FOOD CONTACT CENTER

Accreditated Lab according to EN ISO/IEC 17025 by Accredia,
Accretitation number: 1786L

RT FC20075 Rev.0

To:
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VIA GIACINTO COLLEGNO 11
10143 TORINO (TO)

Pistoia, 23/12/2020

OBJECT: Risk assessment on antitheft fog-producing system

Pic.1: fog-producing system URFOG Modular Pump C2 Sn .. 1030 - FPU03ESM2

INTRODUCTION

The customer produces an innovative security system which protuces a fog wall as an anti-theft. This system is increasingly required, not only to protect homes, but also workplaces, including those for catering, food production and restaurants. In order to check that the fog (WHITE OUT FOOD GRADE) does not constitute a harmful exposition to the food during processing or packaging, an assessment plan has been set.

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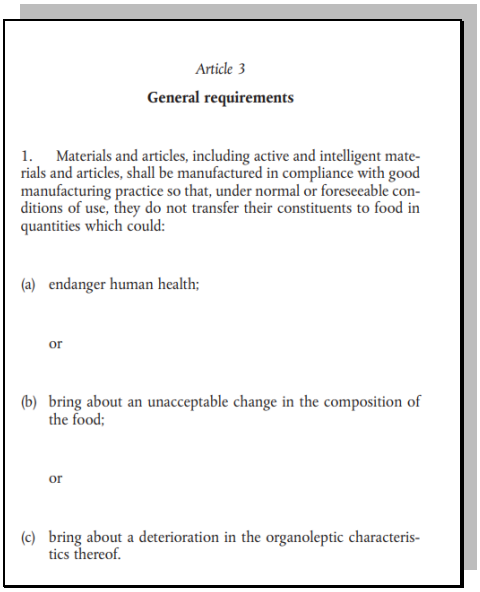
RISK ASSESSMENT PLAN

Food production and sales have laws to be respected and applied for packaging and objects in contact with food. The Regulation 1935/2004 (Fig. 2) of the European Parliament establishes that all materials and objects must be produced in accordance with good manufacturing practices and that during the usual or foreseeable use, they must not transfer to food any substance constituting a danger to human health, of significantly altering the composition of food products and of entailing changes in the organoleptic characteristics.



Article 3

General requirements

1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

(a) endanger human health;

or

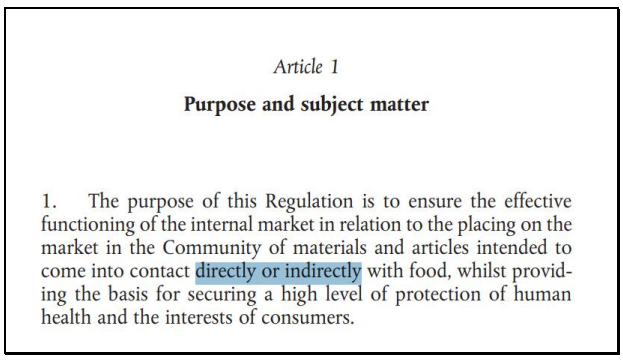
(b) bring about an unacceptable change in the composition of the food;

or

(c) bring about a deterioration in the organoleptic characteristics thereof.

Pic. 2: Art. 3 Reg. 1935/2004/EC

It is necessary to check that the materials in direct or indirect contact with food do not affect the safety of the final product (Pic. 3).



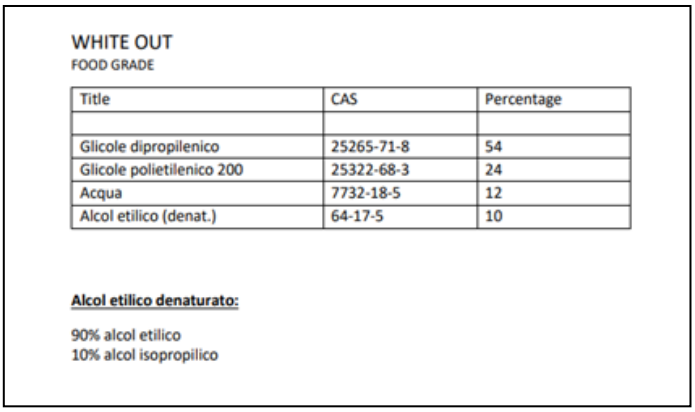
Article 1

Purpose and subject matter

1. The purpose of this Regulation is to ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of human health and the interests of consumers.

