

## Summary of the dossier: Hovenia Dulcis Fruit Extract

Applicant: Hovenia Dulcis AB, Vindelgatan 9 Veberöd, 24762 Sweden

This is an application for authorisation to place on the market the dried fruit and peduncle extract of *Hovenia dulcis* thunb (later “*Hovenia dulcis* fruit extract” or “fruit extract”) to be used as an ingredient in food supplements. The application has been compiled in line with the administrative and scientific requirements of Commission Implementing Regulation (EU) 2017/2469 laying down for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. It is also in line with the European Food Safety Authority (EFSA) guidance on the preparation and presentation of an application for authorisation of a Novel Food in the Context of Regulation (EU) 2015/2283.

The *Hovenia dulcis* fruit extract is produced via hot-water extraction, dried and purified in an approved manufacturing plant following Good Manufacturing Practice (GMP) for functional foods as laid down in the Korean Functional Food Act. The raw material meets the criteria set out for a fruit extract.

The *Hovenia dulcis* fruit and peduncle have history of use in Asia, assumed to have begun more than a millennium ago. The earliest available literature references of food use in Asia are from year 1799 from Uppsala University, Sweden. Currently, a number of products with *Hovenia dulcis* fruit extract are in the Korean market, in the forms of beverages, food supplements and other products, and the fresh fruit of *Hovenia dulcis* is commonly consumed in southern Brazil. *Hovenia dulcis* thunb products are approved for food use at least in Korea and Taiwan; the Brazilian government has also provided technical documentation of the food use. Currently, it is estimated that 5.2 % of Korean adults use *Hovenia dulcis* containing supplements

The novel food ingredient is intended to be used in food supplements only with a maximum daily dose of 2 460 mg. The end-product is a capsule of 410 mg. The capsules are to be consumed as 4-6 portions per day. The product is unlikely to substitute any other food items within the diet and there is no exposure to the fruit or its extract from other food sources.

The application is also supported by a number of toxicological studies, which aim to demonstrate the safety of this novel food. The toxicological studies have shown that there is no acute or sub-chronic toxicity and hence, no NOAEL or ADI values could be determined accurately but only an indicative value could be provided (NOAEL 1 200 mg/kg/day). The toxicological data from literature supports these findings. A pre-clinical investigation in Brazil for a similarly prepared extract showed no acute or chronic toxicity. A clinical human trial has been conducted to assess possible efficacy. No adverse events occurred during the study. In Korea, two acute toxicity cases in humans have been reported as a result of continuous misuse of *Hovenia dulcis*. This number of toxicity cases is still lower than that of for example pumpkin juice or ginkgo biloba, both consumed within the European Community.