



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].¹

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].

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