



# **GUIDE TO THE SUPPLY OF GASES FOR USE IN FOODS**

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# GUIDE TO THE SUPPLY OF GASES FOR USE IN FOODS

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### Amendments to 125/11

Section	Change
	Editorial to align style with EIGA style manual
1	Update to Regulation numbers
2	Clarification on processing aids
3	New definitions added
4.2	Update to applicability from Regulation 1333/2008
4.2	Information transferred to appendix 1
4.4	New section on labelling
4.5	Information transferred to Appendix 2
4.6	Addition of CNR study information
5.1, 5.1.1, 5.1.2	New sections
6.3	Changes to non-conforming product guidelines
7.2	Information added on labelling and marking
7.7	Changes to non-conforming product
8	Re-ordering of section and alignment with EIGA Doc 150

NOTE Technical changes from the previous edition are underlined

## 1 Introduction

The basis for European food legislation is 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* [1].<sup>1</sup> Current and proposed European legislation requires that foods, including gases supplied to the food industry as food additives and ingredients meet increasingly rigorous standards to ensure food safety.

Gases are used for a variety of purposes in the food industry as additives, processing aids and ingredients. Particularly for food additive and food ingredients, there are requirements regarding labelling, purity and hygiene.

For gases used as processing aids in contact with food according to the Regulation (EC) No 1333/2008 on food additives Article 3 §2 b (iii), the purity of the gas should be in compliance with food additive quality as required by the Regulation (EU) No 231/2012 laying down specifications for food additives, in order to avoid that any residues or derivatives in the gas do not represent any health risk [2, 3].

The principal uses of gases in the food industry includes, but is not limited to:

- **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; and
  - sulphur dioxide as a preservative for specified foods.
- **Processing aids:**
  - liquid nitrogen and liquid carbon dioxide for freezing and chilling;
  - carbon dioxide for super-critical extraction; and
  - hydrogen for hydrogenation of fats.
- **Ingredients:**
  - carbon dioxide for carbonated beverages.

This publication provides a summary of the relevant legislation together with advice as to how best to meet their requirements.

## 2 Scope and purpose

### 2.1 Scope

This publication covers all stages of the supply chain including production, storage, re-packaging and distribution of food gases to the final user (customer or consumer).

For this publication, food gases are gases in solid, liquid or gaseous form that are supplied to the food industry and used as additives, processing aids or ingredients. For the applicability of requirements for processing aids, see the definition of food gases. Food gases can be generated on site, delivered as bulk liquid, compressed cylinder gases, or, in the case of carbon dioxide, as solid dry ice.

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

## 2.2 Purpose

The publication 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 can be met. These requirements cover legislation in the following areas:

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

## 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**

Indicate 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 can 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.

#### 3.2.2 **Bulk**

A large amount of gas transported, supplied, stored generally in liquid cryogenic form in a cryogenic vessel.

#### 3.2.3 **Consumer**

The person that eats or drinks the product and will not use the food as a part of any food business

operation or activity as per Regulation (EC) No 178/2002 [1].

#### **3.2.4 Container**

General term used in food law to describe the item used for storage or transport of foodstuffs. Within this publication the term container shall be used to describe any equipment used for the storage or transport of gases in either solid, liquid or gaseous form. Where appropriate, additional descriptions common in the gases industry may be used such as cylinder, bundle, tank, dry ice container etc.

#### **3.2.5 Cryogenic vessel**

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

#### **3.2.6 Customer**

The legal entity that uses the food gases for further processing.

#### **3.2.7 Cylinder**

A transportable non-insulated pressure vessel for storage and containment of gases at above atmospheric pressure.

#### **3.2.8 Food or foodstuff**

Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans as per Regulation (EC) No 178/2002 [1].

#### **3.2.9 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 as per Regulation (EC) No 1333/2008 [2]. Food additives include packaging gases and propellants.

#### **3.2.10 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 as per Regulation (EC) No 178/2002 [1].

#### **3.2.11 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 as per Regulation (EC) No 178/2002 [1].

#### **3.2.12 Food gases**

Gases in solid, liquid, gaseous form intended to be used as a food additive, processing aid or ingredient however, processing aids are not subject to the same legal requirements as food. In this publication the requirements for food gases are indicated with a "shall", for processing aids it may be read as "should" as the legal requirements do not apply to processing aids.

### 3.2.13 Hazard analysis critical control points (HACCP)

A formal method to assess the food safety risks.

