



CGA F-2—2023

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

SECOND EDITION
(Corrected 8/14/2023)

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Food Gases Committee

NOTE—Technical changes from the previous edition are underlined.

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

SECOND EDITION 2023 (Corrected 8/11/2023)

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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 scopes 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.

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 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*. Food gases are additives as defined in the Canadian *Food and Drug Regulations*, Part B, Division 16 [2, 3].

3.2.2 Food gases products HARPC

Includes all process steps, process inputs, and is in accordance with the concepts in 21 CFR Part 117 [1]. Also includes commonly asked questions regarding impurity-related concerns and some requirements outlined in Global Food Safety Initiative (GFSI) benchmarked food safety schemes [4]. Analysis is completed by company experts to identify and implement risk based preventive controls.

3.2.3 Hazard

Biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury in the absence of its control [1].

3.2.4 Hazard analysis and risk-based preventive controls (HARPC)

Process to identify, evaluate, and control food safety related health risks.

3.2.5 Hazards reasonably likely to occur

Hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls [1].

3.2.6 Preventive control (PC)

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 [1]. See 21 CFR 117.3.

3.2.6.1 Critical control point (CCP)

Step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

3.2.6.2 Operational pre-requisite program (oPRP)

Pre-requisite program (PRP) identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards to and/or the contamination or proliferation of food safety hazards in the product(s) or in the processing environment.

3.2.6.3 Pre-requisite program (PRP)

Basic conditions and activities necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling, and provision of safe end products and safe food for human consumption.

NOTE—For the purpose of this publication, the preventive controls definition will be used to encompass what some companies can risk assess as PRPs, operational pre-requisite program (oPRPs), and critical control points (CCPs) as defined in ISO 22000, *Food safety management* [5].

3.2.7 Significant hazard

Known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the control also known as a hazard requiring a preventive control [1].

4 Responsibilities

Personnel engaged in food safety related activities shall have adequate education, training, and experience, or any combination thereof. There shall be an adequate number of qualified individuals to establish and implement a food safety management system.

4.1 CGA guideline development

CGA conducted a general industry hazard analysis utilizing a HARPC approach and is providing general guidance on establishing food safety management systems.

4.2 Company food safety team

The company food safety team, led by a qualified individual, is responsible for overseeing the implementation and maintenance of the food safety management system in their respective company.

4.3 Facility food safety team

The company shall ensure that a food safety team is in place at each site to execute the food safety management system.

5 Product description

5.1 Food gases specification

Food gases are produced to specifications that meet or exceed regulatory or customer requirements, or industry guidelines (e.g., Food Chemicals Codex [FCC], International Society of Beverage Technologists [ISBT], CGA, European Industrial Gases Association [EIGA], etc.).

For additional reference material regarding product specifications, see EIGA Doc 125, *Guide to the Supply of Gases for Use in Foods* and EIGA Doc 126, *Minimum Specifications for Food Gas Applications* [6, 7].

5.2 Shelf life

Product characteristic and storage conditions for pure food gases are such that there is an unlimited shelf life.

NOTE—Local or regional regulations can require a limited shelf life.

6 Intended use

Food gases include gases used as additives, processing aids, or ingredients. Food gases are supplied to the food industry in liquid or gaseous form and can directly or indirectly become a component of food or drink, or otherwise affect the characteristics of food. Gases are commonly used in the food and beverage industry in applications such as inerting, purging, freezing, chilling, carbonation, modified atmosphere packaging, pressurization, and dispensing. Examples of food gas applications include but are not limited to:

- carbon dioxide for carbonated beverages;
- carbon dioxide and nitrogen, alone or in combination, as propellant gases for beverages such as beer or wine;
- carbon dioxide, nitrogen, oxygen, and on occasion carbon monoxide, alone or in combination, as modified atmosphere packaging gases;

- liquid carbon dioxide and liquid nitrogen for freezing and chilling in direct contact with food;
- hydrogen for hydrogenation of fats;
- nitrous oxide as a propellant gas for cream; and
- sulfur dioxide as a preservative.

