Declaration for FST GmbH treatment components for compressed air with food contact

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1. Declaration

(1) A fundamental requirement for the use of compressed air in the food sector is the application of

- VDMA specification 15390-2 in combination with the underlying basic document
- VDMA specification 15390-1.

These regulatory frameworks define the current state of technology and describe, on the level of the entire compressed air system, the subjects of compressed air systems and compressed air purities for compressed air applied in the food sector. The prior consideration of the system level composes a basic requirement for later single considerations on a component level.

(2) FST treatment components are suitable for generating compressed air purities as requested for applications using compressed air in the food sector, assuming the application of the primarily named VDMA specifications and the respective FST product specifications.

(3) FST treatment components of product series

Filtration - Filter					
FCA..	FWS..	FWP..	FMA..	FMS..	

Filtration – Filter elements					
EFST..*1	EFST../HT..	EFST../TC..	EFSTP..*1	ER..*1	

*1 – except filtration grades V, ZF and XF

Drying					
DFX..	DFE..	DFLO..			
DPS..	DPM..	DTS..	DHW..		
DM..					

Adsorption					
DSS..	DSW..				

have been assessed by a risk evaluation related to the treatment of a processing aid in accordance with regulation (EC) no. 1333/2008 article 3 paragraph 2 letter b) point iii) (see chapter 3 – application of regulations) and have been classified as

applicable and thus compliant,

assuming suitable inlet concentrations as well as operational and marginal conditions of the respective treatment component (see chapter 4 – further applicable documents).

Furthermore, recommendations of BfR (German federal institute for risk evaluation) and EHEDG (European Hygienic Engineering & Design Group) concerning materials for food contact have been considered for the evaluation as well. Optional mounting parts or further products of FST do not have any contact to the flow path of the compressed air and, therefore, have not been taken into consideration.

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(4) FST treatment components of product series

Filtration – Filter elements					
EFSTP..STPL*1	EFSTP..SMPL*1				

*1 – flow direction from outside to inside

comply with regulation (EC) no. 1935/2004 ".. of October 27th, 2004 on materials and articles intended to come into contact with food .." and its deviated single procedures, if applicable (when compressed air is intentionally added to a food product as packaging gas or propellant gas ([2;c]) and according to supplement consideration case c) ([2;c])).

2. Fundamentals and definitions to this declaration

The application of compressed air in the food sector is dedicated as «application with potential health risks for humans due to retained impurities of compressed air» ([1]). Therefore, specific requirements are made to the

- **compressed air purity** and thus to the
- whole **compressed air system** that consists of the respective
- **compressed air components.**

A differentiation is made between

- **Indirect contact**
  The compressed air is being expanded during its application and emitted to the ambient air (e.g. expanded air of compressed air consumers like pneumatic components). The expanded compressed air reaches an object only with a certain distance and in a diluted form together with ambient air. ([1]) ([2;a])

  NOTE Concerning indirect contact, the user has to avoid «aerogen contamination of food or limit it to a minimum» according to regulation (EC) no. 852/2004 on hygiene of foodstuffs, annex II, chapter 1, point 2 establishments ([2;a])

- **Direct contact (process air)**
  Compressed air has direct contact with the (food) product or its primary packaging (e.g. as blow (blast) air, which is specifically addressed to the (food) product or the primary packaging that has contact with the (food) product)..... ([1]) ([2;b])

- **Direct contact (process air) as packaging gas or propellant gas**
  Compressed air is intentionally added to a food product as packaging gas or propellant gas and thus has direct and long term contact with the (food) product or its primary packaging, means becomes itself a food product ([2;c])

The terms **«food conformity»** and **«food acceptability»** are not defined by regulations and, thus, have no precise meaning!

