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DECLARATION OF CONFORMITY / COMPLIANCE

Food Contact Materials - Coatings
EU 10/2011 and FDA 21 CFR 175.300

INDEX

Registered in the Mercantile Registry of Tarragona, in volume 2466 of Companies, folio 215, sheet T-39702, Inscription 1ª.

Introduction:

One of FAKOLITH's major specialties are coatings, varnishes, and paints suitable for direct, indirect, or occasional contact with food, beverages, and drinking water. As an SME intensive in Research and after 10 years of continuous official research projects in the field of coatings for food contact and antimicrobial activity, we can affirm that this is an extremely complex and exciting specialty, and in any case of great importance for the health of consumers.

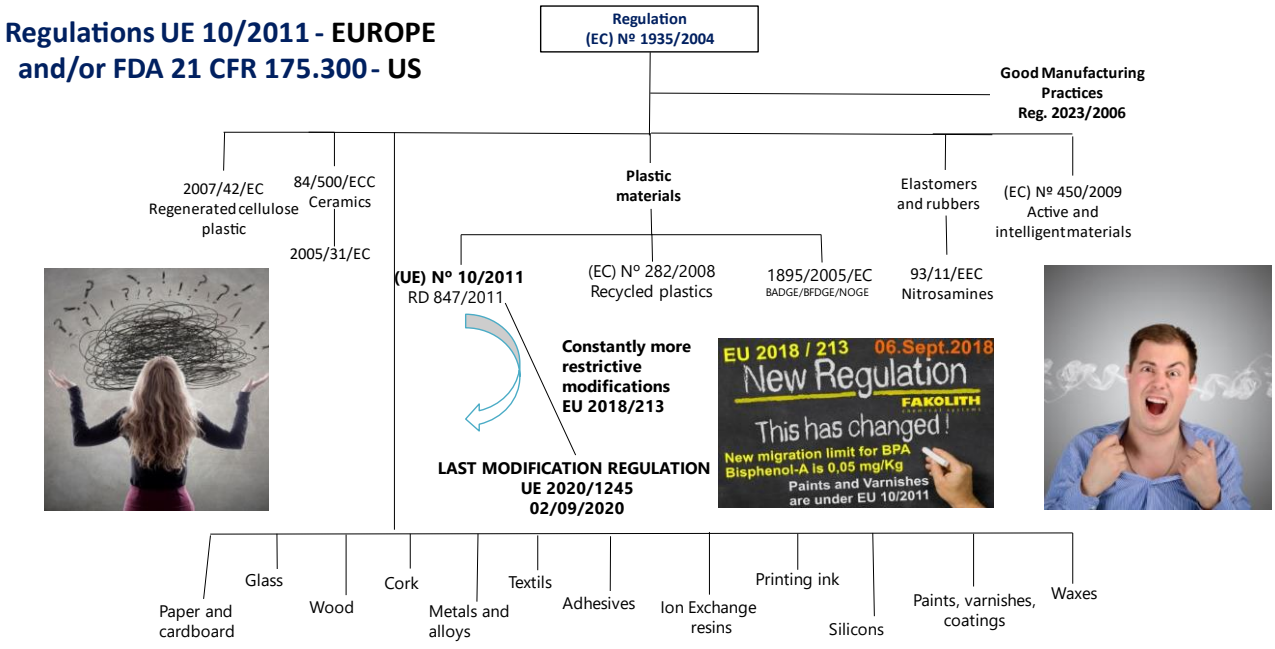
INNOVATIVE SME
Valid until Nov 15th 2021

Given its complexity and relevance, for the food industry, as for the food packaging manufacturer, for the consumer, even for internal and external control, we will try to explain its operation in the simplest possible way, from our specialty in coatings, and through the main document **"The Declaration of Conformity or Compliance Declaration".**

1. Extensive regulations, increasingly changing and restrictive.

All materials suitable for direct contact with food and beverages are regulated in Europe by the Framework Regulation EC 1935/2004. This regulation then defined the materials that could be suitable to be in contact with food; plastic materials, active and intelligent materials, ceramics, adhesives, cork, metals and alloys, glass, paper.... and then develop specific regulations for each of these materials.

Regulation EU 10/2011 on plastic materials is one of the few on which Europe has developed an extensive specific regulation and which is already taken as the reference for the rest. It currently covers various plastic materials, packaging, its components and complements, varnishes, paints, coatings, utensils, parts of machines and equipment, etc.

