# INTERNATIONAL STANDARD

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# Traditional Chinese medicine — Determination of pesticide residues in natural products by gas chromatography

Médecine traditionnelle chinoise — Détermination des résidus de pesticides dans les produits naturels par chromatographie en phase gazeuse





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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 <a href="www.iso.org/directives">www.iso.org/directives</a>).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see <a href="https://www.iso.org/iso/foreword.html">www.iso.org/iso/foreword.html</a>.

This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

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 <a href="https://www.iso.org/members.html">www.iso.org/members.html</a>.

# Introduction

A pesticide is any substance or mixture of substances intended to prevent, destroy or control any pest, unwanted species of plants or animals causing harm during, or otherwise interfering with, the production, processing, storage, transport or marketing of uncontaminated products. At present, there is no uniformly accepted international standard which defines maximum limits for pesticides in natural products used in traditional Chinese medicine (TCM), resulting in disputes about what levels should be considered acceptable.

This document was developed in response to worldwide demand for harmonization of the determination of pesticide residues. This document is applicable to natural products used in TCM.

For reference, the method of determination of pesticide residues by gas chromatography (GC) is provided in Annex A, the maximum limits of pesticide residues in natural products used in TCM are provided in Annex B and the recommended limits of pesticide residues in dried fruit and vegetables, which is similar to TCM materials or herbal medicine from the World Health Organization (WHO) and Food and Drug Administration/Environmental Protection Agency (FDA/EPA), are given in Annex C.

# Traditional Chinese medicine — Determination of pesticide residues in natural products by gas chromatography

# 1 Scope

This document specifies the method of determination of pesticide residues in natural products used in traditional Chinese medicine (TCM) by gas chromatography (GC), including Chinese materia medica (whole medicinal materials) and decoction pieces derived from plants.

#### 2 Normative references

There are no normative references in this document.

#### 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <a href="https://www.iso.org/obp">https://www.iso.org/obp</a>
- IEC Electropedia: available at <a href="http://www.electropedia.org/">http://www.electropedia.org/</a>

#### 3.1

#### pesticide

substance or mixture of substances intended for preventing, destroying, repelling or reducing any pest

[SOURCE: ISO 27065:2017, 3.9, modified — Note 1 to entry removed.]

## 3.2

# pesticide residue

pesticide, pesticide derivative or pesticide adjuvant that remains in or on a natural product

Note 1 to entry: Pesticide residues are expressed in mg/kg.

## 3.3

## acceptable daily intake

#### ADI

estimate of the amount of a pesticide in natural products that can be safely consumed daily over a lifetime without adverse health effects

Note 1 to entry: ADI is expressed in milligrams of the pesticide, as it appears in the natural products, per kilograms of body mass per day (mg/kg/day).

# 4 Sampling

To reduce the effect of sampling in the determination of pesticide residues in natural products used in TCM, ensure that the composition of the sample used is representative of the batch of natural products used in TCM being examined. The sampling procedures may be used if they can be demonstrated to produce representative batch samples.