

## **Materials and articles for contact with packaging gases, propellants, air or compressed air for food production or food processing**

This position paper is intended as a point of reference only, and only offers an overview of opinion regarding materials and articles in relation to gases which come into contact with foodstuffs. It does not claim to be complete or an exact interpretation of the existing laws. It must not replace study of the relevant directives, laws and regulations. The characteristics specific to the relevant products and the different ways in which they may be used must also be taken into account.

### **Introduction**

Enquiries made to companies working in mechanical and systems engineering and to suppliers of components, whose products are employed in the food processing industry, prompted to create this position paper. Such enquiries often arise within the context of internal or external audits. During such enquiries, a certificate is requested regarding materials and articles that come into contact with foodstuffs, such as when parts of machines, systems or components condition, carry or transfer gases for applications used in the field of food production, treatment or processing. Related questions also arise within a company, or in dialogue with suppliers.

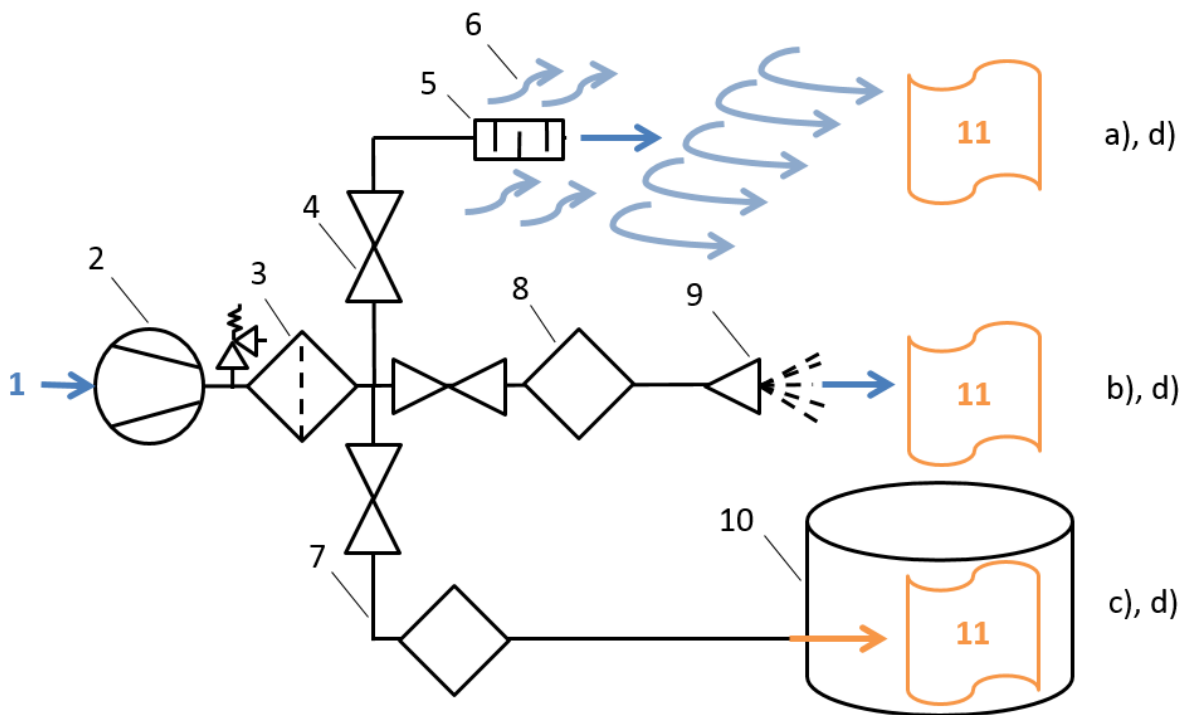
This position paper carries out a distinction of cases for the major practical cases of gas applications in the field of food production and processing. The focus of consideration lies on the scope of application of the relevant legal provisions as defined by the European Union. Goal is to provide a systematic basis which is to help improve understanding, facilitate the necessary considerations, and simplify the discussions thereof.

Suggestions can be directed to VDMA Food Processing Machinery and Packaging Machinery Association.