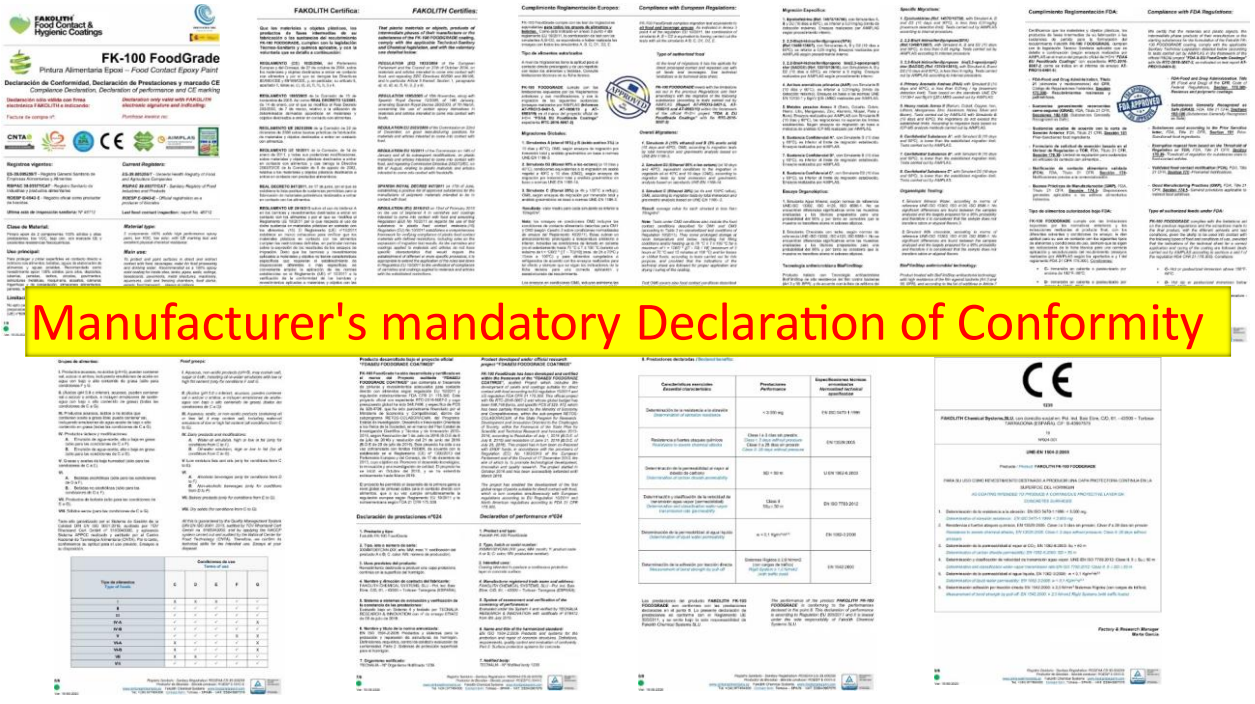


Direct contact with foods, beverages and drinking water

EU 10/2011 Regulation, like all of them, undergoes periodic amendments, which usually tighten the testing conditions for these materials. For example, a relevant amendment for the field of coatings was Regulation EU 2018/213, which among other changes specified that EU 10/2011 applies unequivocally to coatings, varnishes and paints for food contact, and also limited the use and reduced the maximum permissible specific migration limit of Bisphenol A. The last modification to date, is the 15th amendment, specifically the EU Regulation 2020/1245 that although it applies a transition period of 2 years, brings new metals, NIAS (Non-intentionally added substances) and other substances to control, new and stricter migration limits, and changes in the methodology in the specific migration of repeated use, among many other changes that make it **undoubtedly the European regulation of food contact stricter and more difficult to comply with, internationally.**

2. What is the Declaration of Conformity or Compliance for food contact materials?

The Declaration of Conformity, or Compliance Declaration is a mandatory document for the manufacturer of materials in direct contact with food, which will help to dissect the producer and the product, providing the industrialist, those responsible for food safety and inspection, the necessary data to determine that the material is safe for the use to be given. Let us say that "The Declaration of Conformity" is like an X-ray of the manufacturer of this type of materials, and of each product.



The Compliance Declaration must contain all the manufacturer's data, including its RGSEAA Sanitary Registration (in Spain 'code 39' for direct food contact materials). Also, a list of all the Regulations that the registered manufacturer complies with, as well as a description of the product and its basic conditions of use. In addition, it must cite the required tests performed in approved laboratories, global migrations, generic specific migrations, specific migrations according to formulation, organoleptic tests, as well as other additional tests pertaining to the type of product at the functional level.

The responsibility for making the declaration of conformity lies with the manufacturer of paints, varnishes, and coatings for food contact, who, as the developer, is the only one who knows the components of its product. It would be absurd to try to transfer the responsibility of making it to the application company, or to the user industry of our coatings, either in its production process, facilities or as part of its packaging or product.

Given our experience, we can affirm that it is necessary to have a comprehensive scheme of NDAs (Non-Disclosure Agreements) signed with suppliers of food raw materials, as well as with external accredited certification and testing centers.

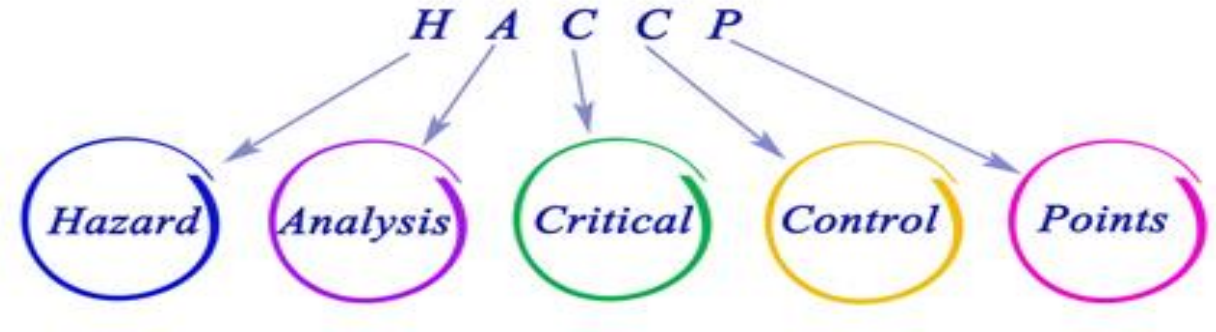
*From the **Declaration of Conformity**, depending on its transparency and content, industrial users, packaging manufacturers and food processors, as well as auditors of food quality standards (ISO, BRC, IFS ...) and health inspection, **can** more easily **verify** that they are dealing with a **supplier and product that complies with food safety:***

- *That the company manufacturing the coating has the mandatory Sanitary Registration for materials in direct contact with food, and therefore is subject to inspection and control by the Health authority.*
- *That it manufactures with raw materials authorized in the positive lists of the corresponding Regulation.*
- *That it has implemented a HACCP system or equivalent.*
- *That manufactures in accordance with GMP, EC Regulation 2023/2006 and/or FDA 21 CFR 174.5*
- *That the product has been tested in external accredited entities and that it complies with the global, specific, organoleptic, and functional migration limits for its intended use, in Europe according to EU regulation 10/2011 and in the USA extractions according to FDA 21 CFR 175.300 in the case of coatings.*

A technical data sheet for a food contact coating, paint or varnish is necessary for its proper use and application at a functional level, but it is not the document required by the Regulation in relation to food safety. It is the Declaration of Compliance that must demonstrate its validity as a safe product and producer, and it must be available at all stages of marketing of the product (except to the final consumer).

