



GUIDELINES FOR THE ASSESSMENT OF SUITABLE MATERIALS IN CONTACT WITH FOOD GASES

Doc 253/24

EUROPEAN INDUSTRIAL GASES ASSOCIATION AISBL



AVENUE DE L'ASTRONOMIE 30 • B – 1210 BRUSSELS

Tel: +32 2 217 70 98

E-mail: info@eiga.eu • Internet: www.eiga.eu



GUIDELINES FOR THE ASSESSMENT OF SUITABLE MATERIALS IN CONTACT WITH FOOD GASES

Prepared by AHG-8.4 of Industrial Gases Council
Published in August 2024

Disclaimer

All technical publications of EIGA or under EIGA's name, including Codes of practice, Safety procedures and any other technical information contained in such publications were obtained from sources believed to be reliable and are based on technical information and experience currently available from members of EIGA and others at the date of their issuance.

While EIGA recommends reference to or use of its publications by its members, such reference to or use of EIGA's publications by its members or third parties are purely voluntary and not binding.

Therefore, EIGA or its members make no guarantee of the results and assume no liability or responsibility in connection with the reference to or use of information or suggestions contained in EIGA's publications.

EIGA has no control whatsoever as regards, performance or non performance, misinterpretation, proper or improper use of any information or suggestions contained in EIGA's publications by any person or entity (including EIGA members) and EIGA expressly disclaims any liability in connection thereto.

EIGA's publications are subject to periodic review and users are cautioned to obtain the latest edition.

© EIGA grants permission to reproduce this publication provided the Association is acknowledged as the source



Table of Contents

1	Introduction	1
2	Scope and purpose	1
2.1	Scope.....	2
2.2	Purpose	2
3	Definitions	2
3.1	Publication terminology	2
3.2	Technical definitions	2
4	European food legislation	4
4.1	Regulation 1333/2008 on food additives [6]	4
4.2	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 [3]	4
4.3	Regulation EC 1935/2004 on materials and articles intended to come into contact with food [1]	5
4.4	Regulation EC 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food [2]	5
4.5	Local legislations and rules about materials and articles intended to come into contact with food	6
5	Food gas production and supply	6
5.1	Primary production.....	6
5.2	Secondary production.....	8
5.3	Supply of food gases to end user	9
5.4	On-site generation	11
6	Material risk analysis.....	12
6.1	Compliance study summaries	12
7	Conclusion	13
8	References.....	13
	Figure 1 – Air separation unit batch food gas production	7
	Figure 2 – Carbon dioxide batch food production	8
	Figure 3 – Cylinder/bundles for filling plant.....	9
	Figure 4 – Modified atmosphere packaging.....	10
	Figure 5 – Cryogenic installation.....	11
	Figure 6 – On-site generator process	12

1 Introduction

Regulation (EC) No 1935/2004 *on materials and articles intended to come into contact with food* has provided to the EU Member States a common regulation on the safety characteristics that materials and objects intended to come into contact directly or indirectly with foodstuffs [1].

According to the Regulation 1935/2004 the Food Contact Materials (FCMs) shall be manufactured in compliance with Reg (EC) No 2023/2006, *on good manufacturing practice for materials and articles intended to come into contact with food* so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could [1, 2]:

- endanger human **health**;
- bring about an unacceptable change in the **composition** of the food; or
- bring about a deterioration in the **organoleptic characteristics** thereof.

Regulation (EC) No 178/2002 *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* defined food additives (and ingredient) as foodstuff and in this approach, gases used as food additives shall be in compliance with the same regulation and legislation applicable to foodstuff and, consequently also to the Regulation 1935/2004 [3, 1].

In consequence, gas companies shall focus on the conformity of the material in contact with the food additive gases during their production, storage but also in all the supply chain till the point of use.

For this reason companies of the gas industry should receive from their suppliers FCM labelled, *inter alia*, "for food contact", and accompanied by "Declaration of Compliance" if and insofar as specific measures have been adopted or to provide the same declaration of compliance if they supply material and equipment that can come in contact with the food additive gas supplied.

This means that the gas containers (cylinders, tanks, minibulks) that constitute their "packaging" and all the materials that can be in contact with the gas additive during the production process and/or the food process shall be checked in compliance according the FCMs regulation.

2 Scope and purpose

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, for example, 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. The food contact materials regarding production, storage and supply of dry ice (solid carbon dioxide) are covered in EIGA Doc 150, *Guidelines for Safe and Hygienic Handling of Dry Ice* [4].

During the production, storage and the distribution the food gases come in contact with different materials that shall be in compliance with the Regulation 1935/2004 in specific containers defined as package [1].

This publication covers all stages of the supply chain including production, storage, re-packaging and distribution of food gases to the final user in which the food gasses can be in contact with different materials.

