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EU's Proposed Safe Limit For Vitamin B6 In Supplements 8 Times Lower Than US Cap

by Tom Gallen

EFSA has halved its tolerable upper intake level for vitamin B6 in supplements to 12mg/day, a limit more than eight times lower than the cap set by the US and the World Health Organization. Hylobates Consulting's Luca Bucchini expects that this lower UL will push the EU to set a maximum permitted level for vitamin B6 in supplements which is "massively lower" than currently applied by some member states.

Manufacturers of dietary supplements containing vitamin B6 sold in the EU are likely facing product reformulations after the European Food Safety Authority recommended halving the tolerable upper intake level (UL) for adults.

In a *draft scientific opinion*, EFSA's panel on Nutrition, Novel Foods and Food Allergens reduces the UL for vitamin B6 in supplements and fortified foods to 12 mg/day for adults, down from 25 mg/day, which was set in 2000 by Europe's Scientific Committee on Food. According to the panel, a 12 mg/day UL is necessary to protect supplement users from the development of peripheral neuropathy, a well-established adverse effect of excess vitamin B6 intake.

By cutting the UL for vitamin B6, EFSA is deviating significantly from assessments made by other scientific bodies around the world. EFSA's UL of 12 mg/day is more than eight times lower than the UL of 100 mg/day for adults set by the US Institute of Medicine's Food and Nutrition Board in 1998.

Vitamin B6 ULs By Age Group

EFSA's new UL for adults of 12 mg/day includes pregnant and lactating women. Lower ULs apply for those under 18 years of age. The UL for infants aged 4-6 months is just

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The World Health Organization and the Food and Agriculture Organization also set the UL at 100 mg/day in 2004 after adopting the position of the IOM.

EFSA's limit is also four-times lower than the Australian and New Zealand National Health and Medical Research Council's UL of 50 mg/day for adults set in 2006.

Among the scientific bodies cited in the draft opinion, only the UK's Expert Group on Vitamins and Minerals (EVM) has made a similar assessment to EFSA, setting a UL of 10 mg/day for adults in 2003.

2.2 mg/day, steadily rising to 4.5 mg/day for those aged 4-6. For children aged 11-14 the UL is 8.6 mg/day, while the UL for adolescents aged 15-17 is 10.7 mg/day.

The IOM in 1998 set vitamin B6 ULs for those aged 1 year and above. For children aged 1-3 years, the UL is 30 mg/day, rising to 80 mg/day for those aged 14-18.

Controversial Study

EFSA's new UL for vitamin B6 is largely based on data from a *1987 study* published in the journal *Neurologica*. The Dalton and Dalton study – which was originally used by the SCF to set the UL of 25 mg/day – investigated women attending a clinic for the treatment of premenstrual syndrome and taking <50-500 mg/day supplemental vitamin B6 for around six months and up to five years.

The decision to again rely on this study to set the UL is problematic, according to Hylobates Consulting's managing director Luca Bucchini.

"EFSA has decided to take exception from the main international bodies that have assessed vitamin B6 upper levels: the US's IOM, the UK's EVM and the WHO," Bucchini told HBW Insight. "All these bodies found the much-criticized Dalton and Dalton study of 1987 unreliable for setting a UL."

The IOM said it had ruled out Dalton and Dalton when setting a UL due to the weaknesses of the study and the inconsistency of the results with the weight of evidence pertaining to the safety of higher doses of vitamin B6.

While the EVM noted that the duration of treatment and the measurement of plasma vitamin levels in the study were useful, it said there were limitations when considering it for risk assessment. "The lack of a control group and potential bias introduced by the focused questioning of the patients on their symptoms detract from the quality of these data," it concluded.

Despite concerns identified with the study, EFSA doubled down on its use and halved the UL "with no apparent good reason," Bucchini argued, "except the fact that there are isolated reports

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in the literature and from Nutrivigilance systems, which EFSA itself admits are poorly characterized and not suitable for assessment."

Industry Facing Lower Max. Limit

As the new UL will eventually be used as a reference point by the European Commission in establishing a maximum limit for vitamin B6 in dietary supplements, EFSA's move will have consequences for industry, Bucchini predicted. "The expectation is that maximum permitted levels (MPLs) will be massively lower than those currently applied by the member states, and possibly as low as 5 mg/day for food supplements and 1-2 mg/day in enriched foods."

"EFSA's claim that most supplements have an amount of 1-2 mg/day is misleading as those are multivitamin supplements," he observed.

Citing Mintel data, the draft opinion states that just under 50% of the 2,210 vitamin B6-containing supplements available in 24 EU member states and Norway have a recommended dose between 1.01 and 2.0 mg. The data shows around 10% of available supplements have a daily dose of 5.01 mg or above.

As noted by Bucchini, some member states have set their own MPLs for vitamin B6 in supplements but these limits differ widely.

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.

With a consultation on the draft opinion now closed, EFSA is expected to publish a final scientific opinion on vitamin B6 ULs in the coming months.

Opinions for a range of other vitamins and minerals – including vitamins A. D. E and iron – are expected later this year. EFSA recently published its opinion on selenium, lowering the UL from 300 µg/day to 255 µg/day for adults, despite protests from the supplements industry. (Also see "*EFSA's Lower Safe Intake Level For Selenium Stands Despite Supplement Industry's Objections*" - HBW Insight, 8 Feb, 2023.)

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