PD CEN ISO/TS 23758:2021



BSI Standards Publication

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

National foreword

This Published Document is the UK implementation of CEN ISO/TS 23758:2021. It is identical to ISO/TS 23758:2021.

The UK participation in its preparation was entrusted to Technical Committee AW/5, Chemical analysis of milk and milk products.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

This publication is not to be regarded as a British Standard.

© The British Standards Institution 2021
Published by BSI Standards Limited 2021

ISBN 978 0 539 15334 7

ICS 67.100.01

Compliance with a Published Document cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 September 2021.

Amendments/corrigenda issued since publication

Date	Text affected

TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

CEN ISO/TS 23758

August 2021

ICS 67.100.01

English Version

Guidelines for the validation of qualitative screening methods for the detection of residues of veterinary drugs in milk and milk products (ISO/TS 23758:2021)

Lignes directrices pour la validation des méthodes qualitatives de dépistage des résidus de médicaments vétérinaires dans le lait et les produits laitiers (ISO/TS 23758:2021)

Leitlinie für die Validierung qualitativer Screening-Methoden zur Detektion von Tierarzneimittelrückständen in Milch und Milcherzeugnissen (ISO/TS 23758:2021)

This Technical Specification (CEN/TS) was approved by CEN on 29 July 2021 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

© 2021 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. CEN ISO/TS 23758:2021 E

European foreword

This document (CEN ISO/TS 23758:2021) has been prepared by Technical Committee ISO/TC 34 "Food products" in collaboration with Technical Committee CEN/TC 302 “Milk and milk products - Methods of sampling and analysis” the secretariat of which is held by NEN.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN websites.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Specification: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO/TS 23758:2021 has been approved by CEN as CEN ISO/TS 23758:2021 without any modification.

Contents

Page

Forewords ..... **iv**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **1**

4 Principle **4**

5 General requirements for the test/kit **5**

6 Reagents **5**
6.1 Standard blank matrix 5
6.2 Antibiotics 6
6.3 Standard stock solution 6
6.4 Working stock solutions 6
6.5 Spiked sample 6

7 Apparatus **7**

8 Sample Preparation **7**
8.1 Stock solution preparation 7
8.2 Working stock solution preparation 8
8.3 Blank matrix sample selection 8
8.4 Spiked sample creation 8

9 Procedure **8**
9.1 Validation 8
9.1.1 General 8
9.1.2 Detection capability (CCβ) 9
9.1.3 Test selectivity/specificity 13
9.1.4 Robustness testing 14
9.1.5 Reader and test repeatability 18
9.1.6 Participation in a(n) (inter)national ring trial 20
9.2 Verification testing of a transferred screening method 20
9.2.1 General 20
9.2.2 Detection capability 21
9.2.3 Test selectivity/specificity 21
9.2.4 Robustness testing 21
9.2.5 Reader and test repeatability 21
9.2.6 Participation in a(n) (inter)national ring trial 23

Annex A (informative) **European legislation on veterinary drugs in cow milk** **24**

Annex B (informative) **USA legislation on animal drug residues in milk** **28**

Annex C (informative) **List of problematic compounds in the preparation of stock solutions** **29**

Annex D (informative) **Summary of the stability of antibiotics in solution and in matrix** **30**

Bibliography **33**

© ISO and IDF 2021 – All rights reserved

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.

© ISO and IDF 2021 – All rights reserved

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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. IDF 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.

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).

© ISO and IDF 2021 – All rights reserved

TECHNICAL SPECIFICATION

ISO/TS 23758:2021(E)
IDF /RM 251:2021(E)

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.

© ISO and IDF 2021 – All rights reserved