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Compressed Gas Association

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CGA F-4—2021

GUIDELINE FOR ANALYTICAL VALIDATIONS FOR FOOD GASES

FIRST EDITION

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Work Item 18-151
Food Gases Committee

FIRST EDITION: 2021

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1 Introduction

Analytical methods for testing food gases are described in monographs contained in the *Food Chemical Codex* (FCC) [1].[1] These analytical methods are called compendial methods. Prior to submitting a new test method to support a food gas monograph submission or proposed revision of an existing compendium method, the method must be appropriately validated. In addition, companies may collect data when testing food gases to justify the use of a method and to demonstrate that it is appropriate for its intended use.

2 Scope

This publication is intended to provide guidance for companies collecting method validation data for food gas monograph submission or updates. It also provides guidance for companies collecting data to support the use of alternate test methods to those in the compendia or those collecting data to support the use of methods to test for gases not listed in the FCC compendia.

This publication is not intended to require validation of a food gas method that does not have an FCC monograph.

This guideline is intended to meet the requirements of General Information/Validation of Food Chemical Codex Methods in the FCC [1].

This publication does not include information on the structure of a validation protocol and report. For more information on these topics see CGA M-6, *Standard for Analytical Method Validation* [2].

3 Definitions

For the purpose of this publication, the following definitions apply.

3.1 Publication terminology

3.1.1 Shall
Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.1.2 Should
Indicates that a procedure is recommended.

3.1.3 May
Indicates that the procedure is optional.

3.1.4 Will
Is used only to indicate the future, not a degree of requirement.

3.1.5 Can
Indicates a possibility or ability.

3.2 Technical definitions

3.2.1 Alternate test method
Analytical method that is not an official compendial method provided a compendial method exists.

NOTE: Alternate test methods are also called noncompendial methods.

3.2.2 Analyte
Substance whose chemical constituents are being identified and measured.

[1] References are shown by bracketed numbers and are listed in order of appearance in the references section.