Pic. 3: Art. 1 Reg. 1935/2004/EC

In the specific case, the safety system constitutes a fog generator, the product of which is formulated as shown in Pic. 4:



WHITE OUT
FOOD GRADE

Title	CAS	Percentage
Glicole dipropilenico	25265-71-8	54
Glicole polietilenico 200	25322-68-3	24
Acqua	7732-18-5	12
Alcol etilico (denat.)	64-17-5	10

Alcol etilico denaturato:

90% alcol etilico
10% alcol isopropilico

Pic. 4: WHITE OUT FOOD GRADE composition

Glycols are among the constituents of the anti-theft product. They are known for their low toxicity for living organisms, including humans. For this reason they are widely used in refrigeration systems, intended to contain food. The glycols present in the fog are listed in Regulation 10/2011 without a specific migration limit (for which a maximum permitted value of 60 mg / kg food is assumed). They are distinguished from other glycols, always listed but with a much more severe migration limit, known for their applications in PET items (e.g. bottles for drinking water).

However, the client's aim was to assess the presence of residues of all the components (including denatured ethyl alcohol) of the fog when used during the processing or packaging of food, in order to preserve the food safety.

Given the raredied nature of the fog, a contact with potentially contaminating agents is to be understood as indirect. Since indirect contact is also legislated by the food contact regulations, the following approach was used. The current regulation considers modified polyphenyl oxide (**MPPO**) as the most appropriate food simulant for the evaluation of a indirect food contact. The simulant is chosen taking into account its **adsorbing power** of **volatile organic substances** without direct contact. The final use of the fog generator was reproduced and the contact conditions of the fog with the MPPO simulant were 2h at room temperature (the time required for the fog to settle following the shot, as indicated by the customer).

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TEST SETTING

The laboratory has used a room in its headquarter where the fog has been generated. Three glass crystallizers were placed in the room - in three positions and different heights - each containing 5g grams of modified polyphenyl oxide (Photo 1).

Photo 1: 5 g of MPPO

A specialized technician of the customer company, went to the laboratory FCC and dispensed the fog using a manual procedure (Photo 2).

Photo 2: manual dispensing of the fog inside the room of FCC

After 2h, the room was free from the fog. The fog was adsorbed, together with its components object of study, by the 3 portions of MPPO contained in the 3 glass crystallizers (Photo.3).

Photo 3: the room after 2h.

The MPPO simulant was taken, extracted with a suitable solvent and analyzed with the aim of identifying potential contaminants related to the fluid constituting the fog (and therefore potentially adsorbed by food). At the same time, the client delivered an aliquot of the fluid that was characterized by the lab technicians with chromatographic technique. A comparison was then made between the substances found in the fluid and those residual in the food simulant contained in the 3 crystallizers. The judgment was expressed on the basis of the limits established by the legislation for the substances contained in the fluid (listed in the Reg 10/2011/EU, with a limit of 60mg/kg).

TESTS AND ANALYTICAL DETERMINATIONS

4 samples were produced:
- FC 425 fog fluid
- FC 425.01 MPPO at a height of 60cm
- FC 425.02 MPPO at floor height
- FC 425.03 MPPO at a height of 30cm

Before carrying out the tests, a blank test was conducted for the room (blank matrix sample), using 5g of MPPO for 2h at room temperature.
On each samples, screening and specific migration analyzes were performed on the solvent extract in order to evaluate the presence of critical or undesired volatile organic compounds, including Not Intentionally Added Substances (NIAS) and any restricted substances (LMS or QM) not occurring in the fluid "recipe". The substances found on the MPPO samples were subtracted from those identified in the blank matrix sample.
The analytical techniques adopted were LC Q TOF and GC-MS, in order to identify respectively volatile, semi-volatile, and non-volatile, polar and non-polar compounds, in line with the analytical and scientific principles of risk assessment recognized at level international.

1. screening LC-HRMS

The LC-HRMS screening is performed by the laboratory with Shimadzu LC30AD UHPLC instrumentation coupled to a high resolution QTOF Sciex 4600 mass spectrometer. Using the LC-Q-TOF analytical technique, it is possible to detect pollutants present in matrices of various kinds, at very low concentrations. This technique performs a first chromatographic separation of the analytes by means of the UHPLC system. Subsequently the analytes are desorbed from the ESI (electron spray ionization) source and enter the QTOF system, where they are further separated by the first quadrupole based on their mass / charge ratio and finally by the time-of-flight analyzer, which allows to obtain a high resolution of molecular ions allowing the identification of the

brute formula. All the ions are acquired in both positive and negative modes with a mass-to-charge ratio between 50 and 1200 Da.

2. Screening GC-MS

The Laboratory carries out the analysis in GC-MS, in order to identify volatile and semi-volatile, non-polar compounds, in line with the analytical and scientific principles of risk assessment recognized internationally. The screening tests performed with GC-MS technique compare the quantities of analytes with internal standard, making a semi-quantitative evaluation. The qualitative recognition is performed through the NIST library supplied with the instrument; the comparison between the detected mass spectra and those present in the library is expressed as a percentage matching probability. The laboratory proposes as LOI (level of interest) a quantity of analyte in simulant / food equal to 90ug / kg (Comsas strategy) and as recognition a match greater than 80% provided by the comparison with NIST. Screening was performed with MS Shimadzu QP2010SE GC instrumentation.

