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COMMITTEE PAPER FOR DISCUSSION
ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

ARISTOTELIA CHILENSIS (MAQUI) – TRADITIONAL FOOD NOTIFICATION NF 2018/0313

ISSUE

A notification has been received under the traditional foods authorisation process for Maqui (*Aristotelia chilensis*) in three forms under the Novel Foods Regulation (EU) No. 2015/2283.

The Committee is asked whether there are safety concerns with the proposed use of this traditional food in the EU market. The information from the Committee will provide the basis for any safety objections raised by the UK at EU level.

BACKGROUND

1. On 25th March 2019 the European Commission forwarded the notification from South Am Freeze Dry S.A. for Maqui (*Aristotelia chilensis*). The applicant proposes to use Maqui fruit in three forms:

    - Maqui fruit juice concentrate 65° Brix,
    - Freeze dried Maqui fruit powder and
    - Maqui fruit powder dried using Radiant Energy Vacuum (REV) drying method.

2. The proposed uses for the products include dairy products and their analogues; edible ices; confectionary; cereals and cereal products; beverages and ready-to-eat savouries and snacks within the EU.

3. Member States have four months, until 25th July, to submit any reasoned objections to the notification. If authorised, the authorisation will be open to any company to use, subject to the specification and conditions of use detailed in the authorisation.

4. The notification dossier is attached as **Annex A** and the key appendices to the dossier are attached as **Annex B**, both of which contain protected commercial information. The Secretariat has prepared a list of all the appendices to the dossier in **Annex C**, these are available to members, on request. **Annex D** and **Annex E** are sections of the Committee paper which include protected commercial details.

This application

Identity, composition and specification

5. Maqui (*Aristotelia chilensis*) a.k.a. Koleón, Clon, Maquei and Queldrón is a small tree belonging to the Eleocarpaceae family. The five species of *Aristotelia* are found in tropical and temperate regions across the South Pacific. *A. chilensis* is endemic to the sub-Antarctic forests of Chile between the Coquimbo and 11th Regions, growing wild as a pioneer species. The applicant states that the leaves and fruit have historically been used for medicinal purposes. The berries are deep purple, 5 mm in diameter and possess at least 2 seeds.

6. The Secretariat notes that in the EU novel foods catalogue Maqui berries are considered not novel in food supplements in the EU. However, they are considered novel when used in foods as a history of consumption in the EU for this use has not been demonstrated.

7. Specification details are provided by the applicant for the three Maqui products. Key nutritional characteristics are summarised in Annex D as the applicant has claimed confidentiality for these aspects and this request is under review.

8. The applicant comments that absolute values are provided rather than ranges to meet with the requirements for nutritional labelling required by Chilean food legislation. Dependent upon the nutrient or dietary factor they may either: only exceed the amount listed on the label by up to 20% or be present in an amount greater than or equal to 80% of the value stated on the label.

9. The applicant presents compositional data from the literature and proximate analyses, as summarised in the table below. Compositional data on Maqui seeds is provided as an annex to the dossier. They declare that no compounds are added to the fruit when dehydrated to form a powder.

	Maqui fruit (Schmidt-Hebbel *et al.* 1990)	**Maqui juice concentrate**	**Powdered Maqui**
Energy (kcal)	150 g/100g	220-230.4 kcal/100g	291-434 kcal
Moisture	56.4 g/100g	40.8- 44.9 g/100g	1.9-7.3 g/100g
Proteins (g)	0.8 g/100g	0.97 to <3.0 g/100g	0.8-6.3 g/100g
Total fats (g)	Tr.	<0.1-3.4 g/100g	9.2-12.1 g/100g
Non-nitrogenous extract	40.8 g/100g	48.3-55 g/100g	-

Raw/total dietary fibre	0.8 g/100g	-	12.3-50.4 g/100g
Ash	1.2 g/100g	2.41-3.0 g/100g	2.4-3.2 g/100g
Calcium	87 mg/100g 1558±33 mg/kg	997 mg/kg	277.8-360.2 mg
Phosphorus	44 mg/100g	-	-
Iron	30.5 mg/100g	17.2 mg/kg	2.18-6.57 mg/100g
Potassium	296 mg/100g 3683±111 mg/kg	14.068 mg/kg	1075 mg/100g
Sodium	-	338 mg/kg	6.9-43 mg/100g
Vitamin D3	-	<2.50 ug/100g	2.5 ug/100g

10. In commenting on the compositional information, the applicant highlights nickel and barium as being hazardous to human health. However, they comment that the levels reported in the literature for Maqui fruit are below those which the EFSA and FDA have indicated may be of toxicological concern.

