

COMMISSION IMPLEMENTING DECISION**of 1 July 2014****authorising the placing on the market of citicoline as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council***(notified under document C(2014) 4252)***(Only the German text is authentic)**

(2014/423/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 ⁽¹⁾, and in particular Article 7 thereof,

Whereas:

- (1) On 29 March 2012, the company Kyowa Hakko Europe GmbH made a request to the competent authorities of Ireland to place citicoline on the market as a novel food ingredient.
- (2) On 2 June 2012, the competent food assessment body of Ireland issued its initial assessment report. In that report it came to the conclusion that citicoline for use in certain foods at the levels proposed by the applicant meets the criteria set out in Article 3(1) of Regulation (EC) No 258/97.
- (3) On 10 July 2012, the Commission forwarded the initial assessment report to the other Member States.
- (4) Reasoned objections were raised within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97. In addition, some Member States explained in their objections that they consider products containing citicoline sodium salt to be a medicinal product.
- (5) On 27 November 2012, the applicant informed the Commission that its application was modified to seek only approval for the use of citicoline in food supplements at a maximum level of 500 mg/day, and in food for particular nutritional uses, specifically foods for special medical purposes, at a maximum level of 250 mg/serving and a maximum daily consumption level of 1 000 mg from these types of foods. These products are aimed at adults and are not intended to be consumed by children.
- (6) On 15 January 2013, the Commission consulted the European Food Safety Authority (EFSA) asking it to carry out an additional assessment for citicoline as food ingredient in accordance with Regulation (EC) No 258/97.
- (7) On 10 October 2013, EFSA adopted a Scientific Opinion on the safety of 'citicoline' as a Novel Food ingredient ⁽²⁾, concluding that it is safe under the proposed uses and use levels.
- (8) The opinion gives sufficient grounds to establish that citicoline in the proposed uses and use levels complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.
- (9) In its opinion, EFSA also considered that citicoline may interact with specific medicines and should therefore not be administered together with those medicines. Directive 2001/83/EC of the European Parliament and of the Council ⁽³⁾ applies where a product, taking into account all its characteristics, may fall both within the definition of 'medicinal product' as laid down in Article 1(2) of that Directive and within the definition of a product covered by Regulation (EC) No 258/97. In that respect, where a Member State establishes in accordance with Directive 2001/83/EC that a product is a medicinal product, it may restrict the placing on the market of that product in accordance with Union law.

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.⁽²⁾ EFSA Journal 2013; 11(10):3421.⁽³⁾ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

- (10) Commission Directive 1999/21/EC ⁽¹⁾ lays down requirements on dietary foods for special medical purposes. The use of citicoline should be authorised without prejudice to the requirements of that legislation.
- (11) Directive 2002/46/EC of the European Parliament and of the Council ⁽²⁾ lays down requirements on food supplements. The use of citicoline should be authorised without prejudice to the requirements of that legislation.
- (12) 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

Citicoline as specified in the Annex may be placed on the market in the Union as a novel food ingredient in food supplements with a maximum dose of 500 mg per day and in dietary foods for special medical purposes with a maximum dose of 250 mg per serving and with a maximum daily consumption level of 1 000 mg from these types of foods without prejudice to Directive 1999/21/EC and Directive 2002/46/EC. Citicoline shall not be used in foods intended to be consumed by children.

Article 2

The designation of citicoline authorised by this Decision on the labelling of the foodstuffs containing it shall be 'citicoline'.

Article 3

Information shall be given to the consumer that foods containing citicoline are not intended to be consumed by children.

Article 4

This Decision is addressed to Kyowa Hakko Europe GmbH, Am Wehrhahn 50, 40211 Düsseldorf, Germany.

Done at Brussels, 1 July 2014.

For the Commission
Tonio BORG
Member of the Commission

⁽¹⁾ Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29).

⁽²⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

ANNEX

SPECIFICATION OF CITICOLINE

Definition:

Citicoline is composed of cytosine, ribose, pyrophosphate and choline.

Chemical name: Choline cytidine 5'-pyrophosphate, Cytidine 5'-(trihydrogen diphosphate) P'-[2-(trimethylammonio)ethyl]ester inner salt

Chemical formula: $C_{14}H_{26}N_4O_{11}P_2$

Molecular weight: 488,32 g/mol

Description: White crystalline powder.

Identification:

CAS No	987-78-0
pH (sample solution of 1 %)	2,5-3,5

Purity:

Assay value	Not less than 98 % of dry matter
Loss on drying (100 °C for 4 hours)	Not more than 5,0 %
Ammonium	Not more than 0,05 %
Total heavy metals (as Pb)	Not more than 10 ppm
Arsenic	Not more than 2 ppm
Free phosphoric acids	Not more than 0,1 %
5'-Cytidylic acid	Not more than 1,0 %

Microbiological criteria:

Total plate count	Not more than 1 000 cfu/g
Yeast and moulds	Not more than 100 cfu/g
<i>Escherichia coli</i>	Absent in 1 g