

PISTOIA-TOSCANA

BRESCIA-LOMBARDIA

CUNEO-PIEMONTE

Specialized center for food contact materials.





27 food contact experts









Microbiology Department www.foodcontactcenter.com



Laboratory expert in the field of FCM .

Chemical, microbiological, and physical testing.

"Our innovations are your success.

Through research, we go beyond standards."

"They work in synergy to provide a complete service to the customer."





Business consulting on processes and materials/objects in contact with food









GLOBAL PRODUCT SAFETY NET





Europe

- Italy: 4 offices Milano, Pistoia, Brescia, Cuneo
- 3 laboratories accredited ISO
 17025 standard lab 1786L
- France
- 1 office Avignon
- Belgium
- 1 office Brussels
- Switzerland
- 1 Office Lausanne

Global Product Safety Net-European presence GPSNet is a network of leading European companies for Consumer Product Safety

- -7 offices
- 3 laboratories



Global Product Safety.Net is composed by:

<u>Dario Dainelli</u> Policy Regulatory

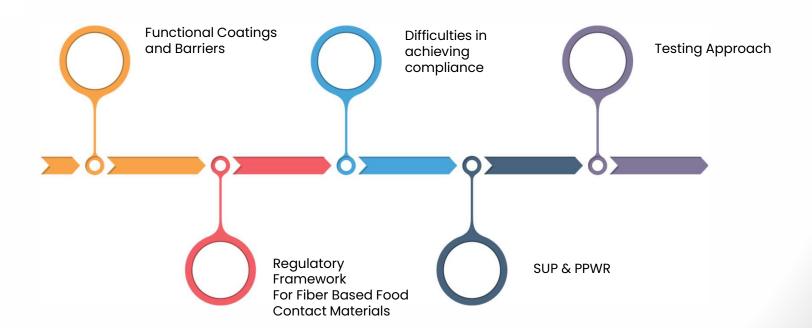
<u>FOOD CONTACT CENTER</u> - <u>Marinella Vitulli</u>

<u>FOOD CONTACT SERVICES</u> - <u>Lisa Filindassi</u>

<u>Marco Scialpi</u>- Global Business Development Head



AGENDA













DIRECTIVES

COMMISSION DIRECTIVE 2007/19/EC of 30 March 2007

amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration from plastic materials and articles intended to come into contact with foodstuffs

(Text with EEA relevance)

Article 1a

b) "functional plastic barrier": a barrier composed of one or more layers of plastic material that ensures that the finished material or article complies with Article 3 of Regulation (EC) No 1935/2004 of the European Parliament and of the Council (*) and with this Directive;

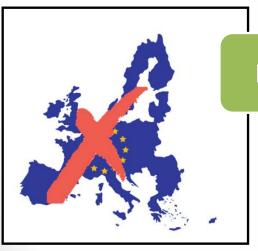
Recital 10

(10) It is appropriate to introduce the concept of a functional barrier of plastic material, i.e., a barrier placed within materials or articles made of plastic that prevents or limits migration into the food product. Only glass and certain metals can guarantee complete blocking of migration. Plastic materials can represent partial functional barriers, whose characteristics and effectiveness must be evaluated, and can contribute to reducing the migration of a substance in such a way that it results below an LMS or a limit of detectability. If separated by a functional barrier of plastic material, some unauthorized substances may be used. Provided they meet certain parameters and migration remains below a certain limit of detectability. Taking into account the diet of infants and other particularly sensitive individuals, as well as the difficulties of this type of analysis characterized by a notable analytical tolerance, it is appropriate to set a maximum content of 0.01 mg/kg in the food or food simulant regarding the migration of unauthorized substances through the functional barrier of plastic material.

Prevents or limits migration into the food

FOOD CONTACT COATING





Lack of a Harmonized Definition



Coating or Plastic Layer

- ➤ Solvent or Water Evaporation
- > Chemical Reaction
- ➤ Sintering
- > Combination of Multiple Processes

COATING





FOOD CONTACT COMPLIANCE OF PAPER ITEMS ACCORDING TO THE MAIN **EUROPEAN REGULATIONS**

EC Reg. 1935/2004 - European Framework Regulation for all FCMs, including paper ones



BUT...