The publication is intended to establish an awareness of the particular legislative requirements as they apply to the food contact materials 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 and ingredients; and

- determination of the criteria for the material food compliance including the good manufacturing practices according to Regulation 2023/2006 and the Hazard Analysis and Critical Control Points (HACCP) according to Regulation (EC) No 853/2004 *on the hygiene of foodstuffs* [2, 5].

2.1 Scope

This publication considers only the liquid and gas phase of food gases and defines when the raw gas becomes food during their production, and when and how it is necessary to follow the FCMs regulation.

2.2 Purpose

The purpose of this publication is to provide:

- an evaluation of materials that can be in contact with food gases in order to be in compliance with the FCMs regulation based on analysis; and
- clarification about the compliance and certification on the FCMs and the good manufacturing practices.

3 Definitions

For the purpose of this publication, the following definitions apply.

3.1 Publication terminology

3.1.1 Shall

Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.1.2 Should

Indicates that a procedure is recommended.

3.1.3 May

Indicates that the procedure is optional.

3.1.4 Will

Is used only to indicate the future, not a degree of requirement.

3.1.5 Can

Indicates a possibility or ability.

3.2 Technical definitions

3.2.1 Batch

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.

3.2.2 Cryogenic receptacle

A thermally insulated vessel for the transport of refrigerated liquefied gases.

3.2.3 Container

A general object for holding or [transporting](#) gases in all the phase (liquid, gas, solid).

3.2.4 Component

A part of equipment.

3.2.5 End user

A person or other entity that makes use of the food gases for their own requirements.

3.2.6 Equipment

All the machines, tools, piping, connection include transport fleet, storage tank in which the gases are stored or transfer.

3.2.7 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 178/2002) [3].

3.2.8 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 (EC) No 1333/2008 *on food additives*) [6]. Food additives include packaging gases and propellants.

3.2.9 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 178/2002) [3].

3.2.10 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].

3.2.11 Food gases

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

3.2.12 HACCP

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

3.2.13 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 *on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs*) [7].

3.2.14 Primary production plant

A factory in which liquid gases are produced in bulk by the Air Separation Unit (ASU) for liquid nitrogen, oxygen and argon and also by recovery plants for liquid CO₂ and production for liquid nitrous oxide and hydrogen.

3.2.15 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 1333/2008) [6].

3.2.16 Non-conforming product

Product which does not meet the relevant company specifications or 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.)

3.2.17 Secondary production plants

The plants in which the bulk liquid gases are repackaged into containers such as cylinders, bundles, mini bulk.

3.2.18 Specific measures

Particular regulations referred to in Article 16 of Regulation 1935/2004 that require FCMs to be supplied with a Declaration of Compliance [1]. Article 34 of Regulation 1935/2004 indicates specific measures may be adopted according to Regulation 178/2002 [1, 3]. National legislation may also require specific measures for FCMs.

4 European food legislation

The information presented in this section is a brief summary, for more information refer to EIGA Doc 125, *Guide to the Supply of Gases for use in Foods* [8].

4.1 Regulation 1333/2008 on food additives [6]

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.

Functional classes of food additives in foods are defined in Annex 1, in particular “Food Additives” are present in “packaging gases” and “propellants”.

4.2 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 [3]

This regulation established the European Food Safety Authority (EFSA) and stipulates general principles of food law. It harmonises national requirements which, hitherto, had varied 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 shall 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.

4.3 Regulation EC 1935/2004 on materials and articles intended to come into contact with food [1]

FCMs are all materials which are or are intended or likely to be in contact with food such as food packaging, kitchenware and tableware, as well as materials for food manufacturing, preparation, storage and distribution. They can thus influence food safety and quality throughout the whole of the food supply chain. FCMs cover a wide range of different materials such as plastic, paper, glass and metal, but also adhesives, printing inks and coatings used in the finishing of the final articles. Actors in the chain include manufacturers of raw materials, intermediate and final FCMs and food products, as well as importers and distributors.

Regulation EC 1935/2004 is the framework legislation for FCMs. Its purpose is to ensure the effective functioning of the internal market for materials and articles intended to come into contact with food and secure a high level of protection of human health, as well as the interests of consumers [1].

The harmonised legislation on food contact materials, FCM, Regulation EC 1935/2004, covers general requirements for all types of FCMs [1]. The regulation applies to FCMs which:

- are intended to be brought into contact with food;
- are already in contact with food and were intended for that purpose; or
- can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

The framework legislation also sets out other rules, including those on labelling and on compliance documentation and traceability, and lays down the risk assessment process involving EFSA as part of the authorisation process for substances.

