A1232 - Food derived from drought tolerant wheat line IND-00412-7
Submission to Application A1232
Allied Pinnacle Pty Ltd (Australia) (Allied Pinnacle)
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Allied Pinnacle is a world class milling and bakery business in Australia. Operating from 12 manufacturing locations across Australia. Allied Pinnacle is Australia's second largest processor of grains supplying processed grains, flours, bakery ingredients to large scale branded food manufacturers and unbranded finished bakery products for sale in the major retailers, franchise outlets and food service outlets. Allied Pinnacle employs over 1100 people in Australia.

As Australia's second largest purchaser and processor of Australian wheat into flour and flour related bakery ingredients, Allied Pinnacle is opposed to the application to Food Standards Australia and New Zealand (FSANZ) to approve the use of food derived from wheat line IND-00412-7, which has been genetically modified for tolerance to drought and the herbicide glufosinate, and FSANZ's decision to prepare a draft variation to amend Schedule 26 -3(4) of the Australia and New Zealand Food Standards Code (Code) to include a new item 'Wheat' as the commodity. The proposed variation would permit the sale and use of food derived from wheat line IND-00412-7, in accordance with the Code.

Allied Pinnacle's opposition to this application and proposed draft variation to the Code, is driven by the fact that Wheat is currently not a permitted food produced using gene technology, as outlined in Schedule 26-3(4) of the Code - Food Produced using Gene Technology. Approval of this variation would permit food derived from wheat line IND-00412-7 to be imported into Australia. These foods may include flour, bread, pasta, biscuits and other baked products.

The inclusion of Wheat in Schedule 26-3(4) of the Code is taking Australia's 'food standards' into unchartered territory. FSANZ acknowledges all genetically modified foods will only be approved after a comprehensive pre-market safety assessment. FSANZ has noted the HaHB4 protein has not previously been assessed, while the PAT protein has previously been assessed.

The safety assessment of wheat line IND-00412-7 in the Supporting Document 1, included consideration of the following key elements

- characterization of the transferred genetic material, its origin, function and stability in the wheat genome
- characterization of novel nucleic acids and protein in the food
- compositional analysis
- evaluation of intended and unintended changes
- assessment of the potential for any newly expressed protein to be either allergenic or toxic to humans.

Allied Pinnacle appreciates FSANZ conducted the safety assessment utilizing the data package provided by the applicant, scientific literature and other similar applications. An independent assessment would be recommended.

Allied Pinnacle's first concern with the application and proposed variation to Standard 26-3(4), is in relation to the final element of the safety assessment considerations, that is, the potential for newly expressed proteins to be either allergenic or toxic. The conclusion drawn in section 3.4 Characterisation of the inserted DNA and site(s) of insertion, states, multiple copies of the HaHB4, bar, gus and bla genes are present, either intact or incomplete, and due to a lack of fully intact or eukaryotic regulatory

elements, the gus and bla genes were unlikely to be expressed and no protein products from the bla and gus genes are expected in the wheat line IND-00412-7. The report also states the bla gene is under the control of the bacterial promoter and lacks regulatory sequences that would be recognized in plants, while the gus gene is truncated and does not contain an intact promoter. However, using a transformation method, such as particle bombardment, there is a chance the gus and bla protein and genes, including the promoter and terminator, could be present as fragments. If fragments or incomplete genes that include promoter-structural gene sequences were inserted into the current wheat chromosome unintentionally, unknown proteins may be produced in the plant cells. These proteins may show allergenicity and/or toxicity. While the bioinformatic analysis for potential allergenicity and toxicity has been conducted using databases of known protein and gene expression, the potential implication to health is unknown.

Given the safety assessment's lack of consideration for particle bombardment to produce fragments and potential expression of unknown protein material, Allied Pinnacle calls for further independent assessment to be undertaken to fully understand the implications to safety of this potential risk.

A further area of concern in relation to the safety assessment of novel substances are herbicide metabolites. While the assessment states FSANZ has reviewed the literature with respect to allergenicity and toxicity, evaluated the PAT sequence of the protein expressed in IND-00412-7, and that there are no new metabolites produced when wheat line IND-00412-7 is sprayed with glufosinate ammonium, approving food derived from a crop with herbicide tolerance continues to fuel the debate on herbicide tolerance or resistance as the assessment doesn't not outline nor comment on the amount of herbicide residue in the grain and ultimately in the food. While FSANZ references residues of agricultural chemicals permitted in food is governed by maximum residue levels [1], there is no reference to the residues and respective levels expected to be found in the foods derived from wheat line IND-00412-7 such as bran or flour from the endosperm, in the safety assessment. With the knowledge that herbicide tolerant GM crops have led to an increase in herbicide usage on farm [2], the presence of levels of chemical residue in the foods derived from wheat line IND-000412-7 is a key consideration that has been overlooked in the information provided by the applicant and assessment. Having this data included in the safety assessment is consistent with FSANZ's approach to monitoring residues in ready to eat foods, to ensure levels are low and not pose any health concerns to consumers. In addition to the concern of residue levels in the foods derived from wheat line IND-00412-7 and potential health impact to the consumer, Allied Pinnacle asks that FSANZ acknowledges the well documented evidence summarizing negative impact of herbicide tolerant crops and related tolerance in weeds, to agronomy, farm practices, weed management and a reduction in biodiversity within the cropping area[3].