The tests cited in the declaration of conformity, and performed on each product placed on the market, must be available to any customer upon request and for inspection.

A piece of advice to the industrialist, which we apply in a similar way in Fakolith when evaluating the raw materials we use, would be to include in the HACCP, ***"before acquiring a material suitable for direct contact with food, ask for the manufacturer's Declaration of Conformity as a first step".***



We remind you that it is the responsibility of the food industry to verify that the materials used are suitable and safe. In addition, **the latest versions of IFS and BRC already indicate the necessary vigilance and verification towards suppliers of this type of materials in direct contact with food.**

The website of the Spanish Agency for Food Safety and Nutrition (AESAN), has a search engine for registered companies, which by typing the manufacturer's company name will indicate its Registration and Key, or the absence of this.

For example, if you type FAKOLITH, you will see that the result is: Fakolith Chemical Systems, SLU with Registration 39.005259/T. '**Key 39**: Materials and articles intended to come into contact with foodstuffs'.

By the way, it is worth remembering that in FAKOLITH, although we have a Sanitary Registration for materials in direct contact, it is not a guarantee by itself, since it is an identification number of the manufacturer, which once obtained, like the VAT number, does not change. What does vary constantly are the regulations linked to it as appropriate, and it will be the responsibility of the manufacturer of materials in direct contact with food to be up to date with them, applying the necessary procedures and tests as appropriate to each product marketed.

We are talking about Food Safety and not about whether a product is cheaper, more expensive, better, or worse. However, a manufacturer with Sanitary Registration (in Spain), is traceable and is under the surveillance of the Health Authority Inspection, national and international. This is important, for example, in case of health alarm due to food contamination, thanks to the protocols established for the manufacture according to CE 2023/2006 and the required traceability of all processes, it will be possible to create and communicate a Food & Feed Safety Alert (RASFF), withdraw batches, investigate the causes and establish the responsibilities that correspond to the manufacturer of the material, to any of its suppliers of raw materials, to the choice of the product, or its application, misuse, etc.

On the other hand, if the same thing happens with a manufacturer that does not have the proper Sanitary Registration, Declaration of Compliance, etc., it is likely that it does not have all the necessary measures to ensure food safety and its associated procedures, and it is also likely that it has never been inspected in this area, since not being registered, it may remain hidden from the vigilance of the Authorities.

3. Why are global and specific migrations test necessary?

Materials authorized to be in direct contact with food may migrate, i.e. transfer chemical substances to food, depending on the type of material, contact time, temperature, and type of food with which they are in contact.

In the EFSA (European Food Safety Authority) video, you will find a basic definition of materials suitable for direct food contact.

*The migration tests in Europe, as well as the extractions tests in the US, are used to **determine that the authorized substances that could migrate into food are within the maximum permitted limits**, so that they do not represent a health risk.*

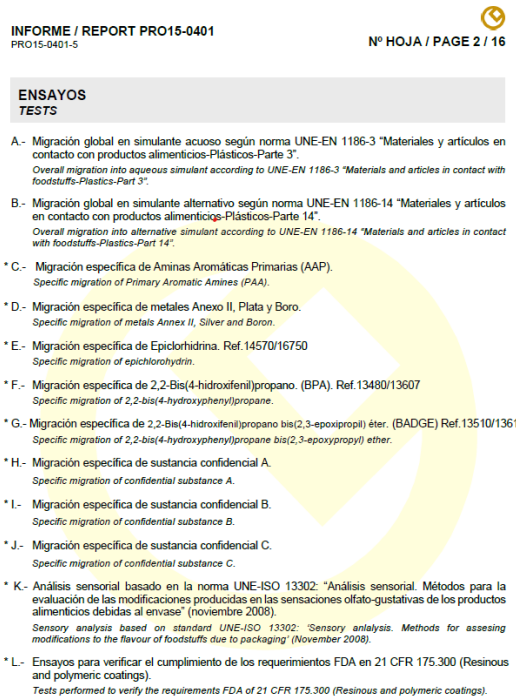
Testing the migration of every packaging or coating in contact with every food on the market would be a virtually impossible task, so the European Regulation EU 10/2011 **has assigned chemical simulants** that encompass several food groups, broadly speaking:

- Food simulants A (Ethanol 10%), B (Acetic acid 3%) and C (Ethanol 20%) are assigned to foods that have hydrophilic character and can extract hydrophilic substances.
- Simulant B shall be used for foods having a pH less than 4.5.
- Simulant C should be used for alcoholic foods with an alcohol content of up to 20%, and for foods containing a significant amount of organic ingredients that make it more lipophilic. This simulant is also used for mineral water.
- Simulants D1 (Ethanol 50% and D2 Vegetable oil or its alternatives Isooctane and Ethanol) are assigned to foods that are lipophilic in character and can extract lipophilic substances.
- Food simulant D1 shall be used for alcoholic foods with an alcoholic strength above 20 % and for oil in aqueous emulsions.
- Simulant D2 will be used for foods containing free fats on the surface.
- Food simulant E (Tenax) is intended for testing specific migration in dry foods.

