Summary of the dossier: Dried mealworms (*Tenebrio molitor*)

Applicant: SAS EAP Group – MICRONUTRIS, 6 rue du partanais, 31650 Saint-Orens-de-Gameville, France

Food Category : Dried mealworms (*Tenebrio molitor*)

The application as a novel food has been drafted in accordance with the requirements of the EFSA guidelines for the preparation of a European dossier for the authorization of a Novel Food. This application for authorisation falls under the transitional period mentioned in the article 35.2 of the Regulation (EU) 2015/2283.

Condition of use : Bread products 10 % whole or ground dried mealworms; Baked products 10 % whole or ground dried mealworms; Breakfast cereals whole or ground dried mealworms; Pre-packaged dried mealworms; Cereal bars 10 % whole or ground dried mealworms; Biscuits, cookies and crackers 10 % whole or ground dried mealworms; Chocolate confectionery 10 % whole or ground dried mealworms; Sweeteners 10 % whole or ground dried mealworms; Salad dressing 10 % whole or ground dried mealworms; Ready to eat meals 10 % whole or ground dried mealworms; Pasta 10 % whole or ground dried mealworms.

Mealworms are insects that present numerous nutritional qualities, including a high rate of protein and fat, and can therefore be considered as an interesting alternative nutritional source for the human population.

The company Micronutris, has implemented, to ensure the quality and security of its mealworms destined for human foodstuff, a system of ISO 22000 quality assurance based on the safety of food products, coupled with a HACCP approach that takes into account all of the stages of production, from the breeding of the insects up until the finished, whole, dried Tenebrio molitor based products for the customers. More specifically, follow-up of microbiological, chemical, and physical dangers has been completed. The mealworms are regularly controlled for the presence of mycotoxins, (such as vomitoxins, aflatoxins, and ochratoxins), and contaminant such as heavy metals, (lead, and cadmium), and organochlorine pesticides, pyrethroids, and organophosphate pesticides: none of these species is quantifiable in accordance with the proposed standardized methods, except cadmium, that has been subject to a risk evaluation. Likewise, the microbiological parameter is regularly controlled on the mealworms. The acceptability of batches of mealworms against microbiological criteria is based on the (CE) Regulation No 2073/2005, updated by the (CE) Regulation No 1441/2007. Furthermore, it is noted that dry products cannot be released until they demonstrate a water activity < 0.6. The absence of the dioxin and the polychlorinated biphenyls is verified on the organics vegetal raw materials used to feed the mealworms. The toxicological tests completed on the dried Tenebrio molitor allow the conclusion of the absence of a genotoxic character of the mealworms and the absence of adverse effect below a dose of 3000 mg/kg of body weight and by day, during the studies of reiterate oral administration, (28 and 90 days). The major toxicological effect identified is the allergen power of the mealworm. In effect, the allergen potential of Tenebrio molitor for people who are particularly sensitive to crustacean has been reported in several studies: it is characterized by symptoms such as rhinitis, asthma, and contact urticaria. The company Micronutris recommend a label like the following: « Contains allergens similar to crustacean ». The Authorities of the Netherlands have established that the consumption of insects,

based on the rate of chitin of 45 g / person / day, is inoffensive for the health of consumers. The total estimated daily consumptions in Europe of recommended applications, (aperitif snack and energy bars for sportspeople), remains inferior to the consumption judged inoffensive of 45 g / person / day, and this, even in consideration of the assumptions of average consumption and at the 95th percentile, is very conservative. Likewise, the level of cadmium measured in the dehydrated insects, (in the order of 70 ppb), leading to average levels of exposure, which ever population is considered, contributes to less than 5% of the Tolerable Daily Dose.

On the basis of the information presented in the file, the dried mealworms raised and processed according to the procedures established by Micronutris are a safe and healthy foodstuff that would allow an improvement in the nutritional state of people who wished to consume an alternative foodstuff to current animal proteins.

The applicant has applied for data protection in accordance with Article 26 of the novel food regulation.