

FIRST PUBLIC CONSULTATION ON PROPOSED REGULATORY FRAMEWORK FOR NOVEL FOOD AND NOVEL FOOD INGREDIENTS IN SINGAPORE

Aim

The Agri-Food and Veterinary Authority (AVA) is seeking feedback from the food industry (local food manufacturers, ingredient suppliers and importers) and interested experts in academia, on the proposed definition and scope of novel foods. This consultation is the first in a series of public consultations that will be held in relation to the regulatory framework for novel foods and novel food ingredients in Singapore. Subsequent consultations will cover specific safety assessment criteria and processes involved for applications for novel food.

Background

2. AVA is tasked with ensuring the safety of food supplied to the nation. Novel foods and novel food ingredients, which could be defined in simple terms as foods which traditionally have not been consumed by humans as food, may pose food safety risks and their safety needs to be assessed before they can be allowed to be used in food for sale in Singapore.

3. At the same time, novel foods and novel food ingredients may also bring potential benefits to consumers. For example, novel foods could include new sources of nutrients, or could allow the food industry opportunities to create new innovative food products to cater to the needs of consumers.

Current regulatory approach

4. All members of the local food industry are responsible for ensuring that any novel foods and novel food ingredients imported / manufactured and sold in Singapore are safe for consumption. AVA currently works closely with the industry members on a one-to-one basis in verifying the safety of such novel foods and novel food ingredients.

5. Industry members have provided feedback that there is a lack of regulatory clarity in the current regulatory approach, which could impede innovation and trade in the food sector. In addition, the current situation does not facilitate the wider adoption of the novel foods and food ingredients by the food industry, as outcomes of safety assessments may be known to only a specific company. This results in potential delays faced by industry in bringing possible benefits to consumers.

Proposed regulatory framework

6. The proposed regulatory framework covers the definition and scope of novel foods, safety assessment criteria of novel foods and the processes involved for applications for the use of novel food.

7. AVA proposes that definitions for novel foods and novel food ingredients be included in the legislation. In addition, AVA proposes that the safety of novel

foods and novel food ingredients must be assessed before they are made available for sale in Singapore. Novel foods and novel food ingredients which have been assessed to be safe would also be listed in legislation, which is openly available to all members of the food industry. Proposed definition and illustrative categories of novel food are described in **ANNEX I**.

8. This proposed approach is consistent with current practice in Australia and New Zealand, Canada, and the European Union, where new foods or new ingredients used in food are regulated as novel foods, and require safety assessment and approval by the respective food safety authorities before they can be marketed.

Benefits to industry

9. The proposed regulatory framework aims to provide clarity and transparency to the industry on the definition and scope of novel foods, approved novel foods and novel food ingredients in Singapore, as well as assessment criteria for novel foods and novel food ingredients.

10. These benefits will help to support the Food Manufacturing Industry Transformation Map (ITM), which envisages Singapore as a leading food and nutrition hub, with a strengthened ecosystem for food innovation and R&D.

Request for comments

11. This consultation is the first in a series of public consultations that will be held on the proposed regulatory framework for novel food. AVA invites views and comments on the proposed definition and illustrative categories of novel foods. Please submit your comments or feedback in the form of the table provided in **Annex II**.

12. For this consultation exercise, AVA is not consulting on the specific safety assessment criteria or processes involved for applications for novel food, but plans to do so in the future.

Procedure and timeframe for submitting views and comments

13. All submissions should be clearly and concisely written, and should provide a reasoned explanation for any proposed revisions.

14. Submissions should reach AVA no later than 12:00 p.m., 07 May 2018, through mail, or email, to the following addresses:

Mail:

52 Jurong Gateway Road #13-01 Singapore 608550
(Attention: Ms Leong Ai Ling, Mr Yeo Kai Liang)

Emails:

leong_ai_ling@ava.gov.sg, yeo_kai_liang@ava.gov.sg

15. We regret that we will not be able to address or acknowledge every feedback or comment received. However, the feedback or comments will be

consolidated and a summary of the key comments received will be published, together with AVA's responses, on the AVA website after the close of the consultation exercise. The summary will not disclose the identity of person(s) or organisation(s) providing the feedback or comments.

ANNEX I - Proposed definition and illustrative categories of novel food

Part A – Proposed definition of novel food

Proposed legal text:

Novel food is food that—

- (a) was not used for human consumption by a significant population in Singapore or by a significant population in a region outside Singapore before 1 January 1997¹; and*
- (b) is from an unconventional food source or is prepared by an unconventional process.*

Illustrations

Food that is from an unconventional food source or is prepared by an unconventional process, includes but is not limited to—

- i. Food consisting of, or isolated from, or produced from plants, or animals or their parts;*
- ii. Food consisting of, or isolated from, or produced from, microorganisms, fungi, or algae;*
- iii. Food with a new chemical structure not previously found in food, whether such food is synthesized from raw materials or manufactured via a process not conventionally used in food production;*
- iv. Food that is derived from biologically synthesised substances, including food produced by a genetically modified microorganism, tissue culture, cell culture or cloning;*
- v. Food consisting of intentionally engineered nanomaterials.*

Explanation on proposed definition:

The proposed definition for “Novel Food” takes into consideration that substances that have been consumed as an ongoing part of the diet by a significant human population², for a period of at least 20 years and without reported adverse human health effects, as having a history of safe use. Food and food ingredients which are shown to have history of safe use will not be considered to be “Novel Food”.

