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Guidelines for the validation of qualitative screening methods for the detection of residues of veterinary drugs in milk and milk products

Lignes directrices pour la validation des méthodes qualitatives de dépistage des résidus de médicaments vétérinaires dans le lait et les produits laitiers

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Forewords

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 5, *Milk and milk products*, and the International Dairy Federation (IDF), in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 302, *Milk and milk products — Methods of sampling and analysis,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement). It is being published jointly by ISO and IDF.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

IDF (the International Dairy Federation) is a non-profit private sector organization representing the interests of various stakeholders in dairying at the global level. IDF members are organized in National Committees, which are national associations composed of representatives of dairy-related national interest groups including dairy farmers, dairy processing industry, dairy suppliers, academics and governments/food control authorities.

ISO and IDF collaborate closely on all matters of standardization relating to methods of analysis and sampling for milk and milk products. Since 2001, ISO and IDF jointly publish their International Standards using the logos and reference numbers of both organizations.

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This document was prepared by the IDF *Standing Committee on Analytical Methods for Additives and Contaminants* and ISO Technical Committee ISO/TC 34, *Food products,* Subcommittee SC 5, *Milk and milk products*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 302, *Milk and milk products — Methods of sampling and analysis,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement). It is being published jointly by ISO and IDF.

This IDF Reviewed method is equal to an ISO Publicly Available Specification (ISO/PAS) or an ISO Technical Specification (ISO/TS) and is therefore published jointly under ISO conditions.

The work was carried out by the IDF-ISO Action Team on A10 of the *Standing Committee on Analytical Methods for Additives and Contaminants* under the aegis of its project leader Dr W. Reybroeck (BE).

Guidelines for the validation of qualitative screening methods for the detection of residues of veterinary drugs in milk and milk products

1 Scope

This document describes general workflows and protocols for the validation and the verification of qualitative screening tests for the detection of residues of veterinary drugs in liquid milk (raw, pasteurized, UHT and reconstituted milk powders and whey protein extracts) including biological methods. This guideline does not cover the validation of residue analysis by HPLC, UHPLC or LC-MS/MS.

This document is intended to be useful for manufacturers of screening test kits, laboratories validating screening methods or tests, competent authorities and dairies or end users of reagents or tests for the detection of veterinary drug residues in milk products. This document facilitates and improves the validation and verification of screening methods. The goals of this document are a harmonization in validation of methods or test kits in order for all stakeholders to have full trust in the result of residue screening and to limit the overlap and multiplication of validation work in different laboratories by sharing the validation results generated by an independent laboratory. Furthermore, a harmonized validation and verification procedure allows for comparison of the performance of different screening methods.

This document does not imply that all end users are bound to perform all verification work proposed.

The verification of the correct use of reagents/kits for the detection of antimicrobials is not part of the scope of this document.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
biological method
method that is used to detect cellular responses to analytes

EXAMPLE Inhibition of bacterial growth, immunological test, and receptor test.

3.2
qualitative method
method that gives a yes/no response, with no indication of the concentration of the putative analyte

EXAMPLE 1 Bacterial growth inhibition tests which give a result of either “no zone” or “zone of inhibition”.

EXAMPLE 2 Inhibition tests which give a colour change of growth medium.