Summary of application: Dried defatted powder of Hermetia Illucens larvae

The company: InnovaFeed SAS, Route de Chaulnes, Lieudit Les Trente, 80190 Nesle, France

InnovaFeed wishes to commercialize a dried defatted powder of *Hermetia illucens* larvae in the European Union (EU) and is therefore applying for the authorization of its ingredient according to Article 10 of Regulation (EC) No 2015/2283 of the European Parliament and of the Council of 25th November 2015 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.

Hermetia illucens larvae present numerous nutritional qualities, including a high rate of protein, and can therefore be considered as an interesting alternative nutritional source for the human population. The present submission seeks approval for intended use of the ingredient in the following food categories: Meat imitates; Cereal bars; Protein and amino acids supplements; Hummus; Beans, meat, and vegetables meals.

To ensure the quality and security of its ingredients, InnovaFeed has developed a 4-step production process (larvae feed formulation, breeding of the insects, reproduction and transformation into final ingredient) and has implemented a HACCP approach for strict controls across all 4 steps. Along the whole process, no processing aids, extraction solvents or other additives are used. The breeding step is realized in a closed environment with closely monitored environmental conditions, with several inprocess controls in place to ensure the microbiological and nutritional quality of larvae before slaughtering. The transformation step was designed to preserve the quality of the nutrients naturally present in the larvae. It leverages only mechanical separation and heating treatments – with two Critical Control Points defined in the HACCP approach to ensure the safety of the final ingredient.

The larvae feed and final dried powder are regularly controlled for the presence of contaminants (heavy metals, mycotoxin, pesticides) and microorganisms. In addition to these routine tests, laboratory analyses were conducted in the final ingredient to confirm the safety of the novel food. No significant risk was identified for the proposed uses and use levels.

In addition, as recommended in EFSA's tiered toxicity testing approach, the novel food has been evaluated in two in vitro genotoxicity tests (Ames tests as per OECD guideline 471 and micronucleus test as per OECD guideline 487) and one subchronic toxicity study on rats (OECD 408) in partnership with a GLP certified laboratory. At the time of submission, no safety concern was identified.

Furthermore, publicly available data and compositional analyses revealed no additional safety concern. No ADME study was thus performed.

Regarding allergenicity, the cross-reactivity and taxonomic similarities of insects with mollusks and crustaceans has been previously demonstrated in scientific literature. Thus, the food products subject to this application should have the compulsory label declarations: 'Not recommended for individuals with shellfish (crustacean) and dust mite allergy". Additionally, the novel food may contain other allergens based on the nature of feed which is also declared on label.

On the basis of the information presented in the dossier, InnovaFeed considers that the dried defatted *Hermetia illucens* powder is safe for human consumption by the European population at the proposed conditions of use and no adverse nutritional effects are expected at the anticipated intake level.