## Overview

Essentially, for **gases and/or air or compressed air in food applications** four cases can be considered (see Figure 1, further cases are possible):

- a) "Indirect" contact **of the gas** with the foodstuff via "ambient air"
- b) "Direct" contact **of the gas** with the foodstuff via a nozzle or similar
- c) Introduction of the gas into the packaging/processing container or into the foodstuff
- d) **Additionally** occurrence of **condensate in contact with the foodstuff**



### Key

- |                |                                   |
|----------------|-----------------------------------|
| 1              | Gas                               |
| 2              | Compressor                        |
| 3              | Filter                            |
| 4              | Valve                             |
| 5              | Outlet, e.g. attenuator           |
| 6              | "Ambient air"                     |
| 7              | Piping                            |
| 8              | Conditioning                      |
| 9              | "Nozzle"                          |
| 10             | Packaging or processing container |
| 11             | Foodstuff                         |
| a), b), c), d) | Cases considered                  |

**Figure 1 – Cases considered for gases in food applications**

## Distinction of cases and considerations

- **Case a):** “Indirect” contact of a **gas** with the foodstuff by way of “ambient air” such as in a production facility, e.g. gas behind an attenuator which does not blow directly into the “food area” (compare definition in EN 1672-2:2009, Food processing machinery - Basic concepts - Part 2: Hygiene requirements).

For the gas which enters the ambient air without becoming the determining part of the ambient air’s properties, likely the same requirements can be collared that apply to the ambient air itself. Also for materials and articles that come into contact with the gas definitely no higher requirements will be collared than for those that come into contact with the ambient air itself.

Were we to consider it an “indirect contact” in terms of Regulation (EC) No. 1935/2004 if and when a material or article came into contact with ambient air and the ambient air, in turn, with foodstuffs, this would then apply to **all** articles which are in contact with the ambient air. Such cases would imply that only “food contact material” could be used in every supermarket (warehouse) and in every production facility where unpackaged foodstuffs are displayed or handled (or need to be displayed or handled). This would affect the use of plastic ceiling lights, plastic shopping baskets, plastic eyewear lenses and frames (both for safety goggles and prescription eyeglasses), as well as entering facilities wearing footwear with “regular” rubber soles. It seems quite obvious that this would neither be feasible nor can it possibly be the intention.

**As a conclusion, for the materials and articles of the gas supply (for compressed air: of the compressed air supply), no food contact material is required to be used in the considered case a).**

Purity and/or quality criteria of the gas do, in themselves, not form part of this consideration; however, they must not categorically be excluded from consideration. It should be without question that contamination of the foodstuff by this gas must be avoided or be restricted to a minimum. Correspondingly, the following applies to food business operators whose area of responsibility includes the ambient air of his/her area, in accordance with

**Regulation (EC) No. 852/2004 on the hygiene of foodstuffs, Annex II, Chapter 1, “2. The layout, design, construction, siting and size of **food premises** are to: a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise air-borne contamination, and provide adequate working space to allow for the hygienic performance of all operations;”**

- **Case b):** “Direct” contact of a **gas** by means of blowing the gas out onto a foodstuff in a targeted manner (or, correspondingly, onto a piece of packaging material), or into the food area (e.g. for “screening” as separation process or for removing undesired particles);

**In accordance with Regulation (EC) No. 1333/2008 on food additives, Article 3 (2) b), a**

“**processing aid**” shall mean any substance which:

- i) is not consumed as a food by itself
- ii) is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and

iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product;”

A gas, which is used for technical reasons only and fulfils all requirements as laid out in Regulation (EC) No. 1333/2008 in terms of it being a processing aid, is not considered a food additive (which would have to be treated like a food) in accordance with this regulation.

**As a result, rules and regulations for food contact material such as Regulation (EC) No. 1935/2004 or any specific measures resulting thereof are not required to be applied in the considered case b).**

However, the provisions detailed above, ii) and in particular iii) of Regulation (EC) No. 1333/2008 on processing aids, must be complied with.

**In the context of a risk assessment, the relevant rules and regulations for food contact material such as Regulation (EC) No. 1935/2004 or any specific measures resulting thereof, as well as national recommendations and/or non-European rules and regulations on food contact material may also be helpful.**

- **Case c):** Introducing a **gas** as packaging gas or propellant into a packaging or into a food processing container, or intentional addition of the same to a foodstuff, in terms of with “Regulation (EC) No. 1333/2008 on food additives”;

**Summary of the consideration of case c):**

**For materials and articles in direct contact with**

- **packaging gases or propellants** which in accordance with the intended use are used as a food additive, or
- **air or compressed air** which is added to a food deliberately, in accordance with the intended use,

**the relevant provisions for materials and articles for contact with foodstuffs have to be applied.** Within the region of the European Community, this includes - among others - Regulation (EC) No. 1935/2004 and, insofar as specific measures exist (such as for plastic materials), also said specific measures, including the obligation of declaration of conformity if required by said specific measures. Insofar as existing, any legal provisions issued in the context of national specific measures also must be followed.

