UK Regulatory frameworks

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5. In the UK there are a number of different regulatory frameworks under which human exposure to fluoride is covered. These are:

6. Section 90A of the Water Industry Act 1991, as amended, requires a "relevant authority", that has entered into fluoridation arrangements to monitor the effects of the arrangements on the health of persons living in the area specified in the arrangements. It also requires that such an authority publishes reports containing an analysis of those effects, making available any information, or summaries of information, collected by it for these purposes. Health monitoring reports are required at intervals of no greater than four years, beginning with the date on which the last report was published, unless the schemes in question are terminated. As of 1 April 2013, the Secretary of State for Health and Social Care is the "relevant authority" in England for the purposes of the fluoridation provisions. The Secretary of State's functions in relation to fluoridation health monitoring and

reporting are exercised by the Water Fluoridation Health Monitoring Working Group.

7. The Drinking Water Inspectorate (DWI) is the regulator for the Water Supply (Water Quality) Regulations 2016 (2018 Wales) and Local Authorities are the regulators for the Private Water Supply Regulations. The maximum concentration for fluoride in both regulations is 1.5 mg F/l, measured at the consumers tap. This is the same as the WHO guideline value for drinking water. The statutory role of the DWI is to ensure compliance with these regulations. Companies submit their monitoring data monthly and DWI Inspectors assess any compliance breaches and take enforcement action to bring the supply back into regulatory compliance. The enforcement policy is a risk-based system with increasing sanctions and is published on the DWI website. The Inspectorate also publishes the Secretary of State's list of approved products for use in drinking water (Regulation 31). Only approved fluoride dosing chemicals (hexafluorosilicic acid, also known as fluorosilicic acid, and disodium hexafluorosilicate, also known as sodium hexafluorosilicate or sodium fluorosilicate) are permitted to be used to ensure there is no contamination of the water supply for example from impurities in the formulation.

8. The DWI has a further role in administering the reporting of operational compliance where artificial fluoridation is practiced, on behalf of the Department for Health and Social Care (DHSC) Office for Health Improvement and Disparities (OHID). Companies report results outside the operational limits to the Inspectorate, along with their regulatory compliance data, and the Inspectorate reports to OHID. The Inspectorate holds the technical guidance on artificial fluoridation on the DWI website. There are regular meetings with OHID, and under performance is also discussed with companies as part of the regular liaison role. Site audits may be carried out. However, the Inspectorate has no powers to enforce the practice of artificial fluoridation, either the application of the correct does (within the regulatory standard) or the health and operation of the fluoridation dosing plant.

9. Under the UK Cosmetics Regulation No. 1223/2009, fluorine compounds as listed in Annex III of the regulation are permitted for use in oral care products at a maximum concentration of 0.15% (1500 ppm) calculated as fluorine. When two or more fluorine compounds are mixed together in a preparation, the total fluorine concentration must not exceed 0.15%. The fluorine compound must be labelled on the product as "Contains [fluoride compound]". Toothpastes containing fluorine concentrations between 0.1% and 0.15% must be labelled

with the following “Children of 6 years and younger: use a pea-sized amount for supervised brushing to minimise swallowing. In case of intake of fluoride from other sources consult a dentist or doctor”. Toothpastes which are indicated for adult use only are exempt from this labelling requirement.

10. The Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency, sponsored by the Department of Health and Social Care (DHSC), regulates dental healthcare products (toothpastes and dental varnishes), containing high concentrations of fluoride ion ranging from 2,800ppm to 22,600ppm, that are authorised for the treatment and prevention of dental caries and hypersensitivity. These products are regulated under two regulatory frameworks:

- Medicines: High-strength toothpastes containing either 2,800ppm or 5,000ppm fluoride, and one dental varnish (Duraphat 50 mg/ml Dental Suspension, 2800ppm fluoride) are licensed for use as medicinal products in accordance with ‘The Human Medicines Regulations 2012 (S.I. 2012/1916)’. Due to the high fluoride concentrations, these products are only available under prescription (POM) where their use can be kept under medical supervision by the dentist or other authorised healthcare practitioners. They are prescribed following an assessment of a patient’s total exposure to fluoride (e.g. fluoridated water, fluoride mouth washes etc.) and guidance is provided to minimise the risk of increased exposure to fluoride ion. In 2024 ‘The Human Medicines Regulations 2012’ were amended through ‘The Human Medicines (Amendments relating to Registered Dental Hygienists, Registered Dental Therapists and Registered Pharmacy Technicians) Regulations 2024’, to allow registered dental hygienists and therapists to supply and administer certain medicines, including high-strength fluoride toothpaste (2,800ppm and 5,000ppm) under specific exemptions without a dentist's prescription
- Medical Devices: Dental Varnishes, indicated for treatment of hypersensitivity and caries prevention, are regulated as medical devices under ‘The Medical Device Regulations 2002’ (as amended).

11. There are no specific provisions for fluoride levels in food. Where a food safety concern is identified, action could be taken under general food law (Assimilated Regulation 178/2002) principles, which sets out the responsibility of food businesses to ensure all products placed on the market are safe for consumption.

12. Fluoride levels in bottled water are not in the remit of the Food Standards Agency (FSA) and are the responsibility of Department for Environment, Food and Rural Affairs (Defra).