Summary of the dossier: Serratiopeptidase from *Serratia marcescens* strain NPSC

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Advanced Enzyme Technologies Ltd. submits the application for the approval of Serratiopeptidase, produced by fermentation of the non-genetically modified *Serratia marcescens* strain NPSC, as a novel food.

Serratiopeptidase is an off-white powder with a typical fermentative odour. It is a proteolytic enzyme intended for use in supplements for the general population over 10 years (excluding pregnant and lactating women) for nutritional purposes. It will not be added to food for a technological purpose or for any therapeutic purposes. It is proposed for use at a maximum level of 30 mg/day at 3,000 to 3,600 U/mg, resulting in provision of up to 108,000 U/day of enzyme activity.

Analytical data for independent representative batches of Serratiopeptidase demonstrate that the manufacturing process results in a consistent final ingredient that meets the established specifications for enzyme activity and for any potential undesirable substances (heavy metals, mycotoxins). The production strain, *Serratia marcescens* strain NPSC, has been thoroughly characterised and is not present in the final novel food. Stability data demonstrate that Serratiopeptidase is stable for at least 24 months when stored under real-time conditions.

A comprehensive battery of toxicology studies was conducted with batches of Serratiopeptidase that are representative of the ingredient intended to be commercially marketed, and in accordance with Good Laboratory Practice and appropriate internationally recognised test guidelines, where applicable. Serratiopeptidase was evaluated by an *in vitro* pepsin digestibility study and using PeptideCutter to determine that it would be effectively digested by humans. It was confirmed as non-genotoxic both *in vitro* and *in vivo* and a 90-day repeat dose study in rats demonstrated the safety of Serratiopeptidase following subchronic exposure. A combination of human studies and historical use of this ingredient are also supportive of the proposed conditions of use. The allergenicity of Serratiopeptidase was assessed using publicly available databases and provided no evidence that an allergic response would occur following its consumption.

Together, the weight of the available evidence on Serratiopeptidase supports the safe use of the ingredient under the proposed conditions of use.