### 3.2.14 Ingredient

Any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form. Residues shall not be considered as ingredients as per Regulation (EU) No 1169/2011 on the provision of food information to consumers [4].

### 3.2.15 Non-conforming product

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.

### 3.2.16 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 as per Regulation (EC) No 1333/2008 [2].

### 3.2.17 Preservatives

Substances which prolong the shelf-life of foods by protecting them against deterioration caused by micro-organisms and/or which protect against growth of pathogenic micro-organisms as per Regulation (EC) No 1333/2008 [2].

### 3.2.18 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 as per Regulation (EC) No 1333/2008 [2].

### 3.2.19 Propellants

Any gas, other than air, which expels a foodstuff from a container as per Regulation (EC) No 1333/2008 [2].

### 3.2.20 Top filling

Filling without completely degassing a cylinder.

## 4 European food legislation

Food legislation is issued in the form of either Directives or Regulations.

Directives are legislative acts that sets out a goal that all EU countries shall achieve. However, it is up to the individual countries how to devise their own laws to achieve these goals. This process can lead to slight differences of interpretation between the member countries and how the directive is transposed.

Regulations on the other hand, are binding legislative acts that member countries shall apply in its entirety and no modification is allowed. Therefore, for example, Regulation (EC) No 178/2002 is legally binding in all member states [1].



#### 4.1 **Regulation (EC) No 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**

Regulation (EC) No 178/2002 established the European Food Authority and stipulates general principles of food law. It harmonises national requirements which, hitherto, had varied slightly between countries [1].

This regulation 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.

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

The regulation 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.

#### 4.2 **Regulation (EC) No 1333/2008 on food additives**

Regulation (EC) No 1333/2008 defines food additives and processing aids and states explicitly that it does not apply to processing aids [2]. Annex I of this regulation defines 26 applications of which 3 are relevant to gases: preservatives, propellants and packaging gases.

The requirements relating to applicable labelling obligations (articles 21, 22 and 23) are given for information in Appendix 1. Additional information relating to batch / lot identification is found in Directive 2011/91/EU on indications or marks identifying the lot to which a foodstuff belongs. [5].

#### 4.3 **Regulation (EU) No 231/2012 laying down specific purity criteria on food additives other than colours and sweeteners**

Regulation (EU) No 231/2012 gives purity criteria for food additives [3]. EIGA Doc 126 *Minimum Specifications for Food Gas Applications* lists the gases which are food additives [6].

#### 4.4 **Regulation (EU) No 1169/2011 on the provision of food information to consumers**

Regulation (EU) No 1169/2011 provides the rules of a common definition of food information to consumers, for them to make informed choices, particularly on the labelling of ingredients.

Chapter IV, Article 4 describes the list of requested food information:

- name of the food;
- list of ingredients (with additive numbers in the cases of the food gases);
- quantity of ingredients;
- net quantity of the food;
- date of minimum durability;

- name and address of the food business operator; and
- country of origin.

#### 4.5 Regulation (EC) No 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 Regulation (EC) No 852/2004 [7].

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 or process, food business operators shall review the procedure and make 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.

Extracts of Regulation (EC) No 852/2004, where there is particular relevance to gas companies, are given either in Appendix 2 or in further sections dealing with specific requirements [7].

#### 4.6 Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food

Regulation (EC) No 1935/2004 consolidates a large amount of earlier legislation on materials that come into contact with foods [8]. 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 is not normally relevant to the gas industry. 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.

In 2014, the Centre for National Research (CNR) based in Italy, published the first study about the migration process of potential metal contamination from carbon steel cylinders to food gases. The result was no hazardous contamination in the food gases. Currently this study supports the authority request about the compatibility of cylinders in contact with food gases, for more information see *Migration processes of metal elements from carbon steel cylinders to food gases* [9].

## 5 General standards 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, for example, ISO 22000, *Food Safety Management*, and the Global Food Safety Initiative (GFSI) scheme FSSC 22000, *Food Safety management systems*, and ISO 9001, *Quality Management System – Requirements* [10, 11, 12].

These standards address:

- premises design and cleanliness;
- raw material and supplier management;
- adherence to product specifications;
- equipment design;
- personal hygiene;
- training; and
- 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 publication 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.

### 5.1 ISO 22000 / FSSC 22000

ISO 22000 was developed using ISO 9001 approach, and tailors it to apply to food safety, incorporating the widely used and proven HACCP principles and Good Manufacturing Principles (addressed by prerequisite programs in ISO 22000) [10, 12].

