Summary of Major Modifications

The Technical Document on Decision Limits for the Confirmatory Quantification of Exogenous Threshold Substances by Chromatography – based Analytical Methods, TD2022DL version 1.0, has been modified to include the following main changes:

Table 1

- A footnote b. has been added to clarify that the cathine Threshold of 5.00 μg/mL and Decision Limit of 6.00 μg/mL are applicable to cathine and its l-enantiomer.

Article 2.0 Target Analytes

- Further clarifications are provided regarding the reporting of findings for Threshold Substances (namely salbutamol, formoterol, cathine, ephedrine, methylephedrine and pseudoephedrine) when detected in conjunction with a diuretic subject to a Minimum Reporting Level (MRL), or in the presence of any other diuretic or a masking agent. Guidance is given in cases where there is an approved Therapeutic Use Exemption (TUE) for the diuretic and/or the Threshold Substance.

The TD2022DL version 1.0 replaces the former TD2021DL and becomes effective on 1 January 2022.