

Possible approaches to addressing data requirements for novel food applications for insects and insect-derived products in the EU

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The present document has been prepared for the International Platform of Insects for Food and Feed (IPIFF) by Exponent International, a scientific and regulatory consultancy.

It concerns the regulatory requirements including risk assessment of insects intended for human consumption in the European Union (EU). Notably provides an overview of the main aspects that should be considered when preparing an application for the authorisation of insects for human consumption under Regulation (EU) 2015/2283 on novel foods.

When considering the data that should be presented to support such an application, two documents from the European Food Safety Authority (EFSA) are particularly relevant, namely the EFSA guidance document on the preparation and presentation of an application for the authorisation of a novel food in the context of Regulation (EU) 2015/2283, and the EFSA Scientific Opinion on the risk profile related to production and consumption of insects as food and feed. These guidance documents address the aspects that need to be considered in relation to the production and preparation of insects and insect derived products and describe the potential safety issues associated with these products.

When an application is being made for the authorisation of whole insects under the novel food regulation, it may not be possible to combine a wide range of different species under a single application. However, it may be possible to seek the authorisation of several closely-related sub-species under one application provided there are sufficient similarities in terms of the phylogenetic characterisation of the insect, the production conditions, growth stage at harvest, and the composition of the final product. In addition, it may be possible to submit an application that covers the whole insect and different preparations derived from the whole insect provided no selective extraction or concentration of particular components occurs, however this will need to be assessed on a case-by-case basis.

Along with providing characteristic information on the species for which the application is submitted, including the zoological family, genus, species, sub-species, and breed of the organism, information should also be provided on the parts of the insect used along with the geographical origin. In addition to the provision of these descriptive data, detailed information will also be required on certain aspects related to the specific insect (or derived insect product), namely; production process, composition data, specifications, history of use, anticipated intakes, absorption, distribution, metabolism and excretion (ADME) studies, nutritional information, toxicological data and allergenicity information.

In relation to the provision of data on the anticipated intakes, a realistic estimate of intake of the insect (or of the derived insect product) by the European population is required. When whole insects are considered, intakes can be based on typical consumption in third countries. In the case of derived products intended to be used as ingredients, then a more detailed exposure assessment will be required that takes account of proposed uses and use levels of the derived ingredient in food using relevant European food consumption data. In addition, an estimate of likely exposure for any potential undesirable substances that may be present should be undertaken and provided in the application.

In general for each type of novel food, a substantial toxicological data package is required to support a novel food application in the EU, which should include as a minimum data in tier 1 related to genotoxicity and sub-chronic toxicity. It is anticipated that further tier 2 toxicity

studies such as chronic or carcinogenicity studies will only be required in a small number of applications. The parameters that need to be evaluated will be relatively consistent between different insect species although each should be considered on a case-by-case basis to identify whether there are any specific additional analyses that are required for that particular insect.

In the case where there is a history of consumption of insect species and no undesirable components are present, then it will likely be possible to make a case for using this in lieu of specific toxicological testing for that species, and toxicity knowledge of closely related species with a similar composition can possibly be used.

Toxicity testing in at least tier 1 is anyway necessary when an insect species has no history of food consumption, a different and unknown stage in its life cycle is used, or when potential hazards are present due to the substrate, methods of farming or processing that are used. In the situation where a derived product has been produced, or where a specific component of the insect has been isolated and concentrated, then there will also probably be a need to undertake some form of sub-chronic toxicity testing.

Insects are considered to be potentially allergenic given they are taxonomically related to edible crustaceans that have known allergenic risk, and they are related to environmental pests, such as dust mites and cockroaches, that are known to elicit allergic reactions. There is a need to undertake an assessment of the allergenic potential of insects intended for human consumption, and this is particularly the case for insects with limited or no history of human consumption. Such an assessment can include an examination of the protein content of the insect, an evaluation of the degree of sequence homology of the protein components with known allergens, and immunological assays that can identify potential allergenic components. In addition, the potential for cross-reactivity should be examined and a literature review should be provided in the application which identifies information on sensitisation, case reports of allergic reactions, and/or allergenicity studies (*in vitro*, in animals, in humans) of the novel food and/or its source(s).

In addition to the points highlighted above, a fundamental aspect of ensuring safety in use of insects for human consumption is the effective application of good hygiene practices during production and harvesting operations.