued insect-like species where the Agency is satisfied that the insect-like species, where made available for consumption by the general public, is not food of higher regulatory concern.

(3) In this section —

“engineered nanomaterial” means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale;

“genetically modified food” means a food coming from an organism that has been altered using any of the following techniques, such that the resulting organism contains a combination of heritable genetic material that could not have occurred naturally or could not have been produced by traditional breeding and selection:

- (a) in vitro nucleic acid techniques, including recombinant nucleic acids and direct injection of nucleic acid into cells or organelles;
- (b) fusion of cells beyond the taxonomic family,

and excludes any novel food and any food that is, consists of or has an ingredient an insect-like species which has not been so altered;

Illustration

An animal, plant or micro-organism which is modified by genetic engineering.

“novel food” means —

- (c) a substance (which may consist of, be isolated from or produced from, cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae) that has not been used to a significant degree as food for a period of at least 20 years, whether within or outside Singapore;
 - (d) a food that 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, whether within or outside Singapore;
 - (e) a food consisting of, isolated from or produced from material of mineral origin; or
 - (f) a food that contains or consists of engineered nanomaterials,
- but does not include any food that is, consists of or has as an ingredient an insect-like species in any form.

PART 5

DEFINED FOOD AND PRE-MARKET APPROVAL

Meaning of “pre-market approval”

2. In this Part, “pre-market approval” means an approval granted under this Part for a novel food or genetically modified food to be available for consumption by the general public, after the Agency makes an assessment of the public health and safety considerations having regard to —

- (a) the potential for adverse effects in humans;
- (b) the composition or structure of the novel food or genetically modified food;
- (c) the process by which the novel food or genetically modified food has been prepared;
- (d) the source from which the novel food or genetically modified food is derived;
- (e) the likely patterns and levels of consumption of the novel food or genetically modified food; and
- (f) any other relevant matters.

Supply of defined food knowingly

3.—(1) A person commits an offence if —

- (a) the person supplies any food in Singapore;
- (b) the food is a defined food; and
- (c) the person knows or ought reasonably to know that the food is a defined food.

(2) A person who is guilty of an offence under subsection (1) shall be liable on conviction —

- (a) where the person is an individual —

- (i) to a fine not exceeding \$15,000 or to imprisonment for a term not exceeding 6 months or to both; or
 - (ii) where the individual is a repeat offender — to a fine not exceeding \$30,000 or to imprisonment for a term not exceeding 12 months or to both; or
- (b) where the person is not an individual —
- (i) to a fine not exceeding \$30,000; or
 - (ii) where the person is a repeat offender — to a fine not exceeding \$60,000.
- (3) In subsection (2), “repeat offender”, in relation to an offence under subsection (1), means a person who —
- (a) is convicted, or found guilty, of an offence under subsection (1) (referred to as the current offence); and
 - (b) has been convicted or found guilty, on at least one other earlier occasion within the period of 5 years immediately before the date on which the person is convicted or found guilty of the current offence, of an offence under subsection (1).
- (4) For the purposes of this section, it is immaterial whether the food concerned is safe.

Supply of defined food — strict liability

- 4.—(1) A person commits an offence if —
- (a) the person supplies any food in Singapore; and
 - (b) the food is a defined food; and
- (2) Strict liability applies to subsection (1).
- (3) A person who is guilty of an offence under subsection (1) shall be liable on conviction —
- (a) where the person is an individual — to a fine not exceeding \$5,000 or to imprisonment for a term not exceeding 3 months or to both; or
 - (b) where the person is not an individual — to a fine not exceeding \$10,000.
- (4) For the purposes of this section, it is immaterial whether the food concerned is safe.

Defence of due diligence

- 5.—(1) In a prosecution of a person for an offence under section 107 or 108, it is a defence for the defendant to prove, on a balance of probabilities, that —
- (a) that the commission of the offence was due to —
 - (i) an act or omission of another person; or
 - (ii) an accident or some other cause outside the defendant’s control; and

- (b) the defendant took all reasonable precautions and exercised all due diligence to prevent the commission of the offence by the person, or by another person under the defendant's control.
- (2) In subsection (1)(a), another person does not include a person who was —
- (a) an employee or agent of the person charged; or
 - (b) if the defendant is a corporation, a director of the corporation.