([1]) VDMA specification 15390-2
([2]) VDMA Positionspapier "Materialien und Gegenstände für Kontakt mit Packgasen, Treibgasen, Luft oder Druckluft für die Lebensmittelherstellung oder -verarbeitung"

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3. Application of regulations

Compressed air, treated by compressed air treatment components, when having direct contact (except application as packaging gas or propellant gas) is supposed to be a 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; ……

according to

- Regulation (EC) no. 1333/2008 ….. of December 16th, 2008 on food additives …….
  article 3 paragraph 2 letter b) „processing aid“ ……..

and, thus, has to be classified as processing aid according to the prior named regulation. ([2;b])

In addition,

- VDMA specification 15390-2
  Compressed air purity – part 2: Typical application specific purity classes according to ISO 8573-1: 2010 and instructions for generation and verification of appropriate compressed air purity for applications in the sector of food and pharma technology

  in combination with the underlying basic document
- VDMA specification 15390-1.
  Compressed air purity – part 1: Typical application specific purity classes according to ISO 8573-1: 2010 and guidance for achieving and monitoring of a respective compressed air purity for industrial applications

shall be applied. VDMA specification 15390-2 has been developed especially in order to close the gap between the rather general regulation (EC) no. 1333/2008 and the requirement of a more detailed description of compressed air purities in the food sector. Measurement of the compressed air purity, as recommended by VDMA specification 15390-2, is done by the according standards of ISO 8573 series. ([1])

The

- Regulation (EU) no. 1935/2004 ….. of October 27th, 2004 on materials and articles intended to come into contact with food …….

which is often quoted or requested in the food sector and its deviated single procedures, e.g.

- Regulation (EU) no. 10/2011 ….. of January 14th, 2011 on plastic materials and articles intended to come into contact with food (single procedures as foreseen by article 5 of regulation (EC) no. 1935/2004)

are to be considered only when compressed air is applied as packaging gas or propellant gas, i.e. when intentionally applied as food additive and thus fulfilling the definition of a food product. ([2;c])

There is no deviated single procedure for elastomer materials (sealing materials) for regulation (EU) no. 1935/2004. Thus the BfR recommendation (German federal institute for risk evaluation) for food contact materials

- XXI. Bedarfsgegenstände auf Basis von Natur- und Synthesekautschuk (Edition 1.7.2015)

is applied. Sealing materials in compressed air treatment technology are classified as category 4 (2.4.1) and thus there are no demands in regards to migration (2.4.2).

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There is also no deviated single procedure for stainless steel materials while stainless steel is considered as suitable food contact materials in general, e.g.

- EHEDG Guideline (European Hygienic Engineering & Design Group) - DOC 8 – Hygienic equipment design criteria (2nd edition April 2004) respectively.
- VDMA - Ergebnisse exemplarischer Untersuchungen zur Migration bei gängigen Edelstählen für den Lebensmittel-oder Pharmabereich (Dezember 2014).

The application of compressed air as a packaging gas or propellant gas is very uncommon. In case, the compressed air purity should correspond at least to class ISO 8573-1:2010 [1:-:1] (sterile). ([1]) Compressed air purity suitable for the intentional food contact as packaging gas or propellant gas and thus the application of the prior named regulation is typically only achieved respectively valid at the downstream side of the last filter stage. ([2;c])

4. Further applicable documents

- FST GmbH – Product data sheets of the respective treatment components
- FST GmbH – Operating manuals of the respective treatment components

5. Notes

- In order to achieve the high requirements for compressed air purity in the food sector, FST GmbH offers additionally an optional wet cleaning procedure for filters applied to the decentral treatment and point of use filters, respectively, i.e. the removal of deposits from ambient air and other impurities that arise during the production process.
- The compressed air purity for indirect contact should correspond at least to class ISO 8573-1:2010 [2:-:2], for direct contact to class ISO 8573-1:2010 [2:-:1] (not sterile) or ISO 8573-1:2010 [1:-:1] (sterile), respectively. ([1])
- The required drying grade of compressed air depends on the food product. For non-dry food it may correspond to class ISO 8573-1:2010 [-:4:-], for dry food it should correspond to class ISO 8573-1:2010 [-:2:-]. ([1])
- Due to the high requirements to compressed air purity in the food sector, compressed air treatment is applied in both ways, as central and decentral treatment. During central treatment the basic purity level (network quality) is being set up, depending on the state and the construction of the compressed air network. The final, requested compressed air purity is established at the stage of decentral treatment, i.e. directly upfront of the application. ([1])
- Applicable procedures and test methods for monitoring of the compressed air purity are described in VDMA specification 15390-1 chapter 9.1 (indirect verification) and chapter 9.2 (direct verification). In addition, chapter 9.2.6 regulates the application of alternative, non-standardised methods of measurement.
- There are no Safety Data Sheets (SDS) for compressed air treatment components since compressed air treatment components are not a (chemical) substance or mixture. All kind of safety-related information is given in the respective operating manual.

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