GUIDE TO THE SUPPLY OF GASES FOR USE IN FOODS

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1. Introduction

The basis for European food legislation is regulation (EC) No178/2002 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. Current and proposed European legislation requires that foods, including gases supplied to the food industry, have to meet increasingly rigorous standards to ensure food safety.

Gases are used for a variety of purposes in the food industry, which may include being used as additives, processing aids and ingredients. In particular they have to meet requirements regarding labelling, purity criteria and hygiene.

This guide has been prepared to provide a summary of the relevant legislation together with advice as to how best to meet its requirements.

2. Scope

Food gases are defined as gases, in liquid, gaseous or solid form that are supplied to the food industry and used as additives, processing aids or ingredients in contact with food. These include gases for modified atmosphere packaging, liquid nitrogen for freezing and carbon dioxide for beverage carbonation. They may be delivered as bulk liquid gases, compressed cylinder gases, generated on-site or, in the case of carbon dioxide, as solid dry ice.

This guide covers all stages of the supply chain including production, storage, re-packingaging and distribution of food gases to the final user.

The guide is intended to establish an awareness of the particular legislative requirements as they apply to food gases and to offer advice as to how these requirements may be met. These cover legislation in the following areas:

- use of gases as food additives including purity criteria;
- hygiene and food safety requirements including use of Hazard Analysis and Critical Control Points (HACCP);
- labelling, and
- lot marking and traceability.

The principal uses of food gases are as follows:

a. Additives

- Oxygen, nitrogen and carbon dioxide as modified atmosphere packaging gases
- Nitrogen and carbon dioxide as propellant gases for beverages
- Nitrous oxide as a propellant gas for cream
- Sulphur dioxide as a preservative for specified foods

b. Processing Aids

- Liquid nitrogen and liquid carbon dioxide for freezing and chilling
- Carbon dioxide for super-critical extraction
- Hydrogen for hydrogenation of fats

c. Ingredients

- Carbon dioxide for carbonated beverages
3. Definitions

3.1 Food or foodstuff

“Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans” (Regulation EC 178/2002).

3.2 Food gases

For the purposes of this guide, food gases are defined as gases intended to be used as a food additive, processing aid or ingredient.

3.3 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” (Regulation EC 178/2002).

3.4 Food business operator

“The natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control” (Regulation EC 178/2002).

3.5 Cryogenic receptacle

A thermally insulated vessel for the transport of refrigerated liquefied gases, and is often referred to as a mini-tank.

3.6 Ingredient

“Any substance, including additives, used in the manufacture or preparation of a foodstuff still present in the finished product, even if in altered form” (Directive 2000/13/EC).

3.7 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 finished product” (Regulation EC 1333/2008).

3.8 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” (Regulation 1333/2008). Food additives include packaging gases and propellants.

3.9 Packaging gases

“Any gas, other than air, which is introduced into a container before, during or after the placing of a food in that container” (Regulation EC 1333/2008).
3.10  Propellants

“Any gas, other than air, which expels a foodstuff from a container” (Regulation EC 1333/2008).

3.11  Top-filling

Filling without completely degassing a cylinder.

3.12  Batch

A batch may be considered as a discrete, defined quantity whose characteristics can be proven, for example 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.

3.13  Non-conforming product

For the purposes of this document, non-conforming product is defined as product that does not meet the relevant company specifications or that has other unspecified impurities which are suspected or known to be at levels that might, when used in contact with foods be injurious to health. (Company specifications are assumed to exceed legislative specifications.)

3.14  Ultimate consumer

A user who does not further sell the product for business purposes.

3.15  HACCP

Hazard Analysis Critical Control Points is a formal method to assess the food safety risks.

4.  European food legislation

This is a summary of European legislation relevant to food gases. Some of this legislation is issued in the form of Directives which have to be enacted by the member countries of the EU. This process may lead to slight differences of interpretation between the member countries. Regulations, on the other hand, are binding on member countries and no modification is allowed. Therefore, for example, Regulation 178/2002 is legally binding in all member countries.

4.1  Regulation 1333/2008 on Food Additives

This regulation defines food additives and processing aids and states explicitly that it does not apply to processing aids. In particular it prescribes labelling requirements.

