

CGA F-1—2018

**STANDARD FOR FOOD SAFETY
MANAGEMENT SYSTEMS AND
GOOD MANUFACTURING
PRACTICES FOR FOOD GAS
MANUFACTURERS**

FIRST EDITION

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Work Item 15-114
Food Gases Committee

NOTE—Appendix A (Informative) is for information only.

FIRST EDITION: 2018

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1 Introduction

On January 4, 2011, the U.S. Food and Drug Administration's (FDA) *Food Safety Modernization Act* (FSMA) was signed into law [1].¹ FSMA aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.

Food gases in liquid, gaseous, or solid form used as additives, processing aids, or ingredients are foods per the U.S. *Federal Food, Drug, and Cosmetic Act* (the Act) because they directly or indirectly become a component of food or drink and affect their characteristics [2]. FSMA emphasizes the importance of controlling known or reasonably foreseeable hazards that have the potential to cause adverse health consequences for consumers [1]. To ensure food safety, food gas manufacturers are required by FSMA to establish and implement a food safety system as outlined in Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) Part 117 "Current Good Manufacturing Practices, Hazard Analysis, and Risk Based Preventive Control for Human Food", and Part 507, "Current Good Manufacturing Practices, Hazard Analysis, and Risk Based Preventive Control for Food for Animals" [1, 3]. A hazard analysis and risk-based preventive controls (HARPC) system is required, unless exempted.

Examples of food gases and their common uses include, but are not limited to:

- carbon dioxide, carbon monoxide, nitrogen, and oxygen, alone or in combination, as modified atmosphere packaging gases;
- carbon dioxide for carbonated beverages;
- carbon dioxide for super-critical extraction;
- hydrogen for hydrogenation of fats;
- liquid nitrogen and liquid carbon dioxide for freezing and chilling in direct contact with food;
- nitrogen and carbon dioxide as propellant gases for beverages;
- nitrous oxide as a propellant gas for cream; and
- sulfur dioxide as a preservative.

Based upon customer request, some companies have chosen to pursue certification to a Global Food Safety Initiative (GFSI) benchmarked scheme [4]. GFSI is a food industry-driven harmonization initiative that recognizes equivalency of food safety management schemes used by companies to develop their own food safety management system [4]. Companies that achieve certification to a GFSI-benchmarked scheme have the framework in place to meet the majority of the requirements of 21 CFR Part 117 [4, 3]. Appendix A provides a cross-reference between these requirements and this publication.

2 Scope

This publication applies to both U.S. and Canadian firms engaged in manufacturing, packaging, storing, and/or distributing food gases and outlines regulatory requirements and industry practices utilized to ensure compliance.

This publication provides inspectors and auditors with an understanding on where and how current food safety manufacturing requirements apply to the food gas manufacturer. It provides guidance on food safety principles in the manufacturing processes that shall be maintained to ensure the quality and safety of the food gas produced for use in the human and animal food industries.

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

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 Adapter

Fitting used to connect one type of gas connection to a different type of gas connection.

3.2.2 Adequate

That which is needed to accomplish the intended purpose in keeping with good public health practice [3].

3.2.3 Allergen cross-contact

Unintentional incorporation of a food allergen into a food [3].

3.2.4 Audit

Systematic, independent, and documented examination through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis, to assess a supplier's food safety processes and procedures [3].

3.2.5 Calibration

Process by which an instrument is adjusted to a known standard.

3.2.6 Calibration check

Process by which an instrument readout is compared to that of a known standard and no adjustment is necessary.

3.2.7 Certificate of analysis (COA)

Document that lists the specific analytical results of a product.

3.2.8 Certificate of conformance (COC)

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

3.2.9 Container

Portable compressed gas cylinder or liquid container made in accordance with the Title 49 of the U.S. *Code of Federal Regulations* (49 CFR) Parts 100-199, Transport Canada (TC) *Transportation of Dangerous Goods Regulations*, or American Society of Mechanical Engineers (ASME) *Boiler & Pressure Vessel Code*, Section VIII Division 1 [5, 6, 7].

3.2.10 Contamination

Any physical, biological, chemical, or radiological foreign material that can cause the food to be adulterated [3].

