

FSANZ-IN-CONFIDENCE

The following questions are to assist the Advisory Committee on Novel Foods (ACNF) in determining if a substance is likely to be considered a novel food or novel food ingredient in Australia and New Zealand. FSANZ reserves the right to ask for further information.

This communication is not to be taken as approval. You are advised to seek independent advice.

QUESTIONNAIRE to be completed by Enquirer

Product Name/Identifier	
Enquirer /Company	
Postal Address/contact details	
Telephone (include area code)	
Email	
If you are not the enquirer, please state your interest in this enquiry	
Date	
Attachments – if any please list	

Please answer **all** of the following questions. It is not sufficient to provide a 'yes' or 'no' response. You must provide justification for your answers and details of any reference material accessed in order to answer the questions.

We are unable to consider your inquiry until all questions are satisfactorily answered.

We recognise that not all questions will be relevant to all enquiries. If you believe that a particular question is not applicable to your enquiry, please provide justification.

FSANZ may request additional information.

1. Identity of food or food ingredient	
1.1 What is the name of the food/food ingredient?	
1.2 What are the specifications for the material?	

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2 If the food is a plant or plant product, please complete the following information on <u>botanical characterisation</u>:	
2.1 What is the common and botanical name of the plant or ingredient?	
2.2 What part of the plant is used or intended for use?	
2.3 What is the form of the final food/food ingredient? For example, does the final food product contain the plant itself, a ground up preparation such as a powder, or an extract?	

3. Proposed use of the food or food ingredient	
3.1 How is the substance to be used in food?	
3.2 What type of products is the substance intended to be used in?	
3.3 At what level (or range of levels) is the ingredient intended to be used?	

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4. Questions relevant to the consideration of whether a food is non-traditional or not	
4.1 Does the food or food ingredient have a history of use as a food in any country? Details should be provided.	
4.2 How long has it been used as a food or food ingredient?	
4.3 Is the food or food ingredient recognised worldwide, regionally, or in isolated populations?	
4.4 Is the food or ingredient approved for use in other countries? Details should be provided (including information on current applications or petitions for approval for use in other countries).	
4.5 Is the food or food ingredient used by the general population or by a specific sub-population?	
4.6 What is the expected level of intake of the food or the substance from its use in food?	
4.7 How does the proposed level of intake compare with any traditional use as a food in any other country or region in which it has been used?	
4.8 Has the food or food ingredient been used as part of the regular diet or only at certain times (e.g. during famine or for ceremonial purposes)?	
4.9 Has the substance been used in the food context or has it been used for other purposes in addition to or instead of food use (e.g. traditional medicine)?	

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4.10 If the substance has been used for medicinal purposes in any country, what are the <u>therapeutic claims</u> associated with its use?	
4.11 If the substance has been used for medicinal purposes in any country, what is the typical <u>use levels prescribed</u> ?	
4.12 How do these medicinal use levels relate to the proposed level of intake from foods?	
4.13 Is the food produced by a process which has not previously been applied to food? Please include a flow process chart to describe the production method.	
4.14 Is the structure or composition of the final food or food ingredient altered because of the process by which the food has been prepared?	
4.15 Is the food or food ingredient produced from a source that in itself is not normally consumed as part of the diet?	

5. Public health and safety considerations

5.1 Are there any known adverse effects associated with the use of the food or food ingredient in any country or region in which it has been used? <u>Please detail the nature and extent of any such adverse effects.</u>	
5.2 Does the food or food ingredient contain any substance known to cause adverse reaction or illness? <u>Please detail the nature and extent of any such adverse effects</u>	

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5.3 At what levels of use have any such adverse effects been noted?	
5.4 Are any such adverse effects based on observations in humans or animal studies? <u>Please provide copies of the referenced studies.</u>	
5.5 What is the approximate amount present of any such substance known to cause adverse reaction or illness?	
5.6 Is any special preparation required before use? Is the food consumed raw or are there any cooking or processing steps required before the food is consumed?	
5.7 Is the structure of the substance similar to any other compound for which there are known safety concerns?	
5.8 Is the structure of the substance completely new, such that its safety for human consumption has not been established?	
5.9 If the food is a complex mix of ingredients, are there known safety concerns for any of the components? Are any of the components similar to those for which there are known safety concerns?	
5.10 If the structure or composition of the final food or food ingredient is altered because of the process by which the food has been prepared, what is the nature of any such alterations? Is the altered structure or composition likely to give rise to any safety concerns?	
5.11 If the source of the food or food ingredient is non-traditional, is the	

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source itself known to contain undesirable substances?	
5.12 Is the source of the food or food ingredient new or uncharacterised such that its safety for human consumption has not been established?	
5.13 Does an altered pattern or level of consumption (refer to questions 4.5, 4.6, 4.10 and 4.11) give rise to any safety concerns?	
5.14 Is the expected level of intake likely to exceed levels at which there are known adverse effects?	
5.15 Is the level of intake likely to exceed any medicinal use levels?	
5.16 Is the level of use likely to exceed use in a country that it is used traditionally?	

6. Additional information

6.1 Is there any other information that you possess and which would assist the ACNF in determining the issue? You should submit all information which is relevant even if not requested.	
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