Article 21: Labelling of food additives not intended for sale to the final consumer

1. Food additives not intended for sale to the final consumer, whether sold singly or mixed with each other and/or with food ingredients, as defined in Article 6(4) of Directive 2000/13/EC, may only be marketed with the labelling provided for in Article 22 of this Regulation, which must be easily visible, clearly legible and indelible. The information shall be in a language easily understandable to purchasers.

2. Within its own territory, the Member State in which the product is marketed may, in accordance with the Treaty, stipulate that the information provided for in Article 22 shall be given in one or more of the official languages of the Community, to be determined by that Member State. This shall not preclude such information from being indicated in several languages.
Article 22: General labelling requirements for food additives not intended for sale to the final consumer

1. Where food additives not intended for sale to the final consumer are sold singly or mixed with each other and/or other food ingredients and/or with other substances added to them, their packaging or containers shall bear the following information:

(a) the name and/or E-number laid down in this Regulation in respect of each food additive or a sales description which includes the name and/or E-number of each food additive;

(b) the statement ‘for food’ or the statement ‘restricted use in food’ or a more specific reference to its intended food use;

(c) if necessary, the special conditions of storage and/or use;

(d) a mark identifying the batch or lot;

(e) instructions for use, if the omission thereof would preclude appropriate use of the food additive;

(f) the name or business name and address of the manufacturer,

(g) an indication of the maximum quantity of each component or group of components subject to quantitative limitation in food and/or appropriate information in clear and easily understandable terms enabling the purchaser to comply with this Regulation or other relevant Community law; where the same limit on quantity applies to a group of components used singly or in combination, the combined percentage maybe given as a single figure; the limit on quantity shall be expressed either numerically or by the quantum satis principle;

(h) the net quantity;

(i) the date of minimum durability or use-by-date;

(j) where relevant, information on a food additive or other substances referred to in this Article and listed in Annex IIIa to Directive 2000/13/EC as regards the indication of the ingredients present in foodstuffs.

2. Where food additives are sold mixed with each other and/or with other food ingredients, their packaging or containers shall bear a list of all ingredients in descending order of their percentage by weight of the total.

3. Where substances (including food additives or other food ingredients) are added to food additives to facilitate their storage, sale, standardisation, dilution or dissolution, their packaging or containers shall bear a list of all such substances in descending order of their percentage by weight of the total.

4. By way of derogation from paragraphs 1, 2 and 3, the information required in paragraph 1 points (e) to (g) and in paragraphs 2 and 3 may appear merely on the documents relating to the consignment which are to be supplied with or prior to the delivery, provided that the indication ‘not for retail sale’ appears on an easily visible part of the packaging or container of the production question.

5. By way of derogation from paragraphs 1, 2 and 3, where food additives are supplied in tankers, all of the information may appear merely on the accompanying documents relating to the consignment which are to be supplied with the delivery.
Article 23: Labelling of food additives intended for sale to the final consumer

If the additive is intended for sale to the ultimate consumer, the following information above shall be on the packaging

(a) the name and E-number laid down in this Regulation in respect of each food additive or a sales description which includes the name and E-number of each food additive;

(b) the statement ‘for food’ or the statement ‘restricted use in food’ or a more specific reference to its intended food use.

4.2 Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners

This gives purity criteria for food additives.

4.3 Regulation 1935/2004 on materials and articles intended to come into contact with food

Regulation 1935/2004 consolidates a large amount of earlier legislation on materials that come into contact with foods. It requires that any packaging, wrapping or process equipment does not transfer its constituents into the food and thereby adversely affect the food. It permits the use of “active” food contact materials that may deliberately release or absorb substances into or from the food to enhance its shelf life. This regulation also covers food contact areas of food processing machinery, such as freezers. Eventually a positive list of authorised food contact materials will be produced but, until then, in case of doubt, consult the supplier of the material.

4.4 Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety

This regulation established the European Food Authority and stipulates general principles of food law. It harmonises national requirements which, hitherto, had varied slightly between countries.

It gives a definition of food that “includes any substance that is intended to be, or is reasonably expected to be ingested by humans”. The reference to ‘reasonably expected’ is formulated to ensure that a substance that may be reasonably expected to find its way into the food supply chain but may find its way into different industry sectors, is handled with the same care as a food until it is clear it will not become a food. This implies that nitrogen, oxygen and carbon dioxide, etc. in the production / distribution process have to be treated as if they are foods until specifically designated otherwise.