Specific measures for groups of materials and articles, including authorisation of substances, may also be introduced. Only where specific measures exist, materials shall be issued with a Declaration of Compliance.

Regulation EC 1935/2004 sets out general requirements that all FCMs shall be manufactured in accordance with Good Manufacturing Practice (GMP) so that they are safe and do not change the properties of food in unacceptable ways [1]. As the general requirements for all FCMs set out under Article 3 are linked to the general obligations on GMP, separate rules on GMP are laid down in Regulation 2023/2006 [2].

Regulation EC1935/2004 was amended by Regulation (EU) 2019/1381 *on the transparency and sustainability of the EU risk assessment in the food chain* with effect from 27th March 2021 [1, 9].

4.4 Regulation EC 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food [2]

GMP, is required in the production of FCMs, as it is in the production of food. GMP comprises quality assurance and identification of critical control points (CCPs) in the manufacturing process.

For food authorities, the requirements are included in Regulation (EC) No 882/2004 *on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules*, whereas for companies and FCM, they are defined in Regulation 2023/2006 [10, 2].

Regulation 2023/2006 defines that GMP “means those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof” [2]. Also, it says that quality assurance “means

the total sum of the organised and documented arrangements made with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use”.

4.5 Local legislations and rules about materials and articles intended to come into contact with food

In the absence of specific EU measures, EU Member States may maintain or adopt their own national provisions on FCMs in accordance with Article 6 of Regulation 1935/2004 [1]. National legislation is in place in the majority of EU Member States, setting out individual rules on different materials and substances. These may differ from one Member State to another.

The European Commission's Joint Research Centre (JRC) issued a report in 2017, which provides a comprehensive description of the current situation concerning FCMs for which there are no specific measures at EU level [11]. The study provides detailed information on the current national measures or other measures in place for these materials.

Over recent years, a number of issues linked to FCMs have raised concerns by Member States, industry, the European Parliament and non-governmental organisations on the lack of specific EU legislation for certain materials. These relate both to the potential safety issues of FCMs and to the functioning of the internal market. National rules in place in Member States may differ from one another and may introduce inconsistencies in the approach to regulating FCMs.

5 Food gas production and supply

5.1 Primary production

5.1.1 Air gases production

An Air Separation Unit (ASU) is a manufacturing process that separates air into its major components of oxygen, nitrogen, and argon. The air separation process was developed in the early 1900s and, though the manufacturing equipment has changed with the times to be more energy efficient, the overall process has not changed. This is a very robust process producing high purity oxygen, argon and nitrogen that are intended for food applications. The process is designed with in-process controls and analysis, which ensure that the process stays within established operating ranges. In the event product does not meet food specifications (see EIGA Doc 126, *Minimum Specifications for Food Gas Applications*), it is discarded to prevent the non-conforming product from entering the storage tank (see EIGA Doc 125) [12, 8].

The gas is then transferred to a storage tank or the tanker. A batch analysis is conducted according to the quality management system. The gas becomes a food after the completion of a batch analysis.

The assessment of the compatibility of materials in contact with food gases is only required for the storage tanks or tankers in which the batch analysis has been completed and in all the materials in contact with food gases in all subsequent steps of the supply chain and secondary production.

Equipment upstream of the batch analysis is not in contact with food and therefore does not require a food contact assessment according to Reg EC 1935/2004, unless determined by risk assessment [1].