Advertising defined food

- 6.**—(1) A person commits an offence if the person —
- (a) advertises any defined food; and
 - (b) the food is a defined food at the time of the advertising.
- (2) A person who is guilty of an offence under subsection (1) shall be liable on conviction —
- (a) where the person is an individual —
 - (i) to a fine not exceeding \$5,000 or to imprisonment for a term not exceeding 3 months or to both; but
 - (ii) where the individual is a repeat offender — to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 6 months or to both; or
 - (b) where the person is not an individual —
 - (i) to a fine not exceeding \$10,000; but
 - (ii) where the person is a repeat offender — to a fine not exceeding \$20,000.
- (3) In a prosecution of a person for an offence under this section, it is a defence for the person charged to prove, on a balance of probabilities, that the person —
- (a) is a person one whose business is to publish or arrange for the publication of advertisements and that the person received the food advertisement for publication in the ordinary course of business;
 - (b) has no financial interest in the food featured in the food advertisement;
 - (c) did not know that the food advertisement is about a defined food at the time of publication; and
 - (d) had taken all reasonably practicable steps as are necessary to ascertain that the food was not a defined food at the time of publication.
- (4) For the purposes of this section, it is immaterial whether the food concerned is safe.

Application for pre-market approval

- 7.**—(1) An application for pre-market approval in respect of a novel food or a genetically modified food must —

- (a) be in the form and manner the Agency specifies;
 - (b) be accompanied by an application fee, if prescribed;
 - (c) contain —
 - (i) an address in Singapore at which notices and other documents under this Act for the applicant may be served; or
 - (ii) the name and address of one or more Singapore-connected persons in Singapore authorised by the applicant to accept on the applicant's behalf service of notices and other documents under this Act; and
 - (d) be accompanied by the prescribed information relating to the novel food or genetically modified food which is the subject of the application, and any other additional information that the Agency requires to decide on the particular application.
- (2) The Agency may refuse to consider an application for pre-market approval with respect to a novel food or genetically modified food if the application —
- (a) is incomplete;
 - (b) is not made in accordance with this section; or
 - (c) does not contain sufficient information for the Agency to make an assessment as to the public health and safety considerations as described in section 106.

Grant of pre-market approval

8.—(1) After considering an application under section 111 for pre-market approval, the Agency may —

- (a) on payment of the applicable approval fee (if prescribed), grant pre-market approval in respect of a novel food or a genetically modified food; or
- (b) refuse to grant the pre-market approval.

(2) In granting a pre-market approval in respect of a novel food or a genetically modified food, the Agency may impose such conditions as the Agency considers requisite or expedient to ensure that the novel food or genetically modified food (as the case may be) —

- (a) is what it says it is; and
- (b) is safe, and after having regard to the public health and safety considerations as described in section 106.

(3) The Agency may, at the request of an applicant for pre-market approval in respect of a novel food or a genetically modified food, grant the pre-market approval subject to an exclusive use condition.

Validity of pre-market approval

9. A pre-market approval granted in respect of a novel food or a genetically modified food has effect until —

- (a) the approval is cancelled under section 114; or
- (b) in the case of a novel food, it earlier ceases to be a novel food.

Cancelling pre-market approval

10.—(1) Subject to subsections (2), (3), (4) and (5), the Agency may cancel (without any compensation) a pre-market approval in respect of a novel food or a genetically modified food if the Agency is satisfied that —

- (a) the pre-market approval had been obtained by fraud or misrepresentation;
- (b) any condition of the pre-market approval is contravened or not complied with;
- (c) after the grant of the pre-market approval, there has been a material change to —
 - (i) the method by which the novel food or a genetically modified food is manufactured, prepared, preserved, packaged and stored; or
 - (ii) any other information relating to the novel food or a genetically modified food which was provided in connection with the application for the pre-market approval;
- (d) the national security or public interest of Singapore requires the cancellation of the pre-market approval.

