EN
E-000193/2023
Answer given by Ms Johansson
on behalf of the European Commission
(23.3.2023)

Kratom is monitored as a new psychoactive substance by the EU Early Warning System under Regulation (EC) No 1920/2006 as amended by Regulation (EU) 2017/2101[1]. This system is operated by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in close cooperation with European Union Agency for Law Enforcement Cooperation (Europol). Kratom is not controlled at Union level, meaning that it is not included in the definition of 'drug' in Council Framework Decision 2004/757/JHA[2]. The Commission is not planning to propose any changes in this regard.

The trend of increased popularity of kratom among minors has not been reported to the EU Early Warning System, and the Commission does not have further information pointing to such developments. According to EU law[3], Member States may maintain or introduce in their territories, with regard to new psychoactive substances, any national control measures that they consider appropriate. This means that Czechia may place kratom under national control. Twelve Member States already reported to the EU Early Warning System that they have placed kratom under control as a drug.

If kratom is placed on the market in the EU as a medicinal product, this should be done in compliance with the rules on packaging established for medicines as well as all other rules applying to medicines as set in Directive 2001/83[4] and Regulation 726/2004[5].

[1] Regulation (EC) No 1920/2006 of the European Parliament and of the Council of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction (recast), OJ L 376 27.12.2006, p. 1.
[2] Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, OJ L 335, 11.11.2004, p. 8.
[3] Ibid.
[4] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67.
[5] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p. 1.