The standard contains requirements for food safety management systems processes and procedures, and requires that the organisation implement prerequisite programmes and HACCP.

Unlike some of the other food safety management systems certification programmes (for example FSSC 22000 and SQF), ISO 22000 does not have specific requirements for prerequisite programmes (PRPs), but requires that the organisation identifies and implements the appropriate programs [10, 11].

FSSC 22000 is a complete certification scheme for food and feed safety management systems, which is in compliance with ISO 22000. The scheme provides a certification model that can be used in the whole food supply chain. It covers sectors where such technical specifications for sector PRPs have been realised. FSSC 22000 follows the food chain category description for example ISO / TS 22002-1

Prerequisite programmes on food safety — Part 1: Food manufacturing (food-grade gases fall into Category K - Production of bio-chemical products) [13].

### 5.1.1 Food defence

Food defence is an important element in protecting businesses and consumers from internal and external threats. It encompasses a range of potential threats from relatively common tamper hoaxes to less probable terrorist attacks. Many examples exist where products have been tampered with deliberately and maliciously. Often supply chain or manufacturing threats can be mitigated to reduce a wide range of threats, for example, using locking lids can reduce a wide range of potential intentional attacks. Food defence programs shall be developed to reduce the risks from both internal and external threats in order to protect your facility and your customers.

FSSC 22000 includes clauses related to Food Defence [11]. Although ISO 22002-1 Chapter 18 addresses this topic, it is now aligned with new GFSI requirements and taken to the management system level, making it a part of the management responsibility process [13].

### 5.1.2 Food fraud

The relevance of food fraud has grown, not in the least following a number of food scandals that have led to a reduction in consumer confidence in the food industry.

Although the driver of food fraud acts (cause) is often economic gain, it can nevertheless result in a food safety risk. Such a risk is very often caused by negligence or lack of knowledge by fraudsters. Consumer food fraud related risks can be:

- (a) Direct food safety risks: the consumer is put at immediate risk (for example addition of melamine to milk powder that results in an acutely toxic exposure; hiding of substances resulting in undeclared allergens);
- (b) Indirect food safety risks: consumer is put at risk through long-term exposure (for example high levels of heavy metals in food supplements causing harm, or lack of benefit, over a longer period of time); or
- (c) Technical food fraud risk: there is no direct or indirect food safety risk (for example misrepresentation of country-of-origin information). However, this indicates that material traceability may have been compromised and the company no longer able to guarantee the safety of their food products.

For food manufacturers, the economic impact can be high (for example recall, loss of sales, cost of rebuilding reputation etc.), but also the consumer trust is important, not only for companies but for food industry (sector) as a whole.

Following the GFSI benchmarking requirements, FSSC 22000 has introduced a chapter on food fraud mitigation [11]. This has become mandatory for FSSC certification holders since January 1<sup>st</sup>, 2018 and includes requirements for a food fraud vulnerability assessment and a food fraud prevention plan applicable to all products.

## 5.2 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 4.5.

## 5.3 General food gases safety considerations

Regulation 852/2004 sets out twelve chapters for consideration when reviewing the controls needed to maintain food hygiene [6]:

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
Chapter 8	Personal Hygiene
Chapter 9	Provisions Applicable to Foodstuffs
Chapter 10	Provisions applicable to the Wrapping and Packaging of Foodstuffs
Chapter 11	Heat Treatment
Chapter 12	Training

General guidance is set out below and only where relevant is further information given in the sections of the guide specific to bulk gases, cylinder gases, dry ice and on-site supply. Matters relating to transport and equipment are covered elsewhere in this publication.

### **5.3.1 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 can require a formal risk analysis where particular circumstances or adverse environmental conditions apply, for example dry ice see Section 8.

For installations on customer sites, the gas supplier, in conjunction with the customer, should agree the identification of a suitable location on the food premises for the siting of product storage 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 storage tank and associated equipment.

### **5.3.2 Temporary and removable premises**

There are no relevant applications in the food gases industry.

### **5.3.3 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.

### 5.3.4 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.

### 5.3.5 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. However, good personal hygiene practices should be encouraged, especially during maintenance activities of components and other items that will be in direct contact with the food gas.

Companies shall have a system in place to deal with health and sickness reporting of personnel involved in the manufacture and distribution of food gases.

### 5.3.6 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.

### 5.3.7 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 wrapping and packing such as cylinders, tanks and dry-ice containers shall not contaminate the gas therein. Nor shall the filling / transfilling process contaminate the gas.

