Summary of the dossier: Chuta® (non-toxic edible Jatropha curcas kernels)

Applicant: JatroSolutions GmbH, Echterdinger Str. 30, 70599, Stuttgart, Germany

This is an application for authorisation to place on the market Chuta[®] (non-toxic edible *Jatropha curcas* kernels) as a novel food (as 100% prepacked Chuta[®] kernels, which will be categorized as nuts) or as part of the composition of other foods, such as cereals and cereal products (by the inclusion of 5% of Chuta[®] kernel fragments). *Jatropha curcas* is a perennial shrub from the Euphorbiaceae family, native to Mexico and Central America. Chuta[®] is a trademark registered in Germany and the European Union by JatroSolutions GmbH.

The applicant submitted a dossier to register Chuta[®] as a novel food on August 2016 pursuant Regulation (EC) No 258/97. However, with the entrance into force of the new Novel Food Regulation (EU) 2015/2283 on 1 January 2018, the applicant adapted the dossier. Article 3(2) of Regulation (EU) 2015/2283 and the EFSA document "Guidance on the preparation and presentation of an application for authorization of a novel food in the context of Regulation (EU) 2015/2283" were consulted to assign the following category to Chuta[®]: "Food consisting of, isolated from or produced from plants or their parts".

Fruits of *J. curcas* contain 2-4 seeds. Each seed has a black shell, enclosing long oval-shaped kernels with high contents of oil and protein. The most important difference between Chuta[®] and other *J. curcas* ecotypes is the absence of toxic compounds known as phorbol esters. These phorbol-ester-free ecotypes were first found in rural communities in the south of Mexico, where indigenous cultures such as the "Totonacs" have consumed non-toxic edible *J. curcas* for centuries. The roasted kernels are used as snacks or to prepare traditional dishes. Nonetheless, Chuta[®] has not a history of human consumption in the European Union.

The EFSA CONTAM Panel (2015) issued an opinion on the risks for human and animal health related to the presence of phorbol esters in *J. curcas* kernel flour (JKF), where various research studies on detoxification (i.e. removal of phorbol esters) of JKF were assessed. The EFSA CONTAM Panel (2015) concluded that i) detoxified JKF would not pose a risk for pigs, ii) that the risk to other animal species is likely to be low, and iii) that more information is needed to confirm risks on humans. Considering this opinion, the fact that the "Totonacs" have consumed phorbol-ester-free *J. curcas* for centuries, and the results from various research studies, it is concluded that phorbol esters are the only compounds of *J. curcas* restricting its edibility. Additionally, detoxified JKF and non-toxic *J. curcas* have proven to be effective protein sources for fish, shrimp, turkeys, goats and pigs; whereas toxicological studies in rats showed no adverse effects when consuming non-toxic JKF.

The production process of Chuta[®] initiates with the establishment of the plantation. In this step, it is very important to use safe and good quality planting material (without phorbol esters and good productivity). The applicant can only guarantee this when establishing the plantation with EdibleNut cultivars (which are used to grow Chuta[®]) from the breeding program of JatroSolutions GmbH, which is under the scientific guidance of qualified breeders. EdibleNut cultivars were developed from the non-toxic germplasm of JatroSolutions GmbH originating from Mexico. JatroSolutions GmbH does not apply any genetic engineering technologies in their breeding program, thus guaranteeing their products to be free of genetically modified organisms.

For sustainable production, the agronomic management of the plantation is done following the concepts of integrated pest management and good agricultural practices. After harvest, the fruits are de-husked to obtain the seeds. Sorting and de-shelling of the seeds is followed by hydrothermal treatment of the kernels, similar to how it is done with other nuts. The packaging is done accordingly to the indications of the manufacturer.

The applicant does not intend to sell Chuta[®] directly to consumers in the European Union, but to manufacturers who might include additional processing (e.g. salting) or re-pack the product for retail sales. The production process is assessed for traceability, quality, and safety and ensures that heavy metals and pesticide residue analyses comply with the European regulations. The results of microbiological tests confirm the absence of mycotoxins or hazardous microorganisms. After hydrothermal treatment, antinutrients such as curcin and trypsin inhibitors are reduced or inactivated, and heat-induced contaminants do not pose any particular concern.

Chuta[®] contains antioxidants and is a good source of protein (about 26 g in 100 g), unsaturated fatty acids and minerals (such as calcium, magnesium, potassium, phosphorus and zinc), representing a good nutritional food alternative to other nuts as a supplementary source for a healthy diet.

The anticipated average intake estimation for an adult is 15-20 g of Chuta[®] per day. Chuta[®] is not intended to replace other foods in the diet, rather be used as a supplement to existing diets. In general, nutritionists indicate nuts are a good nutritional source that also helps reduce the risk of coronary heart disease. Furthermore, to our best knowledge, no reports of allergenic reactions of humans after consumption of Chuta[®] have been recorded.