



GUIDANCE NOTE 14

**PRODUCTION, STORAGE, TRANSPORT
AND SUPPLY OF GASES
FOR USE IN FOOD**

REVISION 2: 2015

British Compressed Gases Association

GUIDANCE NOTE 14

PRODUCTION, STORAGE, TRANSPORT AND SUPPLY OF GASES FOR USE IN FOOD

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PREFACE

The British Compressed Gases Association (BCGA) was established in 1971, formed out of the British Acetylene Association, which existed since 1901. BCGA members include gas producers, suppliers of gas handling equipment and users operating in the compressed gas field.

The main objectives of the Association are to further technology, to enhance safe practice, and to prioritise environmental protection in the supply and use of industrial, food and medical gases, and we produce a host of publications to this end. BCGA also provides advice and makes representations on behalf of its Members to regulatory bodies, including the UK Government.

Policy is determined by a Council elected from Member Companies, with detailed technical studies being undertaken by a Technical Committee and its specialist Sub-Committees appointed for this purpose.

BCGA makes strenuous efforts to ensure the accuracy and current relevance of its publications, which are intended for use by technically competent persons. However this does not remove the need for technical and managerial judgement in practical situations. Nor do they confer any immunity or exemption from relevant legal requirements, including by-laws.

For the assistance of users, references are given, either in the text or Appendices, to publications such as British, European and International Standards and Codes of Practice, and current legislation that may be applicable but no representation or warranty can be given that these references are complete or current.

BCGA publications are reviewed, and revised if necessary, at five-yearly intervals, or sooner where the need is recognised. Readers are advised to check the Association's website to ensure that the copy in their possession is the current version.

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CONTENTS

Section		Page
	TERMINOLOGY AND DEFINITIONS	1
1.	INTRODUCTION	4
2.	SCOPE	4
3.	LEGAL BACKGROUND	5
3.1	The Food Safety Act	5
3.2	General Food Regulations	6
3.3	Hygiene Regulations	6
3.4	The Food Premises Regulations	7
3.5	Materials in Contact with Food Regulations	7
3.6	Labelling Regulations	8
3.7	Food Additives Regulations	10
4.	GENERAL REQUIREMENTS	11
4.1	Requirements for food premises	11
4.2	Health and safety	11
4.3	Management systems	12
4.4	Quality control & traceability	13
4.5	Hygiene requirements	13
4.6	Pest control	14
4.7	Training and qualifications	14
4.8	Transport	15
4.9	Hazard analysis system for food safety	15
4.10	Incidents	18
5.	BULK GAS PRODUCTION, STORAGE & DISTRIBUTION	19
5.1	Introduction	19
5.2	Scope	19
5.3	Requirements for food premises	20
5.4	Requirements in rooms where foodstuffs are prepared, treated or processed	20
5.5	Requirements for moveable and / or temporary premises, domestic premises, etc.	20
5.6	Transport & storage	20
5.7	Equipment requirements	22
5.8	Non-conforming product	23
5.9	Water supply	23
5.10	Personal hygiene	23
5.11	Provisions applicable to foodstuffs	23
5.12	Provisions applicable for wrapping & packaging of foodstuffs	23
5.13	Training	23

6.	GASES SUPPLIED IN TRANSPORTABLE PRESSURE RECEPTACLES AND CRYOGENIC RECEPTACLES	24
6.1	Introduction and scope	24
6.2	Requirements for food premises	24
6.3	Requirements in rooms where foodstuffs are prepared, treated or processed	24
6.4	Requirements for moveable and / or temporary premises, domestic premises, etc.	25
6.5	Transport & transportable receptacles	25
6.6	Equipment requirements	25
6.7	Non-conforming product	29
6.8	Water supply	29
6.9	Personal hygiene	29
6.10	Provisions applicable to foodstuffs	30
6.11	Training	30
7.	DRY ICE PRODUCTION, STORAGE AND DISTRIBUTION	30
7.1	Introduction and scope	30
7.2	Requirements for food premises	30
7.3	Requirements in rooms where foodstuffs are prepared, treated or processed	31
7.4	Requirements for moveable and/or temporary premises, domestic premises, etc.	32
7.5	Transport	32
7.6	Equipment requirements	32
7.7	Non-conforming product	33
7.8	Water supply	33
7.9	Personal hygiene	33
7.10	Provisions applicable to foodstuffs	34
7.11	Wrapping and packaging	34
7.12	Special conditions for certain processing operations	34
7.13	Training	34
8.	ON-SITE GAS GENERATORS	35
8.1	Introduction and scope	35
8.2	Requirements for food premises	35
8.3	Requirements in rooms where foodstuffs are prepared, treated or processed	36
8.4	Requirements for moveable and /or temporary premises, domestic premises etc.	36
8.5	Transport	36
8.6	Equipment requirements	36
8.7	Non-conforming product	36
8.8	Water supply	36
8.9	Personal hygiene	37
8.10	Provisions applicable to foodstuffs	37
8.11	Wrapping and packing	37
8.12	Training	37

9.	REFERENCES *	37
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APPENDIXES:

Appendix 1	Table of Product Specifications	42
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* Throughout this publication the numbers in brackets refer to references in Section 9. Documents referenced are the edition current at the time of publication, unless otherwise stated.

TERMINOLOGY AND DEFINITIONS

Batch	Whilst not defined within the Food Safety Act (1), a batch may be considered as a discrete, defined quantity whose characteristics can be proven e.g. it could be a number of cylinders filled on the same manifold at the same time, an isolated bulk storage tank or tanker or a period of continuous production from an air separation unit.
Beverage	Any potable liquid drink other than water. In the context of this guide it includes lager, ales and soft drinks.
Critical control point	Food safety step at which control can be applied and which is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.
Critical limit	The criterion which separates acceptability from unacceptability.
Food	Any substance or product, whether processed, partially processed or unprocessed, intended to be or reasonably expected to be, ingested by humans. Refer to Section 3.1.
Food additive	Any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may reasonably be expected to result, in it or its by-products becoming directly or indirectly a component of such foods". Refer to Section 3.7.

NOTE: This means a substance deliberately added to food for a technological purpose during any stage of its manufacture, processing, preparation, treatment, packaging, transport or storage. Such substances are not normally consumed as food nor used as characteristic ingredients, but their use results, or may reasonably be expected to result, in their becoming directly or indirectly a component of the foods to which they are added.

Food additives are assigned an E number indicating official approval for use for specified purposes and according to specified purity.

Functional classes of food additives include:

Packaging gas: Any gas, other than air, which is introduced into a container before, during or after the placing of a food in that container.

Propellant: Any gas, other than air, which expels a food from a container.

Food business	Any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food. Refer to Section 3.1.
Food gases	<p>Gases intended to be used as an ingredient, processing aid or as a food additive.</p> <p>Examples are gases used as food additives (packaging gases, propellants), processing aids (nitrogen for freezing) and gases used as ingredients (carbonation, hydrogenation of vegetable oils).</p>
Food premises	Premises used for the purposes of a food business. Refer to Section 3.1
Foodstuffs	A substance suitable for consumption as food.
Food waste	Any food gas which does not comply with the appropriate specification, or which is suspected of being contaminated.
Ingredient	<p>Any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; residues shall not be considered as 'ingredients'. Refer to Section 3.6.</p> <p>NOTE: Ingredient covers all components of a food, i.e. some substances can be an additive and an ingredient.</p>
Lot	Refer to 'batch'. A lot can be a complete batch, or it may be a specific identified portion of a batch.
May	Indicates an option available to the user of this Guidance Note.
Non Conforming Product	Any product with one or more characteristics failing to meet specified requirements.
Operation Pre-Requisite Programme	Identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards and / or the contamination or proliferation of food safety hazards in the product or processing environment.
Potable water	Water of drinking quality, safe for human consumption.
Preservatives	A substance that is added to products, such as foods, to prevent decomposition by microbial growth or by undesirable chemical changes.

Processing aid Any substance not consumed as a food by itself, intentionally used in the processing of raw materials, foods or their ingredients to fulfil a certain technological purpose during treatment or processing, and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the final product. Refer to Section 3.7.

A processing aid is not a food additive; an example is nitrogen for food freezing.

NOTE: Although gases used as processing aids are not defined as food, they must not render the food “injurious to health” or “unfit for human consumption”. Consideration must, therefore, be given to their impact on food safety.

Process-contact items Items of plant and equipment that may come into contact with food gases during production, storage, transport and use under closed system conditions. Specific hygiene arrangements are required when they are exposed during intrusive maintenance operations.

Shall Indicates a mandatory requirement for compliance with this Guidance Note and may also indicate a mandatory requirement within UK law.

Should Indicates a preferred requirement but is not mandatory for compliance with this Guidance Note.

GUIDANCE NOTE 14

PRODUCTION, STORAGE, TRANSPORT AND SUPPLY OF GASES FOR USE IN FOOD

1. INTRODUCTION

This Guidance Note has been prepared by the British Compressed Gases Association (BCGA) to provide advice to producers and suppliers of gases for use in food.

Gases are used for a variety of purposes in the food industry, this can include being used as additives, processing aids and ingredients. There are a plethora of regulations which impose specific requirements for quality control, purity criteria, labelling and hygiene.

The information contained within this Guidance Note provides advice to gas supply companies and end users on their legal obligations and to ensure food safety.

The laws relating to food safety may be either specific UK legislation or will enact European Directives or Regulations from the European Commission, which may be directly applicable.

The Food Safety Act (1) and the General Food Regulations (8) are the primary legislative instruments governing the obligations of food producers in the UK. The legislation lays down the food hygiene rules for all food businesses, applying effective and proportionate controls throughout the food chain, from primary production to sale or supply to the food consumer.