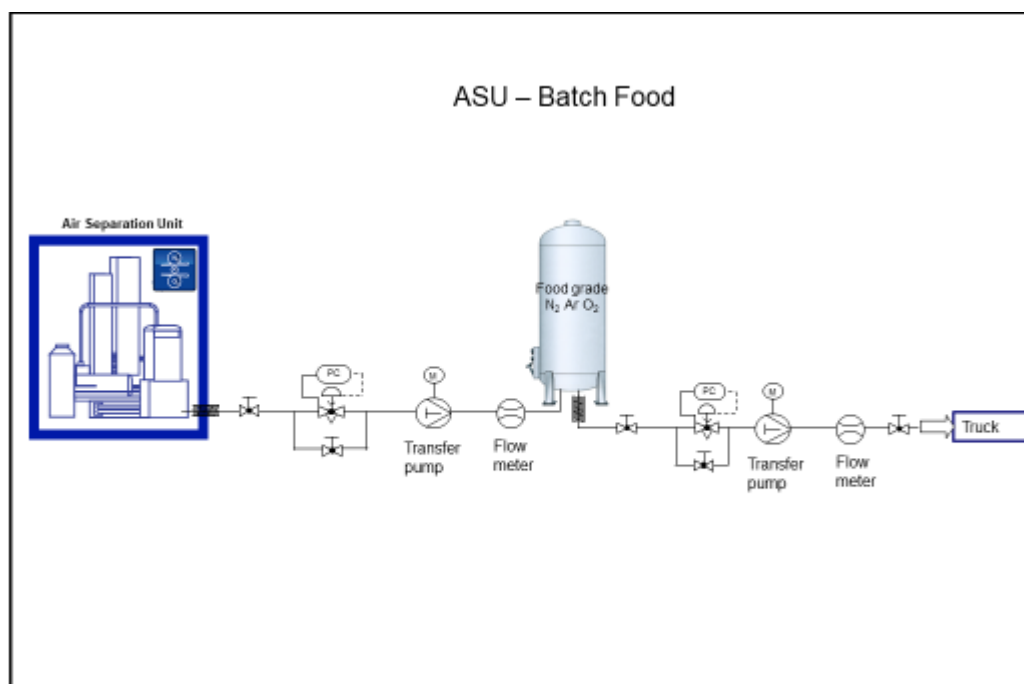


Figure 1 – Air separation unit batch food gas production

5.1.2 Carbon dioxide, nitrous oxide and hydrogen production

A carbon dioxide, nitrous oxide or hydrogen plant is a manufacturing process that separates the product from various industrial raw chemical production for example ammonia, fermentation or ethanol. The raw gas composition determines the design of the plant, specifically the purification steps and procedures and also the analytical controls during the process. The process is designed with in-process controls and analysis, which ensure that the process stays within established operating ranges. In the event product does not meet food specifications (see EIGA Doc 126), it is discarded to prevent the non-conforming product from entering the storage tank (see EIGA Doc 125) [12, 8].

For more information on carbon dioxide, see EIGA Doc 70, *Carbon Dioxide Food and Beverages Grade, Source Qualification, Quality Standards and Verification* [13].

The gas is then transferred to a storage tank or the tanker. A batch analysis is conducted according to the quality management system. The gas becomes a food after the completion of a batch analysis.

The assessment of the compatibility of materials in contact with food gases is only required for the storage tanks or tankers in which the batch analysis has been completed and in all the materials in contact with food gases in all subsequent steps of the supply chain and secondary production.

Equipment upstream of the batch analysis is not in contact with food and therefore does not require a food contact assessment according to Regulation 1935/2004, unless determined by risk assessment [1].

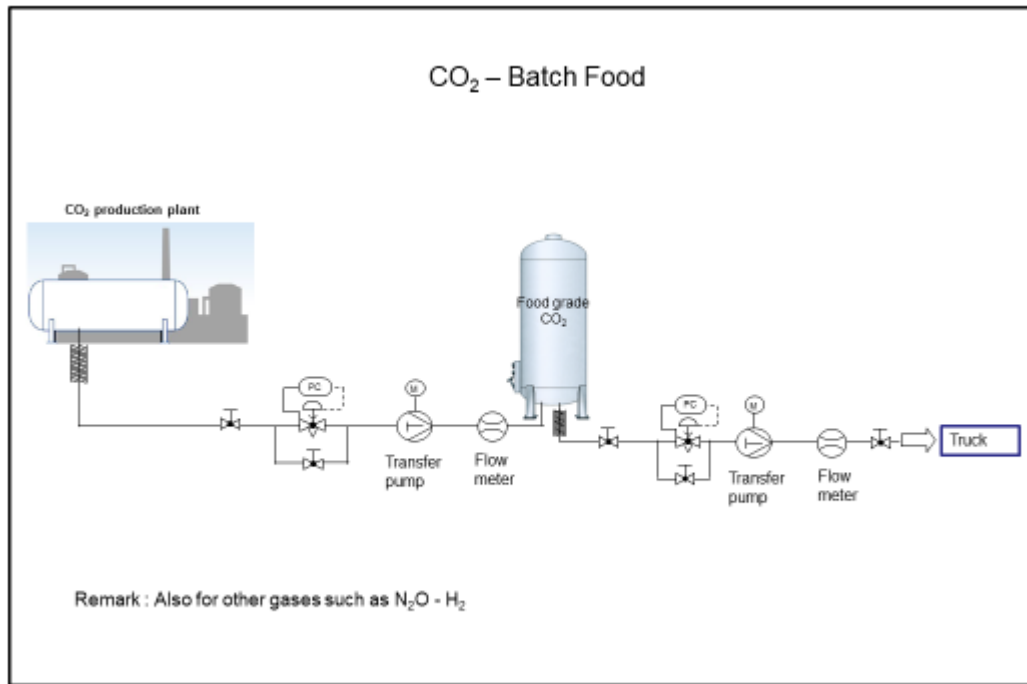


Figure 2 – Carbon dioxide batch food production

5.2 Secondary production

From the primary production plants the food gases can go directly to secondary production plants such as for cylinder filling and onward distribution to end user.