11. The applicant states that based on literature studies the berries are high in anthocyanins, with total average anthocyanin content 137.6±0.4 mg/100g fresh weight or 211.9±0.6 mg/100g dry weight. Glycosylated anthocyanin content in dried berries was 36.9±3.2 g/kg.

12. Analysis of polyphenols, total anthocyanins and oxygen radical absorbance capacity was performed on Maqui juice concentrate and dried powder as summarised in the table below. The applicant explains that variation in the analyses are due to testing methods but remain within the percentage of tolerance.

	Juice concentrate	**Dried powder**
Total anthocyanins (mg/g)	22.16±0.81 – 26.48±0.44	21.65±0.67 – 65.32±2.73
Total polyphenols **Analysis 1 (mg/g)** **Analysis 2 (mg GAE/100g)**	 42.78±1.52 – 50.47±2.13 3093 – 5798	 70.13±1.45 – 102.60±1.35 NA
ORAC **Analysis 1 (umol TE/G)** **Analysis 2 (umol TE/100g)**	 478.96±25.22 – 628.58±27.04 32,282-56,556	 668.73±25.74 – 940±31.82 NA

13. Heavy metal and pesticide analysis is provided in the main dossier for freeze-dried Maqui berries. The applicant states that the levels of arsenic, cadmium, mercury and lead all fall below the detection limits. The tested pesticides in this form of the Maqui powder were below the limit of quantification.

14. Heavy metal analysis of the juice and REV dried Maqui are provided in the annexes but not discussed.

15. Microbiological analyses were performed on both forms of the dried berries. 5 independently produced batches of freeze dried Maqui, were analysed and 8 batches of REV dried berries across a range of testing methods for common foodborne pathogens. The Secretariat notes that not all batches were tested for all analyses and different methodologies may have been employed. Data presented by the applicant is summarised below.

	Freeze dried berries		**REV dried berries**	
Characteristic	**Analysis**	**Specification**	**Analysis**	**Specification**
Recount of aerobic mesophilic bacteria	<10-2300 cfu/g	< 5 x 10^4 cfu/g	<100-3000 cfu/g	< 10 cfu/g
Total Coliforms	<3	< 50 cfu/g	Not provided	0 cfu/g
E. coli	Absence	Absence	Absent except for in batch 654 M1	0 cfu/g
S. aureus	Absence or <10 cfu/g	Absence	Not provided	< 10 cfu/g
L. monocytogenes	Absence	Absence	Not provided	Not provided
Salmonella	Absence	Absence	Absence	Not provided
Mould	Absence or <10-30 cfu/g	< 2 x 10^3 cfu/g	<10-80 cfu/g One batch 166 sample at 9000 cfu/g	< 500 cfu/g
Yeast	Absence or <10-30 cfu/g	< 2 x 10^3 cfu/g	<10-210 cfu/g	< 500 cfu/g
Enterobacteriaceae	Not provided	Not provided	<10	< 10 cfu/g

16. The applicant performed stability analysis. Testing was undertaken on:

- Maqui berry juice concentrate after 54 months of storage at -18 °C,
- Freeze dried Maqui berries after 27 months of storage, and
- REV dried Maqui berries after 600 days.

The applicant reports that the microbiological parameters for all products remained within the specifications. In their view under these storage conditions no microorganisms are capable of developing and causing product deterioration,

and that food safety is guaranteed for up to 27 months of storage in 4-oz doypacks.

Production process

17. The applicant highlights that the Maqui fruit is harvested between October and March from the traditional regions, through hand collection by local people who are trained each year by the processing companies. According to the applicant there are no domesticated plantations and good harvesting practices are followed.

18. Collected fruit is transported to collection points where it is subject to quality control, cleaning, chilling, freezing and packaging and identification (traceability) of each batch before transportation under cold chain conditions to the processing or storage facility. Upon arrival fruit goes through a second quality control check before processing, packaging, storage and shipping. The applicant explains that critical control points have been identified.