The basis for European food legislation is regulation EC 178/2002 (17). Article 3, sets out the general principles and requirements of food law and food safety. Companies that supply gases for food use are defined as food businesses and require compliance with all applicable food laws.

Whilst some guidance in this document will protect people from risks to their health and safety, this Guidance Note does not seek to address such issues. For general safe working practices check other BCGA publications and relevant health and safety legislation.

The European Industrial Gases Association (EIGA) provide further information on the use of gases in food in EIGA Document 125 (35), *Guide to the supply of gases for use in foods*.

2. SCOPE

This Guidance Note provides a summary of food legislation relevant to the use of gases together with advice on meeting these requirements.

It includes:

- A guide to risk assessment for food safety – Hazard Analysis Critical Control Points (HACCP).

- Guidance for businesses responsible for the production, storage, transport and delivery of food gases in bulk form.
- Guidance for businesses that fill, maintain or supply food gases in transportable pressure receptacles or cryogenic receptacles.
- Guidance for dry ice production, storage and distribution.
- Guidance for suppliers and users of on-site gas generators.

3. LEGAL BACKGROUND

The Food Standards Agency (FSA) is the government department responsible for food safety and food hygiene in the UK. Under the Health and Social Care Act (2) public health is the responsibility of local government. The FSA work with local authorities to enforce food safety regulations.

The Chartered Institute of Environmental Health (CIEH) is the professional voice for environmental health officers. The CIEH provide information, evidence and policy advice to local and national government, environmental and public health practitioners and set industry standards, accredit courses and award qualifications.

The following sub-sections explain the relevance of existing legislation in relation to the gases industry.

NOTE: The Regulations listed are those applying to England. Wales, Scotland and Northern Ireland have their own regulations, however the general principles will be similar. Your local national regulations should be checked if you are operating a food business in those geographical areas.

3.1 The Food Safety Act

The Food Safety Act (1) provides the framework for all food legislation in Great Britain – similar legislation applies in Northern Ireland. It is essentially enabling legislation, and lays down general food safety requirements. It also provides for offences and penalties. The Food Safety Act (1) enacts EC 178/2002 (17) which lays down the general principles and requirements of food law, food safety and establishes the European Food Authority.

The regulations define ‘food’ for the first time in European law and require that all food kept on food premises shall be presumed to be for human consumption unless specifically proven otherwise i.e. gases intended for sale for use in food have to be treated as foods.

Any product supplied for use in food, or as a food, has to comply with food safety requirements. A food can fail food safety requirements if:

- It has been rendered injurious to health;
- It is unfit for human consumption; or

- It is so contaminated (whether by extraneous matter or otherwise) that it would not be reasonable to expect it to be used for human consumption in that state.

Where any food fails to comply with the food safety requirements, and it is supplied as part of a batch, lot or consignment of food of the same class or description, then it is presumed that, until the contrary is proved, that all of the food in that batch, lot or consignment fails to comply with those requirements.

The EC 178/2002 (17) regulations:

- Lay down the general principles of food law.
- Establish the European Food Safety Authority.
- Include in the definition of ‘food’ any *substance* intentionally incorporated into the food during its manufacture, preparation or treatment.
- Set out requirements for traceability which is required at all stages of production, processing and distribution such that obligations on food businesses for product recall and withdrawal can be met.

These obligations are:-

- To identify from whom product was received.
- To identify to whom it was supplied.
- To supply this information to the competent authorities on demand.
- To have a procedure in place to withdraw non-conforming product from the market.

3.2 General Food Regulations

The General Food Regulations (8) provide for the enforcement of certain provisions of EC 178/2002 (17) (including imposing penalties) and amends the Food Safety Act (1) to bring it in line with EC 178/2002 (17).

3.3 Hygiene Regulations

The Food Safety and Hygiene (England) Regulations (13) implement EC 852/2004 (18), which sets out the general rules of hygiene for foodstuffs and the procedures for verification of compliance with these rules. It directly applies to food additives and ingredients because they are defined as foods although the basic principles indirectly apply to all food gases. The regulations set out particular requirements for:

- General requirements for food premises.
- Specific requirements for rooms where food is prepared, treated or processed.

- Moveable temporary premises.
- Transport.
- Equipment.
- Food waste.
- Water supply.
- Personal hygiene.
- Provisions applicable to foodstuffs.
- Wrapping and packaging.
- Heat treatment.
- Training.

In particular these regulations require that a food business should put in place, implement and maintain food safety programmes and procedures based on the Hazard Analysis and Critical Control Point (HACCP) principles. Refer to Section 4.9.

3.4 The Food Premises Regulations

The Food Premises (Registration) Regulations (3) and EC 852/2004 (18), Article 6, require the registration of food premises with local authorities. Therefore, all production and distribution premises, including production plants and cylinder filling depots, providing food gases shall be registered with the relevant registration authority.

Specific details can be obtained from the Environmental Health Department of the Local Authority.

The Authorities have to maintain an up-to-date database of food business establishments which have been registered with them, and food business establishments which have been approved or conditionally approved by them.

The food business operators are required to ensure that the appropriate authority always has up-to-date information on their food business establishments, and notifies the relevant competent authority of any significant changes of activities, a change of food business operator or closure. Notification of a change to the operator of a food business establishment should be made by the new food business operator.

3.5 Materials in Contact with Food Regulations

The Materials and Articles in Contact with Food (England) Regulations (11), which implement EC 1935/2004 (19), provide general guidelines to prevent the contamination of food by its packaging or by other materials in contact with it. Users are advised to

check for the acceptability of materials in contact with food gases and particular attention should be given to plastics and other polymers.

The regulations requires that food contact materials:

- are safe;
- shall not transfer their components into food in quantities that could endanger human health, change food composition in an unacceptable way or deteriorate its taste and odour;
- are manufactured according to good manufacturing practice;
- shall be labelled or bear the glass-and-fork symbol. This labelling is not obligatory if food contact is obvious by the article's nature e.g. knife, fork, wine glass;
- used for labelling, advertising and presentation shall not mislead consumers;
- shall have information provided on their appropriate use, if necessary;
- are traceable throughout the production chain.

For more information on how EIGA are considering European legislation on food contact materials, applied to food gases and food gas packaging refer to EIGA Position Paper 22 (40), *Food gases and Regulation No 1935/2004 on materials and articles intended to come into contact with food*.

3.6 Labelling Regulations

The Food Information Regulations (14) implement EC 1169/2011 (23) on the provision of food information to consumers.

The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations (12) implements European Regulation EC 1333/2008 (22) on food additives, and include a requirement for Lot marking for all foods.

The Food (Lot Marking) Regulations (5), which implement 89/396/EEC (16) on indications or marks identifying the lot to which a foodstuff belongs, require a lot marking indication on the container of the food or on a commercial document which accompanies the food, which shall in all cases appear in such a way as to be easily visible, clearly legible and indelible.

As well as complying with the various food regulations there are specific requirements for the marking and labelling of gas containers under the Carriage of Dangerous Goods and the Use of Transportable Equipment Regulations (10), which classifies gases as Class 2 dangerous goods.

All food gas containers shall also be marked and labelled in accordance with EC 1272/2008 (21) on the classification, labelling and packaging of substances and

mixtures (CLP). The CLP regulation is applicable to food gases as they are supplied for use in foods and are not supplied as a food in its finished state as intended for the final user.

Food labelling is a complex issue, but fundamentally requires that the label shall:

- not be misleading;
- be accurate, clear and easy to understand;
- not suggest that the food prevents, treats or cures a human disease.

In so far as food gases are concerned the following applies.

The main labelling provisions apply only to foods ready for delivery to the final consumer or to a catering establishment. Requirements are set out for labelling additives, e.g. packaging and propellant gases. The legislation has different requirements for business sales and consumer sales, but for food gases there is no practical difference.

In the limited number of applications where this is relevant to the gases industry, e.g. beverage dispense gases, the following labelling requirements apply:

- The name of the food.
- The name and/or E-number laid down in EC 1333/2008 (22) in respect of each food additive or a sales description which includes the name and/or E-number of each food additive, refer to Table 1;
- A list of ingredients.

NOTE: The requirement here is to indicate the components of a gas mixture or the pure gas identity.

- The statement 'for food' or the statement 'restricted use in food' or a more specific reference to its intended food use;
- Any special storage conditions or conditions of use.
- Information relating to the manufacturer or packer and/or seller established within the European Community:
 - Name or business name
 - Address or registered office.
- A mark identifying the batch or lot. The letter L must prefix the lot number. It may be on the container or accompanying documents.

NOTES:

- (1) The Lot number and name and address of the supplier need not be on the container but, if it is not, it must be on the accompanying paperwork.
- (2) The container is defined to include a vehicle in which the food additives, not being in any other container, are placed.
- (3) Processing Aids are stated to be outside the scope of food additives and are therefore excluded from EC 1333/2008 (22).

3.7 Food Additives Regulations

The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations (12) implements Regulation EC 1333/2008 (22) on food additives.

These regulations apply to gases with specifically defined uses. The relevant categories are:

- Packaging gases.
- Propellant gases.
- Preservatives.

The Purity Criteria for Colours, Sweeteners and Miscellaneous Food Additives (England) Regulations (9) implements Directive 2008/84/EC (20) laying down specific purity criteria on food additives other than colours and sweeteners. Directive 2008/84/EC (20), Annex 1, provides a list of all food additives.

The range of food gases are detailed in Table 1.

