TECHNICAL SPECIFICATION

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Foodstuffs — Nucleic acid based methods of analysis of genetically modified organisms and derived products — Information to be supplied and procedure for the addition of methods to ISO 21569, ISO 21570 or ISO 21571

Produits alimentaires — Méthodes basées sur les acides nucléiques pour l'analyse des organismes génétiquement modifiés et des produits dérivés — Informations à fournir et procédure pour l'addition de méthodes à l'ISO 21569, l'ISO 21570 ou l'ISO 21571

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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.

ISO/TS 21098 was prepared by Technical Committee ISO/TC 34, *Food products*.

The reasons why this document is published as a Technical Specification are given in the Introduction.

Introduction

ISO has an obligation to ensure that the international standards it develops, adopts and publishes are globally relevant. Among the criteria detailed in Annex 4, paragraph 10, of the Second Triennial review of the operation and implementation of the Barriers to Trade Agreement, dated 13 November 2000, it is stated that a globally relevant standard should be performance based as opposed to design prescriptive. Thus any method submitted for inclusion in an International Standard should contain sufficient information for its performance to be judged.

Although ISO 24276 states "*The criteria for the selection of methods are listed in the standards on the detection of genetically modified organisms and derived products, ISO 21568, ISO 21569, ISO 21570 and ISO 21571. Acceptable levels of performance for methods included in the annexes are those which have preferably been collaboratively trialed/single laboratory validated. Methods selected for inclusion in the annexes have either been validated according to ISO 5725, or the Harmonized Protocol (Horwitz 1995) or according to Thompson et al. (2002)*", there is insufficient guidance in these documents to allow the analyst to test whether a method is specifically suitable for inclusion in the annexes. It is important that an International Standard or Technical Specification should be performance based. For a standard to be performance based, a clear definition of performance characteristics must be available.

It was noted at the 5th meeting of ISO/TC 34/WG 7, held 18th to 20th February 2004 in Seoul, Korea, that there is no formal process for submitting methods for inclusion in the standards. Although a number of specific methods have been proposed as part of the proposed standards (ISO 21569, ISO 21570 and ISO 21571) and associated general document (ISO 24276), there is not sufficient clarity for submitters to be able to judge whether a method meets the standard, and no mechanism is in place to govern acceptability and/or adoption of such method or for retaining methods in the standards.

Therefore, this Technical Specification was developed in order to provide guidance and to define the performance characteristics that should be supplied for each method in order to ensure the global relevance of these standards, and to delineate the process for adding, amending and retaining methods annexed to the standards.

Foodstuffs — Nucleic acid based methods of analysis of genetically modified organisms and derived products — Information to be supplied and procedure for the addition of methods to ISO 21569, ISO 21570 or ISO 21571

1 Scope

This Technical Specification defines the principles and specifies the nature of the information to be supplied for acceptance of a method as an annex to ISO 21569, ISO 21570 or ISO 21571. It also specifies the process for adding, amending and retaining methods annexed to these standards. This Technical Specification is necessary in order to attain consistency in methods that are to be employed as part of the standards. It does not cover the specifics of the development of a method or laboratory set-up. The operation of laboratories is covered in ISO/IEC 17025.

Method validation is instrumental in assessing the reliability of a test method. Its central role is to establish numerical values for the performance criteria that are to be established. ISO 24276 includes details on method validation, taking into consideration specific technical issues related to the detection of genetically modified organisms and derived products. Given the attention to, and widespread use of deoxyribonucleic acid-based tests or protein-based tests, and the implications to trade of any discrepancies in test results, a single-laboratory validation is most likely not warranted in this case and a multi-centre method validation could be performed according to the international guidelines.

2 Deoxyribonucleic acid (DNA)-based analysis

DNA-based analysis is commonly performed using polymerase chain reaction (PCR), although ISO 21569, ISO 21570 and ISO 21571 also allow for other methods. DNA is a high-molecular weight polymer that may be degraded during food processing by, for example, heat, enzymes and mechanical shearing. In addition, the DNA may be chemically altered by the formation of adducts, or by loss of the bases. Any degradation of the DNA shall be considered when assessing method validation and applying performance criteria. Degradation of DNA will affect the limit of detection and the limit of quantitation of the tests. It is important that the performance criteria for a method consider this effect. Additionally, it is important to point out the restrictions that method(s) may have in certain food matrices.

The annexes in ISO 21569, ISO 21570 and ISO 21571 should contain information on performance criteria from which methods fit for ISO purposes may be selected. It is possible that two different methods for the same event/sequence, both fulfilling the performance criteria, once established, will be included in the annexes.

It should be noted that, due to the limitations of the instruments and other factors, quantitative PCR methods in general do not follow a Gaussian distribution for blank values around the zero. Thus, the determination of the limit of detection and limit of quantitation cannot be carried out assuming such a distribution, and will not follow the procedures outlined, for example, in ISO 11843-1 Thus detection limits for quantitative PCR methods cannot be determined using the mean and standard deviation of the blank samples, and shall be determined experimentally, or methods shall be performed at levels which are significantly above the detection limit.

3 Multi-laboratory studies

Under certain circumstances (i.e. when the conduct of a formal collaborative trial is not practicable), methods may be validated via single laboratory validation (see Reference [11]). The methods used for determination of the presence of material originating from biotechnology-derived crops and food are able to be, and are intended to be, performed at multiple laboratories and shall therefore be validated by multi-laboratory