19. The applicant proposes two methods for obtaining powdered Maqui berries. The first uses a freeze-drying process, in which frozen berries are dried without being thawed prior to grinding. The second uses a Radiant Energy Vacuum (REV) drying method, which removes water at low temperatures by applying a combination of pressure and microwave energy.

20. The applicant's response to the Commission's request for additional information states that the REV drying system does not change the composition of fruits and provides results from a study on the effect of REV drying on blueberry and Maqui antioxidant compounds when compared to other drying methods.

21. Juice concentrate 65° Brix is obtained from crushed fruit by a series of steps including thermal treatment before the juice is concentrated.

Experience of continued traditional use in a third country

22. The applicant describes historical consumption of unprocessed Maqui berries in the Mapuche people, highlighting written evidence dating back to the 17th century. Domestic use of the fruit in the beverage "chicha" is noted which is produced by fermenting the fruit, as well as consumption of fresh fruit as part of the general diet. Personal stories report on the consumption of Maqui berries in juices and jams until the late 1980s, however no official records are provided.

23. The applicant claims that historical and current consumption of Maqui occurs across all age ranges of the population, with consumption by pregnant women, children and senior citizens. Chilean customers primarily consume the Maqui fruit as jam and juice, with freeze dried or dehydrated Maqui used as a dietary supplement usually consumed in jams, dairy products, desserts and smoothies.

Dried Maqui fruits can be consumed in hot water infusions. No restrictions of use are presented.

24. The applicant provides details on the traditional medicinal properties of Maqui, including references to studies examining its antioxidant, antibacterial and anti-inflammatory properties.

25. To support long term use of Maqui as a processed product, the applicant has provided additional details and supporting documents highlighting traditional dehydration and storage. The applicant indicates this is required due to the short life span of the fresh fruit. They state that the only changes between the traditional processed use and the processing presented within this application, is the technology utilised for dehydration.

26. They acknowledge that Maqui processed into dried fruit, dehydrated powder, freeze dried powder and juice concentrate only became prominent in late 2000, prior to this it has had some limited use as a food dye.

27. The applicant highlights that today Maqui products are exported from Chile to the USA, South Korea, Japan, Argentina, Brazil and other countries, with USDA and FDA certification of safety. Customs data is provided on global exports from 2010 to 2017, however no consumption data is presented.

Proposed use for the EU market

28. The applicant claims that Maqui does not replace consumption of any other existing product within the EU. The intended target population within the EU will be the general population from 3 to >75 years old.

29. Details on the recommended and maximum intakes are provided by the applicant for the three Maqui products. These are summarised in Annex E as the applicant has claimed confidentiality for these aspects and this request is under review.

30. The applicant recommends no restrictions of use; however, they mention risks of consumption may be present in patients with phenylketonuria due to the phenylalanine content, patients with renal lithiasis due to the calcium oxalates, diabetic patients due to delphinid and individuals allergic to dyes. The applicant additionally comments that excessive consumption could cause acid heartburn.

Additional information provided by the applicant

31. References are provided within the annexes however no literature search was described by the applicant.

32. The applicant highlights the findings of a toxicological animal studies with a concentrated Maqui product and Maqui, which found no evidence of toxicity.

33. The applicant presents the results of *in vitro* and human studies on the regulation of glucose levels by Maqui anthocyanins, in particular delphinidin. References are provided to support the applicants claims of health benefits. The applicant highlights potential health benefits from the high polyphenol content. The Secretariat notes that it is outside the scope of this evaluation to assess scientific evidence for potential health benefits from consuming the product. These are subject to a separate assessment under the health claims legislation.

34. The applicant provides limited information on food allergens. They do not include any discussion or testing to consider the allergenicity of Maqui berries themselves or the potential for cross reactions in individuals allergic to other foods.

COMMITTEE ACTION REQUIRED

- Members are asked whether there are safety concerns that need to be managed with this traditional food from third countries, in the three forms identified.

- The Committee's advice will form the basis for the UK's formal response to the Commission and whether reasoned safety objections are submitted.

Secretariat
May 2019

Annexes attached:

Annex A: Notification dossier for Maqui (*Aristotelia chilensis*) as a traditional food from third countries.

Annex B: Appendices to the dossier.

Annex C: List of all appendices to the dossier.

Annex D: Compositional and nutritional specifications provided by the applicant.

Annex E: Proposed conditions of use for the EU market.