NOTE: There is an inconsistency insofar as hydrogen (E949) is concerned in that within Directive 2008/84/EC (20), Annex 1, the hydrogen purity is specified as not less than 99.9%, yet the nitrogen content is quoted as not more than 0.75 % v/v. BCGA believes that the nitrogen content quoted should be <750 ppm v/v.

The European Industrial Gases Association (EIGA) has published Quality Standards and Verification Criteria for CO₂:

- EIGA Document 68 (33), *Prevention of CO₂ backfeed contamination.*
- EIGA Document 70 (34), *Carbon dioxide source certification, quality standards and verification.*

Refer also to:

- BCGA CP 42 (42), *Implementation of EIGA carbon dioxide standards.*

Carbon monoxide (CO). CO or mixtures containing CO should not be supplied for food processing, refer to EIGA Briefing Note 12 (39), *Use of carbon monoxide (CO) and gas-mixtures with CO for the treatment of meat and fish.*

The gases in Table 1, with the exception of sulphur dioxide, are permitted as additives, *quantum satis*, (i.e. no more than is necessary to fulfil the technological function). Their addition to unprocessed foods is specifically permitted. This legislation permits no other gases as additives.

Gas	E Number
Sulphur Dioxide (SO ₂) (Permitted as a preservative/anti-oxidant in specified foods to specified levels).	E220
Carbon Dioxide (CO ₂)	E290
Argon (Ar)	E938
Helium (He)	E939
Nitrogen (N ₂)	E941
Nitrous Oxide (N ₂ O)	E942
Butane (C ₄ H ₁₀)	E943a
iso-Butane (C ₄ H ₁₀)	E943b
Propane (C ₃ H ₈) for limited applications, consult regulations for further details.	E944
Oxygen (O ₂)	E948
Hydrogen (H ₂)	E949

Table 1: Food gases

4. GENERAL REQUIREMENTS

4.1 Requirements for food premises

All food premises are required to register the premises with the environmental health service at the local authority; registration is free. If you have more than one premises, you will need to register each of them individually. The registration details provided to the Authorities have to be kept up-to-date, including any significant changes of activities, a change of food business operator or closure. Refer to Section 3.4.

4.2 Health and safety

With the exception of oxygen, all food gases, if released, may produce local oxygen deficient atmospheres, which will produce asphyxia if breathed. As a minimum the oxygen concentration in any space should be maintained above 19.5 %, this compares with 21 % oxygen in air in normal circumstances. A space containing a reduced oxygen atmosphere meets the criteria of a confined space within the meaning of the Confined Spaces Regulations (6). These require that employers carry out an adequate risk assessment and put in place appropriate control measures to protect those accessing or working in the area. For further information refer to the Health and Safety Executive

(HSE) document L101 (25), *Safe work in confined spaces. Confined Spaces Regulations 1997. Approved code of practice and guidance.*

In all areas where gases are stored, handled and used ensure that adequate ventilation is provided. BCGA Guidance Note 11 (44), *Reduced oxygen atmospheres. The management of risk associated with reduced oxygen atmospheres resulting from the use of gases in the workplace*, provides additional guidance that can be used in the assessment of risk associated with the use of gases in the workplace, on appropriate control measures to be considered at any workplace where gases are commercially produced, stored or used and, to identify where reduced oxygen atmospheres could occur.

Food gases may also have additional hazards, such as the toxic effects of carbon dioxide. It is a legal requirement that the gas supplier provides a Safety Data Sheet to the customer whenever a product is supplied for the first time. Employers have a responsibility to ensure that all personnel involved in the storage, handling or use of the product have the Safety Data Sheet made available to them and that they have suitable information and instruction to understand the all the potential hazards and associated risks involved.

The HSE provide guidance on the main health and safety hazards in the food and drink industries and give practical advice on how to manage the associated risks in their document HSG 252 (24), *A recipe for safety. Health and safety in food and drink manufacture.*

4.3 Management systems

All businesses should have in place an effective management system for controlling quality such as BS EN ISO 9001 (28), *Quality management systems – Requirements.*

A food business shall have a management system in place to identify and control hazards significant to the safety of food.

For a food safety system to be effective it should be established, operated and updated within the framework of a structured food safety management system and incorporated into the overall management activities of the organisation. This should provide maximum benefit for the organisation and allow for assurance by third parties, via an external audit process.

A food safety management system should have two key components:

- senior management engagement and commitment; and
- a Hazard Analysis and Critical Control Points (HACCP) based system (which will provide a step-by-step approach to managing food safety risks). Refer to Section 4.9.

Examples of food safety management systems include:

- The British Retail Consortium (BRC) – Global standard for food safety.

- BS EN ISO 22000 (29), *Food safety management systems. Requirements for any organization in the food chain.*
- Food Safety System Certification (FSSC) 22000, as recognised by the Global Food Safety Initiative (GFSI).

Food businesses should establish a Food Safety Policy with regard to identification, evaluation and control of risks related to food safety. The policy should define the scope of the food safety management system and shall be relevant to and in compliance with the business goals of the food business and the food safety requirements of customers, authorities and the food business itself.

Food businesses should ensure that the policy is understood, implemented and maintained at all levels of the organisation.

The Food Safety Policy should be a statement of commitment to ensure that the products are safe for use in food. The commitment shall be demonstrated by the implementation of an effective Hazard Analysis system, refer to Section 4.9.

4.4 Quality control & traceability

The food safety management system shall ensure that food gases meet specified requirements.

Where the gases are in the form of a gas mixture, they shall be based on component specifications, each of which complies with relevant legislation.

Appendix 1 provides information on the specification of food gases.

EIGA Document 126 (36), *Minimum specifications for food gas applications*, provides information on the minimum specifications for food gases.

All food gases shall be traceable to a ‘Registered Premises’, refer to Section 3.4.

Each food gas shall include a batch (lot) number, this may be the date of manufacture. For gases supplied in bulk this is normally indicated on the delivery documentation. The system shall enable suppliers of food gases to identify suspect products in case of customer complaint or quality failure in order to recall affected products. Refer to Section 3.6.

The food safety management system shall specify retention periods for records and calibration requirements for instruments and gauges. Refer to Section 4.3.

Gas suppliers may wish to consider the requirements of certain religious groups who may require assurance / certification that the products they are supplied with meet their particular religious beliefs, for example, that the food meets Halal or Kosher standards and therefore does not contain specific animal products.

4.5 Hygiene requirements

With the exception of dry ice, there is no physical contact between the gases supplied and the personnel employed in their manufacture. Therefore, it is not necessary to

implement specific food hygiene procedures. Good personal hygiene practices should be encouraged at all times, however, it is particularly important during maintenance activities of process-contact items. Documented hygiene procedures should be established and implemented.

For further information on dry ice, refer to Section 5.

4.6 Pest control

The food business shall, if defined in the applicable HACCP study on the basis of identified risk, establish appropriate arrangements for the control of pests within the Food Premises and should hold documentary evidence of the measures taken. They may include:

- Preventive measures Good housekeeping practices not allowing the build-up of waste materials and other debris that may encourage vermin or other pests.
- Maintenance Inspections and audits to verify the effective implementation of preventive measures.
- Monitoring Surveys by pest control experts.

Bulk storage areas should be maintained in an appropriate way to prevent contamination of the product. Gas cylinders should be stored and managed in a manner that ensures that they will be delivered in a clean state, compatible with the environment in which they will be used.

4.7 Training and qualifications

All personnel directly involved in the commissioning, operation and maintenance of equipment associated with food gases shall receive suitable information and instruction regarding the hazards associated with these gases and proper training as applicable to the safe operation and maintenance of the equipment.

All staff who are involved with food gases should have the necessary skills and knowledge to carry out their job safely and are to have received appropriate training, including induction and continuation training. Such training shall be both theoretical and practical. It is the duty of the employer to ensure their persons are adequately trained and to establish competency. It is recommended that a training programme is carried out under a formalised system where an acceptable level of competency has to be achieved. Records shall be kept of the training provided and the competence level achieved. The training programme shall make provision for periodic re-training.

Recommendations for the training of personnel are described in EIGA Document 23 (31), *Safety training of employees*. BCGA GN 23 (45), *Identifying gas safety training requirements in the workplace*, provides information on some of the many topics which should be covered when considering gases safety training.

The level of training in food hygiene given to personnel employed on food gas production will be appropriate to their activities. Where personnel are likely to have direct contact with equipment, for example, receptacle filling operations, personnel will

require instruction in the awareness of a basic level of hygiene. This should include personal hygiene standards including the reporting of illness, awareness of food hazards associated with the business (such as visible contamination or damage to receptacles) and an awareness of the hazard from pests.

Personnel are to receive adequate training in the application of HACCP principles commensurate with their responsibilities.

4.8 Transport

Product distribution shall comply with appropriate UK legislation covering transport of dangerous goods. The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (10) regulates the transport of dangerous goods in the UK and implements the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) (15).

ADR (15) provides a framework for dangerous goods to be carried internationally on road vehicles subject to compliance with standards for the packaging and labelling of the dangerous goods, and appropriate construction and operating standards for the vehicles and crew. Gases are classified as Class 2 dangerous goods.

All gas cylinders and bulk tankers containing food gases will be identified as being suitable for use with food, either through labelling or within the transport documentation.

BCGA GN 27 (46), *Guidance for the carriage of gas cylinders on vehicles*, provides further information on the transport of gas cylinders.

4.9 Hazard analysis system for food safety

4.9.1 Hazard analysis

The food hygiene regulations (refer to Section 3.3) require food businesses to conduct a hazard analysis of the process. The gases industry recognises Hazard Analysis and Critical Control Points (HACCP) as its preferred method. HACCP is a food safety risk assessment system that helps food business operators determine how they handle food in a systematic way and introduces procedures to make sure the food produced is safe.

