Summary of the dossier: Dried Miracle Berry (DMB)

Applicant: Baïa Food Co. (Medicinal Gardens S.L.), Calle Marqués de Urquijo 47, 1ºD, Office 1, Madrid, Spain

This is an application for authorisation to place on the market the dried fruit of Synsepalum dulcificum Daniell (referred to as "Dried Miracle Berry" or "DMB") to be used as an ingredient in food supplements. 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, 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". 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 Dried Miracle Berry is produced via blending and dehydrating the pulp and skin of the miracle fruit (Synsepalum dulcificum) in an approved manufacturing plant following BRC standards for dried foods. Traceability, as defined in Regulation (EC) 178/2002, is guaranteed and a HACCP system has been set in place at all stages of the specific food chain, from food production and preparation processes (including cultivation and crop management, harvesting processes and equipment/tools used) to packaging, transport, storage, and distribution, as a systematic preventive approach to food safety. The supply chain of DMB was implemented in cooperation with development agencies (GIZ) and the Ministry of Food and Agriculture of the government of Ghana via the Market-Oriented Agriculture Programme. Furthermore, Baïa Food Co. is contributing to the conservation of this underutilized crop and neglected species, to the sustainable use of its components, and is actively collaborating with smallholders in Ghana to develop an ethical and sustainable value chain for DMB.

The Synsepalum dulcificum fruit (Miracle Berry) has a history of use in West Africa and in several countries of other regions as a fresh fruit, pulp, puree and other types of preparation, and its consumption has been reported since the XVIII century. According to the Commission Novel Food catalogue the miracle fruit, or its source miracle berry plant (Synsepalum dulcificum), produces berries that, when eaten, cause sour foods (such as lemons and limes) subsequently consumed to taste sweet. The molecule responsible is a glycoprotein called miraculin. When the fleshy part of the fruit is eaten, this molecule binds to the taste buds on the tongue, causing sour foods to taste sweet. This effect lasts 15-60 minutes. This naturally functional berry can help to soften bitter flavors and to mask sour taste that often prevents the average consumer from eating many healthy foods, including some fruits, vegetables, and nuts. Therefore, in some cases, DMB may become a valuable partner for the maintenance of good health. Currently, a number of products with Dried Miracle Berry are in the US and Taiwanese markets, in the forms of dried berries, tablets, powders, and other products, and the fresh miracle berry is commonly consumed Ghana. Miracle berry products are approved for food use at least in the US, Japan, Taiwan, and Ghana.

The novel food ingredient is intended to be used in food supplements only with a maximum daily dose of 0.9 g/day distributed in 3 servings a day (0.1 g – 0.3 g), one before each main

meal/food/beverage, which is compatible with a good control of a conscious consumption, according to the habits of people taking supplements. The product is unlikely to substitute any other food items within the diet and there is no exposure to the fruit or its extract from other food sources.

The application is also supported by a thorough systematic safety assessment including extensive proprietary analytical studies of its composition, critical nutrients, potential toxicants and contaminants. The potential allergenicity, genotoxicity, and subchronic toxicity, as well as the previous human exposure to the novel food, have been assessed. The toxicological in vitro and in vivo studies performed by Baïa Food Co. showed no acute or sub-chronic adverse effects and hence, no NOAEL or ADI values could be determined accurately but only an indicative value could be provided (NOAEL 2000 mg/kg/day). To date, no adverse events have been described in the clinical trials and sensory analysis published in the literature.