(2) Before exercising any power under subsection (1), the Agency must give written notice to the person to whom the pre-market approval is granted (called in this section the approval holder) —

- (a) stating that the Agency intends to cancel the pre-market approval;
- (b) specifying the ground for the proposed cancellation; and
- (c) specifying the time (being not less than 14 days from the date of service of notice on the approval holder within which written representations may be made to the Agency with respect to the proposed cancellation.

(3) Upon receiving any written representation referred to in subsection (2), the Agency must consider that representation and may —

- (a) reject the representation and cancel the pre-market approval; or
- (b) withdraw the proposed cancellation of the pre-market approval.

(4) Where the Agency has made any decision under subsection (3), the Agency must serve on the approval holder concerned a notice of its decision.

(5) Subject to Part 10, a decision to cancel a pre-market approval is to take effect from the date on which the notice is given under subsection (4), or on another later date if specified in that notice.

Restrictions on transfer of pre-market approval

115.—(1) Every pre-market approval, and any rights, benefits or privileges under the pre-market approval, are not transferable or assignable to any other person unless —

- (a) the pre-market approval contains a condition authorising the transfer or assignment; and
- (b) the Agency consents in writing to the transfer or assignment.

(2) Any consent under subsection (1) may be given subject to compliance with any conditions that the Agency thinks fit to impose, which may include conditions modifying, or requiring or otherwise providing for the making of modifications to, the conditions of the pre-market approval.

(3) A transfer or an assignment, or a purported transfer or assignment, of a pre-market approval, or of any rights, benefits or privileges under the pre-market approval, is void and of no effect —

- (a) if the pre-market approval is not capable of transfer or assignment;
- (b) if the transfer or assignment, or purported transfer or assignment, is in breach of a condition of the pre-market approval licence; or
- (c) if there has, before the transfer or assignment or purported transfer or assignment, been a contravention of a condition subject to compliance with which the consent required by subsection (1) is given.

“advertise”, or “advertising” as a verb, means to publish or communicate in any way or by any means content to the general public to promote, directly or indirectly, the sale of any —

- (a) goods or services;
- (b) brand of goods or services; or
- (c) person who provides goods or services;

“catalogued insect-like species” means an insect-like species which is listed as a catalogued insect-like species under section 13(2);

“communicate”, in relation to any content, includes to communicate the content by a social media service, by an internet access service, and by a telecommunication service (such as SMS and MMS);

“donate” means —

- (a) a person giving to another any thing for a charitable, benevolent, or philanthropic purpose without receiving any money or money’s worth; or
- (b) a person giving for a charitable, benevolent, or philanthropic purpose, and without the person receiving any money or money’s worth, any thing donated by another;

but excludes an individual giving any thing to another individual as part of a personal relationship between them that is not commercial in nature;

“insect-like species” means a form of animal life within the biological classification Insecta, Arachnida, Myriapoda or Clitellata, and includes an insect-like species at a particular stage of its development;

Meaning of “sell” and “supply”

12.—(1) In this Act, “sell”, in relation to food, means to do, cause or permit the doing of, offer to do, or attempt to do, any of the following (or a combination thereof) in Singapore in relation to food for handling or for human consumption:

- (a) to sell or re-sell;
- (b) barter;
- (c) receive, or having in possession, for sale;
- (d) display for sale;
- (e) send, forward or deliver for sale;
- (f) dispose of by any method for valuable consideration;
- (g) dispose of to an agent for sale on consignment;
- (h) provide as a meal or part of a meal to an employee or other individual in accordance with an employment agreement or an agreement for services under a contract of service for consumption by the employee or individual at the employee’s or individual’s place of work;
- (i) offer or give away for the purpose of advertising or in furtherance of any trade or business;
- (j) provide under a contract (whether or not the contract is made with the consumer of the food), together with any accommodation, service or entertainment, in consideration of an inclusive charge for the food provided and the accommodation, service or entertainment;
- (k) provide food (whether or not for consideration) in the course of providing services —
 - (i) to patients in hospitals;
 - (ii) to children or other individuals in the care or custody of the provider by virtue of any Act; or
 - (iii) to prisoners or inmates in prisons or other places for the detention of individuals under any Act;
- (l) dispose of by way of raffle, lottery or other game of chance;
- (m) offer as a prize or reward.

