II. EXECUTIVE SUMMARY

The present application seeks to amend schedule 18 - Processing Aids of the Australia New Zealand Food Standards Code (the Code) with an enzyme preparation from ***Trichoderma reesei*** *(T. reesei)* host strain genetically modified to produce a ***T. reesei*** **production strain (AR-577) containing a fructanase enzyme** from *Lactobacillus sp*. Based upon the food code, the enzyme is to be used in:

- bakery products such as, but not limited to bread, steamed bread, bread buns, tortillas, cakes, pancakes, and waffles.

Proposed change to Standard 1.3.3 - Processing Aids

The table schedule 18—4(5), **Permitted enzymes (section 1.3.3—6)—Enzymes of microbial origin**, is proposed to be amended to include a genetically modified strain of *Trichoderma reesei* as permitted source for **fructanase** (EC 3.2.1.80).

This application is submitted under a general assessment procedure.

The food enzyme is a biological isolate of variable composition, containing the enzyme protein, as well as organic and inorganic material derived from the microorganism and fermentation process.

The main activity of the food enzyme is fructanase.

Use of the Enzyme and Benefits

Like any other enzyme, the fructanase acts as a biocatalyst: with the help of the enzyme, a certain substrate is converted into a certain reaction product. It is not the food enzyme itself, but the result of this conversion that determines the effect in the food or food ingredient. After the conversion has taken place, the enzyme no longer performs a technological function.

The **substrates** for the enzyme are fructo-oligosaccharide (FOS) and related polysaccharides which can be found in cereal and cereal products and therefore occur naturally in nature and are a natural part of the human diet.

The function of the fructanase is to catalyse the hydrolysis of the fructo-oligosaccharide (FOS) and related polysaccharides. FOS and related polysaccharides cause technical difficulties due to its viscosity properties in processing of raw materials containing this component.

Reaction products: as a result of the catalytic activity of fructanase, low levels of FOS and related polysaccharides are present. These compounds are already present in the human diet.

Like most of the enzymes, fructanase performs its technological function during food processing. The fructanase from *Trichoderma reesei* AR-577, object of this dossier, can theoretically be used as processing aid for bakery products.

In general, the technological need of hydrolysis with the help of fructanase can be described as: degradation of a component (the substrate fructo-oligosaccharide (FOS)) which causes technical difficulties in processing of raw materials containing this component.

As described above, fructanase is naturally present in cereal raw materials fermentations by yeast and lactic acid bacteria. The natural enzymatic conversion of fructo-oligosaccharide (FOS) in such materials is of technological benefit in several industrial food manufacturing processes, like baking, etc. However, not all food manufacturing processes can use sourdough fermentation techniques, further the levels of endogenous fructanase are often inadequate and vary from fermentation to fermentation, and the specificity of the enzyme may not be optimal to give desired process advantages. Therefore, industrial fructanse can be used during food processing.

In general, the benefits of FOS hydrolysis with the help of fructanase in baking are:

- Decreasing mixing time of dough
- Increasing level of fermentable and reducing sugars in dough
- Improving yeast fermentation
- Reducing dough viscosity
- Increasing water absorption

Due to better processing conditions, the specific beneficial effects of using fructanase in baking are:

- Facilitating dough handling hence smoother dough

- Helping with gas production by yeast during fermentation
- Reducing added sugar
- Assisting in the formation of flavour and crust colour
- Less product quality variations hereby ensuring standardised quality products

The use of fructanase in food processing will benefit manufacturers through reducing viscosity, improving processability, enhancing yields and shorten processing times, therefore leading to better and/or more consistent product characteristics and more effective production processes. This will eventually result in better production economy and environmental benefits via the use of less raw materials, energy saving and production of less waste, being overall of high value for the food chain.

Safety Evaluation

The safety of the fructanase produced by the genetically modified *Trichoderma reesei* AR-577 from a toxicological perspective is supported by the historical safety of strain lineage. Toxicological studies were performed on a strain (*Trichoderma reesei* AR-852) which derives from the same intermediate strain within the strain lineage of *Trichoderma reesei* AR-577. These results show that there is no need for any toxicological concern with fermentation products as produced by use of *Trichoderma reesei*. Based on the available data, it is concluded that the organism *T. reesei* is non-pathogenic and non-toxigenic and *T. reesei* AR-577 is safe to use as the production organism for fructanase enzyme preparation.

The product complies with the recommended purity specifications (microbiological and chemical requirements) of the FAO/WHO's Joint Expert Committee on Food Additives (JECFA) and the Food Chemicals Codex (FCC) for food-grade enzymes.

The product is free of production strain and recombinant DNA.

AB Enzymes is in the process of registering the *Trichoderma reesei* AR-577 fructanase production strain in other countries such as EU (EFSA).