DM 21.03.1973 - Italian Ministerial Decree

Fiche MCDA n.04 - French Regulations

BFR Recc. XXXVI - German Recommendation











Coated papers fall within the scope of application

Coated papers are NOT in the scope of application

Again, No Harmonization

HOW TO NAVIGATE THROUGH THE IMPERVIOUS SEA OF LEGISLATIONS



COATED PAPERS - REGULATORY BASES



As is often the case, Reg. 10/2011 is a model for assessing the compliance of analytical tests and this is accepted by the market; in fact, in many guidelines (e.g. the FOOD CONTACT GUIDELINES FOR THE CONFORMITY OF PAPFR AND CARDBOARD MATERIALS AND ARTICLES the CEPI: https://www.cepi.org/wp-content/uploads/2020/09/Food-Contact-Guidelines 2019.pdf), fact. in reference is made to the rules of the Plastic Regulation to verify compliance even if the material is outside the scope of application.

This also applies to coated paper. Therefore, with a view to assessing the risk of the material, analytical plans that provide for global and specific migrations are usual; However, the coating is a very thin layer of polymeric material and its behavior with respect to the simulants used is different from that of plastic.

COMMISSION REGULATION (EU) No 10/2011

of 14 January 2011

on plastic materials and articles intended to come into contact with food

(Text with EEA relevance)

(OJ L 12, 15.1.2011, p. 1)

COATED PAPERS - ANALYTICAL PLANS FOR FATTY FOODS, PROBLEMS AND POSSIBLE SOLUTIONS

In the field of food contact, indications of the possibility of modifying simulants or test conditions are quite frequent.

This problem is essentially due to the poor suitability of the test.



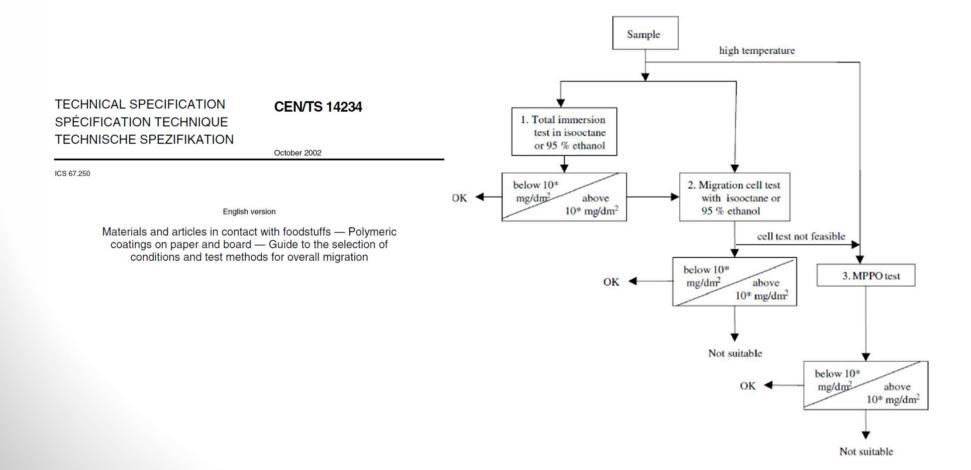
The CEPI Guideline in point 3.3 also expresses the need to avoid the use of vegetable oil for coated paper:

It is important to note that migration tests with vegetable oil are not technically feasible, but appropriate alternative simulants include isooctane and 95% ethanol.

It may also be possible to use 10% ethanol, 3% acetic acid, 20% ethanol, 50% ethanol, and MPPO, depending on conditions.

In some documents, the importance of using appropriate test conditions is emphasized, on the assumption that it is essential to avoid data obtained from unsuitable contacts.

COATED PAPERS - ANALYTICAL PLANS FOR FATTY FOODS, PROBLEMS AND POSSIBLE SOLUTIONS







Paper may contains NIAS (Non Intentionally Added Substances)

3.2.3 Testing for Non Intentionally Added Substances (NIAS)

NIAS could originate both from the raw materials used and from intentionally added applied materials (impurities, reaction/degradation products).

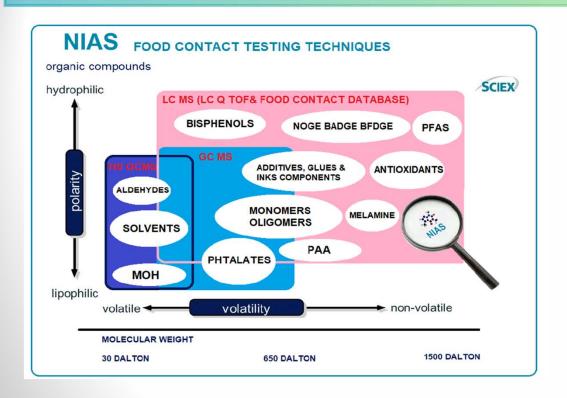
Some NIAS are normally found only in paper and board manufactured from recycled fibre pulp and testing for them will not be needed when examining paper and board manufactured solely from fresh fibre pulp. However, a risk assessment of potential NIAS should be carried out also for fresh fibre grades (in principle chemicals used in a pulping and bleaching process). In addition,