With uncertainty surrounding the potential allergenicity, toxicity and potential chemical residues in all foods derived from wheat line IND-00412-7, Australian consumer attitudes towards genetic modification of plants, specifically wheat to be used in food is an important consideration. The safety assessment report failed to acknowledge Australian's sentiment towards genetically modified foods.

In the systematic literature review conducted by Australian National University on Consumer Responses to the Use of New Breeding Technologies in the Production of Foods, commissioned by FSANZ, there are several points to consider before approving the food derived from wheat line IND-00412-7 and amending Schedule 26-3(4). While the literature on this topic is limited, the review summarized older forms of genetic modification techniques as random and distant[4], as a result there are risks in public understanding, engagement and communication. Consequently, stakeholders need to consider these risks before proceeding with changes to food production processes, such as foods produced using gene

technology. The review summarized Australians are least likely to purchase foods produced using genetic modification techniques[4]. Australian's knowledge of genetic modification has decreased over the last 5 years. Specifically, Cormack and Mercer report Australian's responses to "know enough about genetic modification to explain to a friend has dropped from 33% in 2015 to 22% in 2019[4]. Further, Cormack noted to change Australian's negative attitude towards genetic modification, longer term testing over at least 10 years to show no risk to human health and environment[4].

The need for longer term approach to the application of genetic modification in food is reinforced in by the third review of the National Gene Technology Scheme, Social and Ethical Issues. The review recommended targeted communications be developed to aid public understanding and confidence in the Gene Technology Scheme and identify the most appropriate body to deliver communications materials, and a science-based review of monitoring arrangements to ensure that any post release risks continue to be appropriately managed[5]. This view on consumers' acceptance of gene technology is further supported by two Mintel publications on the future of ingredients and gene-edited crops, respectively which reported that genetic modification technologies hold huge promise to solve problems relating to health, taste and nutrition, that nature alone cannot solve. However, there is a need for scientific research, strict regulations and producers must deliver and communicate tangible benefits to reassure consumers of the safety of genetically modified crops for human consumption, if consumers are to accept the technology[6,7].

Acknowledging, the Code, Standard 1.5.2 - Food Produced using Gene Technology, clearly defines foods for sale in Australia and New Zealand may consist of, or have as an ingredient, a food produced using gene technology, and the requirements to label the food as 'genetically modified'. In market research conducted for the National Gene Technology Scheme exploring attitudes towards genetic modified foods, respondents commonly mentioned genetic modification was not top of mind when they go shopping because labelling of foods containing genetically modified ingredients isn't something they typically see[5].

Despite the requirement to label the foods derived from wheat line IND-00412-7, as containing ingredients that have been genetically modified, Australians remain uninformed of the benefits of genetic modification but more importantly don't understand the technology. They clearly need to understand potential risks to health or environment through extensive trials and how a food containing genetically modified ingredients such as flour, bread, pasta, biscuits and other baked goods, would be labelled to deal with these anticipated concerns.

In recent Australian consumer research of a representative sample conducted by Mintel on Future Food Concepts[8], when asked "I have tried or would be interested in trying food/drink that...is genetically modified to withstand extreme climates, such as drought?" Only 8% of respondents indicated they would be interested.

The approval of food derived from wheat line IND-00412-7, that has been genetically modified for drought tolerance and herbicide resistance, would be a first for Australia. With an intimate knowledge of grain processing, Allied Pinnacle appreciates any flour or derived ingredients, or manufactured foods, would contain novel DNA or novel protein, and therefore must be labelled as 'genetically modified' in conjunction with the name of the genetically modified food. Wheat flour and food derived from genetically modified wheat is unlike the current permitted foods produced using gene technology in Schedule 26-3, by virtue of the processing into ingredients or foods for consumption, such as oils and animal feeds. Therefore, the approval of foods derived from wheat line IND-00412-7, would have a

more significant impact ultimately to the Australian consumer than those genetically modified crops, already approved in Australia.

As a result of Australians lack of understanding of genetic modification and how it is used in food production, Allied Pinnacle opposes the amendment of Schedule 26-3(4) to include wheat and the approval of food derived from wheat line IND-00412-7, to be sold in Australia.

