

## 15. Impact assessment

The impact of the Decision on business is limited, as the Decision only applies to 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. By its Decision of 16 May 2023 on recommendations regarding the sale of nicotine pouches, the Provincial Government announced its intention to prepare amendments to the Tobacco Act to regulate the import and sale of nicotine pouches. However, the amendment may have an economic impact on traders who, despite the above, have started selling nicotine pouches containing 20 mg or more of nicotine.

The Decision could prevent 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 of 16 December 2008 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 listed in Annex VI of the CLP Regulation in the Acute Tox. hazard class. 2, H300 "Fatal if swallowed" (ATE = 5 mg/kg bw). Based on the ATE value for nicotine, it is assessed that a pouch containing 50 mg of nicotine can be fatal for a child weighing 10 kg if all the nicotine in the pouch is swallowed and absorbed into the body. The limit set under the Decision of 20 mg nicotine per pouch has been established according to a safety factor of 2.5 for young children compared with the ATE value.