SLOVENSKI STANDARD
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Analiza molekulskih biomarkerjev - Splošne zahteve za molekularno biološke analize za odkrivanje in prepoznavanje povzročiteljev bolezni rastlin

Molecular biomarker analysis -- General requirements for molecular biology analysis for detection and identification of plant pests

Analyse de biomarqueurs moléculaires -- Exigences générales pour la réalisation d'analyses utilisant la biologie moléculaire pour la détection et l'identification des organismes nuisibles aux végétaux

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

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Molecular Biomarker Analysis — General requirements for molecular biology analysis for detection and identification of plant pests

Produits alimentaires — Exigences générales pour la réalisation d'analyses utilisant la biologie moléculaire pour la détection et l'identification d'organismes ravageurs des végétaux et produits dérivés

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Foreword

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 34/SC 16.

Introduction

The purpose of this document is to provide general requirements for laboratories responsible for using techniques to detect and identify plant pest molecular biomarkers, define baseline requirements and acceptability criteria for development of these tests, and provide guidance for interpretation of procedures as they relate to a plant pest testing laboratory.

A number of molecular biomarker assays have been developed for plant diagnostic laboratories utilizing a wide variety of biomolecular, chemical or small molecule screening technologies. Guidance is provided in this standard for procedure development, routine diagnostics, and reporting of results to correlate the amount and significance of the information generated. As new plant pests emerge, methods and technologies used to detect and identify them must adapt and improve. The goal of this standard is to provide as much flexibility as possible for laboratories to develop harmonized procedures to detect and identify plant pests.

Molecular Biomarker Analysis — General requirements for molecular biology analysis for detection and identification of plant pests

1 Scope

This international standard specifies general principles for use of biochemical and molecular procedures used to detect, identify, quantify, or confirm the presence of plant pests in plant materials, and provide guidelines for these procedures to ensure that different laboratories yield reliable, comparable and reproducible results.

This document specifies and illustrates criteria for conducting assays and results. This international standard is applicable to plant parts and any other respective matrices desired for testing to determine the presence of a plant pest. This international standard is not applicable to detection and/or identification of genetically modified organism (GMO) food stuffs, animal pathogens, and human health pathogens, as well as any materials, material components, or procedures that are not within the scope of the detection of molecular biomarkers for plant pests.

If laboratories comply with the requirements of this international standard, they will also operate a quality management system meeting selected principles of ISO 17025. Annex A provides supporting cross references between this international standard and ISO 17025. This international standard covers selected technical requirements provided in ISO 17025, but also covers technical requirements not covered in ISO 17025.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC Guide 99:2007, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

ISO/IEC 9000:2005, *Quality Management – Fundamentals and vocabulary*

ISO 16577:2016, *Molecular biomarker analysis — Terms and definitions*

ISO/IEC 17000:2004 Conformity assessment – Vocabulary and general principles

ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*

ISO 21569:2015, *Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- Qualitative nucleic acid based methods*

ISO 21570:2005, *Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Quantitative nucleic acid based methods*

ISO 21572:2013, *Foodstuffs — Molecular biomarker analysis — Protein-based methods*

3 Terms and definitions

3.1 General terms and definitions

3.1.1
amplicon
DNA sequence produced by a DNA-amplification technology, such as the PCR technique

[SOURCE: ISO 16577:2016]

Note 1 to entry: This is in contrast to DNA fragments that are generated as a result of non-specific amplification (primer-dimer interactions, matrix inhibitors, etc.)

3.1.2
analyte
component of a system to be analysed

3.1.3
assay
detection assay as defined in ISO 16577:2016

3.1.4
authorization
permission or power granted by an authority or endowed with authority

3.1.5
confirmatory assay
assay used to make a final determination that a plant pest in a sample has or has not been detected

Note 1 to entry: Text of the note.

3.1.6
customer
individual or entity that has submitted a sample to the laboratory that will receive a report of results with the intent of either taking direct action based on those results or generating its own report to be forwarded to a reporting agency

3.1.7
development assay
performed during the process to produce a final developed diagnostic assay

3.1.8
diagnostic assay
used to generate results reported to a customer or reporting agency

3.1.9
equipment
items that are used in the procedure, such as for example tubes, instruments, and weigh-boats

3.1.10
instrument
equipment used in the procedure that has a measureable output, such as centrifuges, pipettes, and signal detectors

3.1.11
single use equipment
equipment deemed for single use (disposable), such as for example pipette tips and weigh-boats

3.1.12
measurand
quantity intended to be measured

3.1.13
pest
any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products

Note 1 to entry: Pest is defined in ISPM No. 5.

