



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

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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].