3.2.11 Correction

Action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce) [3].

3.2.12 Critical control point (CCP)

Point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level [3].

3.2.13 Cylinder

Pressure vessel designed for pressures greater than 40 psia (276 kPa, abs) and having a circular cross section.²

NOTE—For the purpose of this publication, cylinder does not include portable tanks, cargo tanks, tank cars, or multi-unit tank car tanks.

3.2.14 Distributor

Business engaged in the sale or resale of compressed or liquefied gases, or dry ice.

NOTE—A distributor does not change the product or the labeling in any way.

3.2.15 Evacuated

Process of removing residual product by mechanical means, creating a negative atmospheric pressure.

3.2.16 Food additive

Gas that directly or indirectly becomes a component of or otherwise affects the characteristics of a food.

NOTE—For additional information, see Sections 201(s) and 409 of the Act and the Canadian *Food and Drug Regulations*, Part B, Division 16 [2, 9].

3.2.17 Food allergen

Major food allergen as defined in Section 201(qq) of the Act [2].

3.2.18 Food or food gas contact surfaces

Surfaces that contact human food and those surfaces from which venting, filling, or other transfer onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations [3].

3.2.19 Food gas

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, and temperature control/packaging agents defined as a food additive by 201(s) of the *Federal Food, Drug and Cosmetic Act*. Food gases are additives as defined in the Canadian Food and Drug Regulations, Part B, Division 16 [2, 9].

3.2.20 Food gas manufacturer

Person or establishment that produces food gases, fills food gas containers via liquid-to-liquid, liquid-to-gas, or gas-to-gas, or re-labels filled containers of food gases.

3.2.21 Generally recognized as safe (GRAS)

Designation made by FDA given to additives that are considered safe for use in food.

3.2.22 Guideline

Nonbinding interpretation of regulations.

3.2.23 Hazard

Biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury [3].

² kPa shall indicate gauge pressure unless otherwise noted as (kPa, abs) for absolute pressure or (kPa, differential) for differential pressure. All kPa values are rounded off per [CGA P-11](#), *Metric Practice Guide for the Compressed Gas Industry* [8].

3.2.24 Ingredient

Substance used in the manufacture of food that is still present in the finished product, even in an altered form.

NOTE—Additives are considered ingredients.

3.2.25 Known or reasonably foreseeable hazard

Biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food [3].

3.2.26 Labeling

Labels and other written, printed, or graphic material on a food gas container or wrapper. This includes written, printed, or graphic material accompanying the delivery of a food gas.

3.2.27 Lot

Amount of a product produced during a period of time indicated by a specific code or some other unique identifying characteristic [4].

3.2.28 Monograph

Specifications and test methods for food gases found in the *Food Chemicals Codex* (FCC) or other official compendia [10].

3.2.29 Preventive controls

Risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis [3].

3.2.30 Preventive controls qualified individual

Qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system [3].

3.2.31 Qualified auditor

Person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by 21 CFR 117.180(c)(2) [3]. Examples of potential qualified auditors include:

- An audit agent of a certification body that is accredited in accordance with applicable regulations; and
- A government employee, including a foreign government employee [3].

3.2.32 Qualified individual

Person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment [3].

3.2.33 Quality control operation

Planned and systematic procedure for taking all actions necessary to prevent food from being adulterated [3].

3.2.34 Quarantine

Segregation and identification of materials, including gases, pending a decision on their disposition.

3.2.35 Sanitize

To adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer [3].

3.2.36 Significantly minimize

To reduce to an acceptable level, including to eliminate [3].

3.2.37 Small business

Business, for the purposes of this publication, employing fewer than 500 full-time equivalent employees [3].

3.2.38 Subsidiary

Company which is owned or controlled directly or indirectly by another company [3].

3.2.39 Supplier

Establishment that manufactures/processes the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature [3].

3.2.40 Unexposed packaged food

Packaged food that is not exposed to the environment [3].

3.2.41 Validation

Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards [3].

3.2.42 Verification

Application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan [3].

3.2.43 Very small business

Business, for purposes of this part, (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee) [3].