For food use, the food gases delivered to the filling plants shall be in accordance with food specifications. During the filling steps, the equipment in contact with the food gases include:

- pumps;
- vaporisers;
- containers such as cylinders and bundles of cylinders;
- electric heaters;
- high pressure hoses, hoses, manifolds / ramps;
- pressure regulators;
- distribution networks (piping, valves, pressure gauges, thermometers); and
- filtration.

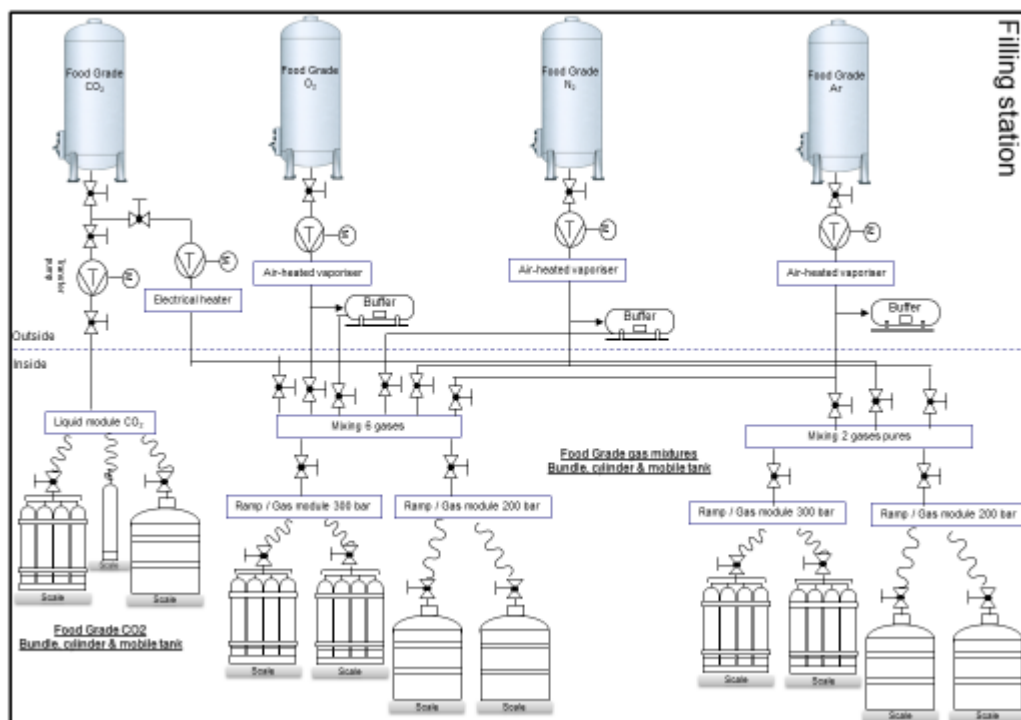


Figure 3 – Cylinder/bundles for filling plant

When food gases are supplied, all the materials of the components mentioned shall have a Declaration of Compliance (where specific measures exist) otherwise materials shall be risk assessed as FCMs.

5.3 Supply of food gases to end user

Food gases are used for a variety of purposes in the food industry.

The principal uses of food gases include:

- oxygen, nitrogen and carbon dioxide as modified atmosphere packaging (MAP) 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;
- liquid nitrogen and liquid carbon dioxide for freezing and chilling;
- carbon dioxide for super-critical extraction;
- hydrogen for hydrogenation of fats; and
- carbon dioxide for carbonated beverages.

In general, the supply of food gases involves the installation of a distribution network from the storage to the point of use involving various components and equipment that comes in contact with the food gas including but not limited to:

- storage tanks (vacuum or conventionally insulated), mobile delivery tanks, pumps, meters and hoses;
- cylinders;

- vaporisers (atmospheric, steam, hot water and electric);
- gas mixers;
- food processing equipment;
- buffer capacities;
- distribution networks (piping, valves, relief devices pressure gauges, thermometers, flow meter);
- filtration; and
- pressure switches, thermostats, etc.