3.1.14
procedure
specified way to carry out an activity or a process

Note 1 to entry: Procedure is defined in ISO/IEC 17000:2004. The procedure can be a specified way to carry out a process for detection and/or identification of a plant pest in the laboratory. Some procedures describe the receipt, processing, measuring, analysis, and reporting of test results, while other procedures are used in combination to describe a method.

3.1.15
reagents
perishable substances such as buffer salts and solutions, oligonucleotides, and proteins that are used during a detection assay

3.1.16
reporting agency
entity responsible for handling the results generated by the laboratory

3.1.17
symptomatic
infected plant tissue with signs and symptoms of disease or damage from plant pests that can be recognized by visual inspection

3.1.18
tissue
material obtained from a plant or insect source that must be disrupted for detection of a component of the sample

3.2 Developmental terminology

Terms and definitions not listed in this section are described in ISO/IEC Guide 99:2007. A method or procedure is developed to a level of confidence that verification or validation can commence. Development terminology used in this guide is synonymous with validation terminology and is used to describe a studied characteristic of the method or procedure in preparation for the validation study.

3.2.1
reproducibility
expression of precision between laboratories (collaborative studies, usually applied to standardization of the procedure)

Note 1 to entry: Reproducibility is defined in IC H Q2. Establishment of reproducibility can be through ring-test studies, also termed as inter-laboratory studies, or as a secondary function of proficiency test programs, as agreed and planned between the procedure developer and collaborating laboratories.

3.2.2
selectivity
extent to which a method can determine particular analyte(s) in a mixture(s) or matrices without interferences from other components of similar behaviour

[SOURCE: ISO 16577:2016]

Note 1 to entry: Measurand refers to a quantity of something to be measured and does not refer to the pest, component of the pest (analyte) or any other individual item.

Note 2 to entry: Examples of other components might include impurities, degradants, matrix, and closely related pests.

Note 3 to entry: Lack of selectivity of an individual analytical method might be compensated by other supporting analytical method(s), or if well characterised, may be useful for screening purposes.

Note 4 to entry: Selectivity is sometimes referred to as specificity, however the terms are defined by two distinctly different equations and applications. In this document, guidance is given for validation activities that measure the extent to which other substances interfere with the determination of a substance according to a given procedure (IUPAC. Compendium of Chemical Terminology, 2nd ed.).

3.2.3
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use have been fulfilled

3.2.4
verification
the process to demonstrate the ability to fulfil specified requirements, where the term verified is used to designate the corresponding status (also referred to as qualification) [ISO 9000:2005]

Note 1 to entry: Verification and validation are defined in ISO/IEC 9000:2005. Verified procedure is synonymous with a validated procedure as defined by ISO/IEC 17025:2005 as a procedure that has been developed as extensively as necessary to meet the needs of the given application, but referred to in this standard as verified to act as a guideline for describing the extent an assay is used for implementing a procedure.

Note 2 to entry: While verification is confirmation that a procedure is fit for use, validation is confirmation that a procedure is fit for its intended purpose. These terms are differentiated between by, for example, a rapidly deployed procedure or minor change in a validated procedure, and a procedure that has been extensively tested for long-term application by multiple laboratories.

3.3 Procedure process terminology

3.3.1
downstream
final steps of a procedure which typically include target assay, analysis and reporting to the customer

3.3.2
fatty acid analysis
chromatographic technique used to characterize and distinguish pesticides and organisms based on a chemical profile of isolated lipids

3.3.3
master mix
mixture of the reagents used to perform the assay and prepared as a single mixture to which the test portion is added

3.3.4
multiplex
detection of at least two distinctly different targets, such as amplification or antibody detection assays that use fluorescent dyes at different light emission wave lengths to detect two distinctly different targets

3.3.5
pheromone analysis
chromatographic technique used to characterize and distinguish organisms based on a chemical profile of volatile compounds