Summary of the application: Ageratum conyzoides L. aerial parts extract

Applicant: GENCOR PACIFIC Limited, 21-E, Elegance Court, Hillgrove Village, Discovery Bay, Hong Kong.

This application for authorisation of a novel food in accordance with Regulation (EU) 2015/2283 concerns a brown powder of a 90% ethanolic extract from the aerial parts of Ageratum conyzoides L. (product called AGEprost™). This plant use is fully novel in Europe, neither mentioned in any plant list nor in the novel food catalogue or the EFSA compendium while it has been used in various parts of Africa, Asia, and South America.

AGEprost™ has been acknowledged as Generally Recognized as Safe (GRAS) and is intended to be used as food supplement to a maximum daily dose of 1000 mg, the dose consumed in the US. This corresponds to ~14.3 mg/kg body weight/day for a 70 kg person. Ageratum conyzoides being fully new and not yet authorised in Europe and the anticipated intake of AGEprost™ will be limited to use in food supplements only, no combined intake from the novel food and other sources can happen. Gencor AGEprost™ will be consumed by adults in the general population. Vulnerable groups (e.g. children, pregnant, lactating women) are not concerned public.

The AGEprost™ manufacturing process is fully described and removes all pyrrolizidine alkaloids, well known to be hepatotoxic, from the extract. All the specifications of AGEprost™ are detailed in this application and are in accordance with European standard and regulations. Analyzes have demonstrated the lack of various contaminants: heavy metals, microbiological contaminants, PAH, mycotoxins, among others.

Regarding safety of AGEprost™, this is hugely substantiated. Genotoxicity studies (AMES, chromosome aberration in vitro and mice micronucleus tests) indicate lack of genotoxicity. In both 14-day and 90-day repeated dose oral toxicity studies in rats the NOAEL were set at 2000 mg/kg body weight/day. In prenatal developmental toxicity study in rats the NOAEL for both maternal toxicity and developmental toxicity were set at 2000 mg/kg body weight/day. Finally, a human safety, tolerability and efficacy clinical study shows the safety of AGEprost™ given at 250 mg/day for 12 weeks in 109 healthy men without treatment-related adverse events. Note while EFSA is used to calculate the safe Human dose from the NOAEL applying a 200 margin of exposure factor, corresponding here to 700 mg AGEprost™ per day for a 70 kg Human with a NOAEL of 2000 mg/kg, current Human consumption in the US show AGEprost™ can be safely used at 1000 mg per day.

In conclusion, AGEprost™ is well characterized and compliant with European Regulations. The product is safe and devoid of allergic potential. AGEprost™ does not present consequently any potential hazard to the European population.