

Summary of the application: Whole and ground mealworm (*Tenebrio molitor*) larvae

Applicant: Fair Insects BV (A Protix Company), Industriestraat 3, 5107 NC Dongen, Netherlands

This novel food dossier contains application for *Tenebrio molitor* larvae, commonly known as yellow mealworm larvae, as novel food. This application falls under transitional period for insect products (that have currently been lawfully placed on the market) mentioned in the article 35.2 of Regulation (EU) 2015/2283.

This novel food dossier is prepared in accordance with EFSA guideline on Regulation (EU) 2015/2283. The *T. molitor* larvae have been processed in the following forms: whole - thermally processed/ thermally processed and frozen; whole - thermally processed, frozen and freeze dried; powder - thermally processed, frozen, freeze dried and ground.

The insects considered in this application are reared in a closed environment on GMP+ certified feed (Substrate group A: Animal feed materials according to the EU catalogue of feed materials stated in Regulation (EC) No 68/2013). They are harvested in larvae stage for further processing. The harvested insects are processed based on the general food principles, food contaminants requirements and microbiological requirements laid in Regulation (EC) No 178/2002, Regulation (EC) No 1881/2006 and Regulation (EC) 2073/2005 (updated by Regulation (EC) 1441/2007), respectively. The processing of insects is performed in accordance with HACCP based principles, including quality control checks.

*T. molitor* larvae are relatively easy to farm, have a short life cycle and are a promising source of nutrition. Dried *T. molitor* larvae have a high amount of protein including all essential amino acids present in the levels higher than that recommended by FAO, 2013. They are rich in omega 3 fatty acids and mono-unsaturated fatty acids. Dried *T. molitor* larvae are rich in P, Mg, Fe, Mn, Zn, vitamin B2, B3, B5 and B8. They are also a source of Cu and vitamin B1.

The laboratory results and production process used demonstrate no safety concerns with respect to heavy metals, mycotoxins, PCB/ dioxins, pesticides, prions and microorganisms. The anti-nutritional compounds are also absent or present in low concentrations imposing no health risks.

The concentration of minerals is considered when calculating anticipated intake data and to ensure that their levels do not exceed the tolerable upper limits mentioned by EFSA, 2014 and EFSA, 2015, respectively. Chitin levels mentioned in the EFSA opinion on chitin-glucan (2010) is also considered to calculate anticipated intake data.

The target group is general population excluding infants and toddlers. The present submission seeks approval for intended use of dried and blanched *T. molitor* larvae (whole and ground) as an ingredient in various food categories including cereal and cereal-like flours; bread and similar products; breakfast cereals; fine bakery wares; pasta, dough and similar products; spices, seasoning, sauces, condiments; fish and seafood processed; dishes, including ready to eat meals; food for particular diet; sausages; meat imitates; soups and salads; fried or extruded cereal, seed or root-based products; alcoholic beverages-beer and beer-like beverage, mixed alcoholic drinks, unsweetened spirits and liqueurs; confectionary including chocolates; processed or preserved vegetable and similar; vegetable and vegetable products;

nut/seeds, paste/emulsion/mass, cream cheese; snacks other than chips and similar and processed whole meat products.

The literature studies did not reveal nutritional or safety concerns related to the absorption, digestion, metabolism and excretion of undesired compounds. Thus, no ADME studies have been performed. Genotoxicity and sub-chronic toxicity studies conducted on comparable freeze-dried *T. molitor* larvae showed the absence of a genotoxic character and no adverse effects. Further, the cellular toxicity study carried out using the aqueous extracts of *T. molitor* larvae from Fair Insects BV on different cell types demonstrated no cytotoxicity.

The cross-reactivity and taxonomic similarities of *T. molitor* with molluscs and crustaceans is demonstrated from studies in literature. The intake assessment was carried out for general population excluding infants and toddlers. Thus, following statements must be declared on the label: 'People who are allergic to dust mites, crustaceans or molluscs may have an allergic reaction to the consumption of insects'; and 'Not recommended for children under three years of age'. Additionally, product may contain other allergens based on the nature of feed which should be also declared on the label.

The applicant considers that *T. molitor* larvae and its products are 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 levels.