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RISULTS

1. screening LC-HRMS

Positive Mode

Sample/Simulant Overlay

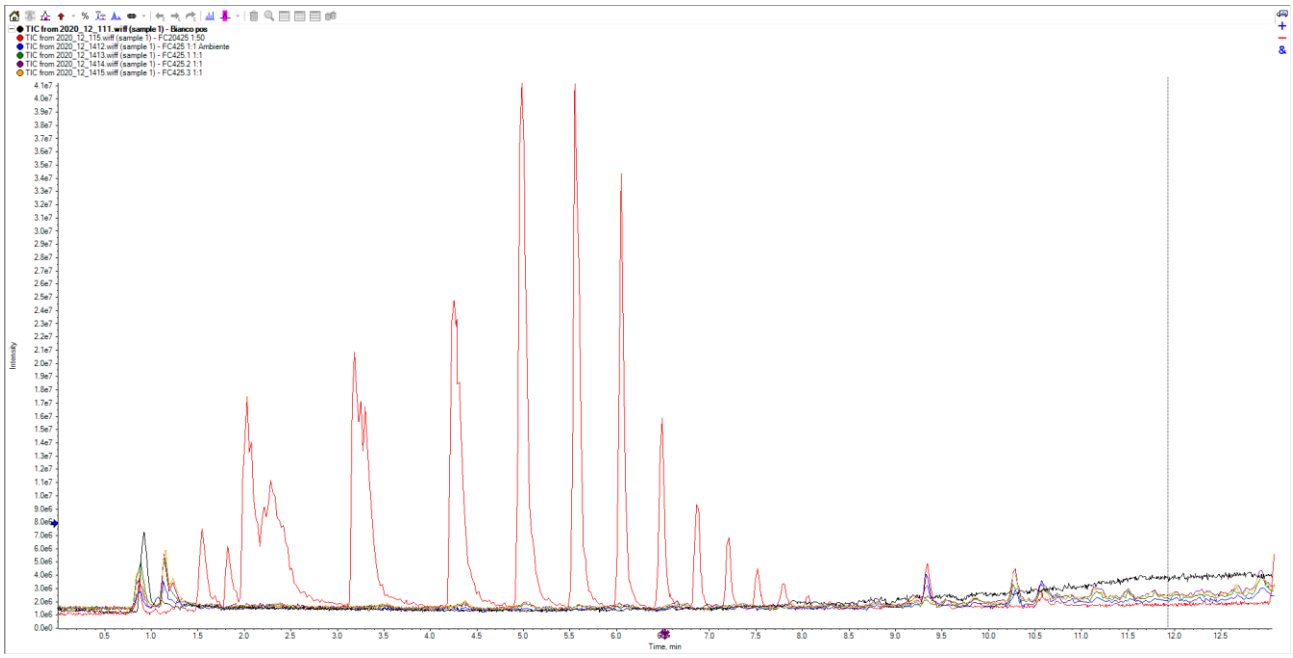

Fig. 4: Overlay TIC, Blank pos (BLACK), FC425 (Rosso), Blank matrix sample (BLUE), FC20425.1 (green), FC20425.2 (violet), FC20425.3 (yellow)

As shown in Fig.4, the characteristic peaks of the fog generator fluid (in red) are not found in any of the 3 extracts of the MPPO placed at different heights in the test room.