**Derivation** of the summary of **case c)** s. Annex.

**Additional considerations on case c):**

However, the question arises, from which moment on during the conditioning process, packaging gases or propellants or the air or compressed air in question are (to be) denominated suitable for this case of application in accordance with intended use. This is because gases might run through several conditioning stages such as fractionize, separation, cleaning, filtration or drying before they reach the point of intended use respectively of supply, and only during these conditioning stages, a gas quality in accordance with intended use suited for contact with foodstuffs is achieved.

Below, a **distinction** of how **case c)** might be viewed in terms of materials and articles for contact with foodstuffs is following:

- If a gas in accordance with intended use suitable for contact with foodstuffs already exists (e.g. a packaging gas or propellant for foodstuffs, or deliberately added air or compressed air for foodstuffs) as per **case c**), such as the content of a gas bottle or a gas container specifically designed for that purpose, only materials and articles suitable for contact with foodstuffs may be used from that point forward.
- If gas in accordance with intended use suitable for contact with foodstuffs is not existent yet, and in a facility intended for this purpose conditioning stages are following, after which the gas or the air or compressed air in accordance with intended use is suitable for contact with foodstuffs as per **case c**), only materials and articles suitable for contact with foodstuffs may be used from that point forward.

**It is incumbent upon the supplier of the respective gas conditioning facilities to describe their limits (suitable cases of application, intended use, exclusions) and to describe appropriate specifications, and to use materials and articles corresponding to the intended use.**

- **Case d)**: Additional occurrence of condensate in contact with the foodstuff, in addition to case a), b) or c).

**If condensate can occur in addition to cases a), b) or c)**, which may come into contact with the foodstuff or may become a constituent part thereof, then that condensate is to be regarded as a foodstuff in relation to the materials and articles that may come into contact with it.

Examples for this are: Condensate which

- enters a tank or container where it collects before, during or after a foodstuff was poured into that tank or container, thereby possibly entering that foodstuff;
- is carried away by the gas, thereby possibly entering the foodstuff;
- may come into contact with the foodstuff following a steaming process e.g. of filters.

**Conclusion in case d):**

For materials and articles that come into contact with condensate which may enter the foodstuff, Regulation (EC) No. 1935/2004 on materials and articles for contact with foodstuffs is relevant. Insofar as specific measures exist (such as Regulation (EC) No. 10/2011 on plastic materials), such measures are also relevant, including the obligation of declaration of conformity if required by said specific measures. Insofar as existing, any legal provisions issued in the context of national specific measures also must be followed.

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## Appendix: Derivation of the summary of case c)

A packaging gas or propellant used as a food additive is to be regarded as a foodstuff; the same also applies to any substances deliberately added to a foodstuff. Air, and thereby compressed air, as a packaging gas or propellant is not classed as a food additive; however, it de facto fulfils the definition of a foodstuff in accordance with Regulation (EC) No. 178/2002, inasmuch as it is deliberately added to such foodstuff during food production and processing.

**Corresponding provisions** for derivation of case c):

- In accordance with **Regulation (EC) No. 1333/2008** on food additives, the following applies:  
**Article 4, Section (1)**  
“Only food additives included in the Community list in Annex II may be placed on the market as such and used in foods under the conditions of use specified therein.”
  - In accordance with **Regulation (EC) No. 1333/2008** on food additives, **Definitions (2), a**  
“a) ‘Food additive’:  
shall mean any substance (...) 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 be reasonably expected to result, in it or its by-products becoming** directly or indirectly **a component of such foods;**”
  - Food additives in accordance with Regulation (EC) No. 1333/2008 on food additives (...) may be assigned to one of the functional classes in Annex I on the basis of the principal technological function of the food additive. The following applies according to **Annex I, Functional classes of food additives**  
“20. ‘packaging gases’ are gases other than air, introduced into a container before, during or after the placing of a foodstuff in that container;  
21. ‘propellants’ are gases other than air which expel a foodstuff from a container.”
  - In accordance with **Regulation (EC) No. 178/2002** laying down the general principles and requirements of food law (...) and (the) procedures in matters of food safety,  
“‘food’ (or ‘foodstuff’)  
means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. ‘Food’ includes drink, chewing gum and **any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment.**”
- Note:** The definition of a food or foodstuff in Regulation (EC) No. 178/2002 contains additional information, such as information regarding water and exceptions; however, these are not relevant for the purpose of these considerations and are therefore not listed.