



28 August 2020

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To whom it may concern:

Submission on A1175 – Rapeseed protein isolate as a novel food

Background

Allergy & Anaphylaxis Australia (A&AA) is a charitable, non-profit organisation established in 1993 to support and assist those affected by allergy and anaphylaxis. A&AA is dedicated to assisting individuals, their caregivers and all in the community in the management of allergic conditions including food allergy. A&AA's aim is to enable individuals and their families to enjoy an optimal quality of life whilst minimising risk to their health and wellbeing.

A&AA strives to raise awareness of allergy in the community and provides evidence-based information, resources and services to support children and adults living with allergic disease including food allergy. A&AA has members across all states and territories of Australia. We have a Medical Advisory Board that consists of several allergy specialists who are also members of Australia's peak medical body, ASCIA (the Australasian Society of Clinical Immunology and Allergy).

Summary

A&AA notes from the Risk Assessment Conclusions and that the "aspects identified as potential public health and safety concerns include the microbiological risk from *Salmonella* spp., the potential allergic responses to individuals who are allergic to mustard, and the need to ensure levels of substances such as phytates and certain metal contaminants are retained as low as reasonably achievable." A&AA does not wish to comment on the microbiological risk from *Salmonella* spp, nor the need to ensure levels of contaminants are retained as low as reasonably achievable. Our comments will be confined to the potential allergic responses.

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With respect to risk management and in regards to cross-reactivity to mustard allergy, A&AA notes that the risk management approach proposed by FSANZ is to “alert ASCIA and allergy consumer support organisations (e.g. Allergy New Zealand, Allergy & Anaphylaxis Australia) to the potential for cross reactivity with mustard allergy.” Noting also that similar approaches had been taken overseas. (A&AA provides comment on this approach on page 4)

Section 2.1.2 discusses cross-reactivity and states “However, FSANZ is not aware of any case studies of mustard allergy in the Australian or New Zealand population, and notes the Australasian Society of Clinical Immunology and Allergy (ASCIA) website does not discuss mustard allergy.” It is important to note that although the ASCIA website does not speak specifically to mustard, it does state that, “almost any food can cause an allergic reaction”. See: <https://www.allergy.org.au/patients/fast-facts/food-allergy>

Nonetheless the A&AA website notes mustard as a potential allergen capable of causing anaphylaxis, and is aware of cases of an allergic response, including anaphylaxis, to mustard in Australia.

In SD1 at 5.3 EFSA concluded that it is likely that rapeseed protein isolate can trigger allergic reactions. So irrespective of cross-reactivity to mustard, this application introduces a new potential allergen into the market. A novel food/ingredient. A novel allergen. With respect to adding a novel food/allergen to the diet which is similar to a major allergen (mustard) in Europe and Canada, A&AA has concerns that this novel food (with similar proteins to mustard) will likely be consumed in much larger amounts than mustard. SD1 outlines uses of the rapeseed isolate in a variety of bakery items including bread and breakfast cereals, meat analogues, protein bars and drinks, pre-prepared meals, fruit juices and dairy products (Table 2.2). This wide variety of **core** foods that this new potential allergen will possibly be used in will likely result in people consuming large amounts of this product. This may lead to a major increase in allergic reactions from potentially unknown sources if the allergen is consumed in a food service setting. At E.2 of the application the applicant believes it is not applicable to address that the novel food ingredient will not create a significant negative public health impact. A&AA would like to see evidence that introducing rapeseed isolate into the Australian diet at the levels mentioned in the application will not have an effect on the Australian population’s food allergy prevalence and events.

A&AA strongly encourages FSANZ to consult the FSANZ allergy expert working group, the Food Allergy and Intolerance Scientific Advisory Group for advice on A1175 as a matter of priority.

Consumer awareness

FSANZ discusses the labelling of foods at section 2.2.5. The section deals only with labelling, which is by and large directed at food sold in packages. Table 2.2 in SD1 lists the types of foods where rapeseed protein isolate may be an ingredient, and includes for example, meals. A significant proportion of allergic responses including anaphylaxis, some fatal, have occurred in food service establishments such as restaurants, where packaging labelling requirements do not apply. Accordingly labelling requirements provide rather limited assurance of consumer awareness.

Section 2.2.5.1 discusses the statement of ingredients (applying to packaged foods, as considered above). It seems possible that in some cases the protein isolate may be added as part of a compound ingredient, for example in combination with a carrier, a stabiliser, or a humectant. If this compound ingredient

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comprises less than 5% of the food, the protein isolate need not be declared, and there is even less assurance of consumer awareness.

In the case of food service, ingredient lists are not required, and the restaurant or café etc is obliged to inform the consumer only if a common allergen that must currently be labelled (no matter the amount) is present in a food. Nonetheless there is no such obligation for mustard, and there seems no immediate prospect for the inclusion of either rapeseed protein isolate or mustard to be included in the relevant standard.