It also confirms that food includes any substance intentionally incorporated into the food during its manufacture preparation or treatment.

It defines traceability as “the ability to trace and follow a food through all stages of production, processing and distribution” and requires food business operators to know from whom they have received food and to whom they supply it. The principal purpose of the traceability requirement is to enable efficient and rapid withdrawal from the market of any food that may be injurious to the consumer’s health.

4.5 Regulation 852/2004 on the Hygiene of Foodstuffs

Hygiene is defined as “measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use”.

Primary responsibility for hygiene rests with the food business operator and food business operators shall ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation.
Food business operators “should establish and operate food safety programmes and procedures based on HACCP principles”.

The HACCP principles consist of the following:

“(a) identifying the hazards that must be prevented, eliminated or reduced to acceptable levels;
(b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels;
(c) establishing critical limits at control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
(d) establishing and implementing effective monitoring procedures at critical control points;
(e) establishing corrective action when monitoring indicates that a critical control point is not under control;
(f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and
(g) establishing documents commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

“When any modification is made in the product, process, or any step, food business operators shall review the procedure and make any changes to it.”

Member States shall encourage the development of national guides to good practice for hygiene and for the application of HACCP which may be used voluntarily by food businesses.

This Regulation specifies hygiene requirements under the following “chapters” (where there is particular relevance to gas companies details are given either below or in the further sections of the guide dealing with specific requirements).

I. General requirements for food premises
II. Specific requirements in rooms where foodstuffs are prepared, treated or processed
III. Requirements for movable and/or temporary premises
IV. Transport

“1. Conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and are, where necessary, to be designed and constructed to permit adequate cleaning and/or disinfection.

2. Receptacles in vehicles and/or containers are not be used for transporting anything other than foodstuffs where this may result in contamination of foodstuffs.

3. Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there is, where necessary, to be effective separation of products.

4. Bulk foodstuffs in liquid, granulate or powder form shall be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers are to be marked in a clearly visible and indelible fashion, in one or more Community languages, to show that they are used
for the transport of foodstuffs, or are to be marked ‘for foodstuffs only’.

5. Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there is to be effective cleaning between loads to avoid the risk of contamination.

6. Foodstuffs in conveyances and/or containers are to be so placed and protected as to minimize the risk of contamination.

7. Where necessary, conveyances and/or containers used for transporting foodstuffs are to be capable of maintaining foodstuffs at appropriate temperatures and allow those temperatures to be monitored."

V. Equipment requirements

“All articles, fittings and equipment with which food comes into contact are to:

- be effectively cleaned and, where necessary, disinfected, Cleaning and disinfection are to take place at a frequency sufficient to avoid the risk of contamination;
- be so constructed, be of such materials and be kept in such good order, repair and condition as to minimize any risk of contamination of the food;
- with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept clean and, where necessary, to be disinfected; and
- be installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area.”

VI. Food waste

VII. Water supply

VIII. Personal hygiene

IX. Provisions applicable to foodstuffs

X. Provisions applicable to the wrapping and packaging of foodstuffs

“Material used for wrapping and packaging is not to be a source of contamination."

“Wrapping and packaging material re-used for foodstuffs is to be easy to clean and, where necessary, to disinfect.”

XI. Heat Treatment

XII. Training

“Food business operators shall ensure that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity.”

Every food business operator shall notify the appropriate competent authority of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each establishment. This information shall be kept up-to-date.

Indirectly these hygiene requirements bring processing aids within the scope of the food legislation. Hitherto processing aids were not classified as foods and were subject to very little legislation, but the hygiene requirements of Regulation 852/2004 require that risk of contamination of foods from any
source shall be assessed. As contamination is possible from processing aids, then they themselves have to be treated in a similar way to foods.

5. General requirements

European legislation demands that the safety of all food is assured by means of a HACCP risk assessment procedure. This shall be part of a documented overall quality management system, e.g. EN 9000:2000 which also addresses:

- Premises design and cleanliness
- Raw material and supplier management
- Adherence to product specifications
- Equipment Design
- Personal Hygiene
- Training
- Traceability and recall

The production and supply of food gases is generally carried out in fully enclosed pressurised equipment frequently at very low temperatures. Therefore the possibility of physical, chemical or microbiological contamination of the product is considerably reduced in comparison with traditional foods. This Guide places emphasis on good manufacturing practices to maintain the integrity of the product during all stages of the supply chain and highlights specific areas where particular care is required.

