

## Public summary

**Summary of the dossier:** Application for authorisation of potato protein (low molecular weight) as a novel food in the context of Regulation (EU) 2015/2283

**Applicant:** Coöperatie Koninklijke Avebe U.A., Prins Hendrikplein 20, 9641 GK Veendam, The Netherlands

This application concerns the authorisation of potato protein (low molecular weight) as a novel food in the context of Regulation (EU) 2015/2283, Article 3(2)(a)(iv), which concerns “*food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by: traditional propagating practices which have been used for food production within the Union before 15 May 1997; or non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances*”.

Potato protein is manufactured from potato juice that is itself obtained from potatoes during potato starch production by physical and membrane-based separation techniques. The further production process of potato protein involves a series of physical and membrane-based separation techniques that improve the organoleptic attributes of the protein product, collect the desired fraction, reduce impurities, and increase the protein content in the liquid. Following purification and fractionation, the potato protein is spray dried to yield the final powder, which contains  $\geq 85\%$  protein (N \*6.25) based on dry matter. The production process involves mild processing conditions throughout that do not alter the native structure of the potato proteins.

It is intended that this potato protein will be used as a novel food ingredient in applications where the added protein concentration may substantially exceed that found in potatoes themselves and will present an alternative plant-based source of protein. Inclusion levels of up to 8% are proposed. The full list of food categories in which this potato protein is to be used is the following: wine; distilled and fortified wine; beer; bread (gluten-free only); cakes (gluten- and egg-free only); cookies, tortilla, pizza (gluten- and egg-free only); marshmallows; non-dairy coffee whiteners; non-dairy whipped topping; non-dairy cheese, cream cheese; non-dairy dessert, ice cream; non-dairy milk; non-dairy yogurt; meringues and macarons; creamy salad dressings (egg-free only); mayonnaise (egg-free only); low fat margarine; fish surimi; sorbet; mousses; bakery fillings; pasta products like spaghetti, noodles (gluten- and egg-free only); jellies; beef patties; deli meats; pate; sausages and hot dogs; yogurt; vegetable-based protein enriched foods; soft candies; powder based soup. The potato protein is not intended to be used in infant formulae or follow-on formulae applications and is not intended to be the sole source of protein in the diet.

The sub-chronic toxicity of the potato protein was investigated in a 90-day study in rats. No significant adverse findings were reported in any animal consuming potato protein at levels of up to 15% in their diet. No mutagenic findings were observed in the Ames tests (OECD 474) or in *in vitro* micronucleus studies (OECD 487) undertaken with potato protein. Considering that the novel

food ingredient is minimally processed and is compositionally similar to unprocessed potato protein with respect to the overall amino acid content, it is anticipated that the novel food ingredient will be digested and handled in a similar manner as potato protein consumed in the normal diet.

Potato is not considered a major food allergen and is not considered a significant allergenic food considering the extent to which potatoes are consumed on a global level. Potato proteins contain several specific proteins that may pose an allergenic risk in sensitive consumers, however, heat processing and the action of digestive proteases on these proteins is generally considered to result in partial or total loss of their allergenic properties. Clinical symptoms are in most cases restricted to the less severe local reactions of the mucosa and skin. It is apparent from the available literature that allergic sensitization of patients to potato proteins seems to be limited. Cross-reactivity, however, exists for various potato proteins in patients allergic to other foods and fruits, pollen or natural rubber, with cooked potatoes exhibiting less allergenic potential than raw potatoes. Taken together, the available information suggests that the use of potato protein in foods may have a low potential to induce allergic sensitization, but that cross-reactivity in at least birch-pollen and latex-fruit syndrome allergic patients may occur. In order to ensure that those who are known to be sensitive to potato protein, as such or as a result of cross-reactivity, can avoid consuming foods in which the protein is used as an ingredient, its presence will be indicated by the designation 'potato protein' in the list of ingredients on the labelling of those foods.

Overall, it can be concluded that the production process of this potato protein does not introduce any issues of nutritional, safety or toxicological significance, and that the proposed use of the potato protein as a novel food ingredient in the food categories and at the use levels described in this novel food application does not raise concerns for human health.