Suitable HACCP procedures shall comply with Codex Alimentarius and examples are described in documents published by:

- Campden BRI. *HACCP - A Practical Guide* (50).
- Leatherhead Food Research Association. *HACCP: A Toolkit for Implementation* (51).
- British Retail Consortium, *Food Industry Guide to Good Hygiene Practice: Retail* (52)

NOTE: The Codex Alimentarius Commission, established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health

Organisation (WHO) in 1963, develops harmonised international food standards, guidelines and codes of practice to protect the health of the consumers and ensure fair practices in the food trade. The Commission also promotes coordination of all food standards work undertaken by international governmental and non-governmental organizations.

Food gas businesses shall implement and maintain a documented system of HACCP to ensure that all known potential risks within the field of application of the HACCP are identified and that all relevant risks are controlled in such a manner that the products supplied by the business do not harm the user/consumer. The system shall include the seven principles of HACCP:

- (i) The identification of any hazards that must be prevented, eliminated or reduced to acceptable levels.
- (ii) The identification of any critical control points (CCPs) and / or an Operational Pre-Requisite (OPR) programme at the step, or steps, at which control is essential to prevent or eliminate the hazard or to reduce it to acceptable levels.
- (iii) The establishment of critical limits or requirements at each of the CCP and / or OPR, which separate acceptability from unacceptability for the prevention, elimination, or reduction of identified hazards.
- (iv) The establishment and implementation of effective monitoring procedures at the critical control points.
- (v) The need to take corrective action when monitoring indicates that a critical control point is not under control.

For each CCP, remedial measures shall be established to ensure that, in the event of a deviation from critical limits, the CCP is brought back under control and that any products manufactured while the CCP was out of control are handled appropriately.

Procedures for Control of Non-conforming Product, Product Recall and Critical Action Planning should be established.

- (vi) Procedures to verify that the measures outlined above are working effectively.

These procedures may include formal auditing of the Hazard Analysis system. Auditors should have specific knowledge of HACCP principles and basic knowledge of the process being audited. This may necessitate a team audit where a single person does not have the necessary skills.

International Life Sciences Institute (ILSI) Report, *Validation and Verification of HACCP* (49) provides guidance on suitable verification measures.

(vii) Documents and records commensurate with the nature and size of the business shall be kept to demonstrate the effective application of the measures outlined above.

4.9.2 HACCP considerations

The HACCP will give consideration to such issues as:

- The selection of appropriate parts and equipment.
- The selection of appropriate supplies including cleaning agents.
- The identification of items of critical plant.
- Action to be taken in the event of contaminated raw materials.
- Design controls, e.g. significant protection from entry of contamination, location of critical equipment such as air intake etc.
- Authority procedures / assigned responsibility for change control.
- Contamination, such as microbial, physical and chemical agents.

NOTE: For further information on the potential for microbial contamination of gases refer to EIGA TB 02 (38), *Microbiological quality of medical, pharmaceutical and food grade gases*.

- Control of non-conforming product – quarantine, product recall, quality assurance (QA) procedures.
- Training for personnel commensurate with the potential of their job specification's ability to impact on food safety. Refer to Section 4.7.
- The application of food gas standard product specifications & other industry guidelines.

4.9.3 Scope and responsibilities for HACCP

The product supply chain will determine the scope of the HACCP system.

Where the food gas business has full control of a process, the HACCP study will be the responsibility of the food gas business and shall be specific to the premise/process – this does not preclude the use of generics, providing specific elements are covered.

Suppliers of raw materials to food gas businesses are in themselves food businesses and as such are responsible for conducting the HACCP of their own undertakings to minimise the risk to food safety. Similarly, equipment suppliers should endeavour to make their equipment suitable for use with food.

Food gases businesses should ensure that suitable supplier verification procedures are established to ensure that their suppliers fulfil their obligations with respect to

food safety. They should also hold documented evidence of verification activities (such as supplier audits) relevant to the elements outside their control.

For carbon dioxide third party audit processes refer to BCGA CP 42 (42).

4.9.4 Review of HACCP

Food businesses shall ensure that HACCP studies are reviewed and maintained. The HACCP shall be reviewed at planned intervals, it is recommended that this is carried out at least every 18 months, or sooner where there have been changes to plant, equipment, materials and / or processes that may impact on the integrity of the product with respect to its suitability for food use.

4.10 Incidents

In accordance with the Food Safety Act (1), businesses are legally required to inform their local authority / port health authority and the Food Standards Agency if there is reason to believe that food or feed is not compliant with food or feed safety requirements. The authorities will advise any actions that they require.

Information about food safety incidents and who to notify can be found on the Food Standards Agency website at:

<https://www.food.gov.uk/business-industry/food-incidents>.

If businesses have reason to believe a food is unsafe, then the food should immediately be withdrawn or, if necessary, recalled.

If the products do not meet food standards requirements, such as labelling or quality issues, where there is no safety issue, then you might wish to ensure that products are withdrawn, rather than face potential prosecution.

To enable and facilitate the complete and timely withdrawal of batches of end products which have been identified as unsafe:

- top management shall appoint personnel having the authority to initiate a withdrawal and personnel responsible for executing the withdrawal; and
- the organization shall establish and maintain a documented procedure for:
 - notification to relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers);
 - handling of withdrawn products as well as affected lots of the products still in stock; and
 - the sequence of actions to be taken.

Withdrawn products shall be secured or held under supervision until they are destroyed, used for purposes other than originally intended, determined to be safe for the same (or other) intended use, or reprocessed in a manner to ensure they become safe.

The cause, extent and result of a withdrawal shall be recorded and reported to top management as input to the management review.

The organization shall verify and record the effectiveness of the withdrawal programme through the use of appropriate techniques (e.g. mock withdrawal or practice withdrawal).

5. BULK GAS PRODUCTION, STORAGE & DISTRIBUTION

5.1 Introduction

This section concerns the large-scale production of gases suitable for use in food and their distribution via bulk road tanker, as either a cryogenic liquid or as a pressurised gas, into bulk storage. From storage the gas may be used either by food producers or by gas suppliers for the production of other gas products, e.g. filling into food gas cylinders or production of dry ice.

The bulk gas production process will be dependent on the particular product but stages will typically involve feed gas intake (air in the case of oxygen, nitrogen or argon production), pre-treatment, purification, liquefaction and production site storage.

Bulk gas production is carried out in closed, pressurised equipment often operating for extended periods of time. This ensures that the risk of environmental contamination of the product is negligible. Particular attention should be paid, however, to the identification and control, through the use of HACCP, of potential hazards resulting from cross contamination with other products, transfer operations and during shutdown/start-up and intrusive maintenance. BCGA CP 42 (42), provides particular information for producers and distributors of bulk carbon dioxide.

NOTE: BCGA members are required to have third party audits on the supply of bulk carbon dioxide, refer to BCGA CP 42 (42).

Bulk gas products are generally manufactured to a single specification and quality level suitable for all intended applications, including use in food. At the point in the distribution chain that the product is supplied only for use in food, it should be marked and labelled accordingly.

5.2 Scope

This section provides guidance for the hygienic production, storage and distribution applicable to the following bulk liquefied and compressed gases:

- Oxygen.
- Nitrogen.
- Carbon Dioxide.
- Argon.
- Helium.
- Nitrous Oxide.

- Hydrogen.

It covers:

- Production and transport of these gases for direct use.
- Storage: intermediate and at customer premises, for transfer to other containers.
- Distribution (tankers, customer tanks and transfers).

HACCP is fundamental to all stages covered by this section.

5.3 Requirements for food premises

Bulk food gases are produced, stored and transported in fully enclosed, pressurised systems. The possibility of contamination at the premises to the product is therefore negligible. The emphasis is placed on good manufacturing practices to maintain the integrity of the product during all stages of the supply chain.

Premises should be designed and constructed to ensure that cleaning and maintenance operations can be carried out effectively to minimise the risk of contaminating product.

By their nature, bulk gas production plants are not typical food premises and many of the traditional food safety and hygiene controls will not be required. The HACCP will determine the extent of control required to ensure that appropriate standards of food hygiene are maintained.

For installations on customer sites, the gas supplier, in conjunction with the customer, should agree the identification of a suitable location on the food premises for the siting of product storage vessels and the vehicle off-loading area. The customer is responsible for ensuring that the location meets the requirements for food safety and is also responsible for the upkeep of food hygiene standards around the tank and equipment.

5.4 Requirements in rooms where foodstuffs are prepared, treated or processed

Consideration should be given as in Section 5.3.

No specific requirements are necessary for bulk gases beyond those required by Workplace (Health, Safety and Welfare) Regulations (4).

5.5 Requirements for moveable and / or temporary premises, domestic premises, etc.

There are no relevant applications in the food gases industry.

5.6 Transport & storage

5.6.1 Prevention of cross contamination and product security

Food gas businesses shall consider the use of appropriate precautions to ensure that the correct product is delivered into the correct delivery point.

Tanks and tank containers will normally be allocated to a single product and marked and labelled accordingly. These tanks and tank containers should be fitted with couplings specific to the type of gas being transported. The gas supplier may also consider the installation of additional control measures such as anti-confusion couplings or alternative means of ensuring that cross-contamination does not occur.

BCGA CP 42 (42) provides particular information for producers and distributors of bulk carbon dioxide to help prevent cross-contamination.

During the transport journey all drivers shall take account of the security provisions within ADR (15), [Section 1.10].

