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#### **COMMISSION DECISION**

#### of 27 May 2011

authorising the placing on the market of Chromium Picolinate as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2011) 3586)

(Only the English text is authentic)

(2011/320/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 6 April 2009 the company Cantox Health Sciences International, on behalf of Nutrition 21, made a request to the competent authorities of Ireland to place Chromium Picolinate on the market as a novel food ingredient.
- (2) On 24 April 2009 the competent food assessment body of Ireland issued its initial assessment report. In that report it came to the conclusion that an additional assessment was required.
- (3) The Commission informed all Member States about the request on 30 April 2009. The European Food Safety Authority (EFSA) was requested to carry out the assessment on 12 August 2009.
- (4) On 10 November 2010 following a request from the Commission, EFSA adopted an opinion (<sup>2</sup>) on the safety of Chromium Picolinate as a source of chromium added for nutritional purposes to foods for the general population and to foods for particular nutritional uses. In the opinion EFSA concluded that Chromium Picolinate is not of safety concern provided the amount of total chromium does not exceed 250 µg per day, the value established by the World Health Organisation for supplemental intake of chromium that should not be exceeded.
- (5) Commission Regulation (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutri-

tional uses (<sup>3</sup>) and/or Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (<sup>4</sup>) lay down specific provisions for the use of vitamins, minerals and other substances in food. The use of Chromium Picolinate should be authorised without prejudice to the requirements of this legislation.

- (6) 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

Chromium Picolinate as a source of chromium as specified in the Annex may be placed on the market in the Union as a novel food ingredient to be used in food without prejudice to the specific provisions of Regulation (EC) No 953/2009 and/or Regulation (EC) No 1925/2006.

#### Article 2

The designation of the novel food ingredient authorised by this Decision on the labelling of the foodstuff containing it shall be 'Chromium Picolinate'.

#### Article 3

This Decision is addressed to Nutrition 21, Inc., 4 Manhattanville Road, Purchase, New York 10577, USA.

Done at Brussels, 27 May 2011.

For the Commission John DALLI Member of the Commission

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

<sup>&</sup>lt;sup>(2)</sup> EFSA Journal 2010; 8(12): 1883.

<sup>(&</sup>lt;sup>3</sup>) OJ L 269, 14.10.2009, p. 9.

<sup>(&</sup>lt;sup>4</sup>) OJ L 404, 30.12.2006, p. 26.

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# ANNEX

## SPECIFICATIONS OF CHROMIUM PICOLINATE

## Description:

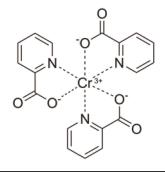
Chromium Picolinate is a reddish free-flowing powder, slightly soluble in water at pH 7. The salt is also soluble in polar organic solvents.

The chemical name of Chromium Picolinate is tris(2pyridinecarboxylato-N,O)chromium(III) or 2-pyridinecarboxylic acid chromium(III) salt.

CAS No: 14639-25-9

Chemical Formula: Cr(C<sub>6</sub>H<sub>4</sub>NO<sub>2</sub>)<sub>3</sub>

Structural Formula:



Chemical characteristics of Chromium Picolinate	
Chromium Picolinate	more than 95 %
Chromium (III)	12-13 %
Chromium (VI)	not detected
Water	not more than 4 %