Due to their extremely cold temperatures, cryogenic and refrigerated gases have contributed significant improvements to the safety of perishable foods over the past decades. As stated in 21 CFR Part 117.80(c)(4), refrigerating and freezing are the most widely practiced methods to control the growth of undesirable microorganisms in foods [1]. The length of time and temperature at which food products are kept throughout manufacturing, handling, storage, and distribution will greatly impact their safety and quality. Liquid nitrogen (-320°F [-196°C] boiling temperature at 1 atm) and carbon dioxide (-109°F [-78°C] sublimation temperature at 1 atm) allow processors to achieve faster chilling or freezing of high quality products than with conventional systems.

7 Food gases production and distribution

7.1 Source materials

Atmospheric air is used as a source material for argon, compressed air, nitrogen, and oxygen used as food gases.

For other food gases, raw materials are obtained from solid, liquid, or gas phase sources for further processing and/or purification.

Evaluation and monitoring of source streams are critical steps in ensuring the safety of food gases.

7.2 Storage and transfer

Food gases typically transferred to and stored in the end user's storage vessels can be either owned by the company or the end user.

Food gases in liquid and gaseous form are held and distributed in closed pressurized systems. Gas characteristics, combined with the closed pressurized process and quality systems approach, substantially reduce the likelihood of potential food safety hazards.

Food gases in solid form (e.g., solid carbon dioxide [dry ice]) have the potential for greater exposure to environmental food safety hazards and shall be assessed to mitigate or control any relevant risk.

8 Process description

A comprehensive summary of the potential process steps can be found in the appendices. All of these steps shall be risk assessed from a food safety perspective.

9 Process visualization

Site specific production/distribution schemes and flow diagrams shall be available at each location with the applicable process steps identified and risk assessed. The appropriate appendices may be used as a guideline to facilitate creation of the site specific process flow diagram.

10 Hazard analysis and risk-based preventive controls

This section describes HARPC methodology the industry should follow and provides the justification for the conclusions of your risk-based hazard evaluation and preventive controls. Generic industry hazard analyses were conducted on various food gas processes, the results of which are contained in the appendices.

10.1 Globally accepted methodology

HARPC methodology was followed to identify, evaluate, and control hazards that are globally accepted as being significant for ensuring that the product is safe and suitable for its intended use.

10.2 Risk classification

Each identified hazard was analyzed for both the likelihood of an event occurring and the potential severity of the consequence of the hazard. Table 1 provides the numerical rankings used in this analysis.

Table 1—Risk rating criteria

Rating	Likelihood	Severity
1	1 occurrence every 10 or more years	No illness
2	1 occurrence every 1-10 years	Mild illness
3	1 or more occurrences every year	Severe illness or death

10.3 Risk index

The risk index was calculated by multiplying the rating given for likelihood and severity. Significant food safety hazards were defined as any hazard with an overall risk index rating of six or higher. See Table 2.

Table 2—Risk index

Risk	Rating
High	6 or 9
Medium	3 or 4
Low	1 or 2

10.4 Contamination types

The following types of contamination shall be considered:

- biological (e.g., bacteria, mold, etc.);
- chemical (e.g., total carbon monoxide, hydrocarbons, nitrogen dioxide, and nitrogen oxide); and

NOTE—This type includes radiological.