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Negative Mode

Sample/Simulant Overlay

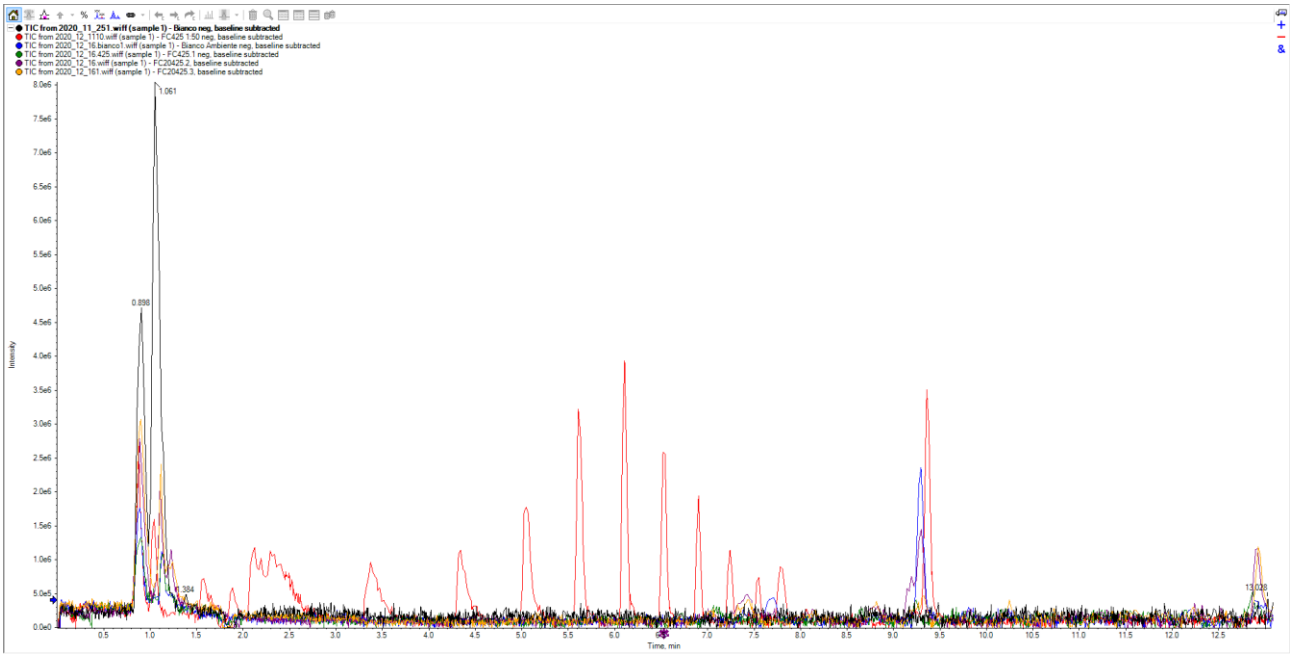

Fig.5: Overlay TIC, Bianco pos (BLACK), FC425 (Rosso), Blank matrix sample (BLUE), FC20425.1 (green), FC20425.2 (violet), FC20425.3 (yellow)

As can be seen from Fig. 5, the characteristic peaks of the fog generator fluid (in red) are not found in any of the 3 extracts of the MPPO placed at different heights in the test room.

2. Screening in GC/MS of the extracts from the sampling with MPPO

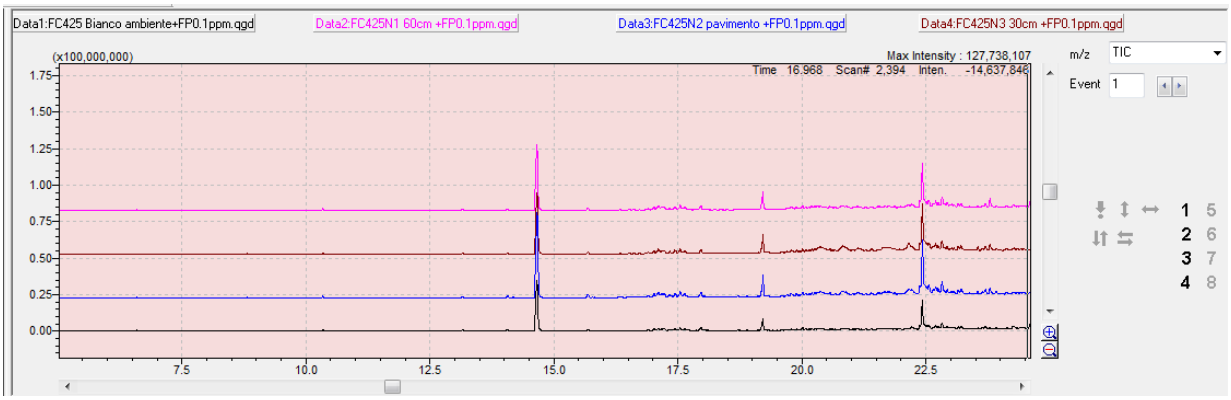

Fig.6 – Overlay of the extracts

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It is noted that the chromatographic profiles are almost identical to the Blank matrix sample (in black), indicating that the substances of the fog generator are not adsorbed by the MPPO.

CONCLUSIONS

The URFOG Modular Pump C2 Sn .. 1030 - FPU03ESM2 fog system did not show any particular critical issues in the risk assessment. The characteristic substances of the fog fluid (consisting of water, ethyl alcohol, glycols) were not found in the solvent extracts of the food simulant MPPO, in any of the positions established within the room.

The fog complies with the requirements of Reg. (EC) No. 1935/2004, as it has been seen not to involve an unacceptable modification of the food simulant (therefore of food) and of Reg. (EU) No. 10/2011 and subsequent updates as the substances subject to specific restrictions are below the defined limits.

Therefore, in the light of the tests conducted, the fog generator system is reasonably considered suitable for use in catering, food production and sales.

The Technical Director
Marinella Vitulli