Section 2.2.5.2 discusses the declaration of sulphur dioxide. The likely levels seem quite low. It may be useful to check if SO₂ is a permitted processing aid in this case. Nothing in schedule 18 appears to allow this and no proposed amendments to the schedule appear here.

Section 2.2.5.3 discusses nutrition information requirements. There seems no reasonable basis for FSANZ to suggest that this will assist consumers to make informed choice about foods containing rapeseed protein isolate. Also, Nutrition Information Panel (NIP) labelling requirements are again not applicable to food service and a several other situations.

Novel Foods at 2.4.3, last paragraph. FSANZ states *“Existing labelling requirements in the Code will require that rapeseed protein isolate is clearly identified in the statement of ingredients, in the same manner as for other food ingredient. The condition to use ‘rapeseed protein isolate’ as an ingredient name will make the nature and identity of the ingredient clear to a consumer.”*

Nevertheless, there is no apparent requirement for rapeseed protein isolate to be described as a novel food. There is also no requirement for rapeseed protein isolate to be declared in an ingredient list if part of a compound ingredient at less than 5% and no requirement for it to be specifically identified in a nutrition information panel. There will be no requirement for it to be declared in a restaurant menu or for the restaurant staff to advise customers if so requested. There will be no declaration on any packaged food exempted by section 1.2.1-6.

A&AA concludes that the likelihood of consumer awareness through labelling is not sufficient to provide adequate assurance capable of addressing potential public health and safety concerns particularly in the potentially troublesome area of food service.

Risk Management

As stated earlier, A&AA notes that the risk management approach proposed by FSANZ is to “alert ASCIA and allergy consumer support organisations (e.g. Allergy New Zealand, Allergy & Anaphylaxis Australia) to the potential for cross reactivity with mustard allergy.” Noting also that similar approaches had been taken overseas.

There is no indication of what action support organisations are anticipated to take. The proposal seems to suggest that once the organisations have been alerted, the risk management responsibility has been resolved, even if the organisations take no further action. This would not seem to adequately address the risk management necessary as alluded to in SD1.

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Consequently, it is not immediately apparent how alerting these organisations addresses the potential risk inherent with cross-reactivity. In this context it should be noted that there has been no earlier consultation with A&AA on this proposed risk management approach, and no indication of what steps FSANZ might expect A&AA to take. The assumption should be that proactive measures are necessary to mitigate any risk, and that circulating information about cross-reactivity would cross the necessary threshold of a duty of care. Conversely, advising a consumer after an allergic reaction has occurred does not equate to risk management.

A food alert to A&AA membership, placement on the A&AA website and/or social media sites would certainly not reach all persons with a mustard allergy, and accordingly many would remain uninformed. But even those with a mustard allergy, armed with this information on cross-reactivity, are likely to be even more anxious about eating packaged food and eating out, especially with the knowledge that rapeseed protein isolate will not need to be labelled if contained in a compound ingredient constituting less than 5% of the product. Wait staff have no obligation to provide information about an ingredient which is not a common allergen that must be communicated, even if they could access that information.

FSANZ appears to have delegated responsibility for risk management to ASCIA, A&AA and Allergy New Zealand, unlike the position in Canada as cited in the Health Canada publication "[Mustard - A priority food allergen](#)".

Similar approaches taken overseas

Call for submissions at 2.2.1 states that FSANZ proposes to alert ASCIA and allergy consumer support organisations (e.g. Allergy New Zealand, Allergy & Anaphylaxis Australia) to the potential for cross reactivity with mustard allergy.

FSANZ notes "We note similar approaches have been taken overseas in regard to managing the risk of cross-reactivity between rapeseed/canola products and for individuals with mustard allergy (Health Canada 2019)."

Noting that the Health Canada publication says in part "More information on canola and the risk for people with mustard allergy is available in the Health Canada publication "[Mustard - A priority food allergen](#)". This publication makes no reference to "alerting allergy consumer support organisations."

A&AA does not consider this proposal to be similar to approaches taken overseas and welcomes information from FSANZ on similar proposals in other jurisdictions where the relevant risk management has been delegated to non-government organisations.

Recommendations

A&AA would be pleased to discuss this application and its ramifications directly with FSANZ to identify options for progressing this issue.

A&AA strongly encourages that the allergy aspects of this application should be put to the FSANZ allergy expert working group, the Food Allergy and Intolerance Scientific Advisory Group for advice before the application is taken any further.

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A&AA believes that a thorough risk assessment of the use of rapeseed isolate as a protein source with respect to allergen risk should be conducted. A&AA also suggests that given its concern over both risk management and consumer awareness, the application be subject to a second round for comment.

Thank you for the opportunity to provide comment. Please do not hesitate to make contact if further information is required.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Maria Said', with a large, stylized initial 'M'.

Maria Said
CEO
Allergy & Anaphylaxis Australia