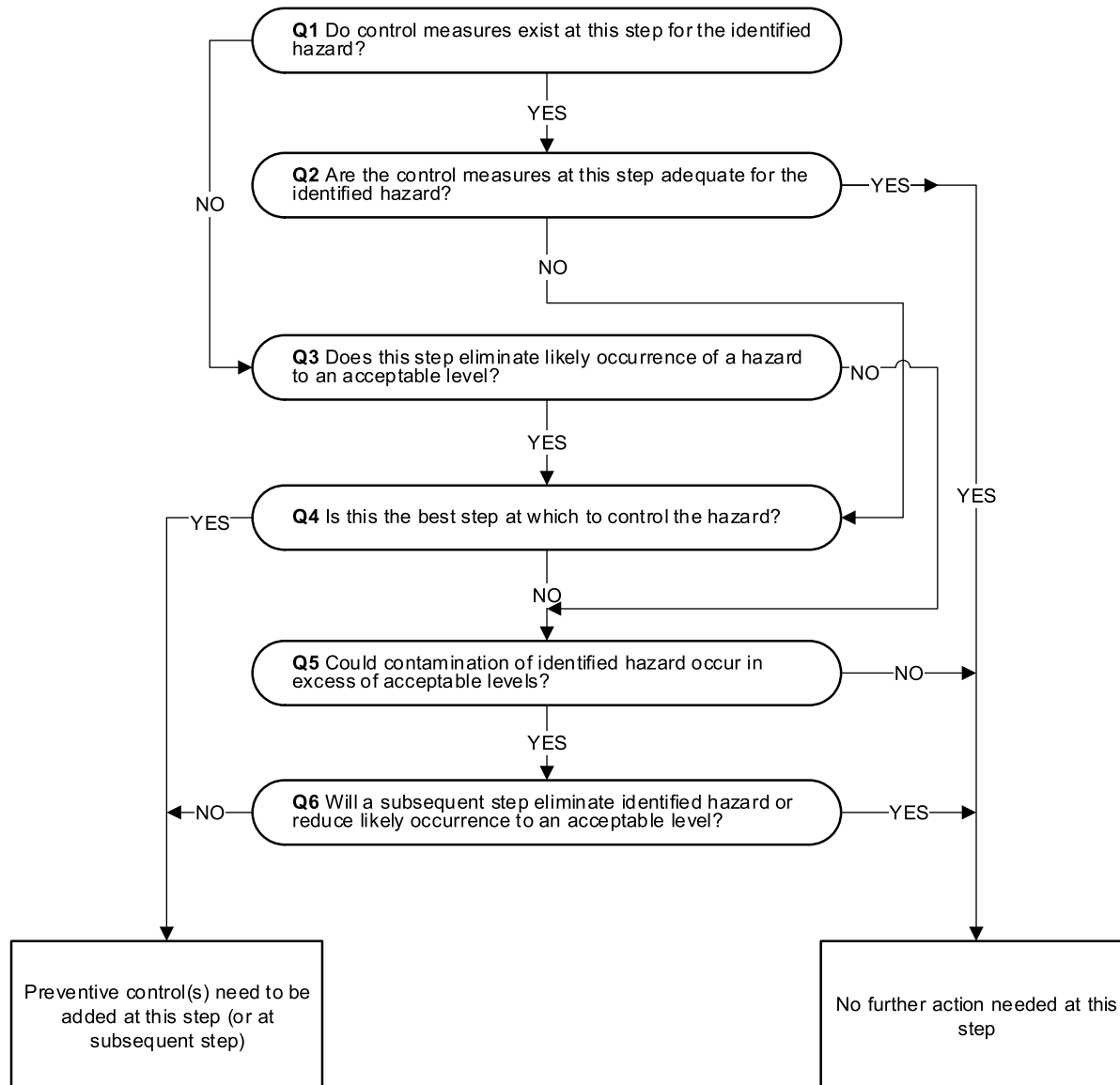
- physical (e.g., particles).

10.5 Identification of risk-based preventive controls

Preventive controls required for food safety shall be identified for each step of the process and shall include parameters associated with the monitoring, control, and corrective action related to hazard mitigation.

To determine if preventive controls are required to mitigate a food safety risk, in the absence of preventive controls, determine if there is a food safety risk at the current step using Table 1 to identify level of likelihood and severity, and Table 2 for risk rating. For additional information see 21 CFR 117.130 Hazard analysis and (c) Hazard evaluation. (1)(i) The hazard analysis shall include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

If the risk rating has been evaluated as a 6 or 9, the following decision tree and questions should be used to evaluate and determine if a preventive control is required:



The preventive controls evaluation columns in the appendices show these types of evaluations. Some preventive controls and good manufacturing practices (GMPs), while not required for food safety, still support safe food gas operations. These controls can be in place for other reasons such as operational, efficiency, process safety, regulatory, or customer requirements. If a previous question provides the answer whether a preventative control is needed, subsequent questions can be marked with an "N/A". If your risk score is less than 6, put a dash in each column for that row.

