Notification under Directive 2015/1535

15. Impact assessment

The Decision has only limited effects on business, as it concerns only nicotine pouches with a nicotine content of 20 mg or above. In addition, the sale of nicotine pouches without a marketing authorisation under the Medicines Act was only liberalised on 4 April 2023 and it has been public knowledge that the intention is to regulate nicotine pouches by means of amendments to the Tobacco Act. However, the change will have an economic impact on businesses that, despite the above, have started selling nicotine pouches containing 20 mg or more of nicotine.

The Decision could prevent cases of life-threatening nicotine poisoning that could result from a child swallowing a nicotine pouch, for example. The toxicity of nicotine has been assessed on the basis of the hazard classification under Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (CLP Regulation). Nicotine is in the ‘Acute Tox.’ hazard class in Annex VI to the CLP Regulation. 2, H300 “Fatal if swallowed” (ATE= 5 mg/kg bw). Based on the ATE, one pouch containing 50 milligrams of nicotine can fatal for a child weighing 10 kg if all the nicotine contained in the pouch is absorbed when swallowed. The nicotine limit set in the Decision (20 mg/pouch) includes a safety factor of 2.5 times the ATE value for young children.