In addition to the Australian's cautious sentiment to foods produced using gene technology, there is a far wider consideration to the Australian wheat and wheat flour industries, wheat related export grain markets, local food and feed industries.

Wheat is the largest production crop in Australia with average annual production yield of 23.6 million metric tonnes over the last 5 years[9]. Annually, approximately 10% of the crop is used in food, 10% in feed and 70 - 75% of the Australian wheat crop is exported to many global markets[10].

In Australia, industry estimates show 2.4 million metric tonnes of wheat is milled to provide 2.0 million metric tonnes of flour for use in manufacture of bread, pasta, biscuit and other bakery products each year [11]. The assessment lists Trade Considerations as a factor in the approval of food derived from wheat line IND00412-7. In 2019, a well-documented drought impacted wheat quantity and quality, Australia only imported 29 thousand tonnes of flour, which equates to less than 1.5% of Australia's flour usage in food manufacture. In a year without extreme drought conditions for wheat cropping, it is hypothesized the amount of imported wheat flour into Australia would be less than 1.5% due to superior quantity and quality of Australian crop to meet local demand.

The compositional analysis of wheat line IND-00412-7 versus control showed statistical differences in Protein, amino acid (Leucine) and Zinc. With Protein quantity the industry standard for wheat receival in Australia[12], a key functional property in manufacture of wheat flour-based foods such as bread[13], and grain-based foods as the primary contributor of Zinc, in the Australian diet[14], there would be limited food industry demand for imported wheat flour or wheat based foods with lower levels of Protein or Zinc. While the application facilitates trade, there is no benefit in supply, functionality or to the Australian population nutritional status, by permitting the sale and use of food derived from wheat line IND-00412-7.

Acknowledging the applicant has indicated there is no intention to apply for commercial cultivation of wheat line IND-00412-7 in Australia, and would require assessment and approval by the Gene Technology Regulator or Environmental Protection Agency, and need to meet biosecurity requirements, the approval of food derived from wheat line IND00412-7 could progress to importation of the wheat line IND-00412-7, as seed. Allowing genetically modified wheat seed into Australia in an uncontrolled wheat supply chain, poses a significant risk to the Australian wheat industry. If wheat line IND00412-7 were imported or to be grown in Australia there are no processes or infrastructure in place to segregate grain during handing, storage, shipping and processing, leaving Australia exposed to unintentional presence of genetically modified wheat in the grains, wheat, feed and food industries. This would have significant impact to the current clean and green environmental and international reputation of Australian agriculture and food value chains[15].

With the bulk of Australian wheat exported to many international markets throughout Asia and Middle East[16] primarily due to functional properties of Australian Wheat and the local market and consumer's demand for health, wellbeing and sustainable foods and ingredients, contamination with a genetically

modified wheat line would be disastrous for the Australian wheat industry. This is supported by CSIRO's recent report on Growth Opportunities for Australian Food and Agribusiness[17], listing a key opportunity for growth in export markets as free-from and natural foods.

Currently, Argentina is the only country to approve wheat line IND-00412-7 for commercial use as seed, in food and feed. In November 2021, Brazil approved food derived from wheat line IND-00412-7 to be imported into Brazil. According to media articles[18], Brazilian millers have threatened to stop buying Argentinian wheat if GMO wheat imports were approved. Approval of food derived from wheat line IND-00412-7 and the potential for the wheat seed to be approved for use in Australia, at a later date, would have significant ramifications to ongoing local and export market access for Australian wheat, wheat-based ingredients and foods.

In summary, Allied Pinnacle reinforces it's opposition FSANZ's proposal to approve the application A1232 – Food Derived from Drought and Herbicide Tolerant Wheat Line IND-00412-7, and amend Schedule 26-3(4) of the Code to include 'Wheat' as the commodity to permit the sales and use in Australia. Key factors supporting Allied Pinnacle's position are

- inconclusive evidence that no unintentional unknown proteins are produced in the wheat grain from broken fragments of gus and bla genes that are generated during the particle bombardment process,
- the impact of herbicide tolerance on chemical residues, human health and the environment including biodiversity has not been considered
- lack of data on any chemical residues in the food (bran or endosperm) derived from wheat line IND-00412-7,
- consumer uncertainty to foods containing genetically modified ingredients,
- Australian food manufacturers have no wheat flour supply concerns, and wheat line IND-00412-7 does not provide any functional benefit to food manufacture,
- a potential longer term risk to the Australia's wheat industry caused by unintentional contamination of genetically modified wheat in the grains, wheat, feed and food industries, and
- as Australia is a net exporter of wheat there is potential reputational damage and ramifications for the Australian grain and wheat feed and food export markets and food manufacturing industries.

There is no overall benefit from food derived from wheat line IND-00412-7, to the Australian food industry or consumer.

For further information in relation to this public comment, please contact

[redacted]

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