

Summary of the dossier: Coffee husk (Cascara) - the dried husk of the coffee fruit or coffee cherry.

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This is an application for authorisation to place coffee husk (commonly referred to as Cascara), from *Coffea arabica* L., on the market in the European Union (EU) for use as an ingredient in non-alcoholic, water-based beverage infusions.

This application is submitted pursuant to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, and specifically corresponds to the category covered in Article 2 (iv) "food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by traditional propagating practices which have been used for food production within the Union before 15 May 1997." The application was prepared according to 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.

In the scientific literature and this application, coffee husk is defined as "the dried husk of the coffee cherry or coffee fruit that is derived from the natural or dry processing method." In this process, the whole coffee fruit is dried first and then dehusked, separating the dried husk from the coffee seed. The dried coffee husk contains the skin and remnants of the pulp, pectin, parchment, and some silver skin. Coffee husk, the percentage of constituents and the processing method differ from that of dried coffee pulp, although the compounds contained are similar. Coffee pulp is obtained from the washed or wet process whereby only the skin and the pulp are removed, and before drying. An infusion is defined as "a product obtained by infusing" and to infuse, "to steep in liquid (such as water) without boiling so as to extract the soluble constituents or principles." The fruit portion of the coffee cherry has been used as a food and an ingredient in food and beverage mixtures for the past 1000 years in the region of Africa of what is now Ethiopia. The use of the coffee fruit, both raw and dried, as an ingredient in food and beverages, is still traditionally in use today in parts of Africa, the Middle East, and South America, in countries such as Ethiopia, Kenya, Yemen, Saudi Arabia and Bolivia.

In addition to its traditional usage in these countries, Cascara and cascara based products are available to consumers on the open market in countries such as Australia, USA, Canada, Japan, and India. No adverse events have been reported from human consumption where cascara consumption takes place.

The intended use of cascara is in soft drinks, tea, and energy drinks, in infusion concentrations up to 60g/L of water targeted to the adult population. The average estimated exposure (average minimum and maximum) to cascara for adults ranges between 0.10 - 0.60 g/kg bw/day using the Food Additive Intake Model (FAIM) tool, taking into account all uses as soft drinks, teas, and energy drinks. This application provides analytical data from a thorough analysis of coffee husk that demonstrates it has positive nutritional characteristics and contains protein, fat, carbohydrates, vitamins, mineral elements, fatty acids, amino acids, alkaloids (caffeine), tannins and polyphenols.

The components that can also have dual roles in both positive nutritional and antinutritional effects, caffeine, tannins, and polyphenols, were found to be present in concentrations that are beneficial

and not harmful to health under the proposed use, intake and concentration levels. Coffee husk does not contain inherent toxic constituents, and the coffee husk tested did not reveal amounts of external contaminants that would deem it unsafe for human consumption under the proposed use, intake and concentration levels.

For the application, analytical studies for the presence of pesticides, mycotoxins, heavy metals, microbes and pathogens, and inorganic and organic contaminants were carried out. The potential allergenic, genotoxic, and subchronic toxicity were assessed. Utilising an allergenic skin prick test, Cascara exerted a low (if any) allergic potential in a subpopulation representing persons susceptible to allergy. From the scientific literature, third party toxicology studies with rats utilizing extracts derived from coffee husk, components of coffee husk, and products that contain coffee husk (whole coffee fruit powder, whole coffee fruit extracts, and coffee silverskin extracts), were used to support subchronic toxicity data. In 14-day oral toxicity studies, whole coffee fruit powder or water extracts thereof were tolerated <2.2g/kg bw/day. In 90-day subchronic toxicity studies, ethanol extracts were tolerated <3.4 g/kg bw/day and regarded as NOAEL. Similar results were obtained separately for coffee husk, parchment and silverskin administered orally in 14-day studies where a dose of 2.0 g/kg bw/day showed no signs of toxicity. Additionally, an analysis of the literature of animal feed studies was included demonstrating that cascara can be consumed safely up to certain amounts. Supporting arguments were made to reinforce the relevance of all of the aforementioned studies for the approval of non-alcoholic, water-based infusions of coffee husk consumption by humans.

Collectively, the scientific evidence in the Application demonstrates that coffee husk would not have a negative impact on human health when used in non-alcoholic, water-based beverage infusions, at the proposed concentration levels.