COMMISSION DECISION

of 15 December 2008

authorising the placing on the market of leaves 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 number C(2008) 8108)

(Only the English text is authentic)

(2008/985/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 (1), and in particular Article 7 thereof.

Whereas:

- (1) On 10 November 2004 Baker & McKenzie on behalf of Morinda Inc., made a request to the competent authorities of Belgium to place the leaves of *Morinda citrifolia* on the market as a novel food ingredient.
- (2) On 30 November 2005 the competent food assessment body of Belgium issued its initial assessment report. In that report it came to the conclusion that an additional assessment was required.
- (3) The Commission forwarded the initial assessment report to all Member States on 21 March 2006.
- (4) Some Member States raised additional questions about the safety of the leaves of *Morinda citrifolia*.
- (5) Therefore the European Food Safety Authority (EFSA) was consulted on 14 November 2006.
- (6) On 10 July 2008 EFSA adopted the 'Opinion of the Scientific Panel on dietetic Products, Nutrition and Allergies on a request from the Commission related to the safety of leaves from *Morinda citrifolia L.*'.
- (7) In the opinion the panel came to the conclusion that the use of dried and roasted M. citrifolia leaves for the preparation of infusions at the anticipated levels of intake is safe.
- (8) On the basis of the scientific assessment, it is established that dried and roasted leaves of Morinda citrifolia comply

- with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.
- (9) 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

Dried and roasted leaves of *Morinda citrifolia* as specified in the Annex may be placed on the market in the Community as a novel food ingredient for the preparation of infusions.

Article 2

The designation of the novel food ingredient authorised by this Decision on the labelling of the foodstuff containing it shall be 'Noni leaves' or 'leaves of Morinda citrifolia'.

Article 3

Dried and roasted leaves of *Morinda citrifolia* shall be exclusively used for the preparation of infusions. They shall be presented in such a manner that a cup of infusion to be consumed would not be prepared with more than 1 g of dried and roasted leaves of *Morinda citrifolia*.

Article 4

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

Done at Brussels, 15 December 2008.

For the Commission Androulla VASSILIOU Member of the Commission

ANNEX

SPECIFICATIONS OF DRIED AND ROASTED LEAVES OF MORINDA CITRIFOLIA

Description

After cutting, the leaves of Morinda citrifolia are subject to drying and roasting steps. The product has a particle size ranging from broken leaves to coarse powder with fines. It is of greenish brown to brown colour.

Composition of dried and roasted leaves of M. citrifolia

Moisture	< 5,2 %
Protein	17 to 20 %
Carbohydrate	55 to 65 %
Ash	10 to 13 %
Fat	4-9 %
Oxalic acid	< 0,14 %
Tannic acid	< 2,7 %

5,15-dimethylmorindol less than 47 mg/kg Rubiadin non detectable Lucidin non detectable