Companies may choose to use a hazard analysis and critical control point (HACCP) based approach, which would include various levels of controls such as PRPs, oPRPs, CCPs. This approach would include the use of the decision tree to identify CCPs. See Codex Alimentarius Figure 2 [8].

10.6 Product/process hazard analysis

10.6.1 Industry process hazard analysis

Examples of process hazard analyses have been completed, which cover common potential process steps for some food gases, see the appendices.

10.6.2 Site process hazard analysis

The food safety team is responsible for implementing and maintaining the food safety management system in their company. The appendices provide examples that support building of site-specific hazard analyses.

11 Food safety plan

Except for qualified facilities, food gas production facilities shall have a written food safety plan prepared (or its preparation overseen) by a qualified individual as required by 21 CFR Part 117.126 [1]. The food safety plan shall include or provide reference to the following, but is not limited to:

- documented hazard analysis, as required by 21 CFR 117.130(a)(2) [1];
- identified and implemented preventive controls, as required by 21 CFR 117.135(b) [1];
- recall plan, as required by 21 CFR 117.137(a) [1];
- documented procedures, and the frequency with which they are to be performed, for monitoring the implementation of the preventive controls, as required by 21 CFR 117.145(a) [1];
- documented corrective action procedures, as required by 21 CFR 117.150 [1]; and
- documented verification activities, as required by 21 CFR 117.155(e) [1]

11.1 Identified preventive controls

Significant hazards reasonably likely to occur are identified in the hazard analysis. Corresponding preventive controls need to be identified and implemented for food gas production and distribution processes.

11.2 Parameters (control limits)

If appropriate to the facility and the food gases, preventive controls shall include:

- maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter shall be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur; and
- parameters associated with the control of the hazard.

NOTE—Not all preventive controls have measurable limits, such as preventive maintenance and housekeeping.

11.3 Monitoring preventive controls

11.3.1 Monitoring systems

The requirements for monitoring are found in 21 CFR 117.145 [1].

The owner, operator, or agent in charge of a facility shall establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls.

The owner, operator, or agent in charge of a facility shall monitor the preventive controls with sufficient frequency to provide assurance that they are consistently performed.

All monitoring of preventive controls in accordance with this section shall be documented in records that are subject to verification in accordance with 21 CFR 117.140 and records review in accordance with 21 CFR 117.165 (a)(4)(i) [1].

NOTE—Not all preventive controls have measurable limits, such as preventive maintenance and housekeeping.

11.3.2 Examples of monitoring

Depending on the unit operation and customer requirements, there are a variety of analyzers and instrumentation that monitor process parameters, including the following:

- level gauges/indicators;
- pressure elements;
- product analyzers;
- temperature elements; and
- third-party testing.

Preventive controls that do not have measurable limits such as preventive maintenance and housekeeping shall be monitored to ensure effectiveness.

11.4 Corrective actions when monitoring results exceed control limits

Each facility shall establish and implement written corrective action procedures to ensure appropriate action is taken whenever monitoring activities detect a deviation from the parameters or a loss of control.

The corrective action shall identify and correct the problem that resulted in the deviation from the preventive control. In addition, the corrective action shall ensure all food gases affected by the deviation have been evaluated for safety. All food gases affected by a deviation are presumptively adulterated or misbranded under Federal *Food, Drug and Cosmetic Act* (the Act) unless proven otherwise [2].

A facility shall implement ad hoc corrective action procedures when encountering a problem not anticipated by the established preventive controls. The occurrence of unanticipated problems shall trigger a reanalysis of the food safety plan, since the unanticipated problem is now one that is reasonably foreseeable and therefore shall have an associated preventive control.

All corrective actions, either planned or unplanned, shall be documented.

