Summary of the dossier: Pig kidney protein extract

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This is an application for the change in the conditions of use of the currently authorised novel food 'pig kidney protein extract which contains 7% of the diamine oxidase (DAO) enzyme. The proposed change in the conditions of use concerns the use of pellets, in addition to the currently authorised encapsulated pellets with enteric coating, as a form of the novel food. The protein extract is manufactured according to the authorised specifications for this novel food included in the Union list of novel foods and is obtained from homogenized pig kidneys through a combination of salt precipitation and high-speed centrifugation. The obtained precipitate containing essentially proteins, of which 7% is the enzyme DAO, is re-suspended in a physiologic buffer system. The pig kidney extract obtained is formulated as encapsulated granules or pellets with enteric coating.

There are other oral medicinal forms that also guarantee intestinal release, retain the enzymatic activity, and the stability, without compromising the product's safety/tolerability. The inclusion of tablets as an additional solid dosage form to the current specifications of the novel food in question, is based on a well-established widespread pharmaceutical knowledge-expertise on the safety and tolerability of tablets. Neither the tablet composition (inactive components), nor the properties conferred to the release kinetics of the contents, will have any impact on the safety and tolerability of the novel food product, as compared to encapsulated pellets. Although the above knowledge is sufficient to fully back the current application, the applicant has generated evidence that confirms that the tablet formulation does not affect the DAO in vitro biological activity and in some instances even improving it.

The tablets which are subject to disintegration and dissolution prior to the expected activity, may therefore confer specific properties to the delivery of the active substance, such as extended or controlled release, or concomitant or subsequent delivery of various compounds. This may allow for a reduction of the frequency of the dosing, and an increase of the effectiveness of the food by localization. They may come into regular size, or mini-tablets, facilitating the intake by the consumer, even in geriatric and paediatric populations. Neither of those tablet types bears any specific risk. Adding tablets of any type as a new solid dosage formulation for the administration of food supplements and foods for special medical purposes that contain the novel food "pig kidney protein extract", to the already approved capsule form, is a minor change of no safety or tolerability concern. In the light of the fact that no specific risk is attributable to the tablet formulation, there is no need for new supporting safety/tolerability data.

The application has been prepared in accordance with the requirements of Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, 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 and EFSA's Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283.