¹ The date of 1 Jan 1997 is for reference only, the actual date will be 20 years prior to the gazettal of the definition in legislation.

² “Significant human population” may refer to consumption by 1) the general population, or by 2) a number of sub-populations in different regional areas, or by 3) a number of sub-populations in combination with some use by the general population. If consumption is only limited to specific sub-populations (for e.g. age, gender, physiological and/or disease conditions), it would not constitute a “significant population”.

When assessing whether a substance has a history of safe use, AVA will take into consideration the following information:

- (i) the length of consumption / use of the ingredient (i.e. how many years the ingredient has been consumed as food or used in food),
- (ii) extent of use of the ingredient (i.e. whether the ingredient is consumed or used by the general population, sub-population, certain tribes, etc),
- (iii) quantity (i.e. the level of the ingredient consumed as food or used in food), and
- (iv) purpose/context of use (i.e. whether the ingredient is used for ceremonial purposes such as weddings, during famines, etc).
- (v) evidence demonstrating lack of adverse effects to human health attributed to the substance during the specific period of use as food.

Information sources that will be considered include scientific/non-scientific publications, books (e.g. cookbooks, books on the history of food culture), patents, affidavits from two or more independent, reputable authorities, etc. History of use as medicine/ alternative medicine, or short term exposure (e.g. for ceremonial use, during famines, etc.) is insufficient evidence to demonstrate history of safe use as food.

Part B – Examples of novel foods within each of the proposed illustrative categories

The following table provides additional clarity on the types of substances that would be considered as novel food or novel food ingredients. Novel foods would not include:

- Food additives falling under the scope of Regulation 15 to 28 of the Singapore Food Regulations
- Genetically modified organisms³

Category	To regulate as novel food	NOT regarded as novel food
1. Food consisting of, or isolated from, or produced from plants, or animals or their parts.	<ul style="list-style-type: none"> • Plants parts (e.g. seeds, leaves) without history of safe use in diet. • Plant extract /isolates /concentrates. 	<ul style="list-style-type: none"> • Whole commodities (e.g. fruits, vegetables, flowers, culinary herbs and spices) with a history of safe use in diet • New varieties of fruits and vegetables developed through conventional

³ Genetically modified organisms can be defined as organisms (i.e. plants, animals or microorganisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination. The safety evaluation of genetically modified organisms in food is overseen by the Genetic Modification Advisory Committee (GMAC).

Category	To regulate as novel food	NOT regarded as novel food
	<ul style="list-style-type: none"> • Insects without history of safe use as food. • Isolates/extracts/concentrates/exudates from insects (e.g. bee venom). • Animals without history of safe use as food. • Refined extracts from animal products. 	<p>breeding programmes (e.g. seedless fruits, golden kiwi)</p> <ul style="list-style-type: none"> • Food additives derived from insects (e.g. shellac, cochineal). • Meat and dairy products traditionally consumed as food.
2. Food consisting of, or isolated from, or produced from, microorganisms, fungi, or algae.	<ul style="list-style-type: none"> • Newly identified microorganisms, fungi (includes spores, mycelia) or algae, or those with no history of safe use in food. 	<ul style="list-style-type: none"> • Traditionally consumed fermented foods such as cheese, yoghurt, and their associated starter cultures.
3. Food with a new chemical structure not previously found in food, whether such food is synthesized from raw materials or manufactured via a process not conventionally used in food production.	<ul style="list-style-type: none"> • Substances that are synthesized using food or food-grade raw materials (e.g. enzymatically modified ingredients). 	--
4. Food that is derived from biologically synthesised substances, including food produced by a genetically modified microorganism, tissue culture, cell culture or cloning.	<ul style="list-style-type: none"> • Substances that are biologically synthesized (e.g. produced by a genetically modified microorganism, tissue culture, cloning) e.g. lab grown meat. 	--
5. Food consisting of intentionally	<ul style="list-style-type: none"> • Intentionally engineered nanomaterials (substances with a 	Naturally occurring nanomaterials such as nanoscale milk proteins.

Category	To regulate as novel food	NOT regarded as novel food
engineered nanomaterials.	particle size of 100 nm or less).	

ANNEX II

Please provide your comments on the proposed definition and categorisation for novel foods and novel food ingredients in the table below.

Questions	Comments
1. Does the proposed definition (page 4) for novel food provide clarity for the industry?	Y / N If "N", please suggest an alternative definition and include explanation for revision.
2. Do the proposed illustrative categories of novel food (pages 5-7) sufficiently characterise novel food and novel food ingredients in the food trade?	Y / N If "N", please suggest additional categories to include, and provide examples of substances falling in the new category.
3. Any other comments?	