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

Gases are generally manufactured to a single specification and quality level suitable for all intended applications, including use in food. The same product manufactured and supplied for use in food may, therefore, be supplied for a range of non-food related applications.

5.1 HACCP (Hazard Analysis and Critical Control Points)

Food gas businesses should implement and maintain a documented system of HACCP to ensure that all potential risk of contamination of the product that could represent a hazard to food safety can be identified and controlled. The system includes the seven principles of HACCP. See Para 4.5.

5.2 General food gases safety considerations

Regulation 852/2004 sets out twelve “chapters” as defined in Section 4.5 for consideration when reviewing the controls needed to maintain food hygiene.

Chapter 1 Premises
Chapter 2 Rooms where foodstuffs are processed.
Chapter 3 Temporary or movable premises
Chapter 4 Transport
Chapter 5 Equipment
Chapter 6 Food Waste
Chapter 7 Water Supply
5.2.1 Premises and rooms where foodstuffs are processed

Since the production and distribution of 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.

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.

Appropriate documented arrangements are required for the control of pests within the premises.

Individual cases may require a formal risk analysis where particular circumstances or adverse environmental conditions apply. See 8.1 (Dry Ice).

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 sitting of product storage and 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.

5.2.2 Temporary and removable premises

There are no relevant applications in the food gases industry.

5.2.3 Food waste

Food waste can be defined as either non-conforming product or product of uncertain quality for which documented handling procedures should be in place.

5.2.4 Water supply

A HACCP study should identify where water is used in the process together with any associated hazards and necessary controls. Where the water comes into contact with the gas then it is necessary to specify potable water or alternative control measures to prevent contamination of the product.

5.2.5 Personal hygiene

With the exception of dry ice, there is no physical contact between the gases supplied and the personnel employed in their manufacture or distribution. Therefore, the personal hygiene controls that would be necessary in a high-risk environment are not required. Good personal hygiene practices should be encouraged, however, especially during maintenance activities of components and other
items that will be in direct contact with the food gas.

5.2.6 Provisions applicable to foodstuffs

This chapter refers predominantly to perishable foodstuffs and to foodstuffs that may be subject to microbiological degradation and, as such, has little relevance to food gases. However, consideration needs to be made to potential contamination of incoming raw materials.

5.2.7 Provisions applicable to the wrapping and packaging of foodstuffs

Wrapping is defined as the placing of a foodstuff in a container in direct contact with the foodstuff concerned, and the wrapper or container itself.

Packaging is defined as the placing of one or more wrapped foodstuffs in a second container, and the latter container itself.

This chapter therefore requires that cylinders, tanks and dry-ice packaging shall not contaminate the gas therein. Nor shall the filling / transfilling process contaminate the gas.

5.2.8 Heat treatment

This is not relevant to the food gas industry.

5.2.9 Training

All personnel contributing to the quality and integrity of products used in food should have undergone relevant food safety awareness training.

The level of training in food hygiene, hazard analysis and control given to personnel employed on food gas production and supply shall be appropriate to their activities and commensurate with the ability of their particular job function to impact on food safety.

Basic level training for appropriate personnel should include personal hygiene standards such as the reporting of illness, awareness of potential food hazards associated with the business (such as visible damage/contamination to cylinders or potential contamination in bulk equipment due to inappropriate maintenance procedures) and awareness of pest control requirements.

Training records should be maintained for all personnel.

5.2.10 Labelling

In addition to hygiene considerations described above, it is also essential that food gases are labelled in accordance with the relevant legislation, see 4.1.

5.2.11 Purity criteria

Purity criteria exist for all gases when used as food additives. These set maximum levels for certain specific impurities, see 4. There is also a responsibility on behalf of the supplier to consider the potential for other non-specified impurities and their effect on food safety.

5.3 Traceability

The general requirement of the traceability legislation is that the food business operator shall have systems and procedures in place to:

- identify from whom they receive product,
• identify to whom they supply product and
• allow this information to be made available to the competent authorities on demand.

This requirement emphasises the need for a robust lot marking system to be in place (see Section 4).