### 5.3.8 Heat treatment

This is not relevant to the food gas industry.

### 5.3.9 Training

All personnel contributing to the quality and integrity of products used in food should undergo 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 shall 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.

### 5.3.10 Labelling

In addition to hygiene considerations described above, it is also essential that food gases are labelled in accordance with the relevant legislation, see [4.4](#).

### 5.3.11 Purity criteria

Purity criteria exist for all gases when used as food additives. These set maximum levels for certain specific impurities, see Section 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. See EIGA Doc 126 *Minimum Specification for Food as Applications* for further information [6].

## 5.4 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 batch 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 and 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 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.

EIGA provides information for producers and distributors of bulk carbon dioxide for food and beverage use in EIGA Doc 68 *Prevention of Carbon Dioxide Backfeed Contamination* and EIGA Doc 70 *Carbon Dioxide Food and Beverages Grade, Source Qualification, Quality Standards and Verification* [14, 15].

## 6.3 Transport and 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.

Vessels for transport and storage shall be allocated to a single product. These vessels should be fitted with couplings specific to the type of gas being transported. The gas supplier can also consider the installation of alternative means to ensure that cross-contamination does not occur, for example procedural control.

### 6.3.2 Gas service conversions

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

- analytical checks for all possible contaminants; and
- purging with an appropriate food gas to achieve required purity.

NOTE Containers are typically purged by pressurising and de-pressurising a specified number of times to remove residual gases in order to achieve a specified purity.

### 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 vessels becoming contaminated during delivery is controlled by means of engineering and / or procedural arrangements. These should be clearly documented as part of the HACCP.

Controls may include:

- hoses protected from ingress of contamination, for example use of end caps;
- purging prior to delivery; and
- common good handling and housekeeping practices such as not dragging hose ends on the ground.

For the reasons given in the introduction to this section, vessels 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 vessels used for the distribution of bulk food gases shall be designated as being suitable for food use. Particular attention should be paid to vessels 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

Procedures shall be in place to avoid releasing non-conforming products. Where non-conformance occurs (or is suspected to occur) at any point in the supply chain, the following procedures apply.



#### 6.3.4.1 Bulk storage

Safely empty and vent the storage tank then purge back to service. (Analyse vessel contents prior to placing back in service).

#### 6.3.4.2 Delivery vessel (detected after filling)

- Quarantine the vessel.
- Safely empty and vent the vessel then purge back to service.
- Analyse vessel contents prior to placing back in service.

#### 6.3.4.3 Suspected non-conforming product at a food customer after delivery

- 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 vessels suspected of carrying non-conforming product. If this analysis shows conformity, inform the customer and no further action is required.
- If analysis confirms non-conformity, the customer shall be informed. Safely empty and vent customer storage. Investigate and complete corrective actions in accordance with food safety management system.

### 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, for example 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 according to Regulation (EC) No 1935/2004 [8].

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 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 vessel 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 Additives and ingredients gases supplied in cylinders and transportable containers**

### **7.1 Introduction and scope**

This section provides specific guidelines on the process of filling containers such as cylinders and transportable containers 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 publication.

The overall process of container filling for additives and ingredients gases shall be the subject of a formalised HACCP review. Particular attention should be paid to the identification and control of potential hazards resulting from cross contamination with other products, 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 additives and ingredients gases**

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

Bulk gas documentation shall clearly indicate which gases are suitable for use in food, including:

- batch or lot numbers (for example in the delivery paper); and
- labelling shall comply with the labelling requirements including the requirement for a best before date (typically three to five years from the date of loading transport tank or in accordance with local regulation).

### **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 according to Regulation (EC) No 1935/2004 [8].

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 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 shall be dried internally prior to filling.

### 7.3.2 Valves

Valves used for 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 64, *Use of residual pressure valves* [16].

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

### 7.4 Pre-fill inspection

ISO 24431 Gas cylinders. Seamless, welded and composite cylinders for compressed and liquefied gases (excluding acetylene). Inspection at time of filling [17] is applicable, but additional requirements apply to additives and ingredients gases.

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

The inspection shall include, but is not limited to, the following:

- The external condition shall be checked to ensure that the container is free from damage or excessive corrosion and that it is suitably clean prior to filling. Previous batch labels should be removed or rendered illegible.
- Liquefied gases cylinders fitted with a dip-tube shall be clearly marked.
- The specific functions of valves on containers should be clearly identifiable.
- 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 shall 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 additives and ingredients gases is not necessary.