12 Verification

12.1 Audit program

The verification program is rolled into existing internal auditing systems where possible (such as operation and engineering audits, management system audits, ISO 9001, *Quality Management Systems—Requirements*, food safety, beverage, and technical audits) [9].

12.2 Validation

Companies shall validate that each preventive control identified and implemented effectively eliminates or mitigates the hazard as described.

12.3 Hazard analysis and risk-based preventive controls program review

Except for qualified facilities, HARPC programs shall be reviewed by the food safety teams at a minimum, every three years or at the addition or removal of a process step.

During the verification process all legislative and regulatory changes in product or intended use, process steps or technology developments, and customer feedback shall be reviewed.

If, as part of this review, or as prior notification from the customer, significant changes are identified to any of the previously mentioned areas within the operation a reverification process shall be immediately initiated.

This review ensures the continuous improvement of the food safety management system and compliance with 21 CFR Part 117 [1].

13 Recordkeeping

Facilities shall keep a written food safety plan, including the hazard analysis. They shall also keep records of preventive controls, monitoring, corrective actions, and verification.

14 References

Unless otherwise specified, the latest edition shall apply.

- [1] *Code of Federal Regulations*, Title 21 (Food and Drugs), U.S. Government Printing Office. www.gpo.gov
- [2] *Federal Food, Drug, and Cosmetic Act*, U.S. Food and Drug Administration. www.fda.gov
- [3] *Canadian Food and Drug Regulations*, Health Canada. www.hc-sc.gc.ca
- [4] *Global Food Safety Initiative*, The Consumer Goods Forum. www.mygfsi.com
- [5] ISO 22000, *Food safety management*, International Organization for Standardization. www.iso.org
- [6] EIGA Doc 125, *Guide to the Supply of Gases for Use in Foods*, European Industrial Gases Association. www.eiga.eu
- [7] EIGA Doc 126, *Minimum Specifications for Food Gas Applications*, European Industrial Gases Association. www.eiga.eu
- [8] *Codex Alimentarius*, U.S. Codex Office. www.fsis.usda.gov
- [9] ISO 9001, *Quality Management Systems—Requirements*, International Organization for Standardization. www.iso.org
- [10] CGA P-8, *Guideline for Safe Practices for Cryogenic Air Separation Plants*, Compressed Gas Association, Inc. www.cganet.com
- [11] CGA P-8.2 *Guideline for Validation of Air Separation Unit and Cargo Transport Unit Filling for Medical Oxygen and Medical Nitrogen*, Compressed Gas Association, Inc. www.cganet.com
- [12] CGA TR-3, *The Impact of Ambient Air Contaminants on Validation Requirements for the Air Separation Process*, Compressed Gas Association, Inc. www.cganet.com
- [13] CGA P-50, *Standard for Site Security*, Compressed Gas Association, Inc. www.cganet.com
- [14] CGA P-8.4, *Safe Operation of Reboilers/Condensers in Air Separation Units*, Compressed Gas Association, Inc. www.cganet.com
- [15] CGA response to FDA proposed rule RE: Focused Mitigation Strategies to Protect Food Against Intentional Adulteration (Docket No. FDA–2013–N–1425)
- [16] CGA F-3, *Guideline for Qualifying Suppliers Used by Food and Beverage Gas Distributors and Manufacturers*, Compressed Gas Association, Inc. www.cganet.com
- [17] *Code of Federal Regulations*, Title 49 (Transportation), U.S. Government Printing Office. www.gpo.gov
- [18] CGA P-31, *Liquid Oxygen, Nitrogen, and Argon Cryogenic Tanker Loading Systems*, Compressed Gas Association, Inc. www.cganet.com