5.6.2 Gas service conversions

In the event of the need for conversion of the tanker from one gas service to another, documented procedures shall be established and implemented to ensure that the gas in the tank, after the change of service, is suitable for food use. Procedures will include such control measures as:

- analytical checks for possible contaminants - the previous contents will have a bearing on the analytes; and
- purging with an appropriate food gas.

5.6.3 Hygiene controls & product integrity

Each food gases business should have in place procedures that will ensure that the integrity of the product is maintained throughout the transfer process. The risk of tankers becoming contaminated during delivery is controlled by means of engineering and / or procedural arrangements. These should be clearly documented as part of the HACCP.

Such controls may include:

- Hoses protected from ingress of contamination, e.g. the use of end caps.
- Purging prior to delivery.
- Common good handling and house-keeping practices, such as not dragging hose ends on the ground.

All bulk tankers containing food gases will be identified as being suitable for use in food, either through labelling or within the transport documentation. Vehicle cleanliness procedures shall be established in order to maintain their fitness for food use. Particular attention should be paid to tanks and tankers undergoing intrusive maintenance. Procedures should be established to ensure the cleanliness of such tanks and equipment prior to their return to service and that contamination of the food cannot occur.

NOTE: All bulk gas manufacturing plants will be configured to provide gases which will meet the specification for food gases. Only at the point of loading into the customer tank is it designated as a food gas.

In addition each load delivered to a food premise shall be accompanied by:

- A statement confirming that the product is suitable for use in food.
- Details of lot traceability.

5.6.4 Control of non-conforming product

For the reasons given in Section 5.1, tankers used for the transport of foodstuffs can also be used for transporting product to a non-food application. An exception to this is where product may be suspected or proved to be not meeting the requirements for use in food in which case special controls established for non-conforming product shall be implemented.

5.7 Equipment requirements

5.7.1 Design

Production plant & equipment used for producing more than one product shall be designed to ensure no cross product contamination can occur.

The equipment used to manufacture and store food gases is designed to operate as a closed, pressurised system for continuous operation over many years, thus retaining its commissioning state of cleanliness.

Equipment selection should be such that such equipment, or maintenance of it, does not introduce food safety hazards, e.g. consideration should be given to eliminating or minimising the need for physical entry into the system. When it is necessary to “break in” to the system for maintenance or inspection, documented procedures should be in place to ensure equipment is clean and will not compromise product integrity when returned to service. This may be incorporated into a Permit to Work system

Validation of cleanliness may involve product analysis to ensure that foreseeable contaminants introduced during the maintenance procedures have been removed and that the product in final storage meets the required specification.

5.7.2 Materials of construction

Materials of construction shall be compatible with both the product and the manufacturing process and shall not introduce contaminants that would present a risk to food safety.

Formalised systems should be in place specifying process-contact items and to ensure that when equipment is transferred from one service to another, or new equipment is stored or installed, cleanliness is assured and / or maintained.

Formal change control systems should ensure that, whenever repairs or modifications are made to plant and / or equipment, consideration is given to their

impact on food safety. Where appropriate it may be necessary to review and revise the HACCP study.

If a tank becomes inadvertently depressurised, it shall be quarantined and considered unfit for food service until it is brought back into service under the control of the food safety management system in accordance with documented re-commissioning procedures.

5.7.3 Quality control and traceability

Food gases are produced under batch control. A batch may be a distinctly isolated storage tank or a defined period of production. For general quality control requirements, refer to Section 4.4.

5.8 Non-conforming product

Food waste is defined as bulk liquid product that has been recovered from a customer's tank, which should be collected and handled in accordance with formalised non-conforming product procedures, refer to Section 5.6.4.

5.9 Water supply

The HACCP study will identify waters used in the process together with any associated hazards and controls. Where the water comes into contact with the gas then it is necessary to specify potable water or alternative control measures.

Any water used during hydraulic testing should be of potable water quality and used only once to prevent possible contamination.

5.10 Personal hygiene

For personal hygiene requirements, refer to Section 4.5.

5.11 Provisions applicable to foodstuffs

No special provisions apply.

For general requirements, refer to Section 4.9, Hazard Analysis.

5.12 Provisions applicable for wrapping & packaging of foodstuffs

Tanks used for the storage and transport of food gases shall be considered to be wrapping and or packaging, as they are in direct contact with food and provide adequate protection.

For the design, use and maintenance elements of the wrapping and packaging with relation to hygiene, refer to Section 5.7, Equipment Requirements.

5.13 Training

For training requirements refer to Section 4.7.

The training in food hygiene and hazard control given to personnel employed on food gas production will be commensurate with their activities.

6. GASES SUPPLIED IN TRANSPORTABLE PRESSURE RECEPTACLES AND CRYOGENIC RECEPTACLES

6.1 Introduction and scope

This section includes the following activities for the supply of transportable packaged gases to the food industry:

- Specification of receptacles and valves.
- Filling procedures.
- Quality control and traceability.
- Distribution.
- Training.

The overall process of receptacle filling for food gases shall be the subject of a formalised HACCP review. Particular attention should be paid, however, to the identification and control of potential hazards resulting from cross contamination with other products, transfer operations and during shutdown / start-up and intrusive maintenance. The HACCP must also take into account the probability of contamination being introduced at customer sites.

6.2 Requirements for food premises

Since the filling of receptacles with gases for use in the food industry does not expose the gases to the environment or to the personnel carrying out the work many of the practices used in typical food premises are inappropriate.

However, the importance of maintaining the areas where food gases are filled in a reasonably clean condition is acknowledged, and rooms where receptacles are filled, and the filling equipment itself should be designed such that the area around it can be cleaned and does not allow the accumulation of contaminants. This will involve regular floor sweeping, and a degree of pest control, refer to Section 4.6. Individual cases may require a formal risk analysis where particular circumstances or adverse environmental conditions apply.

The provision of an adequate number of facilities to encourage appropriate standards of personal hygiene, for example, washbasins dedicated for hand cleaning, should be provided.

6.3 Requirements in rooms where foodstuffs are prepared, treated or processed

Consideration should be given as detailed in Section 6.2.

No specific requirements are necessary for the rooms where receptacles are filled beyond those required by Workplace (Health, Safety and Welfare) Regulations (4).

6.4 Requirements for moveable and / or temporary premises, domestic premises, etc.

No specific requirements are necessary since the food gases are stored and transported in fully enclosed, pressurised systems and purging takes place prior to the transfer of product. The possibility of contamination by delivery vehicles filling outside a customer's registered food premises is therefore negligible. If however, the hygiene and cleanliness is not as expected of a receptacle filling environment, specific attention will be paid to the cleaning of the connections prior to carrying out the filling process since this is the only point where contamination can be introduced.

6.5 Transport & transportable receptacles

Supply arrangements to the user shall ensure that the appropriate information, including an appropriate Safety Data Sheet, is supplied when any product is delivered for the first time to any user. This should include appropriate instructions on the proper use of the food gas.

Customer risk assessments should identify suitable locations for receptacles. Refer to BCGA CP 44 (43), *The storage of gas cylinders*.

Documentation and labelling required for supply shall distinguish clearly between food and industrial gases. Refer to Section 3.6.

Gas cylinders containing products should not be exposed to extreme temperatures. The individual gas suppliers can supply information on their cylinders.

There is no need to consider any other kind of temperature control, as temperature has no effect on the food safety characteristics of food grade gases.

6.6 Equipment requirements

Equipment used for the production of packaged food gases shall be subject to a formal maintenance schedule. Records of equipment inspections and any remedial actions should be maintained.

6.6.1 Receptacles and valves

(i) Materials of construction shall be compatible with both the product and the manufacturing process and shall not introduce contaminants that would present a risk to food safety.

(ii) Formalised systems should be in place specifying receptacles and valves and to ensure that when equipment is transferred from one service to another, or new equipment is stored or installed, cleanliness is assured and/or maintained.

(iii) Formal change control systems should ensure that whenever modifications are made to plant and / or equipment consideration is given to their impact on food safety. Where appropriate it may be necessary to review and revise the HACCP study.

(iv) If a receptacle becomes inadvertently depressurised, then it shall be quarantined and considered unfit for food service until it is brought back into service in accordance with a documented re-commissioning procedure.

(v) Receptacles are designed and manufactured to the standards required in the Carriage of Dangerous Goods and Use of Transportable Equipment Regulations (10) – before their use with foodstuffs they shall be subject to controls identified by the HACCP to ensure hygiene and cleanliness.

(vi) Valves used for food gas applications follow international design codes. However it is strongly recommended that valves fitted to pressure receptacles for food use should be a residual pressure valve (RPV) incorporating a non-return valve. For additional guidance refer to EIGA Document 64 (32), *Use of residual pressure valves*.

Where fitting an RPV is impractical, as in the case of transportable cryogenic receptacles, a level of protection equivalent to that provided by an RPV should be incorporated into the design of the customer installation.

(vii) Before any receptacles are introduced to food gas service, unless they are new and certified as being suitable for food service, they shall be de-valved, internally inspected in accordance with the appropriate documented procedure, cleaned as necessary and preferably fitted with an appropriate RPV.

The external condition shall be assessed and clean. The receptacles should be painted in accordance with the guidelines in BCGA TIS 6 (47), *Cylinder identification. Colour coding & labelling requirements*.

Any valve protection fitted (guard or cap) shall be suitably clean.

(viii) When receptacles are subjected to their periodic inspection and test, which shall be in accordance with documented procedures, any water used during the test should be of potable quality and used once only, to prevent possible internal contamination of the receptacle. The receptacles shall be dried internally prior to filling.