All filling processes shall be formally documented.

### 7.5.2 Specific requirements for filling containers – liquefied gases

Liquefied gases, cylinders shall be vented to be liquid free prior to filling. A check shall be carried out to ensure that this is the case before a cylinder is filled, for example 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 Venting residual pressure prior to filling is good practice, but vacuum is not necessary. For more information see EIGA Doc 83, Recommendation for safe filling of CO2 cylinders and bundles [18].

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 7.6 for details.

### 7.5.3 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; and
- complete emptying of the cylinder of any residual compressed gases.

During filling a check should be made that the cylinders are becoming warm. A cold cylinder can indicate a blocked valve that should then be investigated.

If supplied to the consumer, the package shall carry the expiry date.

### 7.5.4 Specific requirements for filling – cryogenic vessels

Cryogenic vessels may be filled by weight, level indicator or by filling to the full trycock (overfill indicator).

Ensure that the correct product is filled into the vessel. This can 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 vessel without formal authorisation, and to ensure that labelling and product identification operations are complete before filling with the new product.

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

## 7.6 Post-fill inspection

Containers should be checked for product leakage, correct labelling and product identification. Checks include:

- batch or lot labels shall be fitted to the containers
- labelling complies with the labelling requirements including the requirement for a best before date (this should be three years from the date of filling);
- the containers are 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; and
- container valve outlets are 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 procedures shall conform to the guidance in Regulation (EC) No 178/2002 [1]. The procedures below should be followed.

#### **7.7.1 Suspected non-conforming product in bulk tank at filling depot**

- Inform production and distribution management – 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 Suspected non-conforming product in cylinder before delivery**

- Quarantine the batch.
- Analyse / vent as necessary.
- If any of the batches have been delivered, proceed in accordance with 7.7.3.

#### **7.7.3 Suspected non-conforming product delivered**

- Receive notification from customer.
- Obtain as much information from the customer to establish if it is a gas supply problem and not a customer's internal problem.
- 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 following any legal requirements of gas association guidance.

Labelling shall distinguish clearly between food and industrial cylinder gases.

## 8 Dry ice production, storage and distribution

EIGA Doc 150, *Guidelines for Safe and Hygienic Handling of Dry Ice*, covers in detail the production, storage and distribution of dry ice [19]. The information below contains a brief summary of requirements, however reference should be made EIGA Doc 150 for more information [19].

### 8.1 Introduction and scope

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. 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.

The requirements for dry ice as specified below are exclusively for the use of it as food additive or food ingredient and not applicable for food processing aid.

### 8.2 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 [12].

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.

### 8.3 Requirements for dry ice production premises

The following 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.

#### 8.4 Production equipment requirements

The extruders, saws 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 lubricant

Food grade lubricants shall be used wherever there is a risk that 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  $-78.4^{\circ}\text{C}$ . Stainless steel and some non-ferrous alloys 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.

#### 8.5 Containers and transport

Dry ice containers shall be constructed of easily cleanable and maintainable materials for example 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 (EC) No 852/2004 [7].

Containers (full or empty) should be kept closed, whenever possible, and always kept closed if stored outside in the open air. The use of closed vehicles for road transport is recommended to keep the containers clean and dry, see EIGA SL 09, Safe Transport of Dry Ice [20].

Dry ice containers shall be inspected and in a clean state before 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.

### **8.6 Post-fill inspection dry ice containers**

Containers for dry ice for use in food processes shall be segregated from those containing non-food grade dry ice. Containers for use in food processes should be checked for damage, correct labelling and product identification. Checks include:

- batch or lot labels shall be fitted to the containers;
- labelling shall comply with the labelling requirements including, for food additive application, the requirement for a best before date, this should be three years from the date of filling;
- the containers shall be of acceptable finish externally; and
- 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.

### **8.7 Personal hygiene**

During the production of dry ice there can be manual handling of the product. Therefore, good personal hygiene practices are required covering such items as health status, illness and injuries, personal cleanliness, eating and jewellery. Other good hygiene practices include:

- operators shall be removed from the production area, if scabs and wounds cannot be covered;
- 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;
- use of tobacco in any form is strictly forbidden; and
- eating and drinking in the work area is strictly forbidden.

### **8.8 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  $-78.4\text{ }^{\circ}\text{C}$ ). This includes plastic bags, plastic film, paper and composite materials including container liners (if used). See Regulation (EC) No 1935/2004 [8].

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 clearly identified. The use of seals / anti-tampering devices is recommended.