If a food business operator has reason to suspect that a food which it has produced, imported or distributed is non-conforming product then the food business operator shall take steps to withdraw the foodstuff from the market and inform the competent authorities of this. The authorities may then decide if any further action needs to be taken.

A mock traceability exercise at intervals is recommended to evaluate the speed at which product can be withdrawn from the market. It is also beneficial to check that product can be traced from suppliers through to dispatch.

6. Bulk gas production, transport & storage

6.1 Introduction and scope

This section provides specific guidelines on the production of gases suitable for use in food and their distribution via bulk road tanker, as either a pressurised 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, for example filling into food gas cylinders or production of dry ice.

6.2 Production

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.

Bulk gas products are generally manufactured to a single specification and quality level suitable for all intended applications, including use in food. The same product manufactured and supplied for use in food may, therefore, be supplied for a range of non-food related applications.

EIGA provides particular information for producers and distributors of bulk carbon dioxide for food and beverage use in EIGA Docs 68¹ and 70².

6.3 Transport & storage

6.3.1 Prevention of cross contamination

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 shall normally be allocated to a single product. These tanks and tank containers shall usually 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.

¹EIGA Doc 68 Prevention of carbon dioxide back feed contamination
²EIGA Doc 70 Carbon dioxide source certification, quality standards and verification
6.3.2 Gas service conversions

In the event of the need for conversion of the tank or 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. Such procedures shall include such control measures as:

- Analytical checks for all possible contaminants, the previous contents will have a bearing on the analysis required; and
- Purging with an appropriate food gas.

6.3.3 Hygiene controls and product integrity

Hoses and piping used for bulk supply should be stored in clean environments and capped if necessary. Each food gases business should have in place procedures that shall 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 – for example use of end caps
- Purging prior to delivery
- Common good handling and house-keeping practices such as not dragging hose ends on the ground

For the reasons given in the introduction to this section, tankers used for the transport of foodstuffs can also be used for transporting products of at least the same quality to a non-food application.

All vehicles used for the distribution of bulk food gases shall be designated as being suitable for food use. 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.

6.3.4 Control of non-conforming product and traceability

Where a product may be suspected or proven to not meeting the requirements for use in food, the following procedures should be followed:

6.3.4.1 In bulk storage

- Establish if the revised specification is acceptable to a customer (with agreement in writing from the customer) or deliver exclusively to industrial-grade customers, ensuring necessary procedures are in place and applied to prevent subsequent cross contamination with conforming product
- Otherwise vent the storage tank and purge. (Re-analyse tank contents prior to release)

6.3.4.2 In a delivery tanker (detected after filling)

- Quarantine the tanker
- Establish if the revised specification is acceptable to a customer, (with agreement in writing from the customer) or deliver exclusively to industrial-grade customers, ensuring necessary procedures are in place and applied to prevent subsequent cross contamination with conforming product
- Otherwise vent the tanker and purge. (Re-analyse tanker contents prior to release)
6.3.4.3 Suspected non-conforming product at a food customer installation

- Trace all other deliveries to food customers of potentially defective product, (including third party collections)
- If deliveries have been made to other food customers, inform the relevant government agency if impurities are suspected or known to be at levels that might, when used in contact with foods be injurious to health.
- Confirm the source and supplier of the defective product
- Quarantine and analyse the contents of tankers suspected of carrying non-conforming product. If this analysis shows no problem, it should be the end of the process as the problem is due to the customer.
- Vent the customer installation or remove product if necessary

If product in storage or in a tanker is found to be non-conforming then the tank or tanker shall be converted to food use again as described in Section 6.3.2.

6.4 Equipment requirements

6.4.1 Design

Production plant and 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 should be selected and maintained so that 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 shall not compromise product integrity when returned to service.

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.

6.4.2 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 to ensure that materials in contact with the food gases are suitable for the purpose and that when equipment is newly installed or transferred from one surface to another, cleanliness is assured and/or maintained.

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.

If a tank becomes inadvertently depressurised, then it shall be quarantined and considered unfit for food service until designated “suitable for use in food” in accordance with documented re-commissioning procedures.
7. Gases supplied in cylinders & transportable receptacles

7.1 Introduction and scope

This section provides specific guidelines on the process of filling containers such as cylinders and transportable receptacles for the supply of gases to the food industry. Container specification, valves specification, prefilling inspections, filling procedures, post filling inspections, quality control and traceability are within the scope of this section of the document.

