

CGA F-3 — 2024

2ND EDITION

**GUIDELINE FOR
QUALIFYING
SUPPLIERS USED
BY FOOD AND
BEVERAGE GAS
DISTRIBUTORS AND
MANUFACTURERS**

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NOTE—Technical changes from the previous edition are underlined.

NOTE—Appendices A, B, and C (Informative) are for information only.

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Contents	Page
1 Introduction.....	1
2 Scope	1
3 Definitions.....	1
4 Product, food gas equipment, and service assessment.....	2
4.1 Products	2
4.2 Food gas equipment and services.....	2
4.3 Exceptions	3
5 Supplier qualification	3
5.1 General.....	3
5.2 Types of suppliers	3
5.3 Supplier status.....	4
5.4 Supplier evaluation tools	6
6 Records	6
7 References	6

Appendix

Appendix A—Bulk Supplier Quality Agreement (One Way) Form (Informative)	8
Appendix B—Bulk Supplier Quality Agreement (Two Way) Form (Informative)	9
Appendix C—Example letter from supplier to purchaser with list of qualifications (Informative)	10

Appendix Table

Table C-1—FCC specification and CGA QVL H specification liquid and gaseous carbon dioxide.....	10
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1 Introduction

This publication provides guidance for food gas manufacturers or distributors for developing procedures for qualifying suppliers of food gases, food gas equipment, and other services related to the manufacturing and distribution of food gases.

2 Scope

This publication is for food gas manufacturers and distributors developing company-specific standard operating procedures (SOPs) for qualifying or requalifying suppliers who provide, manufacture, distribute, and store food gases, food gas equipment, and services. Food gases are supplied, stored, and distributed for food applications and are used as ingredients, additives, and direct food contact processing aids.

This publication may be used when qualifying new suppliers or when requalifying existing suppliers of food gases including, but not limited to, bulk and packaged gas manufacturers of nitrogen, oxygen, argon, carbon dioxide, nitrous oxide, helium, hydrogen, and carbon monoxide.

This would include bulk to bulk supplier swaps, bulk supplier to customer, and package gas supplier to customer.

Food gases stored or distributed by facilities other than the manufacturer may also include food or beverage gas mixtures (e.g., beer, wine, modified atmosphere packaging applications).

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 Certificate of analysis (COA)

Document that lists the specific analytical results of a product.

3.2.2 Certificate of conformance (COC)

Document that provides a written guarantee that a product meets or exceeds the specified parameters.

3.2.3 Food gas equipment

Equipment used for the manufacturing, distribution, and storage of food gases.

3.2.4 Food gases

Gases alone or in combination with other gases that are foods as defined in the United States by 201(f) of the Federal *Food, Drug and Cosmetic Act*, or used as ingredients, processing aids, propellants, or temperature control/packaging agents defined as a food additive by 201(s) of the *Federal Food, Drug and Cosmetic Act* [1].¹ Food gases are additives as defined in the Canadian *Food and Drug Regulations*, Part B, Division 16 [2].

3.2.5 Product

Food gas or a raw material intended for use in the manufacture of a food gas.

3.2.6 Purchaser

Manufacturer or distributor that procures food gas products, food gas equipment, or services from a supplier.

3.2.7 Supplier

Firm from whom products, components, or services are received.

4 Product, food gas equipment, and service assessment

The purchaser is responsible for determining that all purchased products, services, and food gas equipment are safe for food applications.

In general, facilities have some flexibility in determining which type of verification to use. If the hazard is one for which there is, per Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) 117.430(b)(1), “reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans”, an audit is required [3].

21 CFR 117.410(e) allows a receiving facility to determine that an onsite audit is not required if other verification activities provide adequate assurance that the hazards are controlled [3].

4.1 Products

Food grade products shall be manufactured at sites registered as appropriate with the U.S. Food and Drug Administration (FDA) and maintain compliance with applicable food safety regulations [3].

Food gas products may be qualified using letters of guaranty, certificates of conformance (COC), or certificates of analysis (COA). The receiving facility may also sample and test the product to confirm purity claims.

4.2 Food gas equipment and services

Some food gas equipment and services, although important to food safety, might not directly impact the finished product. Each supplier should be evaluated based on their risk to food safety and assessed accordingly. The purpose of this evaluation is to ensure that the impact on food safety is understood and does not create additional food safety risks.

Assessments can include, but are not limited to:

- third-party certification (i.e., ISO or NSF International certification) [4, 5];
- questionnaires or customer audits;
- compliance with applicable CGA guidelines; or
- written declaration of FDA compliance and/or food compatibility.

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