



# CGA F-5—2022

## STANDARD FOR FOOD GAS FOOD DEFENSE

FIRST EDITION

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## 1 Introduction

Food defense is an important element in protecting food gas manufacturers, distributors, and consumers from internal and external threats of intentional adulteration by:

- acts intended to cause wide scale public health harm, such as acts of terrorism focused on the food supply; and
- acts of disgruntled employees, consumers, or competitors [1].<sup>1</sup>

Therefore, food defense programs shall be developed for the protection of public health.

The FDA *Food Safety Modernization Act* (FSMA) added to the *Federal Food, Drug, and Cosmetic Act* (FD&C Act) several new references related to intentional adulteration including:

- Section 418 of the FD&C Act (21 U.S.C. 350g) addresses intentional adulteration in the context of facilities that manufacture, process, pack, or hold food, and that are required to register under Section 415 (21 U.S.C. 350d) [2].
- Section 420 of the FD&C Act (21 U.S.C. 350i) addresses intentional adulteration in the context of high-risk foods [2].

FDA implemented these intentional adulteration provisions through a rule entitled “Mitigation Strategies to Protect Food Against Intentional Adulteration” (IA rule) [3]. The final rule was published in the Federal Register on May 27, 2016. (81 FR 34166). The rule, which includes the requirements for food defense measures against intentional adulteration, and related requirements, can be found in 21 CFR Part 121 [1].

This standard is intended to provide the food gas industry with a plan to assess and identify the threats for intentional adulteration and then implement appropriate control measures.

CGA also provides guidance on other FSMA regulations. The reader should refer to CGA F-1, *Standard for Food Safety Management Systems and Good Manufacturing Practices for Food Gas Manufacturers* for other regulations associated with food gas manufacturing, CGA F-2, *Guideline for Food Gases Product Hazard Analysis and Risk-Based Preventive Control (HARPC) Program* for evaluating risk, and CGA F-3, *Guideline for Qualifying Suppliers Used by Food and Beverage Gas Distributors and Manufacturers* for supplier qualification [4, 5, 6].

## 2 Scope

This standard applies to both U.S. and Canadian firms engaged in manufacturing, packaging, storing, and/or distributing food gases. It outlines regulatory requirements and industry practices in the United States utilized to ensure compliance with 21 CFR Part 121 with respect to acts of intentional adulteration intending to cause wide scale harm to public health. This standard does not apply to very small businesses as defined in 21 CFR Part 121.3 or other exemptions listed in 21 CFR Part 121.5. This standard provides guidance on the steps required for a food defense plan and how to incorporate it into their food and safety management system. It provides inspectors and auditors with an understanding on where and how defense against intentional adulteration is implemented at food gas facilities.

The food defense plan is a set of written documents based upon food defense principles and incorporates a vulnerability assessment, includes mitigation strategies, and delineates food defense monitoring, corrective action, and verification procedures to be followed.

This standard assists the food gas industry with the development of a plan on how to assess and identify internal and external threats for intentional adulteration and then implement appropriate control measures to mitigate those threats during the manufacture, storing, and distribution of food gases.

The standard does not cover economically motivated adulteration. See PS-63, *Position Statement on Mitigating Food Fraud Risk in Food Gases* [7].

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<sup>1</sup> 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 Actionable process step

Step in the food gas process where a significant vulnerability exists to which a mitigation strategy can be applied [1].

##### 3.2.2 Contaminant

Any biological, chemical, or physical agent that can be added to a food gas to intentionally cause illness, injury, or death [1].

##### 3.2.3 Food

As defined in section 201(f) of the Federal *Food, Drug, and Cosmetic Act* and includes raw materials and ingredients [1, 2].

##### 3.2.4 Food defense

Effort to protect food from intentional acts of adulteration where there is an intent to cause wide scale public health harm [1].

##### 3.2.5 Food defense monitoring

To conduct a planned sequence of observations or measurements to assess whether mitigation strategies are operating as intended [1].

##### 3.2.6 Food defense verification

Application of methods, procedures, and other evaluations, in addition to food defense monitoring, to determine whether a mitigation strategy or combination of mitigation strategies is or has been operating as intended according to the food defense plan [1].

##### 3.2.7 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, 8].

##### 3.2.8 Holding

Storage of bulk and packaged food gases in cryogenic, liquified, or gaseous form, and dry ice for either use in manufacturing or for distribution.

### 3.2.9 Intentional adulteration

Deliberate contamination of a food gas with a biological, chemical, or physical agent.

### 3.2.10 Mitigation strategies

Those risk-based, reasonably appropriate measures that a person knowledgeable about food defense would employ to significantly minimize or prevent significant vulnerabilities identified at actionable process steps, and that are consistent with the current scientific understanding of food defense at the time of the analysis [1].

### 3.2.11 Packing

Placing food gas liquids, solids, and gases into containers for distribution.

### 3.2.12 Qualified individual

Person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under subpart C of this part, as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment [1].

### 3.2.13 Significant vulnerability

Vulnerability that, if exploited, could reasonably be expected to cause wide scale public health harm. A significant vulnerability is identified by a vulnerability assessment conducted by a qualified individual, that includes consideration of the following: (1) Potential public health impact (e.g., severity and scale) if a contaminant were added, (2) degree of physical access to the product, and (3) ability of an attacker to successfully contaminate the product. The assessment must consider the possibility of an inside attacker [1].

### 3.2.14 Vulnerability

Susceptibility of a point, step, or procedure in a facility's food process to intentional adulteration [1].

## 4 Differences between food gas manufacturing and other food chemical operations

For differences between food gas manufacturing and other food chemical operations and the unique characteristics of food gas operations see CGA F-1 [4].

Specifically, the manufacturing, storage, and shipping of food gases occurs in closed, pressurized systems and containers and personnel do not directly handle or come in contact with food gases. However, solid carbon dioxide (dry ice) is the only food gas that is not completely manufactured, stored, and shipped in closed, pressurized systems and containers.

## 5 General provisions (21 CFR Part 121 Subpart A)

### 5.1 Applicability (21 CFR Part 121.1)

Applies to the owner, operator, or agent in charge of a domestic or foreign food facility that manufactures/processes, packs, or holds food for consumption in the United States and is required to register under section 415 of the Federal *Food, Drug, and Cosmetic Act*, unless one of the exemptions in 121.5 applies.

### 5.2 Definitions (21 CFR Part 121.3)

The definitions included in 21 CFR Part 121 applicable to food gases are included in 3.2 of this publication.

### 5.3 Qualifications of individuals performing food defense activities (21 CFR Part 121.4)

Food gas manufacturers shall assure that personnel that perform activities with regard to food defense activities found in the IA rule and shall be a qualified per the requirements of 21 CFR 121.4 such that:

- The person has the education, training, or experience (or a combination thereof) necessary to perform an activity related to food defense, as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment;
- Individuals shall receive food defense training commensurate with the level of food defense awareness required in the food defense process steps in which they participate;