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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*.

This third edition cancels and replaces the second edition (ISO 21572:2013), which has been technically revised. The main changes compared with the previous edition are as follows:

- the title has been changed to specify that the document is focused on immunochemical protein detection methods;
- an introduction has been added;
- terms, definitions and references have been updated;
- the text has been modified to improve the document's applicability to general protein analysis applications.

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.

Introduction

Analytical techniques based on highly specific immunochemical-binding interactions have become key tools for analysing many different chemical and macromolecular analytes, including proteins. Methods utilizing these techniques are widely accepted in the scientific and regulatory communities. Immunochemical assay methods are most commonly used to detect (presence or absence) and/or quantify specific protein analytes such as allergenic proteins, disease marker proteins or newly expressed proteins in biotech crops.

Prior to analysis, samples generally need to be ground or processed in a manner that facilitates extraction of the analyte from the sample matrix. An important step in analytical method development is therefore the selection of a suitable extraction buffer that does not interfere with the analytical method performance and that ensures an appropriate level of analyte stability during the analytical process.

The immunochemical assay process generally incorporates at least two steps:

— binding or capturing the analyte of interest present in samples with an antibody targeted specifically to the analyte;

— detection of the antibody-analyte complex using a technique that signals the specific interaction.

Once an analytical method has been developed and optimized, it should be validated to demonstrate that its performance is reliable and suitable for the intended use and to characterize the method limitations. This involves performing several experiments with real samples to evaluate parameters such as accuracy, precision, sensitivity, selectivity and the detection or quantification limits. Validation also allows for the establishment of method performance criteria, against which routine analytical performance can be compared to ensure that acceptable analytical results are consistently reported.

This document provides a set of general procedures and analytical considerations for using immunochemical techniques to analyse target proteins. It discusses aspects of sample processing, extraction, assay set-up, interpretation and reporting of results, and relevant assay performance parameters. Two annexes are included containing example procedures that can be followed when analysing a protein of interest (POI) in a variety of background matrices using methods based on enzyme-linked immunosorbent assays (ELISAs) and lateral flow devices (LFDs).