

## COMMISSION DECISION

of 21 April 2010

authorising the placing on the market of puree and concentrate of the fruits of *Morinda citrifolia* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2010) 2397)

(Only the English text is authentic)

(2010/228/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients<sup>(1)</sup>, and in particular Article 7 thereof,

Whereas:

- (1) On 20 April 2006 Tahitian Noni International Inc. made a request to the competent authorities of Belgium to place puree and concentrate of the fruits of *Morinda citrifolia* on the market as a novel food ingredient.
- (2) On 28 February 2007 the competent food assessment body of Belgium issued its initial assessment report. In that report it came to the conclusion that the use of the puree and concentrate of the fruits of *Morinda citrifolia* as a food ingredient was acceptable.
- (3) The Commission forwarded the initial assessment report to all Member States on 28 March 2007.
- (4) Within the 60-day period laid down in Article 6(4) of Regulation (EC) No 258/97 reasoned objections to the marketing of the product were raised in accordance with that provision.
- (5) Therefore the European Food Safety Authority (EFSA) was consulted on 7 November 2007.
- (6) On 13 March 2009, EFSA in the 'Scientific opinion of the Panel on Dietetic Products Nutrition and Allergies' on a request from the European Commission on the safety of '*Morinda citrifolia* (Noni) fruit puree and concentrate' as a novel food ingredient came to the conclusion that the Noni fruit puree and concentrate was safe for the general population.

(7) On the basis of the scientific assessment, it is established that the fruit puree and concentrate from *Morinda citrifolia* (Noni) complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

*Article 1*

*Morinda citrifolia* (Noni) fruit puree and concentrate as specified in Annex I may be placed on the market in the Union as a novel food ingredient for the uses listed in Annex II.

*Article 2*

The designation of the *Morinda citrifolia* fruit puree authorised by this Decision on the labelling of the foodstuff containing it shall be '*Morinda citrifolia* fruit puree' or 'Noni fruit puree'.

The designation of the *Morinda citrifolia* fruit concentrate authorised by this Decision on the labelling of the foodstuff containing it shall be '*Morinda citrifolia* fruit concentrate' or 'Noni fruit concentrate'.

*Article 3*

This Decision is addressed to Tahitian Noni International Inc., 333 West River Park Drive, Provo, Utah 84604, USA.

Done at Brussels, 21 April 2010.

For the Commission

John DALLI

Member of the Commission

<sup>(1)</sup> OJ L 43, 14.2.1997, p. 1.

## ANNEX I

**Specifications of *Morinda citrifolia* fruit puree and concentrate**

## Description:

The fruits of *Morinda citrifolia* are harvested by hand. Seeds and skin are separated mechanically from the pureed fruits. After pasteurisation, the puree is packaged in aseptic containers and stored under cold conditions.

*Morinda citrifolia* concentrate is prepared from *M. citrifolia* puree by treatment with pectinolytic enzymes (50-60 °C for 1-2 h). Then the puree is heated to inactivate the pectinases and then immediately cooled. The juice is separated in a decanter centrifuge. Afterwards the juice is collected and pasteurised, prior to being concentrated in a vacuum evaporator from a brix of 6 to 8 to a brix of 49 to 51 in the final concentrate.

Composition of *Morinda citrifolia* fruit puree and concentrate

Moisture	89 – 93 %	48 – 53 %
Protein	< 0,6 g/100 g	3 – 3,5 g/100 g
Fat	< 0,2 g/100 g	< 0,04 g/100 g
Ash	< 1 g/100 g	4,5 – 5 g/100 g
Total carbohydrates	5 – 10 g/100 g	37 – 45 g/100 g
Fructose	0,5 – 2 g/100 g	9 – 11 g/100 g
Glucose	0,5 – 2 g/100 g	9 – 11 g/100 g
Dietary fibre	1,5 – 3 g/100 g	1,5 – 5 g/100 g
5,15-dimethylmorindol (*)	0,19 – 0,20 µg/mL	0,11 – 0,77 µg/mL
Lucidin (*)	Not detectable	Not detectable
Alizarin (*)	Not detectable	Not detectable
Rubiadin (*)	Not detectable	Not detectable

(\*) By an HPLC-UV method developed and validated by the applicant for the analysis of anthraquinones in *Morinda citrifolia* puree and concentrate.

Limits of detection: 2,5 ng/mL (5,15 dimethylmorindol); 50,0 ng/mL (lucidin); 6,3 ng/mL (alizarin) and 62,5 ng/mL (rubiadin).

## ANNEX II

Uses of *Morinda citrifolia* fruit puree and concentrate

Use group	Maximum use level of <i>Morinda citrifolia</i> fruit	
	puree	concentrate
Candy/Confectionery	45 g/100 g	10 g/100 g
Cereal bars	53 g/100 g	12 g/100 g
Powdered nutritional drink mixes (dry weight)	53 g/100 g	12 g/100 g
Carbonated beverages	11 g/100 g	3 g/100 g
Ice cream & sorbet	31 g/100 g	7 g/100 g
Yogurt	12 g/100 g	3 g/100 g
Biscuits	53 g/100 g	12 g/100 g
Buns, cakes & pastries	53 g/100 g	12 g/100 g
Breakfast cereal (whole grain)	88 g/100 g	20 g/100 g
Jams and jellies (fruit preserves)	(*) 133 g/100 g	30 g/100 g
Sweet spreads, fillings and icings	31 g/100 g	7 g/100 g
Savoury sauces, pickles, gravies, and condiments	88 g/100 g	20 g/100 g
Food supplements (in accordance with Directive 2002/46/EC of the European Parliament and of the Council <sup>(1)</sup> )	26 g per daily dose as recommended by the manufacturer	6 g per daily dose as recommended by the manufacturer

(\*) Based on pre-processing quantity to produce final 100 g product.

<sup>(1)</sup> OJ L 183, 12.7.2002, p. 51.