- [19] CGA V-6, *Standard Bulk Refrigerated Liquid Transfer Connections*, Compressed Gas Association, Inc. www.cganet.com
- [20] ASME *Boiler & Pressure Vessel Code*, American Society of Mechanical Engineers. www.asme.org
- [21] CGA P-35, *Guideline for Unloading Tankers of Cryogenic Oxygen, Nitrogen, and Argon*, Compressed Gas Association, Inc. www.cganet.com
- [22] CGA P-51, *Standard for Transportation Security in the Compressed Gas Industry*, Compressed Gas Association, Inc. www.cganet.com
- [23] CGA F-1, *Standard for Food Safety Management Systems and Good Manufacturing Practices for Food Gas Manufacturers*, Compressed Gas Association, Inc. www.cganet.com
- [24] CGA G-4.1, *Cleaning of Equipment for Oxygen Service*, Compressed Gas Association, Inc., www.cganet.com
- [25] CGA P-82, *Standard for Maintenance of Transfer Hoses*, Compressed Gas Association, Inc., www.cganet.com
- [26] CGA G-6.3, *Carbon Dioxide Cylinder Filling and Handling Procedures*, Compressed Gas Association, Inc. www.cganet.com
- [27] CGA, P-15, *Standard for the Filling of Nonflammable Compressed Gas Cylinders*, Compressed Gas Association, Inc., www.cganet.com
- [28] CGA P-1, *Standard for Safe Handling of Compressed Gases in Containers*, Compressed Gas Association, Inc., www.cganet.com
- [29] CGA C-6, *Standard for Visual Inspection of Steel Compressed Gas Cylinders*, Compressed Gas Association, Inc., www.cganet.com
- [30] CGA C-6.1, *Standard for Visual Inspection of High Pressure Aluminum Alloy Compressed Gas Cylinders*, Compressed Gas Association, Inc., www.cganet.com
- [31] CGA P-30, *Guideline for Portable Cryogenic Liquid Containers—Use, Care, and Disposal*, Compressed Gas Association, Inc., www.cganet.com
- [32] CGA C-7, *Guide to Classification and Labeling of Compressed Gases*, Compressed Gas Association, Inc., www.cganet.com
- [33] CGA V-1, *Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections*, Compressed Gas Association, Inc., www.cganet.com
- [34] CGA G-4.3, *Commodity Specification for Oxygen*, Compressed Gas Association, Inc., www.cganet.com
- [35] CGA G-6.2, *Commodity Specification for Carbon Dioxide*, Compressed Gas Association, Inc., www.cganet.com
- [36] CGA G-8.2, *Commodity Specification for Nitrous Oxide*, Compressed Gas Association, Inc., www.cganet.com
- [37] CGA G-10.1, *Commodity Specification for Nitrogen*, Compressed Gas Association, Inc., www.cganet.com
- [38] CGA G-11.1, *Commodity Specification for Argon*, Compressed Gas Association, Inc., www.cganet.com
- [39] CGA V-7, *Standard Method of Determining Cylinder Valve Outlet Connections for Industrial Gas Mixtures*, Compressed Gas Association, Inc., www.cganet.com
- [40] CGA G-6.9, *Dry Ice*, Compressed Gas Association, Inc., www.cganet.com

Appendix A—Example air separation unit hazard analysis and risk-based preventive control program

This appendix provides a hazard analysis for the air separation process. It is an example risk assessment for the manufacturing and storage of bulk oxygen, nitrogen, and argon as food gases.

The following are included in this Appendix:

- Table A-1—Air separation – Example air separation unit (ASU) HARPC
- Table A-2—ASU preventive controls management – Preventive controls management summary
- Table A-3—Process description – ASU process description
- Figure A-1—Process visualization – ASU process visualization

Notes to Table A-1

The following description provides the explanation for the number system in the Step # column:

- “##” (e.g., 1)—the base numbers represent the process step in the process visualization
- “##.All” (e.g., 1.All)—means this hazard would be applicable to all plant types
- “##.#” (e.g., 1.1)—means this hazard would be applicable to plants that implement this process/equipment type

The letter in the Biological, Physical, Chemical column indicates the type of contamination considered possible:

- B indicates biological
- C indicates chemical
- P indicates physical
- The lack of a letter indicates no risk exists of this type of contamination.

