

GOVERNMENT IN CONFIDENCE

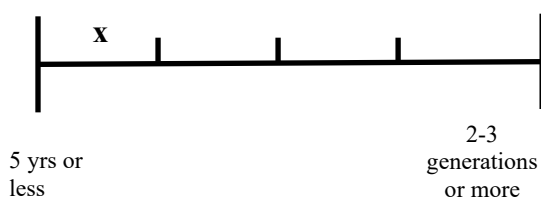
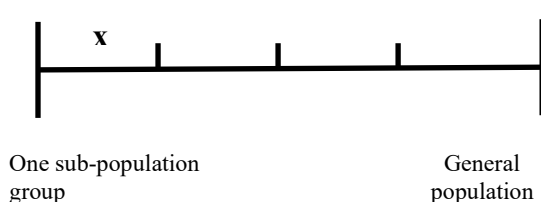
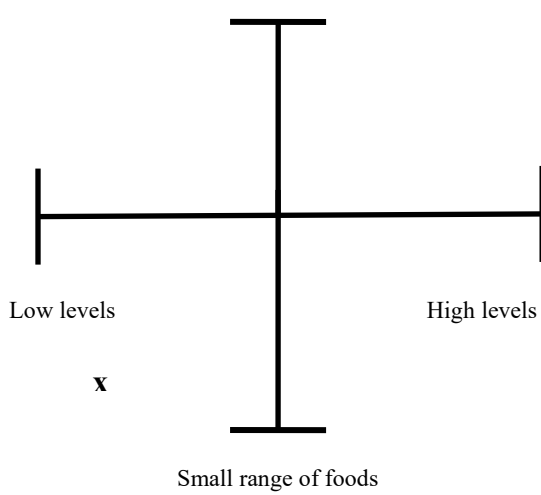
Advisory Committee on Novel Foods

26 November 2014

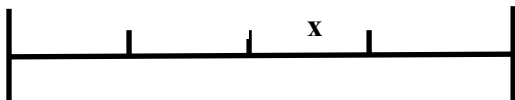
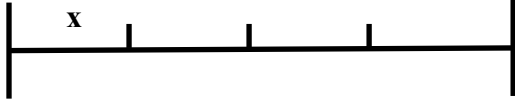
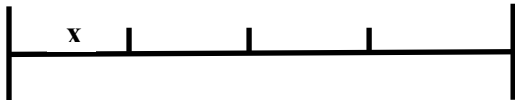
Item 4.1
ACNF-52

DIATOMACEOUS EARTH

Part 1 of Guidance Tool: To be used for making a recommendation as to whether a food should be considered non-traditional or not

History of human consumption	Notes	Rating
1. Length of use	<ul style="list-style-type: none">Diatomaceous Earth is a generally permitted processing aid (clause 3 of Standard 1.3.3 of the Code. It acts as a filtering aid, and is not expected to be present in final food products (generally beverages).Use as a food in Australia and New Zealand appears to be very recent.	 <p>5 yrs or less</p> <p>2-3 generations or more</p>
2. Extent of use (traditional or current rather than proposed)	<ul style="list-style-type: none">Use as a food in Australia and New Zealand appears to be isolated and very recent.Little evidence to suggest widespread consumption.	 <p>One sub-population group</p> <p>General population</p>
3. Quantity of use (traditional or current rather than proposed)	<ul style="list-style-type: none">Use as a processing aid is unlikely to result in the presence of diatomaceous earth in food or beverage products.Little evidence to suggest widespread consumption as a food product.Intended use levels (by enquirer) include 1 heaped teaspoon (per day) in a beverage product, 2 heaped teaspoons as an ingredient in a spelt bread loaf.Other serving suggestions include 1 teaspoon, 3 times a day or 1 tablespoon per day (generally with water or other beverages).	 <p>Wide range of foods</p> <p>Low levels</p> <p>High levels</p> <p>Small range of foods</p>