(2) In this Act, “supply” —

(a) in relation to food, includes do, cause or permit the doing of, offer to do, or attempt to do, any of the following in Singapore in relation to food for handling or for human consumption:

(i) sell;

(ii) donate; and

(b) in relation to non-packaged drinking water, means providing the water within the meaning of section 117.

(3) For the purposes of this Act —

(a) food or equipment that is displayed for the purpose of being offered as a prize or reward or given away for the purpose of advertising or in the furtherance of trade or business is taken to have been displayed for sale by the owner of the food or equipment;

(b) food that is donated to a person who distributes food for a charitable, benevolent or philanthropic purpose is not to be taken to be food that was given away for the purpose of advertising or in furtherance of trade or business;

(c) food which is exposed or deposited in any premises for the purpose of being so offered as a prize or reward or given away is taken to have been exposed for sale by the occupier of the premises;

(d) food that is sold for the purpose of being mixed with any other food is to be treated, unless the contrary is proved, as sale if the bulk or product produced by the mixing, or any part of the bulk or product, is intended to be sold; and

(e) food that is sold, offered for sale, or displayed for sale is to be treated, unless the contrary is proved, as a sale, offer for sale or display for sale of the food for human consumption.

(4) Despite subsections (1) and (2), this Act does not extend to the following:

(a) exchanging food for food or other goods or services as part of a personal relationship between individuals that is not commercial in nature;

(b) providing food together with accommodation to an individual residing at another individual’s private residence in exchange for services or labour by the firstmentioned individual.

EXPLANATORY STATEMENT

Clause 13 defines the expression “defined food” for the purposes of the Bill. This expression covers the range of food which is of higher regulatory concern, and the lawful supply of which in Singapore for human consumption will require prior approval.

There are 3 categories of defined foods. They are —

- (a) novel food
- (b) genetically modified food
- (c) insect-like species as food. These are a form of animal life within the biological classification Insecta, Arachnida, Myriapoda or Clitellata, and includes an insect-like species at a particular stage of its development, like the larvae or pupae.

Of the 3 categories of defined food, insect-like species that are edible are defined food until they are declared by subsidiary legislation to be a catalogued insect-like species.

The subsidiary legislation is to be made by the Agency under clause 13(2) with the Minister’s approval. The subsidiary legislation may be made only where the Agency is satisfied that the insect-like species is no longer of higher regulatory concern. The list of catalogued insect-like species can expand or reduce over time by changes to the subsidiary legislation. This is envisaged to be a positive list.

Unless it is catalogued, an insect-like species, even if edible, cannot be supplied for human consumption in Singapore; see Part 5.

However, food that just contains an unapproved insect that is not a catalogued insect-like species (or part of such an insect) is not defined food. For example, a plate of chicken rice with a black soldier fly would be considered “unsuitable”, as the fly is alien to that particular food. To be defined food, the edible insect-like species has to be, consists of or has as an ingredient the insect-like species.

Insects for animal feed purposes, such as black soldier fly larvae, will not be catalogued but will be treated as animal feed for live food producing animals and the rearing and production of feed from these insects will be regulated separately via a licensing framework for the production of animal feed.

The other 2 categories of defined food viz. novel food and genetically modified food, remain defined foods until the Agency grants pre-market approval under Part 5 of the Bill. Pre-market approval is granted on application and is case-specific.

The term “genetically modified food” is defined by clause 13(3) to mean a food coming from an organism that has been altered using certain techniques, such that the resulting organism contains a combination of heritable genetic material that could not have occurred naturally or could not have been produced by traditional breeding and selection. Those techniques are —

- (a) in vitro nucleic acid techniques, including recombinant nucleic acids and direct injection of nucleic acid into cells or organelles;
- (b) fusion of cells beyond the taxonomic family.

Any food that is, consists of or has an ingredient, an insect-like species which has been so altered will be treated as genetically modified food. If the insect-like species has not been so altered, the food remains defined food until the insect-like species is a catalogued insect-like species.