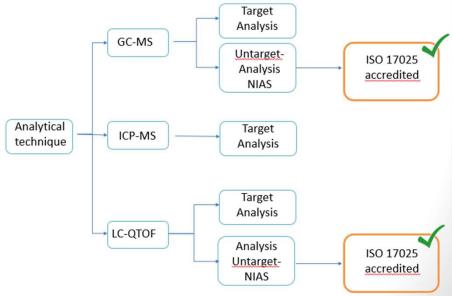
P.17 FOOD CONTACT GUIDELINES FOR THE COMPLIANCE OF PAPER & BOARD MATERIALS AND ARTICLES https://www.cepi.org/wp-content/uploads/2020/09/Food-Contact-Guidelines_2019.pdf

IAS NIAS Specifically added during the Impurities present in the material production process, substances used, reaction with a function in the intermediates formed during the manufacturing process or in the production process, or reaction final product or decomposition products. Raw Additive degradation Materials Polymer degradation Monomers Residues Additives Newly formed products Solvents Impurities Colorants

COATED PAPERS - NIAS TESTING







233

Paper and Board
Paper and board samples contained 233
unique compounds.

COATED PAPERS – REGULATORY CONTEXT, SUP and PPWR



SUP Directive

The presence of polymer coatings means that the material is included in the category of plastics in accordance with the SUP Directive.

Coated papers often have coatings derived from modified natural polymers, such as starches, cellulose or other substances of biological origin, which are subjected to chemical processes to improve their functional performance. These coatings are mainly used to give paper barrier properties, in particular greater resistance to greases, oils and moisture, making it suitable for use in the food sector or for specific packaging. However, despite the natural origin of the polymers used, the chemical modification to which they are subjected makes them fall, according to the definition provided by the SUP (Single Use Plastics) Directive, into the category of plastics. As a result, the resulting composite material – while predominantly made up of paper – is subject to the same restrictions and regulatory obligations as single-use plastic products.

Qualitative Evaluation

PPWR Regulation

Among the main innovations, the Regulation introduces a specific definition of 'composite packaging', applicable to products made of two or more different materials (e.g. paper and plastic) that cannot be separated manually. According to the provisions, a package can only be classified as composite if the secondary material – i.e. the material present in lower quantities – constitutes at least 5% by weight of the total mass of the packaging.

This weight threshold represents a fundamental technical criterion for the correct categorization of the material for the purposes of recycling, separate collection and labeling. In addition, within the recital of the Regulation – in particular Recital 13 – the concept of 'insignificant part of the packaging' is introduced, defined as a component or material whose mass is less than 5% of the total mass of the packaging. This concept is intended to simplify the identification of minor elements within the packaging structure, without affecting the overall regulatory functionality.

Quantitative Evaluation

COATED PAPERS - REGULATORY CONTEXT, SUP and PPWR



However, it is important to underline that, although the PPWR Regulation and Directive (EU) 2019/904 (SUP) pursue complementary objectives, they are not overlapping with each other. However, they are interconnected, especially in the management of packaging containing polymeric components. As clarified within the PPWR, a component that represents less than 5% of the total mass of the packaging is considered 'insignificant' for the purposes of composite material classification. However, this does not automatically imply that such packaging is exempt from the obligations under the SUP Directive.

In fact, according to the interpretation provided by the European Commission, the SUP Directive is based on a qualitative criterion for the identification of single-use plastic products: the mere presence of plastic – even in very small percentages – is sufficient to make a product fall within the scope of the legislation. Therefore, cellulose-based packaging coated with a thin layer of polymeric material (less than 5% of the mass) can still be classified as a single-use plastic product and, consequently, subject to the restrictive measures of the SUP Directive, such as the prohibition of placing on the market or the obligations of labelling and extended producer responsibility.

ITALIAN DO IT... WORST?



If a material contains plastic below 10%, it is considered paper and does not fall into the SUP

COATED PAPERS – ANALYTICAL TECHNIQUES





How do we help companies characterize their product?