The overall process of container 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 shall also take into account the possibility of contamination being introduced at customer sites.

7.2 Bulk gases for container filling

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

The storage of bulk gases shall clearly indicate which are suitable for use in food and which are not.

7.3 Container requirements

Containers shall be regularly inspected to ensure their condition to remain acceptable for use with food. Records of container inspections and any remedial actions should be maintained.

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 containers and valves and to ensure that when containers are transferred from one service to another, or new containers are stored or installed, cleanliness is assured and / or maintained.

Formal change control systems should ensure that whenever modifications are made to plant and/or containers consideration is given to their impact on food safety.

7.3.1 Containers

If a container becomes depressurised, then it shall be quarantined and considered unfit for food service until designated “suitable for use in food” in accordance with documented re-commissioning procedures.

Before containers are introduced into food gas service, unless they are new and previously specified as being suitable for food service, they shall be de-valved and, if possible, internally inspected in accordance with the appropriate documented procedure, cleaned as necessary and fitted with the appropriate valve.

When containers are subjected to their periodic inspection and test, they shall be in accordance with documented procedures. If water is used, it shall be either drinking water or of such a quality that possible internal contamination of the container is avoided. The containers should be dried internally prior to filling.

The design and specification of the containers should follow international design codes.
7.3.2 Valves

Valves used for food gas applications follow international design codes. Valves fitted to cylinders for food use should be of the residual pressure type incorporating a non-return valve (RPV). For additional guidance refer to EIGA Doc 643.

Where an RPV is not employed, an equivalent level of protection as provided by an RPV should be incorporated in the pre-fill procedure for receptacles and/or the design of the customer installation.

7.4 Pre-fill inspection

Before filling containers for food gases a pre-fill inspection shall be carried out.

The inspection shall include the following:

The external condition shall be checked to ensure that the container is free of 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) should be completed before filling commences. Liquefied gases cylinders fitted with a dip-tube shall be clearly identified. The specific functions of valves on containers should be clearly identifiable (see EN 1919, EN 1920).

The valves shall be inspected and shall be free from any external contamination or damage before filling commences.

The containers shall be within their due date for inspection and re-test.

The compatibility of the containers and their valves with their intended gas fill shall be checked.

The safe filling pressure of containers shall be established for the gas service and checked against the intended filling pressure.

The functionality of the RPV, where fitted, shall be checked. For containers 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 containers are free from contamination and appropriate control should be employed such as purging or internal inspection before filling.

7.5 Filling

7.5.1 General

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

Dedicated filling equipment for food gases is not necessary; however batches of food gas containers (or containers containing food gases) shall be kept separate from containers designated for non-food applications.

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

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3 *EIGA Doc 64 Guidelines on the use of residual pressure valves.*
7.5.2 Specific requirements for filling containers – liquefied gases

All cylinders shall be completely emptied prior to filling. A check shall be carried out to ensure that this is the case before a cylinder is filled, e.g., tare weight check. No filling shall be carried out until any discrepancy has been investigated and resolved. Under no circumstances shall any container used for drinks dispense gas be top-filled.

NOTE-liquefied gas cylinders (particularly carbon dioxide) become cold during filling and it is therefore recommended that all labelling be completed prior to filling – see post-fill section for details.

7.5.2 Specific requirements for filling – 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 cylinders, which do not have an RPV fitted
- Complete emptying of the container 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.

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

If supplied to the ultimate consumer, the package should carry the expiry date.

7.5.3 Specific requirements for filling – cryogenic receptacles

Cryogenic receptacles may be filled by weight or by filling to the full tri-cock (overfill indicator).

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. A system shall be in place to prevent change of service of the receptacle without formal authorisation, and to ensure that labelling and product identification operations are complete before filling with the new product.

If the previous container content cannot be verified, then the container shall be quarantined and its contents shall be analysed against the relevant product specification prior to supply.