6.6.2 Pre-fill inspection

Before filling receptacles for food gases a pre-fill inspection shall be carried out. For pressure receptacles, this shall conform to the requirements of the following international standards:

- BS EN 1919 (26), *Transportable Gas Cylinders. Cylinders for liquefied gases (excluding acetylene and LPG). Inspection at time of filling.*
- BS EN 1920 (27), *Transportable Gas Cylinders. Cylinders for compressed gases (excluding acetylene). Inspection at time of filling.*
- BS ISO 24431 (30), *Gas cylinders. Cylinders for compressed and liquefied gases (excluding acetylene). Inspection at time of filling.*

NOTE: BS ISO 24431 (30) is being revised and will in due course incorporate information on the inspection at time of filling for liquefied and compressed gases, and cylinders of composite construction. BS EN 1919 (26) and BS EN 1920 (27) will then be withdrawn.

The inspection shall include the following:

- The external condition shall be checked to ensure that the transportable receptacle is free from damage or excessive corrosion and that it is suitably clean prior to filling – previous batch labels should be removed or rendered illegible.
- Any painting (taking suitable care to protect the valve) shall be completed before filling commences. Pressure receptacles fitted with a dip-tube shall be clearly identified. The specific functions of valves on transportable receptacles should be clearly identifiable.
- The valves shall be inspected and shall be clean and free from any external contamination or damage before filling commences.
- The receptacles shall be within their due date for inspection and re-test.
- The compatibility of the receptacles and their valves with the intended gas fill shall be checked. This is particularly important when oxygen is to be filled.
- The safe filling pressure of receptacles shall be established for the gas service and checked against the intended filling pressure. BCGA CP 32 (41), *The safe filling of beverage gas cylinders*, specifies safe filling procedures and provides information on pressures for CO₂ and mixed gas receptacles for use in beverage dispense applications.
- The functionality of the RPV, where fitted, shall be checked. For receptacles not fitted with an RPV a check of the residual pressure should be made. Where the residual pressure is zero or very low, procedures shall be established to ensure that the receptacles are free from contamination and appropriate control measures should be employed, such as purging or internal inspection before filling.
- Unless positive confirmation is made that the receptacle is already in food gas service, then the quarantine procedure, as per Section 6.6.1.(iv), shall be applied.

6.6.3 Filling – general

During any filling process the receptacle valve shall be checked for leakage, paying particular attention to glands. After the filling process is complete and the receptacle disconnected, ensure that no gas is escaping through the valve.

Dedicated filling equipment for food gases is not necessary. However batches of food gas receptacles (or receptacles containing food gases) shall be kept separate from receptacles designated for non-food applications. The HACCP shall establish the controls required to prevent cross-contamination between food and non-food gases.

Prior to commencing the filling process for food gases the filling connections shall be inspected for cleanliness and shall be free of all external contamination.

A formalised product specific procedure shall be in place for all filling operations for food gas receptacles specifying fill quantities (pressure / temperature or weight) and the sequence of operations.

6.6.3.1 Specific requirements for filling pressure receptacles - liquefied gases

Liquefied gas pressure receptacles (particularly CO₂) become cold during filling and it is therefore strongly recommended that all labelling be completed prior to filling – refer to Section 6.6.3.4, post-fill.

6.6.3.2 Specific requirements for filling pressure receptacles - compressed gases

Due to the potential for contaminated gas being returned from the customer, consideration shall be given to appropriate methods for preserving product integrity such as:

- Fitting an RPV.
- Purging receptacles which do not have an RPV fitted.
- Complete venting and evacuation of the receptacle of any residual compressed gases.

Where an RPV is fitted, attention is drawn to the practicalities of top-filling gas mixtures with respect to preserving gas mixture integrity.

For the filling of beverage gas cylinders refer to BCGA CP 32 (41).

During filling a check should be made that the receptacles are becoming warm. A cold receptacle may indicate a blocked valve which should then be investigated.

6.6.3.3 Specific requirements for filling - cryogenic receptacles

Cryogenic receptacles can be filled by weight or by filling to the full try-cock.

Great care is necessary to ensure that the correct product is filled into the receptacle – this may be achieved by the fitting of gas specific couplings or similar protective devices. In the event of the need for the conversion of the receptacle from one gas service to another, documented procedures shall be established and implemented to ensure that the gas in the receptacle, after

the change of service, is suitable for food use. Procedures will include control measures such as:

- Analytical checks for possible contaminants (the previous contents will influence these checks).
- Purging with appropriate food gas.

It is essential to ensure that labelling and product identification operations are complete before filling with the new product.

If there is uncertainty about what has been in the receptacle, it shall be quarantined and its contents shall be analysed against the relevant product specification prior to supply.

6.6.3.4 Post-fill inspection

Pressure receptacles for industrial applications shall be segregated from those containing food gases. Receptacles should be checked for product leakage, correct labelling and product identification.

- Lot labels shall be fitted to the receptacles. Refer to Section 3.6.
- As the receptacles will be used in a food premises the exterior of the receptacle has to be clean with an acceptable finish.

Receptacles ready for dispatch should be stored in such a way as to prevent any accumulation of debris that may provide a refuge for pests. This will also provide benefits in stock rotation and safety. Refer to BCGA CP 44 (43).

6.6.3.5 Quality control and traceability

For general quality control requirements, refer to Section 4.4.

After all quality control checks have been carried out satisfactorily receptacle valve outlets shall be plugged or capped. A tamper proof seal or cover is recommended as this will indicate to the end user that the cylinder has not been used, and will have the benefit of preventing contamination. The receptacles may then be released for dispatch to the customer.

6.7 Non-conforming product

Any food gas which does not comply with the appropriate specification, or which is suspected of being contaminated, shall not be used as a food product.

6.8 Water supply

The only relevant process is the water used during the (periodic) inspection and test of the receptacle, where the use of potable water is required.

6.9 Personal hygiene

For personal hygiene requirements, refer to Section 4.5.

6.10 Provisions applicable to foodstuffs

The bulk gases used for receptacle filling shall be in accordance with the requirements of recognised food gas product quality standards.

The HACCP will give due consideration to any additional controls required to ensure product integrity.

For general requirements, refer to Section 4.9, Hazard Analysis.

6.11 Training

For training requirements, refer to Section 4.7.

7. DRY ICE PRODUCTION, STORAGE AND DISTRIBUTION

7.1 Introduction & scope

‘Dry ice’ is the gases industry term for solid carbon dioxide. It is a translucent white material that at a temperature of $-78.4\text{ }^{\circ}\text{C}$ sublimates to cold carbon dioxide gas as it absorbs heat. Dry ice is made by expanding liquid carbon dioxide to atmospheric pressure - this produces ‘snow’, solid flakes, which normally is compressed into one of several different forms - large blocks, slices or small cylindrical pellets. The product is generally packed into plastic, paper or composite bags that are stored and transported in insulated containers. However, some products (particularly pellets) can also be supplied ‘loose’ in containers, with no primary packaging.

Dry ice has no nutritional value to animals, insects or micro-organisms and is therefore a low-risk food product. However, at the point-of-use it is often used as a cooling medium and added directly to other high-risk foods, such as raw meat, so it is important to consider its possible role as a carrier of contamination. In the gases industry, it is the only solid product and one of the few that is not kept in a closed pressurised system. Accordingly, it requires a more rigorous approach to hygiene than bulk or packaged products.

This guide covers the supply chain of all dry ice products, from the receipt of bulk liquid carbon dioxide to the delivery of finished products to end-users.

BCGA TIS 7 (48), *Guidelines for the safe transportation, storage, use and disposal of dry ice products*, provides further information on dry ice.

7.2 Requirements for food premises

Food premises are to be kept clean and maintained in good repair and condition. Floors, walls and ceilings should be constructed from suitable easily cleanable materials. Documented cleaning and preventive maintenance schedules should be established and appropriate records maintained.

The layout shall ensure adequate access for cleaning and maintenance and should allow, as far as possible, for finished product to be separated from manufacturing machinery (e.g. hydraulic systems) to prevent contamination.

There is to be suitable and sufficient means of natural or mechanical ventilation, with appropriate screening to prevent pest ingress. If forced air ventilation is installed it must be constructed such as to prevent the introduction of contaminated air into the premises and consideration should be given to filtering the air at intake points. Consideration should be given to control measures for pest ingress when ventilation systems are shut down, i.e. at the end of production, such as fly screens or self-closing louvres. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.

Adequate cleaning facilities shall be available e.g. pressure washers and/or steam hoses. All water for washing purposes shall be of potable quality. Cleaning agents and disinfectants are not to be stored in areas where food is handled.

Adequate drainage should be installed and regularly cleaned and maintained. They are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area.

Food premises are to have adequate natural and/or artificial lighting.

A register shall be kept of acceptable engineering materials permitted for operational use, i.e. food safe lubricants, glass, plastics and other contact materials.

A documented, recorded pest control regime (for rodents, birds and insects) should be established, refer to Section 4.6.

Welfare arrangements are to be provided as required under the Workplace (Health, Safety and Welfare) Regulations (4). Washbasins are to be available, suitably located and designated for cleaning hands; antibacterial soap is to be provided. Sanitary conveniences are to have adequate natural or mechanical ventilation. Lavatories are to be flush activated, connected to an effective drainage system and are not to open directly into rooms in which food is handled. Smoking in the work area shall be prohibited.

7.3 Requirements in rooms where foodstuffs are prepared, treated or processed

Floors, walls and ceilings should be constructed from suitable easily cleanable materials.

Any openings that allow outside air to enter the premises should be fitted with fly-screens to prevent the ingress of insects and other pests. Windows should not be of an opening type in order to prevent airborne contamination.

