



Allergy & Anaphylaxis Australia

Standards Management Officer
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7 December 2020

To whom it may concern

Re: Application A1204 - Beta-amylase from soybean (Glycine max) as a processing aid (enzyme)

Summary

Allergy & Anaphylaxis Australia (A&AA) is not opposed to the application, but has issues and concerns which do not appear to have been fully addressed. The labelling obligation seem to be stated ambiguously and should be expressed more emphatically. The issues surrounding allergenicity, processing and digestion may need investigation in greater depth, and accordingly A&AA urges the referral of matters of allergenicity to the FSANZ Food Allergy and Intolerance Scientific Advisory Group of experts in allergic disease as a matter of routine.

Labelling

A&AA notes that FSANZ indicates that the current labelling requirements will apply, see 2.2.4 “Labelling requirements will apply if soy is present in a food for sale to inform soy-allergic individuals”. The labelling standards indicate that a declaration must be made if soy or a soy product is present, regardless of whether soy can be detected. A&AA also notes FSANZ’s statement that the product is “unlikely to pose an allergenicity concern”, recognising that this is not the basis for determining whether or not allergen labelling requirements apply.

Allergenicity

A&AA notes that at 3.3 it is stated “Soybean β -amylase is not an allergen to individuals with soybean food allergy. No reports of food allergy to β -amylase from soy were identified in the scientific literature.” It seems that beta amylase from soy is currently only permitted in China. If there is limited soy allergy in China this statement is made from a fairly limited database.

Processing

A&AA is concerned about the statement in 2.2.2 “in starch processing, the applicant has indicated that it is expected that the enzyme will be removed during production and refining processes (denatured by heat or removed during carbon or ion exchange treatments).” There is research to

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suggest that proteins that are denatured by heat can still be allergenic by making a new epitope not found in the original food. See <https://pubmed.ncbi.nlm.nih.gov/9826012/>

Digestion

A&AA notes there is an issue with wheat allergy as well as soy allergy. FSANZ states “Bioinformatic analysis identified a degree of amino acid sequence homology between β -amylase from soybean and an allergenic protein from wheat, but FSANZ does not consider β -amylase to be of allergenic concern in wheat allergic individuals given the likely very low exposure and that the enzyme is likely to be digested in the stomach like other dietary proteins.” FSANZ should be aware that an allergic response can be triggered from the initial moment of ingestion, and the likelihood of digestion in the stomach should not allay any concerns of allergenicity.

Thank you for the opportunity to provide comment on Application 1204. We look forward to hearing about progress on the application.

Yours faithfully

[Redacted Signature]

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Chief Executive Officer
Allergy & Anaphylaxis Australia

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