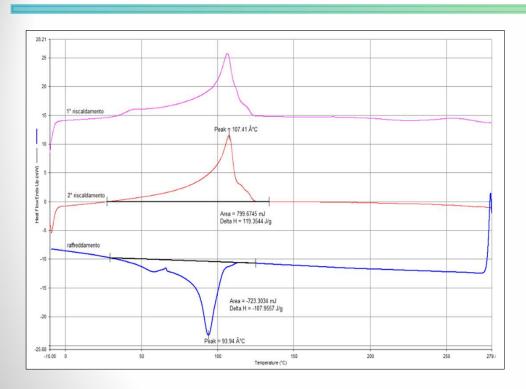
ATR imaging spectroscopic – ATR, allows us to determine the structure of molecules and the thickness of the various layers

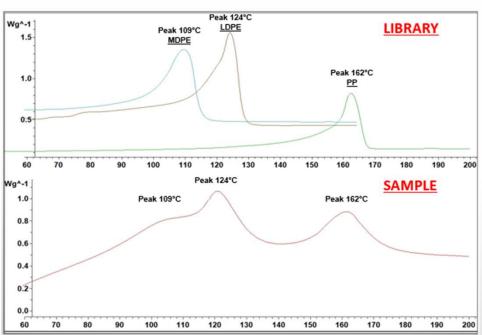
Differential Scanning Calorimetric Analysis (DSC), it allows us, through a programmed heating and cooling of the sample, to study the typical characteristics of polymers (thermal characteristics) such as glass transition T, melting and crystallization.

Thermogravimetric Analysis (TGA), a material characterization technique that measures the change in mass of a sample as a function of temperature or time, under a controlled atmosphere (such as air and nitrogen).



CHARACTERIZATION OF THE FINISHED PRODUCT - DSC

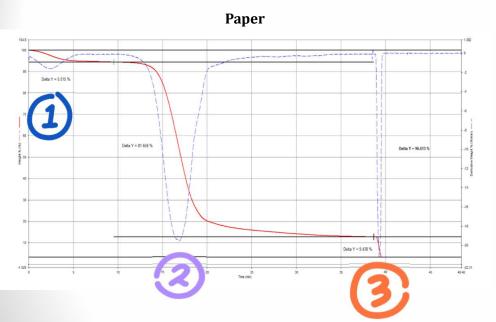




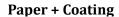
Melting and crystallization temperature associated with LDPE

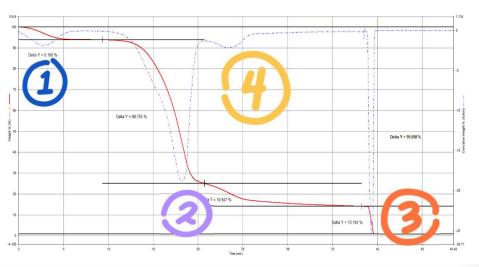






- 1. Initial weight loss associated with H2O evaporation,
- 2. Weight loss at about 350°C associated with cellulose degradation
- 3. Loss of weight in O2, associated with the degradation of the carbonaceous residue formed following the degradation of cellulose.

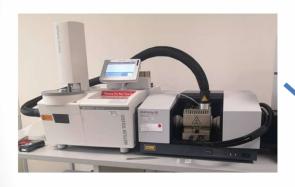


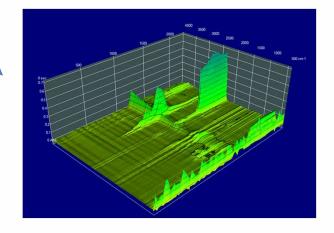


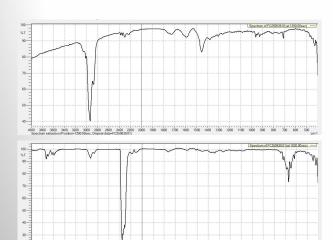
- 1. Initial weight loss associated with H2O evaporation
- 2. Weight loss at about 350°C, associated with cellulose degradation,
- 3. Weight loss after switching to O2, associated with the degradation of the carbonaceous residue formed by the degradation of cellulose and polymer.
- 4. Weight loss at about 450°C, associated with the degradation of the polymer component

CHARACTERIZATION OF THE FINISHED PRODUCT - TGA-IR









Identifying the polymer as PE

Combined TGA-IR technique, which combines thermal and spectroscopic analysis methods to obtain detailed information about the chemical composition and thermal behavior of a sample.

In a TGA-IR system, the sample is first analyzed by TGA to determine mass losses, the gases developed during heat treatment are simultaneously analyzed by FT-IR spectroscopy. The combined information makes it possible monitor to the gases generated and associate mass loss with the formation or decomposition of certain chemical compounds.

Thank you for your attention!







No need to be shy – hit me with your questions, I can take it!

FOOD CONTACT CENTER & FOOD CONTACT SERVICES

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