4 Key laws, regulations, and guidelines

The following provides the key federal laws, regulations, and guidelines applicable to food gases. Food gas manufacturers should contact state, provincial, and local authorities to determine any additional requirements these jurisdictions may have regarding the manufacture and/or distribution of gases used in food applications. Any food gas product to be exported shall comply with the regulations of the receiving country.

4.1 Laws

Food gas manufacturers shall comply with all applicable laws.

4.1.1 Bioterrorism Act

The *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (the Bioterrorism Act) directs FDA, as the food regulatory agency of the Department of Health and Human Services (HHS), to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies [11].

To carry out certain provisions of the Bioterrorism Act, FDA established regulations including the requirement for food facility registration with FDA [11]. These regulations became effective December 12, 2003 (see Section 415 of the Act) [2].

This law was modified under FSMA to give FDA additional authority over registered facilities [1]. See 4.1.2 for more information on FSMA.

4.1.2 Food, Drug and Cosmetic Act (United States)

The Act includes definitions, prohibited acts and penalties, specific information for food and food additives, and general administrative provisions [2]. The regulations promulgated under the Act are enforced by the FDA [2].

FSMA amended Section 415 of the Act, in relevant part, to require that facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States submit additional registration information to FDA [1, 2]. Included in the additional registration information needed to be submitted to FDA is an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the Act [2].

Section 415 of the Act, as amended by FSMA, also requires food facilities required to register with FDA to renew such registrations every other year [2, 1]. The Act also gives FDA authority to suspend the registration if they determine there is a reasonable probability that the food facility could cause serious adverse health consequences or death to humans or animals [2].

4.1.3 Food and Drugs Act (Canada)

In Canada, the Canadian *Food and Drug Regulations*, Part B “Foods”, contains regulations applicable to food [9]. These regulations include good manufacturing practices (GMPs) that specify the minimum requirements for the manufacture, processing, packaging, or holding of food to ensure food safety [9]. The regulations promulgated under the *Food and Drugs Act* are enforced by the Canadian Food Inspection Agency (CFIA) [12, 13].

4.2 Regulations

4.2.1 U.S. regulations

In the United States, 21 CFR Parts 100-199 contain the regulations applicable to human food and 21 CFR Parts 500-599 contain the regulations applicable to food for animals [3].

4.2.1.1 21 CFR Part 101, Food Labeling

Food gas manufacturers and distributors can meet the intent of 21 CFR Part 101 through quality agreements, customer contracts, statements of conformance, labeling of cylinders following [CGA C-7, Guide to Classification and Labeling of Compressed Gases](#), certificates of analysis (COA), certificates of conformance (COC), or other similar labeling activities that indicate the gas provided is appropriate for food use [14].

4.2.1.2 21 CFR Part 117, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

21 CFR Part 117 contains current good manufacturing practices (CGMP) that specify the minimum requirements for the manufacture, processing, packaging, or holding of human food to ensure food safety. The CGMP regulations are general in nature and are not specific for food gas manufacturers. This regulation also defines and identifies the HARPC required for manufacturing food. All food gas manufactures should be familiar with these regulations. Appendix A provides a cross-reference between 21 CFR Part 117 and this publication.

4.2.1.3 21 CFR Part 507, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

21 CFR Part 507 contains CGMP that specify the minimum requirements for the manufacture, processing, packaging, or holding of animal food to ensure food safety. Although the contents of this publication focus on 21 CFR Part 117 and other regulations concerning human foods, the requirements applicable to food gases in this publication also satisfy the requirements in 21 CFR Part 507.

4.2.1.4 21 CFR Part 170, Food Additives

21 CFR Part 170 contains general requirements for food additives. This regulation defines food additives as all substances not exempted by Section 201(s) of the Act with the intended use of which results or may reasonably be expected to directly or indirectly result in their becoming a component of food or otherwise affecting the characteristics of food [2]. It also provides definitions for terms used in conjunction with the term “food additive” and discusses the principles for evaluating the safety of food additives including the safety factors to be considered and the eligibility for classification of a food additive as generally regarded as safe (GRAS).