

(English version)

**Question for written answer E-002751/25
to the Commission
Dimitris Tsiodras (PPE)
(7 July 2025)**

Subject: Potential harmonised classification of sodium fluoride and its impact on oral health in the EU

The World Health Organisation (WHO) recognises that ensuring access to affordable fluoride toothpaste is a key public health measure for reducing tooth decay across the population.

The French health and safety agency has recently proposed a harmonised classification of sodium fluoride as a Category c material for its reproductive toxicity and endocrine-disrupting properties.

If confirmed, this classification would automatically prohibit the use of sodium fluoride in cosmetic products such as toothpastes and mouthwashes, unless an exemption is granted under Article 15 of the Cosmetic Products Regulation ⁽¹⁾.

This would significantly restrict EU consumers' access to essential oral-care products that are widely recognised by scientists, healthcare professionals and public health authorities worldwide as both safe and effective.

1. In the event that fluoride toothpastes cease to be available in the EU, what public health measures is the Commission considering to prevent the potential increase in dental caries among the EU population?
2. How does the Commission assess the potential loss of competitiveness and jobs in the EU's oral care industry, especially among small and medium-sized enterprises, in comparison to global competitors, and what support measures are being planned for companies and workers affected by this proposed classification?

Submitted: 7.7.2025

**Answer given by Executive Vice-President Séjourné on behalf of the European Commission
(3 September 2025)**

France has submitted, in May 2025, a dossier to the European Chemicals Agency (ECHA) proposing a harmonised classification of sodium fluoride as endocrine disruptor for human health Category c and as toxic for human reproduction Category cB under the Classification, Labelling and Packaging (CLP) Regulation ⁽¹⁾. Only once the dossier is validated, ECHA will open a public consultation and the process for harmonised classification will begin.

Should ECHA confirm these classifications as scientifically valid, the Commission will decide whether it is appropriate to include these harmonised classifications in the CLP Regulation. In that case, sodium fluoride would be banned in cosmetics, unless a derogation is requested, scientifically assessed and granted.

It would be premature to already discuss alternative public health measures and implications for the EU oral care industry, before the classification process has been concluded and before any subsequent regulatory actions under the Cosmetic Products Regulation ⁽²⁾ have been assessed.

The Commission is fully aware of the role of fluoride in preventing dental caries, as underlined by the World Health Organisation and national health authorities. The Commission remains committed to supporting public health and promoting access to effective preventive care across the EU.

The Commission is also conscious of potential implications that regulatory changes may have on economic operators, including small and medium-sized enterprises, as well as of its potential impact on workers. It would take account of risk/benefit aspects in the regulatory process under the Cosmetic Products Regulation.

¹ Regulation (EC) No 1223/2009 of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59, ELI: <http://data.europa.eu/eli/reg/2009/1223/oj>).
⁽¹⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02008R1272-20250201>, OJ L 353, 31.12.2008, p. 1.
⁽²⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02009R1223-20250501>, OJ L 342, 22.12.2009, pp. 59.