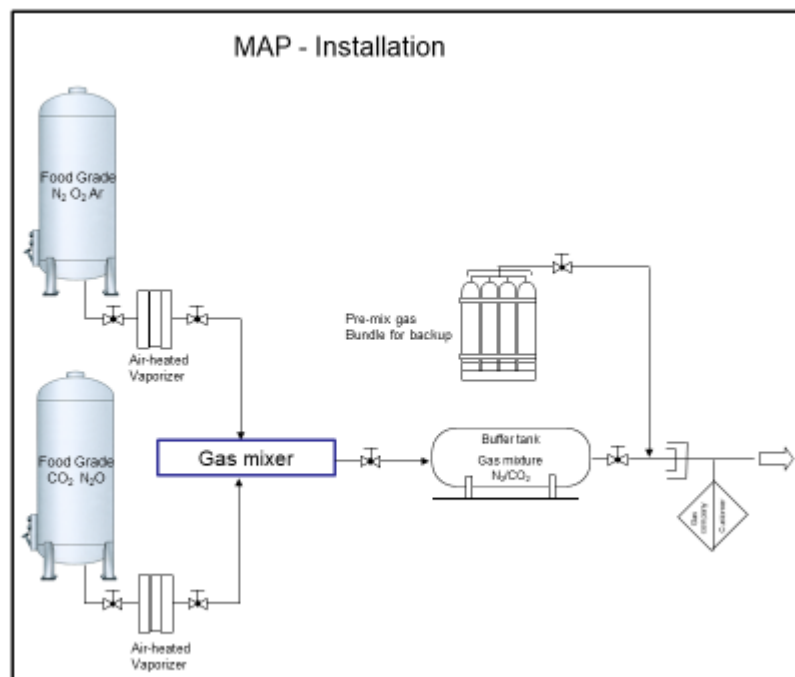


Figure 4 – Modified atmosphere packaging

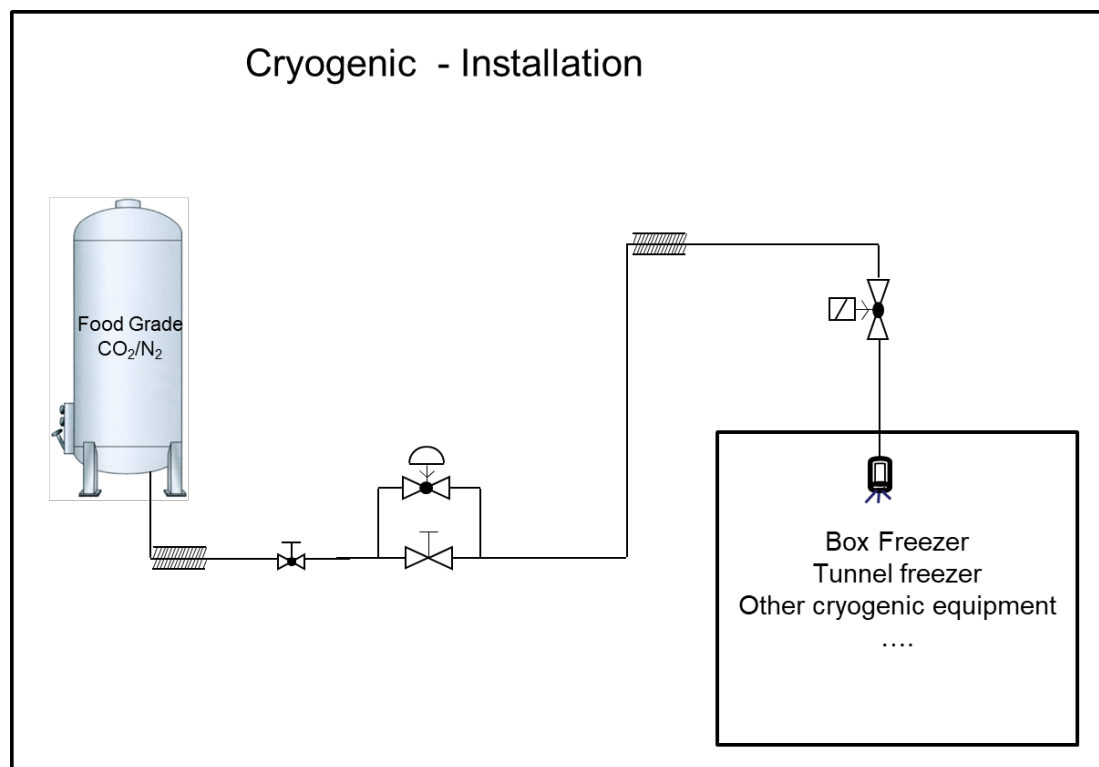


Figure 5 – Cryogenic installation

When food gases are supplied, all the materials of the components mentioned shall have a declaration of compliance (where specific measure exist) otherwise materials shall be risk assessed as FCMs.

All components should be assembled according to GMP in order to avoid any modification of the material composition and / or chemical characteristics thus maintaining the compliance of the assembled components and equipment.

5.4 On-site generation

An on-site generator separates nitrogen or oxygen from air for use directly at the user location and delivered by pipeline. The air is initially filtrated, compressed and dried. The compressed pre-treated gas feeds a PSA, VSA, membrane or cryogenic separator to produce nitrogen or oxygen for use in food applications.