Lighting shall be sufficient to allow workers to see if the area and equipment is clean and suitable for food production. A level of 500 lux at normal working height (at average eye level) is generally regarded as sufficient to enable adequate product inspection. Protective covers shall be fitted to lamp fittings located over open food production areas, or the areas shall be protected from glass contamination in case of breakage by other means.

Doors, and any other barriers, should be made of materials allowing easy cleaning and maintenance. External doors should be kept closed whenever possible to prevent the ingress of pests and/or airborne contamination. Where doors are opened on a regular basis, additional barriers should be provided such as drop down curtains.

Surfaces in contact with dry ice shall be constructed of materials that can be easily cleaned and disinfected, e.g. stainless steel or suitable plastics. Building and equipment design should provide for suitable water run-off from condensation and as a result of cleaning.

7.4 Requirements for moveable and/or temporary premises, domestic premises, etc.

Not relevant to dry ice production.

7.5 Transport

Dry ice containers shall be constructed of easily cleanable, compatible and maintainable materials e.g. stainless steel, plastic or non-ferrous alloys. Where this is not possible, e.g. single use disposable containers, the use of disposable plastic container liners should be considered, especially for 'loose' product, which has no primary packaging. Refer to Section 3.5.

Containers (full or empty) should be kept closed, whenever possible, and always kept closed if stored outside in the open air. Dry ice shall not be placed in totally sealed containers, as the CO₂ gas evolved during sublimation has to be free to escape to atmosphere, otherwise the container will pressurise and could rupture.

Dry ice containers shall be regularly cleaned; only potable quality water should be used. Where cleaning with a disinfectant is necessary, pressure washers using a food grade detergent or sanitizer (a combined detergent / disinfectant) are recommended as good practice for cleaning containers. The container cleaning area should be separate from the dry ice production and packaging area and unclean containers should be stored clearly separated from clean containers.

An inspection / maintenance program should be established. Containers should be identifiable (e.g. by a number) and the inspection / maintenance programme should be documented and recorded.

Dry ice containers shall only be used for the carriage of dry ice and appropriately labelled.

Where product is being supplied for food related applications it is recommended that containers be fitted with an anti-tamper device or indicator to ensure product integrity.

7.6 Equipment requirements

Chutes, conveyors, weighing systems and packaging equipment should be regularly inspected and cleaned as necessary; only potable quality water should be used for cleaning purposes. Where cleaning with a disinfectant is necessary, pressure washers using a suitable food grade detergent or sanitizer (a combined detergent and disinfectant) are adequate cleaning equipment.

Equipment must be constructed of materials that are easily cleanable, resistant to corrosion, non-toxic and capable of withstanding contact with dry ice at a temperature of -78.4 °C. Stainless steel and some non-ferrous or plastic materials have been found to be acceptable. Refer to Section 3.5.

Equipment should be designed and manufactured to avoid dirt traps etc. Surfaces shall be smooth and free from pits, crevices and chips.

Equipment shall be regularly inspected and maintained in accordance with a preventative maintenance schedule, to ensure that its condition remains acceptable for use with food. Records of equipment inspections and any remedial actions should be maintained.

Consideration should be given to exposed sections of the production line to prevent airborne contamination / foreign bodies whilst allowing easy access for maintenance and cleaning. Special consideration should be given to the separation of food contact components from potential contaminants e.g. hydraulic oil or lubricants.

7.7 Non-conforming product

Normal good housekeeping practice is adequate for dry ice production facilities and containers, as dry ice itself is not a hygiene risk as waste. Food waste and other refuse must not be allowed to accumulate in production areas, but should be regularly removed to a suitable storage area. It is good practice to exclude other foodstuffs from the production area to prevent contamination.

Dry ice as a food waste shall not be stored in closed containers. There is a serious risk from pressure build up inside a closed container.

All waste shall be stored in a designated area, preferably outside the production area. Care shall be taken to ensure that the store does not attract pests. Refer to Section 4.6.

NOTE: Consideration should be given to the potential risk for returned dry ice to contain or be mixed with other types of waste.

7.8 Water supply

It is good practice to use only potable water in dry ice production areas. Non-potable water outlets, if present, shall be clearly marked as such.

Potable water from the mains supply in the UK is generally to an acceptable standard. Other sources (e.g. boreholes), where there is a risk of contamination, shall be regularly checked or not used.

If likely to contact food, steam must be made from potable water and any chemicals used for water treatment shall be food compatible. It is good practice to make all steam used in the production area and used for cleaning machinery and / or dry ice containers from potable water.

7.9 Personal hygiene

For personal hygiene requirements, refer to Section 4.5, Hygiene Requirements.

Personnel handling dry ice can be in direct contact with the product and therefore a policy on the wearing of jewellery should be adopted to minimise any associated risks.

7.10 Provisions applicable to foodstuffs

Dry ice must be made only from liquid carbon dioxide that is certified as being suitable for use in foods. Incoming supplies and storage should be subject to a recognised, documented quality system, refer to Section 4.3.

NOTE: BCGA recognises EIGA and the International Society of Beverage Technologists (ISBT) food quality standards as used for liquid carbon dioxide which is the feedstock for dry ice production.

HACCP analysis of the production operation including the supply & storage of bulk liquid carbon dioxide and the dry ice manufacturing facility shall be carried out. Where contract hauliers are used the supplier shall carry out appropriate risk analysis.

Hazardous materials such as lubricants, hydraulic fluid and cleaning chemicals etc. shall be stored separately from dry ice products. They should not be kept in production areas and shall be clearly labelled, refer to the Control of Substances Hazardous to Health (COSHH) Regulations (7). Such products should only be brought into production areas when necessary, and should be removed again into safe storage as soon as possible.

Dry ice shall be traceable to a registered premises and the batch number, refer to Section 3.4 and 3.6. The system shall enable suppliers of dry ice to identify suspect products in case of customer complaint or quality failure in order to recall affected products. These procedures should be part of the overall quality system.

Returned dry ice shall not be used for food grade applications.

7.11 Wrapping and packaging

Primary packaging for use with dry ice must be made from food-compatible materials that are suitable for use at low temperature (-78.4 °C). They include plastic bags, plastic film, paper and composite materials including container liners (if used). Refer to Section 3.5.

Where inks are used for direct printing onto packaging they shall be compatible with food.

All packaging shall be designed to prevent pressure build up due to sublimation.

All primary packaging materials for use with dry ice shall be transported and stored in suitable conditions to prevent any risk of contamination.

7.12 Special conditions for certain processing operations

Not applicable to dry ice.

7.13 Training

For training requirements, refer to Section 4.7.

8. ON-SITE GAS GENERATORS

8.1 Introduction and scope

An 'On-Site' generator makes gas for use directly at the location where the equipment is installed. The equipment usually supplies the gas to a distribution pipework system but on large installations there may be intermediate storage tanks.

On-site gas generators range in size from gas flows of a few litres per minute up to a few tonnes per hour. The most common installations are non-cryogenic systems for producing nitrogen for use in beverage dispense.

Typical gases produced by on-site generators are:

- Nitrogen (gaseous or liquid) from air.
- Carbon Dioxide from fermentation processes.
- Hydrogen from electrolysis of water.
- Oxygen from air.

The on-site generator will be designed to produce gas to a specification derived on the basis of its suitability for all intended applications. This will include the requirements for use in foods.

This section provides guidance on the hygienic operation of on-site gas generators. HACCP is fundamental to all stages covered.

EIGA Document 194 (37), *Safe design and operation of on-site nitrogen generators for food use*, provides additional information for on-site nitrogen generators.

NOTE: EIGA Document 194 (37) does not cover small scale beverage dispense systems.

8.2 Requirements for food premises

The on-site gas generators must be installed in a location that is in accordance with the installation requirements of the supplier. In particular, where air is the feedstock for the on-site generator, the feedstock must be of fresh air that is free of any contaminants that will compromise final product integrity. For example, waste solvents and boiler / engine exhausts shall not be adjacent to the air intake into a nitrogen generator.

On site generators are pressurised closed systems and thus have a level of intrinsic protection from the environment provided that appropriate hygiene controls are in place for intrusive maintenance operations.

The owner of the location where the on-site generator is installed is responsible for the upkeep of food hygiene standards around the equipment.

Any special requirements e.g. temperature / humidity / power supply shall be specified by the manufacturer of the on-site generator.

There shall be adequate access to the on-site generator for maintenance operations. Any intrusive maintenance operations should be covered by documented procedures that take account of the hygiene requirements of the operation and shall include checks required for return to service.

Attention is drawn to the need for a risk assessment where a 'confined space' may result from the installation of an on-site gas generator. In such instances there may be hazards of oxygen deficiency or oxygen enrichment depending on the gas being generated. If carbon dioxide is being produced then the additional hazards of this gas in a confined space shall be considered in the risk assessment.

8.3 Requirements in rooms where foodstuffs are prepared, treated or processed

The protection afforded by the pressure gradient within on-site generators, and the closed nature of the process, means that no special requirements are applicable.

8.4 Requirements for moveable and /or temporary premises, domestic premises etc.

This is not relevant to on-site generators.

8.5 Transport

This is not relevant to on-site generators.

8.6 Equipment requirements

The equipment shall be designed in accordance with statutory requirements for pressure systems.

The equipment shall be designed to produce gas that complies with the requirements for use in foods. It is normal for on-site generators to be designed to produce gas of a consistent quality. Such generators shall be installed and maintained according to formal written procedures. Consequently the design process shall include validation of the design to prove the capability of the equipment. With the exception of very large on-site generators it is neither normal nor necessary for on-site analytical equipment to be installed to analyse the gas produced. Compliance of the gas to requirements is assured by the equipment design and the inclusion within the equipment of alarms and / or trips to warn of malfunction, e.g. pressure or flow alarms.

