CONSIDERATION BY THE ACNFP OF SACHA INCHI AS A TRADITIONAL FOOD FROM THIRD COUNTRIES

Background

At the 140th meeting of the Advisory Committee on Novel Foods and Processes (ACNFP), the traditional food from a third country notification dossier for sacha inchi roasted seeds (*Plukenetia volubilis* Linnaeus) was considered.

The product seeking authorisation is a seed that is peeled, washed and roasted before packaging for consumption. The applicant claimed that sacha inchi roasted seeds have been consumed in Peru for over 25 years. The oil of sacha inchi was previously authorised as a novel food under the substantial equivalence process of 258/97 EC due to its similarity to linseed oil.

The applicant intends to market roasted sacha inchi seeds for use in the following categories: Legumes, Oilseeds and Spices, to be consumed as a snack. The summary of the application can be viewed on the Commission website.

The Committee's discussion

The advice of the Committee to the Food Standards Agency is summarised below. Please note the Committee did not consider any potential health benefits or claims arising from consuming the food, as the focus of the novel food assessment is to ensure the food is safe, not misleading and not putting consumers at a nutritional disadvantage.

The Committee made several general comments, including that the dossier presented a greater level of detailed information than numerous previous traditional food applications and supported this approach.

Identity of the traditional food

The Committee were content that the evidence presented showed the product had been used in Peru for a long time and had been commercialised in recent years. However, despite the information provided on the trading practices of the product, information on the frequency, and quantity, of consumption in third countries was not present, making it difficult to understand the pattern of traditional consumption and how this would relate to potential consumption in a European population.

Production process

The Committee recognised that the production process was described to an acceptable level of detail but noted that no minimum temperature and time of processing was provided for the roasting process. This was felt to be important and could explain the inconsistencies seen in the data provided across batches on the levels of saponins and alkaloids and may be important in ensuring that the contents of these anti-nutritional factors was reduced sufficiently. Concerns were also raised regarding the measurement of lectin and further information was sought on whether

the roasting process will affect the presence of this anti-nutritional factor in the final product.

Similarly, the committee recognised that the roasting process is said to not exceed 120^{o}C and 30 minutes of exposure to avoid the formation of acrylamide, but noted that the specification of the product did not include maximum levels of acrylamide. The Committee suggested that analytical data should have been presented showing acrylamide content in the final product.

Compositional data and specification

Members also commented on the challenge of evaluating the safety of an application presenting information from multiple producers and whether five batches was sufficient to address composition variability across all producers. Members pointed out that the application lacked a complete fatty acid profile and that inclusion of erucic acid concentration, for example, would assist evaluation of the product.

The Committee raised concern over the lack of rationale given by the applicant for rejecting two test batches in which mercury was detected, and how similarly contaminated batches would be handled in the future. The committee commented that this was a high failure rate and an explanation as to how this mercury contamination occurred, and how this risk would be handled, should be required from the applicant.

Under the traditional food authorisation process there is no requirement to provide toxicological studies. However, a peer-reviewed publication reporting two toxicology studies was provided by the applicant and evaluated by the Committee. In the Committee's view the two studies described were not relevant for the product under evaluation, as the substance tested was a defatted cake made from powder obtained by press-filtering crude sacha inchi oil, not the whole seed for which approval was being sought. Therefore, this sample material was not representative of the product that would be consumed and would not allow evaluation of any toxic elements present in other parts of the seed.

An acute toxicity study on "roasted seeds of sacha inchi" was also described. It is not typically a requirement to perform an acute toxicity study for a novel foods application as an LD50 value does not add value to the risk assessment, but given that it was performed it provides additional reassurance that the roasted seed is not acutely toxic.

The Committee highlighted the high levels of potassium and potential for heavy metals such as cadmium to be present in the seed. High levels of some chemicals may cause concern if they are contaminants but may also result from the soil on which the plant is grown. This is particularly relevant for this application in which the product is expected to be grown on a variety of soils with different properties. No specification for maximum levels of elements in the final product was given by the applicant and it was recommended that risk managers should consider how the chemical composition could be kept consistently under maximum EU allowance levels if authorised. This is particularly the case for cadmium, which was measured above the limit of detection in

the analysis provided. The applicant's proposal was that the level of cadmium would be the same as found in any other nut, but additional assurance can be provided by comparing expected intake of cadmium from the product in a quantitative risk assessment using the EU derived tolerable weekly intake (TWI) for cadmium derived by EFSA in 2009.

The Committee found the information regarding food allergy and the potential allergenicity to be insufficient to address the allergenic potential of this seed given its high protein content. While members noted that no allergic reactions have been reported to sacha inchi through the traditional use, given the overall nutritional parallelism with other tree nuts further consideration would be needed. Members highlighted that sacha inchi is closely botanically related to castor beans, whose albumin protein is known to be a strong allergen. The Committee considers it is possible that the seed will cause reactions in people allergic to tree nuts and could cause *de novo* sensitisation when introduced to the UK population. Further information comparing the protein sequence information from castor beans and sacha inchi would provide an evidence base to understand if risk management measures may be required.

Members also raised concerns over the lack of an assessment on the environmental impact and the sustainability of the large-scale exploitation of sacha inchi crops in the Amazon region. They remarked that the environmental risk assessment should play a more relevant role in the evidence package provided by the applicant in order to understand how the production conditions may impact the food safety risks under assessment.

Proposed conditions of use for the EU market

No specific points were raised in relation to this section of the notification.

Consultation response

The Secretariat posted this advice online for a 10-day consultation to allow members of the public to review the advice. The Secretariat received no comments from the public during the consultation period. This final version was sent to members for final proofing and was agreed on. It has now been uploaded to the summary section of the website.

Conclusions

The Committee identified several areas of concern where further information and assessment would be required to provide reassurance on the conditions under which sacha inchi roasted seeds could be used safely by the EU population.

The Committee considers there are several uncertainties related to roasting process, to the frequency and amounts of the product consumed traditionally, to the maximum specified levels of cadmium, acrylamide and anti-nutritional factors such as lectin and

saponins across all batches of the final product, as well as the need for further consideration of the potential allergenicity of the product.

Although traditional use and safety of sacha inchi roasted seeds had been partially established, the Committee could not reach a conclusion on its safety, and therefore more information would be necessary to properly inform risk management decisions.