The gas becomes a food after the analyser to confirm that the minimum purity criteria for according to the Regulation (EU) No 231/2012 *laying down specifications for food additives* (see also EIGA Doc 126, and for nitrogen see also EIGA Doc 194, *Design and Operation of On-site Nitrogen Generators for Food Use*) [14, 12, 15]. This means that the materials before the analyser do not need to conform to the materials in contact with food regulations such as compressors, membranes, mol sieves etc.

FCMs include but are not limited to:

- buffer capacities;
- distribution networks (piping, valves, relief devices pressure gauges, thermometers, gasometers;
- point of use filtration; and
- pressure switches, thermostats, etc.

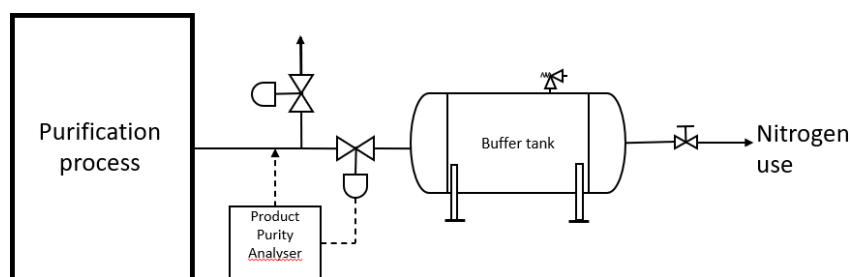


Figure 6 – On-site generator process

6 Material risk analysis

When food gases are supplied, all the materials of the components in contact with food gases mentioned shall have a Declaration of Compliance (where specific measure exist) otherwise such materials shall be risk assessed as FCMs.

When components and equipment in contact with Food Gases are assembled, it shall follow the requirements of GMP Regulation 2023/2006, HACCP shall be qualified in compliance with the FCMs Regulation EC 1935/2004 [2, 1]. Each modification of the assembly shall be monitored and documented by the owner of the equipment and components involve in the modification.

The choice of materials used in food gases are generally driven by the safety requirements of the design of pressurised and cryogenic equipment (for example Pressure Equipment Directive and Transport of Dangerous Good Regulations) [16, 17].

Many materials for the safe supply of food gases (for example cylinders) have been in use for well over 100 years to supply of gases to food customers for example carbonation of beverages without any known issues of contamination from the materials coming in contact with food gases used.

6.1 Compliance study summaries

Introduction to the CNR study

In 2013 the University of Florence completed a detailed study (the CNR study) on the potential contamination from the carbon steel cylinders and bundles used as packages of food gases [18]. The study analysed potential metal element contamination from the package to the food gases. The analysis of gases in cylinders is relevant as this gas has passed through the entire production supply chain (i.e. generation, production storage, bulk transport, delivery, on-site storage, pumping, vaporisation and filling), meaning the gas was exposed to various metals and plastics commonly used in the supply chain.

This study defined a protocol for sampling and analysis of elements potentially released in food gases (CO₂, N₂ and O₂) through migration processes from carbon steel cylinders and used the analytical data to provide a preliminary evaluation of the impact of migration processes on food gas quality.

Currently there is no defined acceptable data for metallic contamination in the food gases, as a result the study was used the limit concentrations for mineral waters (CEE/CEEA/CE no. 83, 03-11-1998; D.Lgs no. 3, 2001; D.M. 29-12-2003) [19].

The study presents an efficient and simple sampling and analytical procedure. The definition of a methodological protocol is to be considered of fundamental importance because the European regulations impose a strict control on the quality of food in contact with packages of different material, including carbon steel, but they do not provide any guideline to indicate how to carry out these controls on food gases.

The tests showed that metallic migration from cylinders was very low (especially Al, Fe, Ni and Zn) in the food gases (CO₂, N₂ and O₂), even if considering a long storage period (5 years). A preliminary evaluation of these results was carried out by comparing the element concentrations measured in CO₂-filled cylinders with the limit concentrations for mineral waters. These tests have shown that food gases contamination related to migration from carbon steel cylinders is not significant.

So according to this study the cylinders in carbon steel without any FCMs declaration and general used as container for food gases can be considered suitable to be in contact with food gases.

Introduction of the French study

In 2017 the University of Florence completed a detailed study with the aim to carry out tests regarding the possible contamination of food grade CO₂ from copper pipe and other components (from cylinder to point of use) used for gas storage and distribution [20]. For this study, the sampling and analytical protocol developed for carbon steel packages was modified to be include to other materials (i.e. copper and its alloys).

The results concluded that migration processes, i.e. the progressive release of chemical elements from copper, do not produce any significant contamination of the food gas (Ag, Al, Cu, Cr, Fe, Ni, Pb and Zn), so copper can be suitable to be in contact with food gases.

