Summary of the dossier: Phenylcapsaicin

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This is an application for authorisation to place on the market phenylcapsaicin, a synthetic analogue of naturally occurring capsaicinoids found in chili extracts, for use as an ingredient in food supplements and foods for special medical purposes 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.

Phenylcapsaicin is produced via chemical synthesis using substances commonly used in food production. Phenylcapsaicin is targeted to the adult population and is intended for use in food supplements at a maximum level of 2.5 mg phenylcapsaicin/day (i.e. 250 mg/day supplement) and in foods for special medical purposes at a maximum level of 2.5 mg/day.

Phenylcapsaicin is a synthetic derivative of capsaicin that occurs naturally in Capsicum fruits (chili, paprika, peppers of the nightshade family Solanaceae, etc.) and contributes to its pungent character. While capsaicinoids have a substantial history of use through the consumption of chillies, synthetically derived phenylcapsaicin itself has no existing history of use in food.

Phenylcapsaicin is a high purity synthetic compound that is intended to be marketed as a functional ingredient in its own right and is not intended to replace another food. As such, phenylcapsaicin would not consist of any traditional measures of nutrition. Using the EFSA Comprehensive European Food Consumption Database (EFSA Comprehensive database hereafter; EFSA, 2015) of the average exposure to capsaicins from foods in the diet in the EU, were estimated. Total mean intakes of capsaicins were obtained for each population class within each survey by summing the mean intakes from each food category of the total population dataset (EFSA, 2011). Mean intakes of capsaicin ranged from <0.01 to 2.65 mg/day (identified for very elderly). These intakes represent total population intakes at the average level of consumption, this level is likely higher among consumers only, and among heavy consumers of capsaicin-containing foods. Considering that phenylcapsaicin is proposed for use at a level of up to 2.5 mg/day in food supplements and foods for special purposes, this level is within the range of daily intake of capsaicin from common foods consumed in the EU, as estimated using the EFSA Comprehensive database. Furthermore, the estimated exposure to phenylcapsaicin under the intended conditions of use is within the capsaicin exposure levels reported in the public domain (range of 0.77 to 350 mg/day).

The application is supported by a number of toxicological studies, which aim to demonstrate the safety of this novel food. Specifically the studies report that the absorption, distribution, metabolism and excretion of phenylcapsaicin is similar to naturally occurring capsaicinoids like capsaicin, that it is not mutagenic and not genotoxic. In a sub chronic (90 day oral administration) toxicity study, the no-observed adverse-effect level (NOAEL) for systemic toxicity was determined to be 100 mg/kg body weight/day. Based on the local irritation effects observed in the stomach and forestomach in mid-dose and high-dose rats, the NOAEL for local effects was determined to be 30 mg/kg body weight/day. Given its high purity and the chemical synthetic route or its production, phenylacapsaicin contains no known allergens and is expected to be absent of any significant amount of protein making its allergenic potential essentially negligible.