It is important to always consult the latest consolidated version of Regulation EU 10/2011, which is the one that includes all amendments to date, as well as the necessary details, tables, exceptions, correction factors and alternatives for various cases.

Thus, coatings and packaging in Europe must be tested in immersion/contact with these chemical simulants to determine **the overall migration capacity** of substances to each simulant, the maximum migration limit allowed being 10 mg/dm^2 of contact surface or 60 ppm (60 mg/kg food).

In addition, there are **different migration test conditions, currently from OM0 to OM9**, in practical terms, from cold temperatures and short contact time to prolonged contact and temperatures up to 175ºC. The higher the temperature, the greater the possible migration of substances into the food.



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ENSAYOS
TESTS

A.- Migración global en simulante acuoso según norma UNE-EN 1186-3 "Materiales y artículos en contacto con productos alimenticios-Plásticos-Parte 3".
Overall migration into aqueous simulant according to UNE-EN 1186-3 "Materials and articles in contact with foodstuffs-Plastics-Part 3".

B.- Migración global en simulante alternativo según norma UNE-EN 1186-14 "Materiales y artículos en contacto con productos alimenticios-Plásticos-Parte 14".
Overall migration into alternative simulant according to UNE-EN 1186-14 "Materials and articles in contact with foodstuffs-Plastics-Part 14".

* C.- Migración específica de Aminas Aromáticas Primarias (AAP).
Specific migration of Primary Aromatic Amines (PAA).

* D.- Migración específica de metales Anexo II, Plata y Boro.
Specific migration of metals Annex II, Silver and Boron.

* E.- Migración específica de Epiclorhidrina. Ref.14570/16750
Specific migration of epichlorohydrin.

* F.- Migración específica de 2,2-Bis(4-hidroxifenil)propano. (BPA). Ref.13480/13607
Specific migration of 2,2-bis(4-hydroxyphenyl)propane.

* G.- Migración específica de 2,2-Bis(4-hidroxifenil)propano bis(2,3-epoxipropil) éter. (BADGE) Ref.13510/13610
Specific migration of 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether.

* H.- Migración específica de sustancia confidencial A.
Specific migration of confidential substance A.

* I.- Migración específica de sustancia confidencial B.
Specific migration of confidential substance B.

* J.- Migración específica de sustancia confidencial C.
Specific migration of confidential substance C.

* K.- Análisis sensorial basado en la norma UNE-ISO 13302: "Análisis sensorial. Métodos para la evaluación de las modificaciones producidas en las sensaciones olfato-gustativas de los productos alimenticios debidas al envase" (noviembre 2008).
Sensory analysis based on standard UNE-ISO 13302: 'Sensory anlalysis. Methods for assesing modifications to the flavour of foodstuffs due to packaging' (November 2008).

* L.- Ensayos para verificar el cumplimiento de los requerimientos FDA en 21 CFR 175.300 (Resinous and polymeric coatings).
Tests performed to verify the requirements FDA of 21 CFR 175.300 (Resinous and polymeric coatings).

The test conditions will determine the safe use conditions for which the coating/packaging **is suitable for** direct food contact, both in terms of contact time and maximum temperature. For example, a take-away coffee cup is not the same as an industrial level tank where a food or beverage is stored in a food transformation process.

From this we can understand that, if we leave a plastic water bottle in the sun in the car, the water will taste bad, since this bottle is probably designed for use in a certain range of temperatures and exposure, which is not contemplated in this case. There are plastics designed to withstand high temperatures, for

example, those that indicate their suitability for use in the microwave, while others are not. If we exceed the limits of use, it is possible that undesired migrations may occur that can significantly alter the organoleptic, food safety and functionality. As a curious fact, for example, the migration and extraction tests for our FK-100 FoodGrade paint take up no less than 20 pages, because if multiple uses need to be tested, many migration tests will be required.

But this is not the end of the story, if they are **coatings** for surfaces or packaging of **single-use**, which are what the consumer usually uses when buying food, for example, a bottle of milk or a fruit and vegetable packaging, the coating must comply with all the maximum limits at the first migration, which is where the greatest risk is concentrated. For **repeated use** packaging and surfaces, more at the industrial level, or reusable packaging, the third migration is taken as a reference.

Once the necessary tests have been carried out with the chosen simulants, and they comply with the maximum permissible overall migration limits, ***we must move on to testing the specific migrations.*** *Each coating or packaging,* ***depending on its formulation/composition****, must comply with the maximum specific migration limit (SML) of certain substances.*

For example, all coatings and packaging must always comply with the maximum limits for specific migration of aromatic amines and heavy metals, among others, but also with those specific to their formulation; for example, in the case of products based on epoxy resins, they must comply with the maximum limit of specific migration of Bisphenol A of the latest EU Regulation 2018/213, which reduced 10 times the allowed SML of BPA, but they must also comply with the specific Regulation for this epoxy group, EC 1895/2005, which contemplates another series of specific migrations such as BADGE, NOGE, BFDGD, etc.

According to our experience, it should be noted that ***only some calculations of specific migrations can be performed theoretically,*** *i.e. without testing, by mathematical model and according to the indications of EU 10/2011 regulation, with a scientifically based overestimation. On a practical level, for example, it will be possible in cases where we know perfectly well the composition of each substance contained in each raw material, which, being on the positive list, has an SML, and it is the case that this content is lower than the maximum permitted migration limit.*

As mentioned above, this implies having confidentiality agreements between raw material suppliers, and generally with an accredited external laboratory, which ensures that these theoretical calculations are verified.