7.6 Post-fill inspection

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

- Batch or lot labels shall be fitted to the containers
- Labelling shall comply with the labelling requirements including the requirement for a “best before” date. EIGA suggests that this should be three years from the date of filling.
- The containers shall be of acceptable finish externally
- Containers ready for dispatch should be stored in such a way as to prevent any accumulation of debris that may provide a refuge for pests
- Container valve outlets shall be plugged or capped after quality control checks have been carried out. The containers may then be released for dispatch to the customer.

7.7 Quality control and traceability

To comply with the traceability requirements, all records should be kept for the time of durability of the
product plus one year.

Where a product may be suspected or proven to not meeting the requirements for use in food, the following procedures should be followed:

7.7.1 Defective product in bulk tank at filling depot

- Inform Bulk Operations – and then treat as if it were non-conforming bulk product in a customer tank.
- Do not use to fill food grade cylinders

7.7.2 Defective product in cylinder before delivery

- Quarantine the batch
- Analyse/vent as necessary.
- If any of the batches has been delivered, proceed as per Section 7.7.3.

7.7.3 Defective product delivered

- Receive notification from customer
- Obtain as much information from the customer to establish if it is indeed a gas supply problem and not a customer’s internal problem.4
- Establish filling depot and batch number of the suspected product
- Identify all other customers for that batch
- Make no further deliveries of that batch
- Inform customers who have already received some of this batch.
- Inform the relevant food standards authority if impurities are suspected or known to be at levels that might, when used in contact with foods be injurious to health.

7.8 Delivery

Appropriate information including the safety data sheet shall be supplied when any product is delivered for the first time to any user. Customer risk assessments should identify suitable locations for gas cylinders.

Labelling shall distinguish clearly between food and industrial cylinder gases.

8. Dry ice production, storage and distribution

8.1 Introduction and scope

This section provides specific guidelines for the production and distribution of dry ice. Dry ice is carbon dioxide in its solid form, produced by expanding pressurised liquid carbon dioxide to atmospheric pressure.

The product is supplied as either blocks, slices or in pellet form and is generally packed into plastic, paper or composite bags that are stored and transported in insulated containers. Some products (particularly pellets) may also be supplied “loose” in containers, with no wrapping.

Dry ice creates a protective, bacteriostatic atmosphere.

Dry ice is used in practically all type of industries, mainly because of its cooling properties. It is

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4 A “reasonable” time is allowed for this.
particularly interesting for applications where "spot cooling" is needed. The most important uses in the food industry are:

- Cooling of catering trolleys in aircraft, trains
- Cooling of food, meals, ice-products, etc. during transport (to maintain the cold chain)
- Cooling of food by contact between dry ice and the product

It is added directly to foods such as raw meat so it is important to consider its possible role as a carrier of contamination.

In the gases industry, dry ice is the only solid product and, unlike other food gas products, is not kept in a pressurised or closed system. It therefore requires specific attention to food hygiene and training requirements.

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

8.2 Requirements for dry ice production premises

Good manufacturing principles shall be applied:

- The floors, walls and ceilings of production premises shall be designed in a way to avoid all contamination and facilitate cleaning. The room where the dry ice presses, the sawing/reforming and other packing processes are located, shall be separated from the other factory and storages areas.
- Wood should be kept out of the production area.
- The lighting equipment above open containers and other uncovered production equipment shall be protected in case of breakage of glass and particles. In general, glass shall be kept out of the production area or protected to prevent to fall in the containers.
- The toilet areas shall be clean and separated from the production area. The doors shall close automatically. There shall be sufficient wash-basins with cleaning material, hot and cold running water, and hygienic hand drying. Notices shall be visible encouraging workers to wash their hands.
- Adequate ventilation should be provided and precautions taken to prevent ingress of dust, odours and pests. The drains and water evacuation systems shall be correctly installed and maintained.
- The production and packaging operation shall be carried out under hygienic conditions. The use of disposable packaging is preferred including the use of plastic liners for bulk dry-ice containers.
- A pest control system is necessary. Regular checks shall be made. Checks shall be recorded.

8.3 Production equipment requirements

The extruders or presses, used for the production of dry ice, shall be inspected regularly to make sure there is no contamination from the equipment or from oil.

“Food grade” lubricants shall be used wherever lubricants could come into contact with the product.

Chutes, conveyors, weighing systems and packaging equipment shall be regularly inspected and cleaned.

Pressure washers using a detergent are adequate for cleaning equipment. Only suitable quality water should be used for cleaning purposes.

