
Analiza molekularnih biomarkerjev - Metoda za statistično vrednotenje rezultatov analiz, pridobljenih pri preskušanju podvorcev skupin gensko spremenjenih semen in zrn - Splošne zahteve (ISO 22753:2021, popravljena verzija 2022-11)

Molecular biomarker analysis - Method for the statistical evaluation of analytical results obtained in testing sub-sampled groups of genetically modified seeds and grains - General requirements (ISO 22753:2021, Corrected version 2022-11)

Untersuchung auf molekulare Biomarker - Verfahren zur statistischen Auswertung von Analyseergebnissen aus der Untersuchung von Untergruppen von gentechnisch verändertem Saatgut und Getreide - Allgemeine Anforderungen (ISO 22753:2021, Korrigierte Fassung 2022-11)

Analyse moléculaire de biomarqueurs - Méthode pour l'évaluation statistique des résultats d'analyse obtenus lors des essais de sous-échantillons multiples de semences et de graines génétiquement modifiées - Exigences générales (ISO 22753:2021, Version corrigée 2022-11)

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ICS:

67.050	Splošne preskusne in analizne metode za živilske proizvode	General methods of tests and analysis for food products
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English Version

Molecular biomarker analysis - Method for the statistical
evaluation of analytical results obtained in testing sub-
sampled groups of genetically modified seeds and grains -
General requirements (ISO 22753:2021, Corrected version
2022-11)

Analyse moléculaire de biomarqueurs - Méthode pour
l'évaluation statistique des résultats d'analyse obtenus
lors des essais de sous-échantillons multiples de
semences et de graines génétiquement modifiées -
Exigences générales (ISO 22753:2021, Version corrigée
2022-11)

Untersuchung auf molekulare Biomarker - Verfahren
zur statistischen Auswertung von Analyseergebnissen
aus der Untersuchung von Untergruppen von
gentechnisch verändertem Saatgut und Getreide -
Allgemeine Anforderungen (ISO 22753:2021,
Korrigierte Fassung 2022-11)

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European foreword

The text of ISO 22753:2021, Corrected version 2022-11 has been prepared by Technical Committee ISO/TC 34 "Food products" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 22753:2022 by Technical Committee CEN/TC 275 "Food analysis - Horizontal methods" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2023, and conflicting national standards shall be withdrawn at the latest by May 2023.

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Endorsement notice

The text of ISO 22753:2021, Corrected version 2022-11 has been approved by CEN as EN ISO 22753:2022 without any modification.

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Molecular biomarker analysis — Method for the statistical evaluation of analytical results obtained in testing sub-sampled groups of genetically modified seeds and grains — General requirements

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*Analyse moléculaire de biomarqueurs — Méthode pour l'évaluation
statistique des résultats d'analyse obtenus lors des essais de sous-
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ISO 22753:2021(E)

Foreword

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).

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This document was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 16, *Horizontal methods for molecular biomarker analysis*.

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.

This corrected version of ISO 22753:2021 incorporates the following corrections:

- [Formula C.1](#) has been corrected.

Introduction

Seed and grain testing is used throughout the world to commercially define the purity of seed and grain lots.

Commercial requirements for labelling agricultural products with genetically modified organism (GMO) content at a specified threshold level both as a seed/grain contaminant and a food ingredient have become common to satisfy regulations and consumer demands. Conformance with these specifications is evaluated at various points of the supply chain, often starting with the harvested grain.

Quantitative real-time polymerase chain reaction (PCR) can be used to determine the GMO content by analysis of the ratio of GMO DNA copy numbers to plant-species specific DNA copy numbers followed by a conversion to genetically modified (GM) mass fraction.

Multiple events stacked in a crop, such as those generated by crossing two or more single events, are widely used in agricultural production. A stacked event seed or grain containing GMO DNA corresponding to two or more GM events commingled in lot cannot be differentiated by quantitative PCR alone from multiple seeds within the lot each containing a single GM event. Consequently, if the actual measured GMO arises only from GM stacked event seeds, GM content measured by quantitative real-time PCR of a single sample will lead to an overestimation of the actual number of GM seeds or grains present.

The group testing strategy described in this document provides a reliable alternative to estimate the GM content on the basis of the fact that whole seeds/grains are the sample material.

The process described in this document can provide a method to accurately estimate the percentages of GM seeds/grains in a lot irrespective of the presence of stacked event seeds/grains. GM content is determined for representative subsampled groups of seed/grain from a lot and statistically analysed.

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