## **9 Onsite gas generators**

### **9.1 Introduction and scope**

This section provides specific guidelines for onsite generators.

An onsite generator produces 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 can be intermediate storage tanks.

Onsite 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 onsite generators are:

- nitrogen (gaseous or liquid) from air;
- oxygen from air; or
- hydrogen from electrolysis of water.

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

Onsite generators shall be designed to produce gases suitable for the intended applications. This includes the requirements for use in foods. See EIGA Doc 194 *Design and Operation of On-Site Nitrogen Generators for Food Use* [21].

## 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 onsite generator, the air intake shall be free from certain 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 operator where the on-site generator is installed is responsible for the upkeep of food hygiene standards around the equipment.

Requirements for items such as temperature / humidity / power supply shall be specified by the manufacturer of the on-site generator.

There shall be access to the on-site generator to allow 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 can be located outdoors in some circumstances and thus consideration shall be given to appropriate enclosures according to established international standards.

## 10 References

Unless otherwise stated the latest edition shall apply.

- [1] 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](http://www.europa.eu).
- [2] Regulation (EC) No 1333/2008 *on food additives*, [www.europa.eu](http://www.europa.eu).
- [3] Regulation (EU) No 231/2012 *laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council Text with EEA relevance*, [www.europa.eu](http://www.europa.eu).
- [4] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, [www.europa.eu](http://www.europa.eu).
- [5] Directive 2011/91/EU on indications or marks identifying the lot to which a foodstuff belongs, [www.europa.eu](http://www.europa.eu).
- [6] EIGA Doc 126. Minimum Specifications for Food Gas Applications, [www.eiga.eu](http://www.eiga.eu).
- [7] Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, [www.europa.eu](http://www.europa.eu).
- [8] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food, [www.europa.eu](http://www.europa.eu).
- [9] Migration Processes of Metal Elements from Carbon Steel Cylinders to Food Gases, National Research Council, Istituto Geochimica e Georisorse, Florence, Italy (CNR-IGG), Packing Technology and Science, Volume 27, Issue 10, February 2014, [www.onlinelibrary.wiley.com](http://www.onlinelibrary.wiley.com).
- [10] ISO 22000, *Food Safety Management Systems – Requirements for any Organization in the Food Chain*, [www.iso.org](http://www.iso.org).
- [11] FSSC 22000, *The Foundation Food Safety System Certification*, [www.fssc22000.com](http://www.fssc22000.com).
- [12] ISO 9001, *Quality Management Systems – Fundamentals and Vocabulary*, [www.iso.org](http://www.iso.org).
- [13] ISO 22002-1, Prerequisite programmes on food safety — Part 1: Food manufacturing, [www.iso.org](http://www.iso.org).
- [14] EIGA Docs 68, *Prevention of Carbon Dioxide Backfeed Contamination*, [www.eiga.eu](http://www.eiga.eu).
- [15] EIGA Doc 70, *Carbon Dioxide Food and Beverages Grade, Source Qualification, Quality Standards and Verification*, [www.eiga.eu](http://www.eiga.eu)
- [16] EIGA Doc 64, *Use of Residual Pressure Valves*, [www.eiga.eu](http://www.eiga.eu).
- [17] EN ISO 24431, Gas cylinders. Seamless, welded and composite cylinders for compressed and liquefied gases (excluding acetylene). Inspection at time of filling, [www.iso.org](http://www.iso.org).
- [18] EIGA Doc 83, Recommendations for safe filling of CO2 cylinders and bundles, [www.eiga.eu](http://www.eiga.eu).
- [19] EIGA Doc 150, Guidelines for Safe and Hygienic Handling of Dry Ice, [www.eiga.eu](http://www.eiga.eu).
- [20] EIGA SL 09, Safe Transport of Dry Ice, [www.eiga.eu](http://www.eiga.eu).
- [21] EIGA Doc 194, Design and Operation of On-Site Nitrogen Generators for Food Use, [www.eiga.eu](http://www.eiga.eu).

## 11 Additional references

[https://ec.europa.eu/food/safety/biosafety/food\\_hygiene/guidance\\_en](https://ec.europa.eu/food/safety/biosafety/food_hygiene/guidance_en)

## Appendix 1 - Main articles describing labelling requirements of Regulation 1333/2008 on Food Additive [2]

### 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,[4] 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 may be 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 [4] 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.

## Appendix 2 - Hygiene Requirements to follow according to Regulation 852/2004 [7]

### 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 [7] 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.