

Summary of the application: Citicoline

Applicant: Kyowa Hakko Bio Co., Ltd, 1-9-2, Otemachi, Chiyoda-ku, Tokyo, 100-0004, Japan

Citicoline is approved for use as a novel food ingredient in food supplements for middle-aged to elderly adults (providing up to 500 mg/day), and in foods for particular nutritional uses (specifically foods for special medical purposes) at levels of up to 250 mg/serving (providing up to 1,000 mg/day). In 2017, citicoline produced via a new manufacturing process was determined by the Food Safety Authority of Ireland (FSAI) to be substantially equivalent to the same ingredient authorised in 2014. Kyowa now seeks approval of an extension of use of citicoline in a range of food/beverage products in the EU, including flavoured water and liquid/powder drink bases, foods and drinks intended to meet the expenditure of intense muscular effort especially for sportsmen, functional water-based beverages, and coffee-based drinks.

The highest intakes of citicoline on an absolute basis were calculated to be up to 670 mg/person/day for very elderly individuals (≥ 75 years of age) at the mean, and up to 1,436 mg/person/day for adults at the high level. When expressed on a body weight basis, citicoline intakes were highest in the elderly and very elderly, with mean intakes of up to 10 mg/kg body weight/day, and in adults with high-level intakes of up to 20 mg/kg body weight/day, respectively.

To prevent cumulative exposure from food supplements and the new proposed uses in foods, foods containing citicoline may bear a statement that the foods should not be used if food supplements containing citicoline are consumed on the same day. Therefore, the use of citicoline in food supplements will not add to the daily intake of citicoline from food the new proposed food uses.

In their scientific opinion on the safety of citicoline for use as a novel food ingredient, the European Food Safety Authority (EFSA) concluded the following regarding human studies: "The Panel notes that numerous human studies providing up to 2,000 mg per day citicoline for up to 12 weeks or up to doses of 1,000 mg for nine months to both healthy subjects and patients were conducted from 1997 onwards. In none of these studies were adverse events reported by the subjects attributed to citicoline intake, and it was concluded that citicoline is well tolerated".

Worst-case intakes to citicoline from its new proposed uses in foods (1,436 mg/person/day) are well below the 2,000 mg/day considered as well tolerated by EFSA in human studies using the same ingredient.

Since no data have been generated that call in to question the safety of citicoline since EFSA reviewed its safety as a novel food ingredient in 2013, and worst-case maximum daily intakes from the new proposed food and beverage uses are well below the 2,000 mg/day considered as well tolerated by EFSA in human studies using the same ingredient, extending the use of citicoline for use in the new proposed food categories is considered to be of no safety concern.