

EN
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Answer given by Mr Várhelyi
on behalf of the European Commission
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Under EU law, all food additives, including sweeteners, are subject to a rigorous safety assessment based on the totality of available scientific data, including studies on long-term toxicity and potential neurological effects, as evaluated by the European Food Safety Authority (EFSA). EU legislation assures that only safe and technologically justified¹ food additives can be authorised.

EU legislation further requires that allowed additives are kept under continuous observation and that their safety is re-evaluated whenever necessary in the light of changing conditions of use and new scientific information². In addition, EFSA systematically considers new scientific evidence, including long-term adverse effects and neurotoxicity, in the safety re-evaluation of food additives, including sweeteners³, permitted before 20 January 2009⁴. For sweeteners already re-evaluated by EFSA, the conclusions indicate they are safe within established acceptable daily intake levels. Findings from observational studies reporting associations with cognitive outcomes, while suggestive, do not themselves demonstrate causality and are considered in the broader weight-of-evidence approach⁵ applied by EFSA.

Based on the outcomes of the EFSA scientific assessments, the Commission, assisted by the Member States, takes appropriate risk management measures when needed.

EU labelling rules ensure that sweeteners are clearly indicated in ingredient lists⁶, including specific labelling requirements for polyols⁷. These provisions enable informed consumer

¹ In addition to the general conditions for inclusion and use of food additives in Community lists outlined in Article 6 of Regulation (EC) No 1333/2008 on food additives, the legislation lays down additional specific conditions for sweeteners (Article 7) to be met to ensure their use is justified: the sweetener can only be used (1) to replace sugars for the production of energy-reduced food, noncariogenic food or food with no added sugars; or (2) to replace sugars where this permits an increase in the shelf-life of the food; or (3) to produce food intended for particular nutritional uses.

² Recital 14 of Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

³ The list of sweeteners authorised for use in the EU and the status of EFSA's respective safety assessments is available at <https://www.efsa.europa.eu/en/topics/topic/sweeteners>. For the re-evaluation of sweeteners, a protocol on hazard identification and characterisation of sweeteners has been developed, available at <https://zenodo.org/records/7788969>.

⁴ Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (OJ L 80, 26.3.2010, p. 19–27).

⁵ EFSA's weight-of-evidence approach is a structured, transparent process for evaluating and integrating diverse scientific data from various sources to reach conclusions in risk assessments. See 'Guidance on the use of the weight of evidence approach in scientific assessments' available at <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4971>.

⁶ Product labels have to specify both the functional class (e.g. sweetener) and the specific substance used, either by referring to the appropriate E-number or by its name. In addition to the listing of the given sweetener in the ingredient list, the label of a foodstuff containing sweeteners should indicate 'with sweetener(s)' and the label of a foodstuff containing sweeteners and sugars should indicate 'with sugar(s) and sweetener(s)'.

⁷ Foods containing more than 10% added polyols, as well as table-top sweeteners containing polyols, should also bear the following statement: 'excessive consumption may produce laxative effects'.

choice, including for vulnerable groups. Therefore, the Commission considers the existing framework for safety assessment, re-evaluation, and labelling to be appropriate.