

## Summary of the dossier: Refined Shrimp Peptide Concentrate

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This is an application for authorisation to place on the market the Refined Shrimp Peptide Concentrate (RSPC) to be used as a novel food ingredient in food supplements in the European Union (EU). The application has been compiled in line with the administrative and scientific requirements of Commission Implementing Regulation (EU) 2017/2469 laying down for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council 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.

The RSPC is derived through the hydrolysis of Northern shrimp (*Pandalus borealis*) shells and contains more than 87% protein (as peptides) with the range of 2-24 amino acids. Northern shrimp as such has been a part of diet of consumers to a significant degree in the European Community through centuries. However, the peptides isolated from shrimp shells have no history of significant use and are therefore considered as a novel food ingredient.

Specifications for Refined Shrimp Peptide Concentrate and batch data analysis demonstrate that Refined Shrimp Peptide Concentrate is manufactured to a consistent quality. Stability data demonstrates that Refined Shrimp Peptide Concentrate is stable under intended storage conditions. The proposed level of use of Refined Shrimp Peptide Concentrate in food supplements is max 1200 mg per day. Refined Shrimp Peptide Concentrate is a source of Angiotensin-I-Converting-Enzyme (ACE) -inhibitory peptides, and is therefore effective in lowering blood pressure values in subjects with mild to moderate hypertension

The application is also supported by a number of toxicological studies, which aim to demonstrate the safety of this novel food. The safety of Refined Shrimp Peptide Concentrate has been systematically investigated in in vitro and in vivo tests and no safety concern has been raised. Two clinical studies made in humans have demonstrated that the use of Refined Shrimp Peptide Concentrate in food supplements with the intended dose is safe. The scientific literature also documents that no adverse effects or safety concerns have been reported in the clinical trials made with bioactive peptides from different natural sources having ACE-inhibitory activity.