The materials of construction shall be compatible with foods and the environment.

The equipment shall be designed to afford adequate protection from the environment. On-site generators may be located outdoors in some circumstances and thus consideration shall be given to appropriate enclosures according to established international standards for electrical equipment.

8.7 Non-conforming product

This is not relevant to on-site generators.

8.8 Water supply

There is generally no direct contact between water and the gas stream in on-site generators and hence this is not relevant to on-site generators.

8.9 Personal hygiene

For personal hygiene requirements refer to Section 4.5.

8.10 Provisions applicable to foodstuffs

No special provisions apply.

8.11 Wrapping and packing

This is not relevant to on-site generators.

8.12 Training

For general training requirement refer to Section 4.7.

On-site generators are completely automated and unattended operation is usually the norm.

Appropriate training should be provided to responsible personnel to allow for normal operation, for routine inspection and to respond to emergencies.

9. REFERENCES

The Regulations listed are those applying to England. Wales, Scotland and Northern Ireland have their own regulations, however the general principles will be similar. Your local national regulations should be checked if you are operating a food business in those geographical areas.

1. The Food Safety Act 1990. (as amended)
2. Health and Social Care Act 2012
3. SI 1991: No 2825 The Food Premises (Registration) Regulations 1991
4. SI 1992: No. 3004 Workplace (Health, Safety and Welfare) Regulations 1992.
5. SI 1996: No 1502 The Food (Lot Marking) Regulations 1996
6. SI 1997: No 1713 The Confined Spaces Regulations 1997
7. SI 2002: No. 2677 The Control of Substances Hazardous to Health Regulations, 2002 (COSHH)
8. SI 2004: No 3279 The General Food Regulations 2004 (as amended).
9. SI 2009: No 891 The Purity Criteria for Colours, Sweeteners and Miscellaneous Food Additives (England) Regulations 2009

10. SI 2009: No. 1348 The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (as amended).
11. SI 2012: No. 2619 The Materials and Articles in Contact with Food (England) Regulations 2012.
12. SI 2013: No. 2210 The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013
13. SI 2013: No. 2996 The Food Safety and Hygiene (England) Regulations 2013.
14. SI 2014: No. 1855 The Food Information Regulations 2014.
15. ECE/TRANS/242 European Agreement concerning the international carriage of dangerous goods by road (ADR).
16. 89/396/EEC European Council Directive of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs.
17. EC 178/2002 Regulation of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
18. EC 852/2004 Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.
19. EC 1935/2004 Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.
20. 2008/84/EC COMMISSION DIRECTIVE 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners
21. EC 1272/2008 Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP).
22. EC 1333/2008 Regulation (EC) No. 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.
23. EU 1169/2011 Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers.
24. HSE HSG 252 A recipe for safety. Health and safety in food and drink manufacture.
25. HSE L101 Safe work in confined spaces. Confined Spaces Regulations 1997. Approved code of practice and guidance.

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| 26. | BS EN 1919 | Transportable Gas Cylinders – Cylinders for liquefied gases (excluding acetylene and LPG). Inspection at time of filling. |
| 27. | BS EN 1920 | Transportable Gas Cylinders – Cylinders for compressed gases (excluding acetylene). Inspection at time of filling. |
| 28. | BS EN ISO 9001 | Quality management systems – Requirements. |
| 29. | BS EN ISO 22000 | Food safety management systems. Requirements for any organization in the food chain. |
| 30. | BS ISO 24431 | Gas cylinders. Cylinders for compressed and liquefied gases (excluding acetylene). Inspection at time of filling. |
| 31. | EIGA IGC
Document 23 | Safety training of employees. |
| 32. | EIGA IGC
Document 64 | Use of residual pressure valves. |
| 33. | EIGA IGC
Document 68 | Prevention of CO ₂ backfeed contamination. |
| 34. | EIGA IGC
Document 70 | Carbon dioxide source certification, quality standards and verification. |
| 35. | EIGA IGC
Document 125 | Guide to the supply of gases for use in foods. |
| 36. | EIGA IGC
Document 126 | Minimum specifications for food gas applications. |
| 37. | EIGA IGC
Document 194 | Safe design and operation of on-site nitrogen generators for food use. |
| 38. | EIGA Technical
Bulletin 02 | Microbiological quality of medical, pharmaceutical and food grade gases |
| 39. | EIGA Briefing
Note 12 | Use of carbon monoxide (CO) and gas-mixtures with CO for the treatment of meat and fish. |
| 40. | EIGA Position
Paper 22 | Food gases and Regulation No 1935/2004 on materials and articles intended to come into contact with food. |
| 41. | BCGA Code of
Practice 32 | The safe filling of beverage gas cylinders. |
| 42. | BCGA Code of
Practice 42 | Implementation of EIGA carbon dioxide standards. |
| 43. | BCGA Code of
Practice 44 | The storage of gas cylinders. |

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| 44. | BCGA Guidance
Note 11 | Reduced oxygen atmospheres. The management of risk associated with reduced oxygen atmospheres resulting from the use of gases in the workplace. |
| 45. | BCGA Guidance
Note 23 | Identifying gas safety training requirements in the workplace. |
| 46. | BCGA Guidance
Note 27 | Guidance for the carriage of gas cylinders on vehicles. |
| 47. | BCGA TIS 6 | Cylinder identification. Colour coding & labelling requirements. |
| 48. | BCGA TIS 7 | Guidelines for the safe transportation, storage, use and disposal of dry ice products. |
| 49. | ILSI Report | Validation and Verification of HACCP. |
| 50. | Campden BRI | HACCP - A Practical Guide. |
| 51. | Leatherhead Food
Research
Association | HACCP: A Toolkit for Implementation. |
| 52. | British Retail
Consortium | Food Industry Guide to Good Hygiene Practice: Retail. |

Further information can be obtained from:

UK Legislation	www.legislation.gov.uk
Health and Safety Executive	www.hse.gov.uk
Food Standards Agency (FSA) - England	www.food.gov.uk
Food Standards Agency - Wales	www.food.gov.uk/wales
Food Standards Scotland	www.foodstandards.gov.scot
Food Standards Agency - Northern Ireland	www.food.gov.uk/northern-ireland
British Standards Institute (BSI)	www.bsigroup.co.uk
International Organization for Standardization (ISO)	www.iso.org
European Industrial Gases Association (EIGA)	www.eiga.eu

British Compressed Gases Association (BCGA)	www.bcgga.co.uk
International Society of Beverage Technologists (ISBT)	www.bevtech.org
International Life Sciences Institute (ILSI)	www.ilsi.org
The Codex Alimentarius Commission	www.codexalimentarius.org
British Retail Consortium	www.brc.org.uk
Leatherhead Food Research Association	www.leatherheadfood.com
Campden BRI	www.campdenbri.co.uk
Chartered Institute of Environmental Health	www.cieh.org
The Foundation for Food Safety Certification	www.fssc22000.com

PRODUCT SPECIFICATIONS

GAS	RELEVANT LEGISLATION	E NUMBER	Assay ^(a) v/v	Water v/v	Nitrogen v/v	Hydrocarbons as CH ₄ v/v	NO ₂ & NO v/v	Oxygen v/v	CO v/v	Oil mg/l	Lead mg/kg	Copper (c) mg/kg	Zinc (c) mg/kg	Methane v/v	Ethane v/v	Propane v/v	Iso-butane v/v	N-butane v/v	1.3-butadiene v/v
Argon	SI 2009:891 (9)	E938	f99%	<0.05%		<100ppm					10	50	25						
Helium	SI 2009:891 (9))	E939	f99%	<0.05%		<100ppm					10	50	25						
Nitrogen	SI 2009:891 (9)	E941	f99%	<0.05%		<100ppm	<10ppm	<1%	<10ppm		10	50	25						
Nitrous Oxide	SI 2009:891 (9)	E942	f99%	<0.05%			<10ppm		<30ppm		10	50	25						
Propane	SI 2009:891 (9)	E944	f95%	<50ppm										<0.15%	<1.5%		<2%	<1%	<0.1%
Butane	SI 2009:891 (9)	E943a	f96%	<50ppm										<0.15%	<0.5%	<1.5%	<3%		<0.1%
Iso-butane	SI 2009:891 (9)	E943b	f94%	<50ppm										<0.15%	<0.5%	<2%		<4%	<0.1%
Hydrogen	SI 2009:891 (9)	E949	f99.6% (d)	<50ppm	<7500ppm (d)			<10ppm											
Oxygen	SI 2009:891 (9)	E948	f99%	<0.05%		<100ppm					10	50	25						
Carbon Dioxide	SI 2009:891 (9)	E290	f99%	<50ppm					<10ppm	<0.1 mg/l (b)	10	50	25						
Sulphur Dioxide	SI 2009:891 (9)	E220									10	50	25						

(a) The legal requirement demands an assay of 99% (generally) then, if the supplier cannot or does not wish to supply this level of purity, then he must not say that it does, e.g. 98 % N₂, 2 % O₂ must not be described as Nitrogen.

(b) Measured in the vapour phase.

(c) Maximum limit of 50 mg/kg of any combination of copper and zinc.

(d) The figures for N₂ and assay are as per the EU Directive 2008/84/EC (20). There is an inconsistency, as they appear to be conflicting. BCGA believes that the limit for N₂ should be 750 ppm v/v and that the industry should meet this limit.



British Compressed Gases Association

www.bcgga.co.uk