Summary of application: Tenebrio molitor protein concentrate

The company: Ynsect

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The company Ynsect wishes to market ŸnMeal™, consisting of a protein-rich powder from larvae of Tenebrio molitor (yellow mealworm) in the European Union (EU) and is therefore applying for the authorization of its ingredient according to Regulation (EC) No 2015/2283 of the European Parliament and of the Council of 25th November 2015 on novel foods for consumption as an ingredient in additional food groups.

The target group is the general population excluding pregnant and lactating women and children under 3 years of age. The present submission seeks approval for intended use of ŸnMeal™ as an ingredient in the following food categories: Protein products, excluding products covered in category 1.8.; Dairy analogues, including beverage whiteners; and food supplements.

The protein powder has been obtained through a traditional process. The manufacturing process of ŸnMeal™ includes four main steps: the breeding of Tenebrio molitor larvae, their slaughtering by scalding, and afterwards sieving, the mechanical separation of the different parts of larvae and the final drying of cuticles and cake mechanically obtained from larvae. Only mechanical separation and heating treatments are applied during production of the novel food. No processing aids, extraction solvents or other additives are used during the manufacturing process (other than the feeding of the larvae). Sensitive breeding, feeding, and sieving ensures the right and appropriate nutritional composition of larvae, particularly with regards to their protein concentration. The insects considered in this application are reared in a closed environment in the appropriate conditions for their growth and quality (feed composed of by-product from agriculture, tap water, and with conditions of darkness and temperature suitable for their growth). The final drying is identified as the Critical Control Point of the manufacturing process according to HACCP analysis. The conditions of drying are directly associated to the microbiological quality and the protein content of ŸnMeal™. Several in-process controls are put in place to ensure the quality (microbiological and nutritional quality) of larvae before slaughtering and the quality of the finished product ŸnMeal™.

According to the general food principles and to food contaminant requirements laid out in Regulation (EC) No 178/2002 and Regulation (EC) No 1881/2006 (consolidated versions) respectively, the presence of chemical contaminants is controlled via the current control procedures for the presence of contaminants in the substrate and the environment. For chemical agents that may accumulate in Tenebrio molitor larvae, laboratory results permit to confirm the safety of the novel ingredient with respect to heavy metals, mycotoxins, PCB/ dioxins, pesticides, and microorganisms. ŸnMeal™ contains chitin, A fibre found in cell walls in fungi and arthropods such as insects and crustaceans. At the concentration present in the novel food ingredient, which is similar to the normal range for insects according to the Netherland Authority report and the literature, the safety is ensured.

To support the safety of ŸnMeal™, as recommended in EFSA's tiered toxicity testing approach, the novel food was evaluated in two in vitro genotoxicity tests. ŸnMeal™ has been assessed in an Ames test (GLP, OECD 471) and an in vitro micronucleus test (GLP, OECD 487). With this battery of tests, ŸnMeal™ showed no mutagenic or genotoxic effect. All in vitro endpoints are clearly negative; therefore, it can be concluded

that ŸnMeal™ is not a genotoxic hazard. Literature data has confirmed the absence of genotoxic potential. Published data and Ynsect manufacturing process revealed no remaining safety concern. Thus, no ADME and subchronic toxicity studies were performed.

The daily dosage of ŸnMeal™ was set to 45 g/day considering the advice of the 2014 report of the Netherlands Food and Consumer Product Safety Authority (NVWA). NVWA concluded, based on a previous EFSA scientific report for a chitin containing product and the chitin content of insects, that a daily insect ingestion of 45 g/day will not raise public health safety concerns. Regarding allergenicity, in vitro studies with human sera were conducted using ŸnMeal™ by two public laboratories specialized on food allergies: Institut National de la Recherche Agronomique (INRA) and University Medical Centre Utrecht (UMCU). The studies concluded that ŸnMeal can cause an allergic response in patients with known shellfish (crustacean) and dust mite allergies, although the response (IgE binding) is lowered compared to unprocessed mealworm larvae. Human case reports have also shown an allergic response in patients with known shellfish (crustacean) and dust mite allergies following consumption of general insect products. To manage this risk, ŸnMeal™ will therefore be labelled with a specific warning “not suitable for individuals with shellfish (crustacean) and dust mite allergy” in accordance with Regulation (EU) No 1169/2011. The applicant considers that ŸnMeal™ is safe for the consumption by the European population at the proposed conditions of use and no adverse nutritional effects are expected at the anticipated intake level.