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E-002751/2025

Answer given by Executive Vice-President Séjourné
on behalf of the European Commission
(3.9.2025)

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 1 and as toxic for human reproduction category 1B under the Classification, Labelling and Packaging (CLP) Regulation¹. 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 Regulation² have been assessed.

The Commission is fully aware of the role of fluoride in preventing dental caries, as underlined by the World Health Organization 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 <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.