CONSIDERATION BY THE ACNFP OF *ARISTOTELIA CHILENSIS* (MAQUI) AS A TRADITIONAL FOOD FROM THIRD COUNTRIES

Background

At the 137th meeting of the Advisory Committee on Novel Foods and Processes (ACNFP), the traditional food from a third country notification dossier for *Aristotelia chilensis* (maqui) in three forms was considered.

The products seeking authorisation were: maqui fruit juice concentrate 65° Brix, freeze dried maqui fruit powder and maqui fruit powder dried using Radiant Energy Vacuum (REV) drying method.

The applicant provides evidence of historical consumption of unprocessed maqui berries by the Mapuche people and highlights use of maqui in jams and juices until the late 1980s. The product is a wild harvested product that is not currently commercially cultivated. They acknowledge that Maqui processed into dried fruit, dehydrated powder, freeze dried powder and juice concentrate only became prominent in late 2000.

The applicant intends to market maqui in its three forms for use in food categories including: edible ices; confectionary; cereals and cereal products; beverages and ready-to-eat savouries and snacks. 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 while it was useful to have a wide range of information presented, the dossier lacked accessibility and coherence. This made evaluating the information provided for safety assessment difficult. It was noted that many of the resources provided were irrelevant to the safety assessment and made accessing key information harder.

Identity of the traditional food

Critically, members commented that a history of safe use for 25 years had not been clearly demonstrated for the products seeking authorisation. Evidence of traditional consumption of the berries and leaves has been provided, but sufficient evidence for concentrated processed maqui products was not supplied. The Committee considered that the risks associated with a processed concentrated product would not the same as those of the traditionally consumed product – a wild berry.

Production Process
Questions were raised by members around the use of chemicals for sterilisation within washing steps of the production process and whether these were effective in reducing potential microbial contamination ahead of the pasteurisation. Of particular concern was the lack of residual concentration checks to both ensure no chemical contamination and to provide confidence in the effectiveness of this step. The Committee also noticed gaps in the information provided about the Radiant Energy Vacuum process used in the production and how this might impact on the nature of the product.

Compositional data
The Committee expressed significant concerns around inconsistencies in the information presented, such as incorrect or missing units, or presence of compounds such as vitamin D3 that would be unlikely to be present in the products. This raised questions on the robustness of the data and the proficiency of laboratories undertaking the analytical testing and therefore its suitability for assessment.

The Committee noted that the applicant had chosen not to provide analysis of 5 batches of the product. This made understanding the natural variation in the product and the significance of any anomalies difficult.

The nutritional data within the dossier detailed unexpectedly high levels of sodium within concentrated maqui juice. The Committee commented that the high polyphenol content of the product could impact on the absorption of calcium and iron which would be a concern for certain subgroups in the population, such as children. Further issues were raised around high and variable potassium levels potentially having unintended cardiac effects which were not explored and the low pH of the product.

Specification
The applicant draws attention to potentially high levels of biologically active compounds in maqui berries, such as polyphenols and anthocyanins that would be concentrated within the products. Members highlighted that over consumption of these compounds in the diet could be of concern. They noted that it would have been useful if the applicant had compared the levels of substances in maqui berries to those of other fruits to understand the contribution the berries would make to the wider diet if consumed in the EU. This could then have been compared to EFSA opinions considering levels of dietary exposure to these compounds from the diet that are considered safe.

The Committee had further concerns around the impact of pharmacologically active compounds that may be present, particularly upon glucose levels when dose levels are not controlled. This was of particular importance as the applicant is seeking authorisation for a concentrated form of the berries. Members felt that adequate discussion around the risks of such bioactive compounds and how they would be mitigated was not provided by the applicant.

The Committee observed that information provided on intake was based on a proxy of polyphenol content rather than intake of the actual products. This made it difficult to understand the likely exposure of consumers and how this related to any risks identified.

The Committee noted the specifications were unclear and that microbiological and heavy metal contaminant limits were not provided for all products. In particular there had been no consideration of mycotoxins.

Proposed conditions of use for the EU market

Within the precautions and restrictions of uses the applicant refers to consumption not being advised for phenylketonuria patients; however, the Committee questioned the reasoning behind this as Maqui is a low protein food and there is no evidence that it contains high levels of phenylalanine.

Members noted that while allergenicity concerns had not been identified for this fruit, the consumption of seeds in the powdered product, might constitute a future risk if consumers become sensitised, as found in other fruit-based products.

Conclusions

The Committee highlighted that the applicant has not sufficiently demonstrated 25 years of consumption within a third country of maqui in a processed/powdered form. The Committee were unable to reach a conclusion on the safety of the three proposed maqui products due to insufficient data.

Furthermore, the Committee noted there were inconsistencies in the data provided and that the accessibility of the notification made assessment difficult.

Of particular concern, was the lack of consideration of the potential safety risks from biological active components in the berry. In addition, the exposure data as presented did not allow risk characterisation of the likelihood of adverse effects if maqui was consumed as part of the EU diet.