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4. Purpose or context of use	<ul style="list-style-type: none"> Intended use as a food product. Numerous health claims associated with consumption of diatomaceous earth, some of which are likely to be therapeutic. 	 <p>Medicinal use / extracted from food at high levels</p> <p>Regular food</p>
5. Confidence in quality and quantity of information provided in relation to points 1-4 above	<ul style="list-style-type: none"> Limited information available. 	 <p>Low level of confidence</p> <p>High level of confidence</p> <p>Reason for rating:</p>
6. Overall consideration	<ul style="list-style-type: none"> Non-traditional food. 	 <p>Non-traditional</p> <p>Traditional</p>

Recommendation: That Diatomaceous Earth meets the definition of ‘non-traditional food’

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Part 2 of Guidance Tool: To be used for making a recommendation as to whether an assessment of public health and safety considerations is required for a non-traditional food

Matters to be considered	Explanatory notes	Evaluation ¹
(a) The potential for adverse effects in humans	Relevant information could include: reports of adverse reactions from food use in other countries; demonstration of safe use in other countries; reports of adverse reactions from medicinal use ² ; animal toxicity studies; observations in humans participating in clinical trials; or the presence of a particular component known to cause adverse reaction or illness.	No concerns identified. EFSA opinion (2012 – use as a processing aid) noted: “No dietary reference values were derived or considered not necessary due to the low toxicological concern of the substance by the oral route”.
(b) The composition or structure of the food	Relevant information could include: the presence of a particular component known to cause adverse reaction or illness (e.g. a natural toxicant, contaminant or allergen); analyses of the amount of any such substances known to cause adverse reaction or illness; structural similarity of any of the components to substances for which there are known safety concerns; special preparation required to enable safe use; or whether the structure of the substance is completely new such that its safety for human consumption has not been established.	Diatomaceous Earth is used in food production as a filtering agent. However, filtration is achieved through physical means, based on particle size, rather than any chemical or other means of binding materials. Therefore, no expected concerns relating to binding or accumulating contaminants.
(c) The process by which the food has been prepared	If the structure or composition of the food or food ingredient is altered because of a process by which the food has been prepared, what is the nature of any alterations? Do the alterations give rise to any safety concerns (relevant information would include that listed in the explanatory notes for (a) and (b))?	N/A
(d) The source from which it is derived	If the food is considered non-traditional because of the source from which it is derived, does the source itself give rise to any particular safety concerns? Relevant information could include: whether the source is known to contain undesirable substances; whether the source is uncharacterised such that its safety for human consumption has not been established; relevant information is listed in the explanatory notes for (a) and (b).	ACNF considers that its view relates only to Diatomaceous Earth that complies with the specifications set out in JECFA and FCC publications. Specifications relate to use as a processing aid, but will provide a level of assurance of product quality.
(e) Patterns and levels of consumption of the food	Does an altered pattern or level of consumption of the food give rise to safety concerns? Is the expected level of intake likely to exceed levels at which there are known adverse effects? Is the level of intake likely to exceed any medicinal use levels? Is the level of use likely to exceed use in a country that it is used traditionally?	No concerns identified – see (a) above.
(f) Any other relevant matters	Any other relevant matters are guided by, but not limited to, considerations in (a) to (e). This enables a recommendation to be based on specific issues that although not listed would be relevant to public health and safety considerations related to the food.	N/A

Recommendation: That an assessment of public health and safety considerations is not required for Diatomaceous Earth.

¹ The evaluation will include consideration of the quality of the information available on the product. Consideration is given to information provided by the enquirer as well as information gathered independently by FSANZ or other Committee members.

² Reference to information about adverse reaction reports has been included in (a) because it is recognised that some ingredients could be used in both foods and complementary medicines (regulated as therapeutic goods). Any adverse reaction report on such an ingredient when used in a therapeutic good would raise safety concerns about its use in food and would be a trigger for requiring a public health and safety assessment for that ingredient when proposed for use in a food. Consideration will be given to whether a product should be regulated as a food or therapeutic good.