Once the above is fulfilled, ***organoleptic tests must be carried out to*** *verify that, in spite of being compliant in relation to food safety, there are* ***no significant alterations in odor and taste****, in accordance with the intended use. The* ***UNE-ISO 13302:2008*** *standard is used as a reference to evaluate olfactory and taste modifications.*

4. Fakolith is committed to transparency and excellence

In our case, from www.foodgradepaint.com of Fakolith, we have opted for transparency and we have published the Declarations of Conformity of our varnishes, paints and coatings for direct, occasional or indirect contact with food and beverages, link here.

Our Compliance Declarations are regularly updated to include new required tests by changes in regulations.

In food safety, sufficient is insufficient, only excellent is possible.

It is true, in Fakolith we have taken this matter very seriously, although in the rules and regulations, there is room for certain interpretations. In our case, for the sake of **food safety we have decided to always work with the most demanding interpretation of the regulations,** as well as to constantly investigate with official Research projects in this field to improve food safety, sustainability, and functionality.

5. Pioneers in official research in food contact coatings and antimicrobial protection

Since 2009 Fakolith has participated in more than 8 official research projects, in consortiums with universities, technology centers and other companies, and in the last 4 years it has also been the designer and leader of these projects, which is why it is considered by the Ministry of Science and Innovation as a European R&D&I Intensive SME.

A clear example is that thanks to the **Official R&D&I FDA & EU FoodGrade Coatings Project, FAKOLITH** has been the first global manufacturer to certify varnishes and paints suitable for food contact, with antimicrobial technology, which simultaneously comply with the 2 international food contact reference regulations, the American FDA 21 CFR 175.300 and also the European EU 10/2011.

The development of paints and varnishes with double FDA and EU certification has represented a great innovative effort for our R&D department. Both regulations differ in their conception, evaluation of raw materials and testing criteria, while the European one is based more on migrations, the American one is based on extractions. Complying with both simultaneously in the same product provides our customers with the best possible guarantee in terms of food safety and hygiene.

FAKOLITH and the constant improvement of sustainability

Fakolith is already looking to this future with the official R&D&I project **"BioHybrid Food Contact Coatings"** in which the first range of bio-based hybrid coatings suitable for direct contact with food and beverages is being developed and certified in accordance with European and North American regulations.

It is necessary to know that biodegradable is not always synonymous with safe for food contact, as it can compromise functionality and increase permitted migrations, or even generate problems for celiacs in some cases.

Therefore, Fakolith in this project is investigating all options to develop and certify bio-based hybrid coatings with an ideal balance between sustainability, recycling, and functionality, all without compromising food safety, which we must never lose sight of.

BIOHYBRID

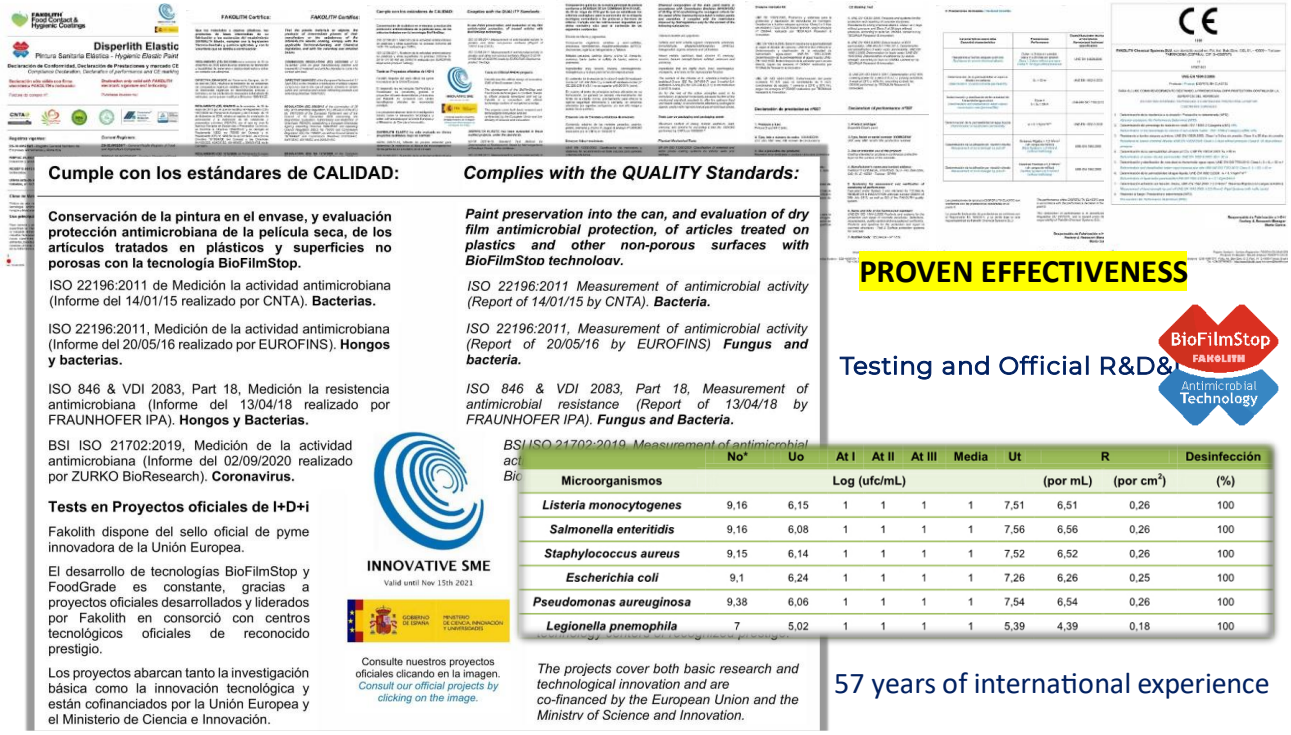
Here you can find information about our R&D&I projects.

