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CGA F-2—2023

GUIDELINE FOR FOOD GASES PRODUCT HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROL (HARPC) PROGRAM

SECOND EDITION

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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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1 Purpose

This publication provides guidelines for conducting a hazard analysis and risk-based preventive controls (HARPC) of the manufacture and distribution of food gases where required by regulation. See CGA F-1, *Standard for Food Safety Management Systems and Good Manufacturing Practices for Food Gas Manufacture* for the HARPC regulatory requirements. This publication should be referenced by companies to:

- ensure proper documentation is in place for an effective food safety plan;
- ensure there are sufficient preventive measures in place to eliminate, control, or mitigate to an acceptable level the identified food safety risks; and
- identify potential hazards in relation to food safety when considering the production and distribution of food gases.

This publication will assist with the industry's compliance with:

- Subpart C of 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
- Subpart C of 21 CFR Part 507, Current Good Manufacturing Practices, Hazard Analysis, and Risk-Based Preventive Control for Food for Animals [1]. [1]

This publication is meant for guidance and should be used in conjunction with other CGA food gas publications and is not intended to replace a site specific hazard analysis.

2 Scope

This publication, unless exempted per 21 CFR 117.3 (qualified facility definition) or 21 CFR 117.206, applies to company facilities that produce and distribute food gases and are responsible for the safety and quality of their products when those products are used in food applications [1]. Appendices to this publication provide example HARPCs for different types of food gas manufacturing processes.

Appendix A provides an example hazard analysis for the air separation process.

Appendix B provides an example hazard analysis for packaged gas operations which includes some food gases filled as liquids and gases.

Appendix C provides an example hazard analysis for the dry ice manufacturing process.

For more details about the scope of the example hazard analyses, see the appropriate appendices.

Sections 5 through 13 are components of the HARPC program.

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.

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