

## Summary of the dossier:

Applicant: H. Holstein GmbH & Co. KG, Ferdinandstraße 12, 22559, Hamburg, Germany

Name and description of the novel food: Fucoidan extract from *Cladosiphon okamuranus*

The applicant, H. Holstein GmbH & Co. KG, submits an application in order to include Fucoidan extract from *Cladosiphon okamuranus* in the Union list of novel foods to be used in food supplements at a maximum recommended use level of 1770 mg/day (provided in 6 capsules with 295mg/capsule). Fucoidan extract from *Cladosiphon okamuranus* is not intended to be an alternative or replacement to any existing foods consumed as part of the normal diet.

The development of aquaculture technologies for Okinawa Mozuku, which has formed part of the traditional Okinawan diet since ancient times, began in the 1970s, and today, about 20,000 tons are produced every year, with Okinawa prefecture accounting for over 90% of production in Japan. It is harvested by water pump, and used mainly for food, in medicine and for alginate production (Titlyanov, Titlyanova & Belous 2016, [algaebase.org](http://algaebase.org) 25.08.2020). Fucoidan out of *Cladosiphon okamuranus* is a sulphated polysaccharide with a linear backbone of 1-3-linked  $\alpha$ -fucopyranose with 50% sulfate substitution at 4-positions and some O-acetylated fucose residues (Nagaoka et al. 2009).

The daily intake for this supplement of 6 capsules with 295 mg/capsule makes a daily dosage of 23.6 – 29.5 mg/kg body weight for an average adult with a body weight of 60 -75 kg. Toxicity tests showed that *C. okamuranus* shows no significant toxic side effects in rats at a dosage of 600 mg/kg body weight. Studies on healthy humans about the absorption of Fucoidan extract from *Cladosiphon okamuranus* in human bodies show that Fucoidan is absorbed and digested from human bodies and a part of it is eliminated through the kidneys (Kadena., et al. 2018, Tokida., et al. 2016).

Fucoidan extract from *Cladosiphon okamuranus* is produced by the biggest manufacturer in Okinawa, selling a huge amount of this supplement since several years without any report of side effects of this product. Furthermore, Fucoidan extracts from *Undaria pinnatifida* and *Fucus vesiculosus* are already registered in Europe as Novel food.

The available evidence demonstrates that under the proposed conditions of use, Fucoidan extract from *Cladosiphon okamuranus* does not pose a safety risk to human health.