6. And apart from this, does Fakolith perform any other tests?

In our case, paints, varnishes, and coatings for direct contact with food, beverages and drinking water, from FAKOLITH, we also understand as fundamental, additional tests that determine the functionality of the product, that is to say that apart from not representing a health risk in direct contact with food and beverages, they fulfill their function as a coating. The most common tests that we perform, both in external organizations and in our R+D+i projects are:

In general:

- *Antimicrobial effectiveness as treated articles with BioFilmStop FG technology, against pathogenic microorganisms.*
- *Physicochemical resistance.*
- *Resistance to cleaning and disinfection.*
- *The entire battery of CE Marking tests when feasible.*
- *The characterization of each type of paint, varnish or coating.*
- *Those of interest to a food, health or pharmaceutical sector.*
- *Those carried out within each official R&D&I project.*



Microorganismos	No*	Uo	At I	At II	At III	Media	Ut	R (por mL)	R (por cm²)	Desinfección (%)
	Log (ufc/mL)									
Listeria monocytogenes	9,16	6,15	1	1	1	1	7,51	6,51	0,26	100
Salmonella enteritidis	9,16	6,08	1	1	1	1	7,56	6,56	0,26	100
Staphylococcus aureus	9,15	6,14	1	1	1	1	7,52	6,52	0,26	100
Escherichia coli	9,1	6,24	1	1	1	1	7,26	6,26	0,25	100
Pseudomonas aureuginosa	9,38	6,06	1	1	1	1	7,54	6,54	0,26	100
Legionella pnemophila	7	5,02	1	1	1	1	5,39	4,39	0,18	100

To simplify the location of these tests, FAKOLITH includes them in the Declaration of Conformity, Performance and CE marking.

Here you can find information about our Compliance Declarations

7. A wide range of food and sanitary solutions

While the primary function of FAKOLITH's FoodGrade paints, varnishes and coatings is to prevent the migration of toxic substances into food and their manufacturing environments, this range is not only used for direct contact, but also due to its performance and **proven antimicrobial effectiveness against pathogenic microorganisms**, it is used on multiple surfaces in the food, healthcare, pharmaceutical and general industry sectors.

*Using **Fakolith's FoodGrade and BioFilmStop** range of **coatings in the food, healthcare and pharmaceutical sectors contributes positively to compliance with hygiene and food safety and sanitary standards** in general.*

