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COMMISSION IMPLEMENTING DECISION (EU) 2026/375

of 20 February 2026

on harmonised standards drafted in support of Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council ([1]), and in particular Article 10(6) thereof,

Whereas:

(1) Regulation (EC) No 765/2008 of the European Parliament and of the Council ([2]) defines 'accreditation' as an attestation by a national accreditation body that, in addition to any additional sector-specific requirements, a conformity assessment body meets the requirements set by harmonised standards.

(2) By Commission Implementing Decision C(2021) 9277 ([3]) the Commission made a request to the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) for the drafting of and the revision of harmonised standards in support of Regulation (EC) No 765/2008 and the Union legislation listed in point 2 of Annex II to that request. It was requested to base the harmonised standards listed in Table 2 of Annex I to that request on standards of the International Organization for Standardisation (ISO) and of the International Electrotechnical Commission (IEC).

(3) On the basis of the request set out in Implementing Decision C(2021)9277, CEN prepared harmonised standard EN ISO 20387:2020 *Biotechnology – Biobanking – General requirements for biobanking*, however it was not published in the *Official Journal of the European Union* because there was no Annex Z.

(4) CEN has revised the standard and added an Annex Z, which resulted in its amendment EN ISO 20387:2020/A11:2024.

(5) The Commission together with the CEN has assessed whether the standard EN ISO 20387:2020 as amended by EN ISO 20387:2020/A11:2024 complies with the request set out in Implementing Decision C(2021)9277.

(6) The standard EN ISO 20387:2020 as amended by EN ISO 20387:2020/A11:2024 satisfies the requirements which it aims to cover and allows for National Accreditation Bodies to fulfil its obligations under Article 8(10) of Regulation (EC) No 765/2008. It is therefore appropriate to publish the reference of that harmonised standard and its amendment in the *Official Journal of the European Union*.

([1]) OJ L 316, 14.11.2012, p. 12, ELI: http://data.europa.eu/eli/reg/2012/1025/oj.

([2]) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30, ELI: http://data.europa.eu/eli/reg/2008/765/oj).

([3]) Commission Implementing Decision C(2021) 9277 of 17 December 2021 on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation as regards accreditation and conformity assessment in support of Regulation (EC) No 765/2008 of the European Parliament and of the Council.

(7) Conformity with the criteria laid down in the relevant harmonised standard confers a presumption of conformity with requirements for accreditation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the day of its publication,

HAS ADOPTED THIS DECISION:

Article 1

The reference of harmonised standard EN ISO 20387:2020, as amended by EN ISO 20387:2020/A11:2024, *Biotechnology – Biobanking – General requirements for biobanking (ISO 20387:2018)* drafted in support of Regulation (EC) No 765/2008 is hereby published in the *Official Journal of the European Union*.

Article 2

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 20 February 2026.

For the Commission
The President
Ursula VON DER LEYEN