7 Conclusion

Gases produced in the primary production plant (ASU, CO₂ recovery, ...) becomes food after the release by batch analysis. So in general the food gases are define in the last stage of the production process when the gas is stored in a storage tank and analysed in compliance according to the food gas specification (Reg 231/2012)..... All the equipment and components coming in contact with those food gases shall be in compliance with FCMs.

In the secondary production plant in which the food gases are packaged in different systems and containers all the materials in contact with food gases, shall be in compliance with FCMs

When the food gases is requested by the end user all the materials in contact with food gases shall be in compliance with FCMs

Equipment and components suppliers for materials in contact with food gases shall supply certification of materials suitable for food and associated Declaration of Compliance according to Reg 1935 and 2023 (where specific measures have been adopted in legislation or local regulation). In case is not possible to get a certification or declaration of conformity for FCMs by suppliers such materials shall be risk assessed as FCMs by end users.

When components and equipment in contact with Food Gases are assembled, it shall follow the requirements of GMP Regulation 2023/2006, HACCP shall be qualified in compliance with the FCMs Regulation EC 1935/2004 [2, 1]. Each modification of the assembly shall be monitored and documented by the owner of the equipment and components involve in the modification..Containers for packaging gases (storage, transportation) are designed and assembled according to well-known technical rules and a wide knowledge about materials and the behaviour of gases. This knowledge is incorporated in a number of regulations and standards; these include Pressure equipment Directive (PED), European **Agreement concerning the International Carriage of Dangerous Goods by Road** (ADR), the Transportable Pressure Equipment Directive (TPED), and also some national and local requirements [16, 17, 21]. These requirements take into account the compatibility (chemical and physical properties) of gases that are intended to be stored in pressure containing equipment.. The choice of materials is not an arbitrary decision, but based on detailed technical knowledge combined with experience over many years in order to guarantee the safety in using the gases. A negative influence on the food gases is not known by using materials chosen in such a way and is demonstrated by the studies undertaken by the University of Florence [18, 20].

8 References

Unless otherwise specified, the latest edition shall apply.

- [1] Regulation EC 1935/2004 *on materials in contact with food*, www.europa.eu.
- [2] Reg (EC) No 2023/2006, *on good manufacturing practice for materials and articles intended to come into contact with food*, www.europa.eu.
- [3] Regulation (EC) No 178/2002 *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*, www.europa.eu.
- [4] EIGA Doc 150, *Guidelines for Safe and Hygienic Handling of Dry Ice*, www.eiga.eu.
- [5] Regulation (EC) No 852/2004 *on the hygiene of foodstuffs*, www.europa.eu.
- [6] Regulation (EC) No 1333/2008 *on food additives*, www.europa.eu.
- [7] Directive 2000/13/EC *on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs*, www.europa.eu.
- [8] EIGA Doc 125, *Guide to the Supply of Gases for Use in Foods*, www.eiga.eu.
- [9] Regulation (EU) 2019/1381 *on the transparency and sustainability of the EU risk assessment in the food chain*, www.europa.eu.
- [10] Regulation (EC) No 882/2004 *on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules*, www.europa.eu.
- [11] *Non-harmonised food contact materials in the EU: regulatory and market situation*, European Commission Joint Research Centre, www.europa.eu/jrc.
- [12] EIGA Doc 126, *Minimum Specifications for Food Gas Applications*, www.eiga.eu.
- [13] EIGA Doc 70, *Carbon Dioxide Food and Beverages Grade, Source Qualification, Quality Standards and Verification*, www.eiga.eu.
- [14] Regulation (EU) No 231/2012 *laying down specifications for food additives*, www.europa.eu.
- [15] EIGA Doc 194, *Design and Operation of On-site Nitrogen Generators for Food Use*, www.eiga.eu.
- [16] Directive 2014/68/EU *on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment*, www.europa.eu.
- [17] *Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)*, www.unece.org.
- [18] *Migration Processes of Metal Elements from Carbon Steel Cylinders to Food Gases*, (F Tassi, F Capeccchiacci, O Vaselli), University of Florence, www.onlinelibrary.wiley.com.
- [19] Council Directive 98/83/EC *on the quality of water intended for human consumption*, www.europa.eu.
- [20] *Migration Processes of Metal Elements from Carbon Steel Cylinders to Food Gases*, University of Florence 2014, Assogastecnici-Federchimica
- [21] Directive 2010/35/EU *on transportable pressure equipment*, www.europa.eu.
- [22] FSSC 22000, *Food Safety System Certification*, www.fssc22000.com.
- [23] ISO 22000, *Food Safety Management*, www.iso.org.