	No*	Uo	At I	At II	At III	Media	Ut	R		Desinfección
Microorganismos			Log (ufc/mL)					(por mL)	(por cm^2)	(%)
Listeria monocytogenes	9,16	6,15	1	1	1	1	7,51	6,51	0,26	100
Salmonella enteritidis	9,16	6,08	1	1	1	1	7,56	6,56	0,26	100
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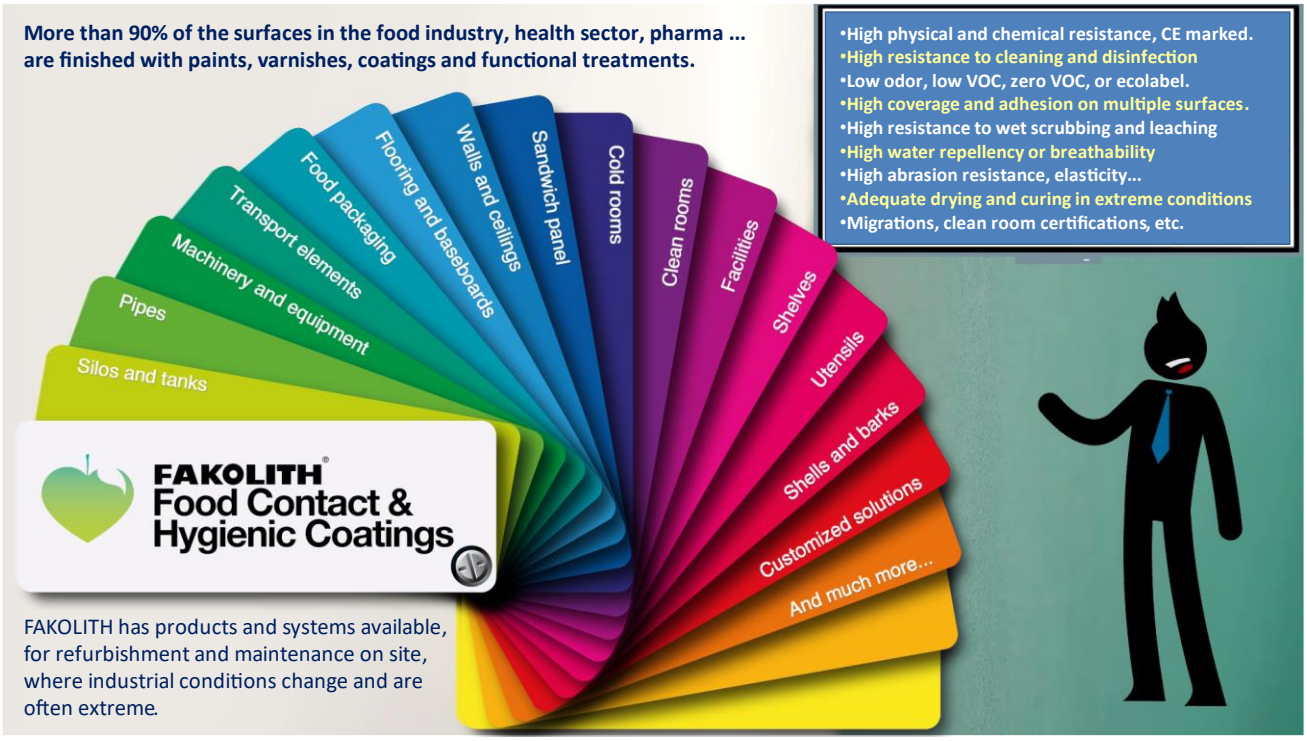
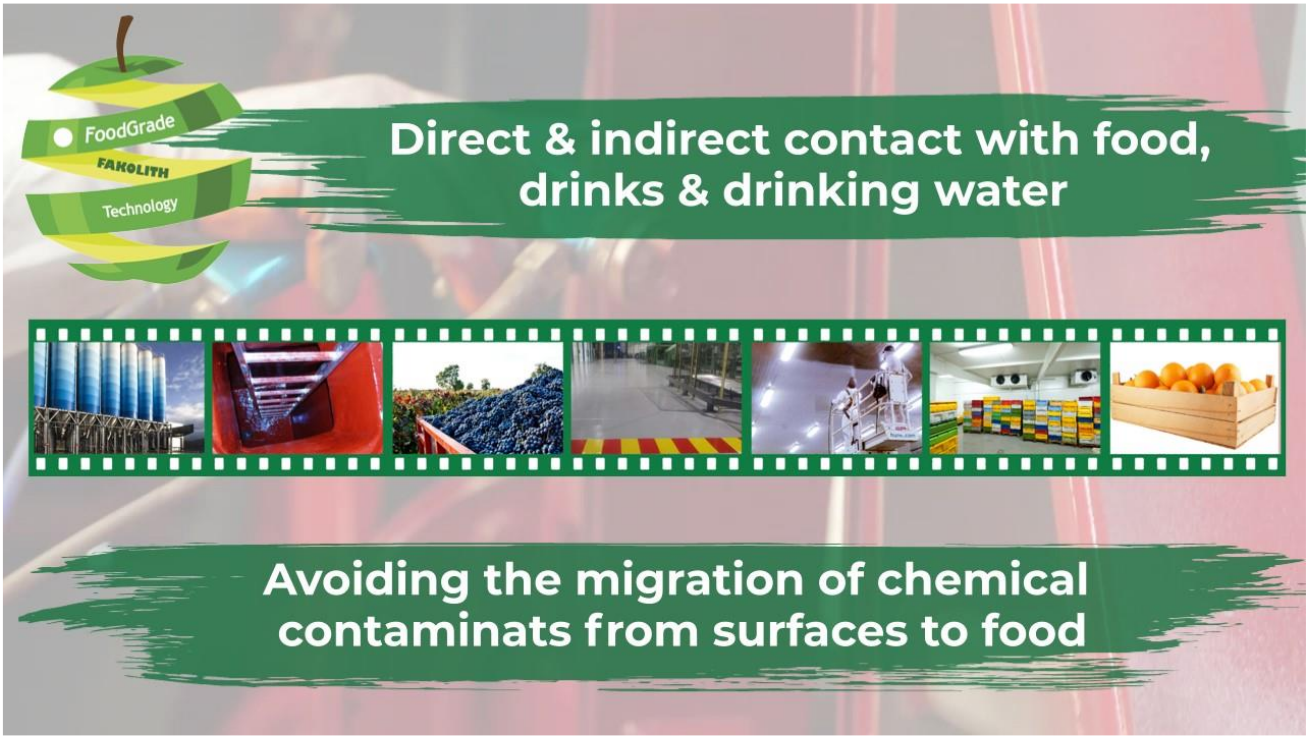
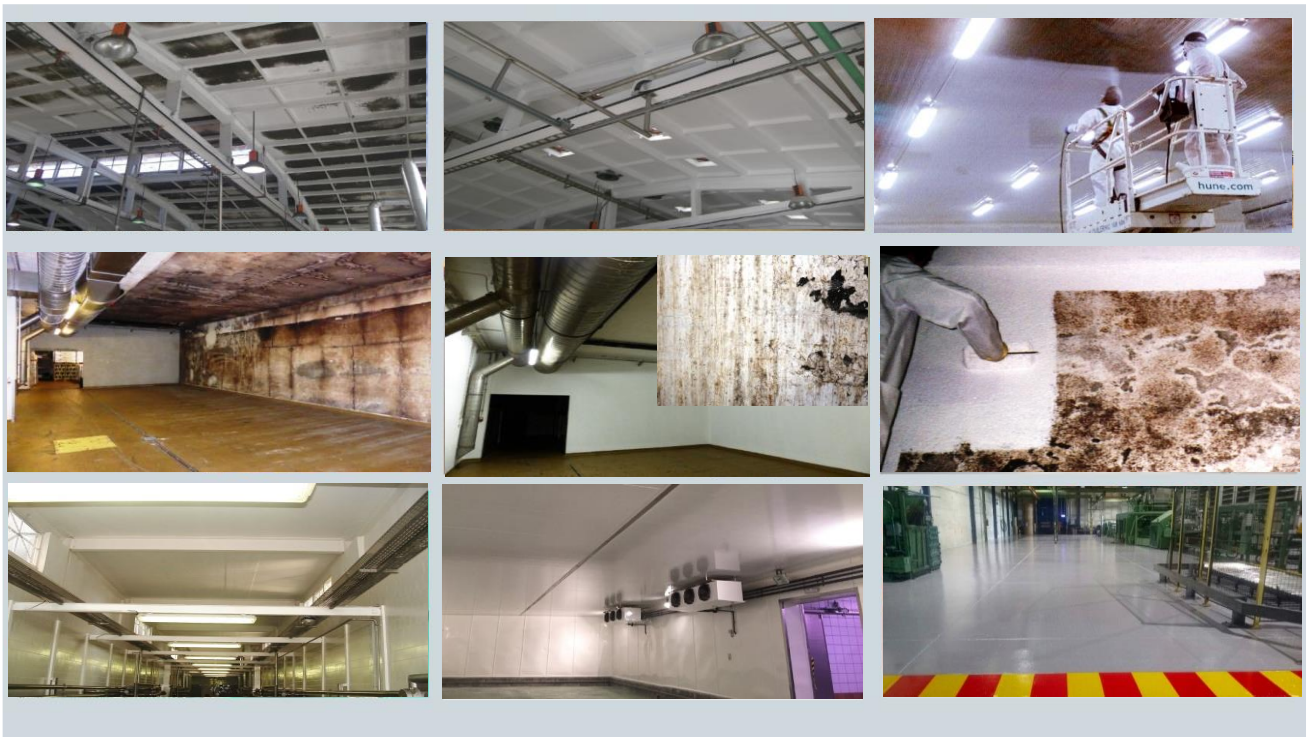
Escherichia coli	9,1	6,24	1	1	1	1	7,26	6,26	0,25	100
Pseudomonas aureuginosa	9,38	6,06	1	1	1	1	7,54	6,54	0,26	100
Legionella pnemophila	7	5,02	1	1	1	1	5,39	4,39	0,18	100

