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# EU Plan To Set Maximum Levels For Vitamins In Supplements Further Delayed

by Tom Gallen

The European Commission's goal of introducing harmonized maximum permitted levels for vitamins and minerals in dietary supplements has been set back by further delays to scientific assessments being carried out by EFSA.

Plans to introduce harmonized maximum permitted levels for vitamins and minerals in dietary supplements sold in the EU have been further delayed with key work more than a year behind schedule.

The European Food Safety Authority said it requires an additional six months to deliver its scientific opinions on tolerable upper intake levels (ULs) for select vitamins and minerals. This is the second extension requested by EFSA after it missed the initial deadline of March 2023.

Only once it has EFSA's ULs can the European Commission begin the process of setting maximum permitted levels (MPLs) for vitamins and minerals in supplements.

When the Commission asked EFSA to deliver its scientific opinions on ULs for eight nutrients in June 2021 it was hopeful that MPLs could be in place by the end of its mandate in 2024. But with the European Parliament elections scheduled for June 2024, implementation of MPLs will now fall to a new cohort of commissioners.

## Latest Setback

Writing to inform the Commission about the latest delay, Ana Afonso, head of EFSA's nutrition and food innovation unit, said preparatory work required for setting ULs had overrun for four nutrients.

EFSA now hopes to adopt its final opinion on its UL for manganese by 14 December, with a

consultation on its draft opinion having recently closed. This had been expected by 30 September after the March deadline was missed.

The due date for EFSA's scientific opinion on a UL for iron has been pushed back by a further six months from 31 December 2023 to 30 June 2024. A public consultation on the opinion is anticipated in February.

ULs for Vitamin A and  $\beta$ -Carotene will go out for consultation from February to March, with adoption also pushed back from 31 December to 30 June.

Preparatory work is ongoing to set a UL for vitamin E, but EFSA remains hopeful it can finalize its opinion by 30 June, according to Afonso.

To date, EFSA has delivered scientific opinions on ULs for three of the eight nutrients requested by the Commission.

While concluding that the existing maximum safe daily intakes for vitamin D and folate could be maintained, EFSA recommended halving the UL for vitamin B6 to protect supplement users from the development of peripheral neuropathy. (Also see "[EU Set To Maintain Safe Intake Levels For Vitamin D And Folate In Supplements](#)" - HBW Insight, 7 Jun, 2023.) (Also see "[EU's Proposed Safe Limit For Vitamin B6 In Supplements 8 Times Lower Than US Cap](#)" - HBW Insight, 14 Feb, 2023.)

## Original Deadline Missed

After missing the Commission's original deadline in March 2023, EFSA's executive director Bernhard Url bemoaned the "tight nine-month timeline" for completion of preparatory work.

"This preparatory work required several systematic reviews and analyses to be conducted, and important efforts are needed from EFSA staff and experts to review the methodological quality of the preparatory work received, and to integrate it into the scientific assessments. Also, complementary work that could not be anticipated at the time of the call preparation was needed," Url wrote to Sandra Gallina, head of the Commission's Directorate General for Health and Food Safety.

"In addition, the scientific complexity of UL assessments demands sufficient time for expert deliberations to ensure the delivery of robust and fit-for-purpose scientific outputs, and time needs to be allowed for the draft opinions/guidance documents to be released for public consultation to get input from the scientific community and stakeholders before finalization."

## Member States Diverge

Setting harmonized MPLs for supplements is prescribed in European Parliament and Council

Directive 2002/46/EC. According to the Directive, MPLs should be set taking into account upper safe levels of vitamins and minerals established by scientific risk assessment, and the intake of vitamins and minerals from other dietary sources.

In the absence of action by the Commission, some EU member states have set their own MPLs for certain vitamins and minerals in supplements, but these limits differ widely.

In the case of vitamin B6, the Netherlands, Ireland and Poland are at the upper end of the scale with MPLs of 21 mg/day, 20 mg/day and 19 mg/day respectively. Italy falls in the middle with a limit of 9.5 mg/day, while France permits just 2.0 mg/day.