Table A-1—Example air separation unit HARPC

	Hazard identification (potential contamination types/considerations)			Hazard evaluation (potential consequences)			Preventive controls evaluation							Preventive controls				
Step #	Process step	Food safety hazard/process inputs	Biological Physical Chemical	Likelihood	Severity	Risk	Food safety risk?	Q1	Q2	Q3	Q4	Q5	Q6	Preventive control required for food safety? (Y/N)	Preventive control description (at this step of process for food safety)	Description of preventive controls and GMPs (at other process step(s) or overall process)	How does the control mitigate potential risk or support food safety?	References
1	Atmospheric Air																	
1.All	Air quality/ composition/ impurities	Impurities in the air feed which could end up in the final ASU products	C	3	1	3	N							N	None required	Process and equipment design; maintenance and/or operational procedures; may be identified in final product testing	Applies to local regulation. Check legal compliance. Site air analysis is part of process and equipment design considerations. Accidental release of contaminants, that would likely not be completely or adequately removed by the process, require operational procedures to address the risk, such as emergency notification.	CGA P-8 CGA P-8.2 CGA TR-3 [10, 11, 12]
1.All	Air quality/ composition/ impurities	Physical contamination in the air	B,P	3	1	3	N							N	None required	Process and equipment design; maintenance and/or operational procedures; may be identified in final product testing	Filtration captures particulate matter (physical debris, dust, insects, etc.) entering the ASU process.	CGA P-8 CGA P-8.2 CGA TR-3 [10, 11, 12]
1.All	Intentional adulteration of air intake	Unknown impurities intentionally added to cause harm	B,P,C	1	3	3	N							N	None required	Process and equipment design; maintenance and/or operational procedures; may be identified in final product testing; site security	Process and equipment design and operational procedures are designed to remove various types of contamination. Security restricts access.	CGA P-8 CGA P-50 [10, 13]

Hazard identification (potential contamination types/considerations)				Hazard evaluation (potential consequences)			Preventive controls evaluation							Preventive controls				
Step #	Process step	Food safety hazard/process inputs	Biological Physical Chemical	Likelihood	Severity	Risk	Food safety risk?	Q1	Q2	Q3	Q4	Q5	Q6	Preventive control required for food safety? (Y/N)	Preventive control description (at this step of process for food safety)	Description of preventive controls and GMPs (at other process step(s) or overall process)	How does the control mitigate potential risk or support food safety?	References
1.All	Accidental adulteration of air intake	Impurities accidentally released near air intake	B,P,C	1	3	3	N							N	None required	Process and equipment design; maintenance and/or operational procedures; may be identified in final product testing; site security	Process and equipment design and operational procedures are designed to remove various types of contamination. Security restricts access.	CGA P-8 CGA P-50 [10, 13]
1.All	Impurities which could be present in the nitrogen product	Hydrogen, helium, carbon monoxide, oxygen, moisture	C	2	1	2	N							N	None required	Operational procedures; final product testing; process and equipment design; maintenance procedures	Contaminants are vented or removed; non-condensable vent on high pressure column; molecular sieve adsorber; reversing heat exchanger and rich liquid adsorber	
1.All	Impurities which could be present in the oxygen product	THC, BTX, nitrous oxide, nitrogen oxides, carbon dioxide, water, dust	P, C	3	1	3	N							N	None required	Process and equipment design; maintenance and/or operational procedures; final product testing	Contaminants are removed; can include periodic analysis for THC & carbon dioxide; molecular sieve adsorber/filtration; reversing heat exchanger and rich liquid adsorber	CGA P-8 CGA P-8.2 CGA TR-3 CGA P-8.4 [10, 11, 12, 14]
1.All	Impurities which could be present in the argon product	Nitrogen, oxygen, THC, moisture	C	3	1	3	N							N	None required	Process and equipment design; maintenance and/or operational procedures; final product testing	Process and equipment design and operational procedures are designed to remove various types of contamination.	CGA P-8 [10]
1.1	Air inlet air: ambient air	Risks evaluated in 1.All; no additional issues	B,P,C															
1.2	Air inlet: third party air supply	Non-typical impurities in the air feed which could end up in the final ASU products	B,P,C	2	1	2	N							N	None required	Process and equipment design; maintenance and/or operational procedures; purchasing	Purchasing and supplier evaluation procedures ensure expectations are met	CGA P-8 CGA TR-3 [10, 12]