A clear example of indirect food contact are **ceilings, walls, floors and other surfaces in food processing industries, where condensation droplets can carry chemical and biological contaminants into the food, which can cause cross-contamination.**


More than 90% of the surfaces in the food industry, health sector, pharma ...
are finished with paints, varnishes, coatings and functional treatments.
•High physical and chemical resistance, CE marked.
•High resistance to cleaning and disinfection
•Low odor, low VOC, zero VOC, or ecolabel.
•High coverage and adhesion on multiple surfaces.
•High resistance to wet scrubbing and leaching
•High water repellency or breathability
•High abrasion resistance, elasticity...
•Adequate drying and curing in extreme conditions
•Migrations, clean room certifications, etc.
Silos and tanks
Pipes
Machinery and equipment
Transport elements
Food packaging
Flooring and baseboards
Walls and ceilings
Sandwich panel
Cold rooms
Clean rooms
Facilities
Shelves
Utensils
Shells and barks
Customized solutions
And much more...
FAKOLITH
Food Contact &
Hygienic Coatings
FAKOLITH has products and systems available,
for refurbishment and maintenance on site,
where industrial conditions change and are
often extreme.


FoodGrade
FAKOLITH
Technology
Direct & indirect contact with food,
drinks & drinking water
Avoiding the migration of chemical
contaminats from surfaces to food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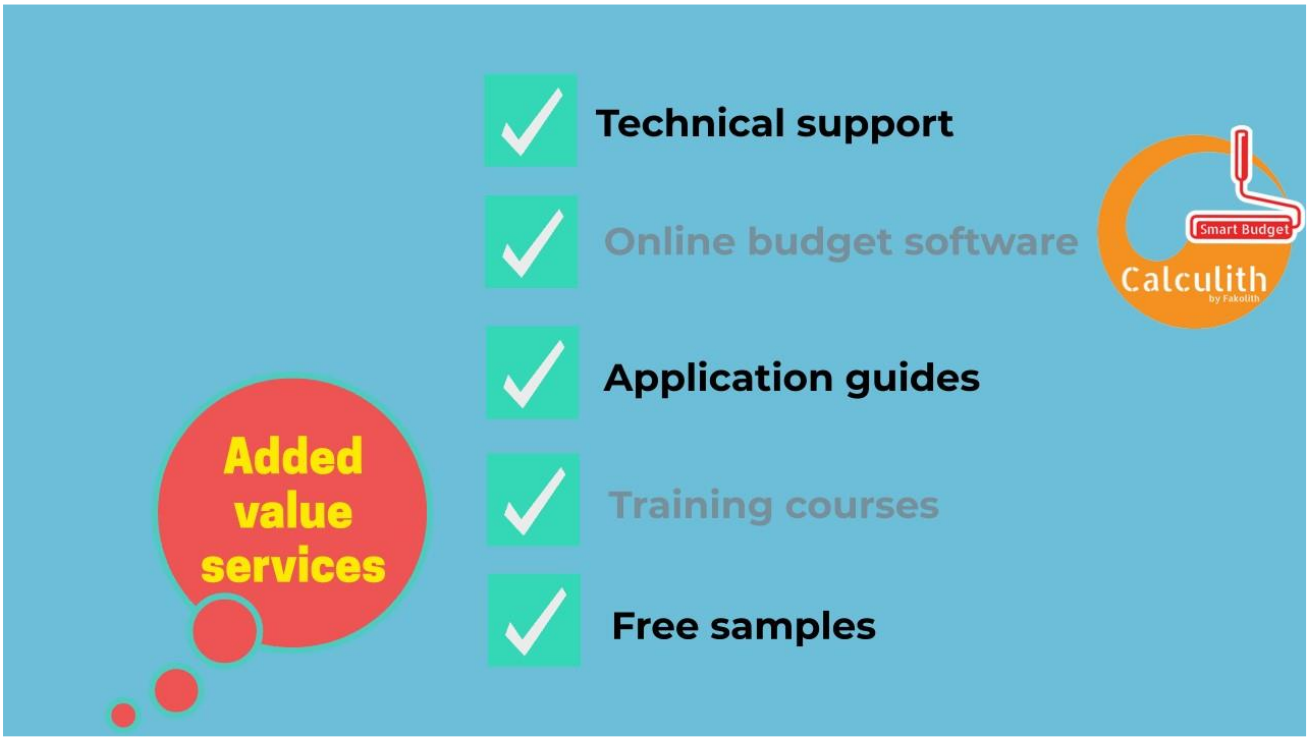
8. FAKOLITH's added value, contact us.



FAKOLITH TECHNICAL DEPARTMENT (09-04-21)