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

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.

8.4 Containers and transport

Dry ice containers shall be constructed of easily cleanable and maintainable materials e.g. stainless steel, fibreglass and epoxy, plastic or non-ferrous alloys. The use of disposable plastic container liners should be considered, especially for "loose" product, which has no primary wrapping. Reference should be made to the wrapping and packaging requirements of Regulation 852/2004 on the hygiene of foodstuffs.

Containers (full or empty) shall be kept closed, whenever possible, and always kept closed if stored outside in the open air. To keep the containers clean and dry, the use of closed vehicles for road transport is recommended.

Dry ice containers shall be inspected and cleaned for each use. Only suitable quality water shall be used. Pressure washers using a detergent are adequate for cleaning containers. Because the dry-ice can be used in direct contact with food stuff, all cleaning agents and water shall be suitable for use in food industry. The cleaning area shall be separated from the production area. Containers should be identifiable (for example by a number) and the inspection / maintenance program should be documented and recorded.

Containers shall not be used for non-foodstuffs where this poses a risk of contamination. Adequate cleaning shall be carried out if containers have been used for other foodstuffs before use for dry ice.

The transport of dry ice containers to the customer is preferably carried out using closed vehicles provided with ventilation to prevent the build-up of carbon dioxide.

8.5 Personal hygiene

During the production of dry ice there is physical contact between the personnel and the product. Therefore good personal hygiene practices are required covering such items as health status, illness and injuries, personal cleanliness, eating and jewellery.

- Operators shall be removed from the production area, if scars and wounds cannot be covered.
- The wearing of clean and proper protective clothing for all personnel working in the production area is necessary. Documented hygiene procedures should be established and implemented.
- The use of tobacco is strictly forbidden (in any form).
- Eating in the work area is strictly forbidden.

8.6 Provisions applicable to foodstuffs

Dry ice shall 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, such as ISO 9001:2008– Quality management systems – requirements.

HACCP analysis of the entire supply chain including the supply and storage of bulk liquid carbon dioxide, the dry ice manufacturing facility and transport arrangements to the point-of-sale shall be carried out.

Hazardous materials such as lubricants, hydraulic fluid and cleaning chemicals etc. shall be stored separately from dry ice products. They shall not be kept in production areas, and shall be clearly
labelled. Such products shall only be brought into production areas when necessary, and shall be removed again into safe storage as soon as possible.

Dry ice shall be traceable to a registered premises and batch / lot. 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, see Section 5.3.

8.7 Wrapping and packaging

Wrapping for use with dry ice shall be made from food-compatible materials, which are suitable for use at low temperature (down to -78.4°C). This includes plastic bags, plastic film, paper and composite materials including container liners (if used). See Regulation 1935/2004.

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

Material, scrap and waste shall be correctly stored: separated from the production area and well identified.

Finished product shall be stored in a separate area and well identified. The use of seals is recommended.

9. On-site gas generators

9.1 Introduction and scope

This section provides specific guidelines for “On-site” generators.

An “On-site” generator makes gas for use directly at the location where the equipment is installed without the need of transport. The equipment usually supplies the gas to a distribution pipe work 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.

Typical gases produced by on-site generators are:

- Nitrogen (gaseous or liquid) from air
- Oxygen from air
- Hydrogen from electrolysis of water

The most common on-site generators are non-cryogenic systems for producing a mixture of gases (typically nitrogen and oxygen) with a variation of content of the different gases.

The on-site generators shall be designed to produce gases suitable for the intended applications. This includes the requirements for use in foods.

9.2 Requirements for food premises

The on-site gas generators shall be installed in locations that are suitable for the purpose. In particular where air is the feedstock for the on-site generator, the air intake shall be free of contaminants. For example, waste solvents and boiler/engine exhausts shall not be adjacent to the air intake to a plant.

On-site generators are pressurised systems and thus have a level of good protection from the environment provided that appropriate hygiene controls are in place for 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.

9.3 Equipment requirements

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 as a standard product that shall produce gas of a consistent quality provided that it is 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.

Any requirement to control and track the quality of the produced gas may require the installation of on-site analytical equipment. There may be additional requirements such as flow and pressure alarms. The materials of construction shall be compatible with foods and the environment.

The equipment shall be designed to give adequate protection from contamination of 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.