Hazard identification (potential contamination types/considerations)				Hazard evaluation (potential consequences)			Preventive controls evaluation							Preventive controls				
Step #	Process step	Food safety hazard/process inputs	Biological Physical Chemical	Likelihood	Severity	Risk	Food safety risk?	Q1	Q2	Q3	Q4	Q5	Q6	Preventive control required for food safety? (Y/N)	Preventive control description (at this step of process for food safety)	Description of preventive controls and GMPs (at other process step(s) or overall process)	How does the control mitigate potential risk or support food safety?	References
																and supplier evaluation procedures		
1.3	Air inlet: argon vapor recovery to air inlet	Impurities in the argon vapor which could end up in the final ASU products	C	1	1	1	N							N	None required	Process and equipment design; maintenance and/or operational procedures	Process and equipment design and operational procedures are designed to remove various types of contamination	CGA P-8 [10]
2	Filtration																	
2.All	Filter	Filter material enters the process	P	1	1	1	N							N	None required	Process and equipment design; maintenance and/or operational procedures	Routine maintenance and operations protect the integrity of the filters; can include differential pressure monitoring	CGA P-8 [10]
3	Compression																	
3.All	All compression	Oil enters the process	C	1	2	2	N							N	None required	Process and equipment design; maintenance and/or operational procedures	By current design, the oil is not in contact with the process. Cryogenic downstream conditions would not allow oil to reach final product storage.	CGA P-8 [10]
3.All	All compression	Water or glycol from coolers enters the process	B,C	2	2	4	N							N	None required	Process and equipment design; maintenance and/or operational procedures; may include final product testing	By current design, the water or glycol is not in contact with the process. Cryogenic downstream conditions would not allow water or glycol to reach final product storage.	CGA P-8 [10]

Hazard identification (potential contamination types/considerations)				Hazard evaluation (potential consequences)			Preventive controls evaluation							Preventive controls				
Step #	Process step	Food safety hazard/process inputs	Biological Physical Chemical	Likelihood	Severity	Risk	Food safety risk?	Q1	Q2	Q3	Q4	Q5	Q6	Preventive control required for food safety? (Y/N)	Preventive control description (at this step of process for food safety)	Description of preventive controls and GMPs (at other process step(s) or overall process)	How does the control mitigate potential risk or support food safety?	References
3.All	All compression	Contaminated seal gas enters the process	C	1	1	1	N							N	None required	Process and equipment design; maintenance and/or operational procedures; may include final product testing	Process and equipment design and operational procedures are designed to prevent and/or remove various types of contamination.	CGA P-8 [10]
3.All	All compression	Physical debris from the equipment enters the process	P	2	1	2	N							N	None required	Process and equipment design; maintenance and/or operational procedures; may include final product testing	Physical debris is removed from the process by downstream unit operations (multiple levels of filtration). Debris from the compressor itself would likely result in catastrophic failure and plant shutdown.	CGA P-8 [10]
4	Precooling																	
4.All	All precoolers	Physical debris from the equipment enters the process	P	3	1	3	N							N	None required	Process and equipment design; maintenance and/or operational procedures; may include final product testing	Physical debris is removed from the process by downstream unit operations (multiple levels of filtration).	CGA P-8 [10]
4.1	Direct contact cooler	Water carries over into the process	B,C	3	1	3	N							N	None required	Process and equipment design; maintenance and/or operational procedures; may include final product testing	Cryogenic downstream conditions would not allow water to reach final product storage.	CGA P-8 [10]
4.2	Indirect contact cooler	Water leaks in the process	B,C	3	1	3	N							N	None required	Process and equipment design; maintenance and/or operational procedures; may include final product testing	By current design, the water is not in contact with the process. Cryogenic downstream conditions would not allow water to reach final product storage.	CGA P-8 [10]

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