The expression “novel food” is defined to mean one of the following:

- (a) a substance (which may consist of, be isolated from or produced from, cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae) that has not been used to a significant degree as food for a period of at least 20 years, whether within or outside Singapore;

- (b) a food that 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, whether within or outside Singapore;
- (c) a food consisting of, isolated from or produced from material of mineral origin; or
- (d) a food that contains or consists of engineered nanomaterials

Food that is, consists of or has as an ingredient an insect-like species in any form is not novel food.

The policy intention is to take into account the history of consumption as food anywhere in the world, when determining whether or not food is novel food.

PART 5

DEFINED FOOD AND PRE-MARKET APPROVAL

Clause 106 defines the expression “pre-market approval”. This is an approval granted by the Agency, on application, with respect to either a novel food or a genetically modified food for the food to be available for consumption by the general public in Singapore.

A pre-market approval with respect to a novel food or a genetically modified food may be granted after the Agency makes an assessment of the public health and safety considerations having regard to —

- (a) the potential for adverse effects in humans;
- (b) the composition or structure of the novel food or genetically modified food;
- (c) the process by which the novel food or genetically modified food has been prepared;
- (d) the source from which the novel food or genetically modified food is derived;
- (e) the likely patterns and levels of consumption of the novel food or genetically modified food; and
- (f) any other relevant matters.

Clause 107 sets out the offence of supplying defined food in Singapore and the person supplying knows or ought reasonably to know that the food is a defined food. It is immaterial whether the food concerned is safe.

Clause 108 sets out the offence of supplying defined food without a fault element in clause 105. This strict liability offence and attracts a lower maximum punishment. It is immaterial whether the food concerned is safe.

Clause 109 sets out a defence of due diligence for offences under clause 107 or 108.

Clause 110 sets out the offence of advertising defined food. A person advertises a defined food if —

- (g) the person publishes or communicates in any way or by any means content to the general public to promote, directly or indirectly, the sale of any food in Singapore; and
- (h) the food is a defined food at the time of the publication or communication.

The advertising may be by the traditional media like newspapers and magazines, radio or television broadcasts or by social media and other digital forms of publicity. Again, it is immaterial whether the food concerned is safe.

In a prosecution of a person for an offence under this clause, it is a defence for the person charged to prove, on a balance of probabilities, that the person —

- (a) is a person whose business is to publish or arrange for the publication of advertisements and that the person received the food advertisement for publication in the ordinary course of business;
- (b) has no financial interest in the food featured in the food advertisement;

- (c) did not know that the food advertisement is about a defined food at the time of publication; and
- (d) had taken all reasonably practicable steps as are necessary to ascertain that the food was not a defined food at the time of publication.

Clause 111 provides for applications for pre-market approval.

Clause 112 deal with the grant of pre-market approval. The Agency may, at the request of an applicant for pre-market approval in respect of a novel food or a genetically modified food, grant the pre-market approval subject to an exclusive use condition.

A refusal by the Agency to grant pre-market approval is an appealable decision, and the unsuccessful applicant may appeal to the Minister against that refusal. Please see Part 11.

Clause 113 provides that a pre-market approval is valid until it is either cancelled under clause 114, or in the case of a novel food, it earlier ceases to be a novel food. There is no expiry date for a pre-market approval.

Clause 114 sets out the circumstances where a pre-market approval may be cancelled by the Agency. These circumstances can be one of the following:

- (a) the pre-market approval had been obtained by fraud or misrepresentation;
- (b) any condition of the pre-market approval is contravened or not complied with;
- (c) after the grant of the pre-market approval, there has been a material change to —
 - (i) the method by which the novel food or a genetically modified food is manufactured, prepared, preserved, packaged and stored; or
 - (ii) any other information relating to the novel food or a genetically modified food which was provided in connection with the application for the pre-market approval;
- (d) the national security or public interest of Singapore requires the cancellation of the pre-market approval.

Due process needs to be observed before a pre-market approval is cancelled. A cancellation by the Agency of a pre-market approval is an appealable decision. The holder of the cancelled pre-market approval may appeal to the Minister against that cancellation. Please see Part 11.

Clause 115 provides for the transfer of pre-market approval subject to the approval of the Agency.