



CGA F-2—2017
GUIDELINE FOR FOOD
GASES PRODUCT HAZARD
ANALYSIS AND RISK-BASED
PREVENTIVE CONTROL
(HARPC) PROGRAM

FIRST EDITION

PLEASE NOTE:

The information contained in this document was obtained from sources believed to be reliable and is based on technical information and experience currently available from members of the Compressed Gas Association, Inc. and others. However, the Association or its members, jointly or severally, make no guarantee of the results and assume no liability or responsibility in connection with the information or suggestions herein contained. Moreover, it should not be assumed that every acceptable commodity grade, test or safety procedure or method, precaution, equipment or device is contained within, or that abnormal or unusual circumstances may not warrant or suggest further requirements or additional procedure.

This document is subject to periodic review, and users are cautioned to obtain the latest edition. The Association invites comments and suggestions for consideration. In connection with such review, any such comments or suggestions will be fully reviewed by the Association after giving the party, upon request, a reasonable opportunity to be heard. Proposed changes may be submitted via the Internet at our web site, www.cganet.com.

This document should not be confused with federal, state, provincial, or municipal specifications or regulations; insurance requirements; or national safety codes. While the Association recommends reference to or use of this document by government agencies and others, this document is purely voluntary and not binding unless adopted by reference in regulations.

A listing of all publications, audiovisual programs, safety and technical bulletins, and safety posters is available via the Internet at our website at www.cganet.com. For more information contact CGA at Phone: 703-788-2700, ext. 799. E-mail: customerservice@cganet.com.

Work Item 13-094
Food Gases Committee

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

FIRST EDITION: 2017

© 2017 The Compressed Gas Association, Inc. All rights reserved.

All materials contained in this work are protected by United States and international copyright laws. No part of this work may be reproduced or transmitted in any form or by any means, electronic or mechanical including photocopying, recording, or any information storage and retrieval system without permission in writing from The Compressed Gas Association, Inc. All requests for permission to reproduce material from this work should be directed to The Compressed Gas Association, Inc., 8484 Westpark Drive, Suite 220, McLean, VA 22102. You may not alter or remove any trademark, copyright or other notice from this work.

Contents	Page
1 Purpose	1
2 Scope	1
3 Definitions.....	1
4 Responsibilities	3
4.1 CGA guideline development.....	3
4.2 Company food safety team.....	3
4.3 Facility food safety team.....	3
5 Product description.....	3
5.1 Food gases specification	3
5.2 Shelf life.....	3
6 Intended use.....	3
7 Food gases production and distribution	4
7.1 Source streams	4
7.2 Storage and transfer.....	4
8 Process description	4
9 Process visualization.....	4
10 Hazard analysis and risk-based preventive controls.....	4
10.1 Globally accepted methodology	4
10.2 Risk classification	4
10.3 Risk index.....	5
10.4 Contamination types.....	5
10.5 Identification of risk-based preventive controls.....	5
10.6 Product/process hazard analysis	6
11 Food safety plan.....	6
11.1 Identified preventive controls.....	6
11.2 Parameters (control limits).....	6
11.3 Monitoring preventive controls.....	7
11.4 Corrective actions when monitoring results exceed control limits	7
12 Verification.....	7
12.1 Audit program	7
12.2 Validation.....	8
12.3 Hazard analysis and risk-based preventive controls program review	8
13 Recordkeeping	8
14 References	8
Appendix	
Appendix A—Example air separation unit hazard analysis and risk-based preventive control program	10
Appendix Tables	
Table A-1—Air separation unit (ASU) HARPC.....	10
Table A-2—ASU preventive controls management	27
Table A-3—Process description.....	28
Appendix Figure	
Figure A-1—Process visualization	29

This page is intentionally blank.

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. 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].

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.

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.

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