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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

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

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Foreword

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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.