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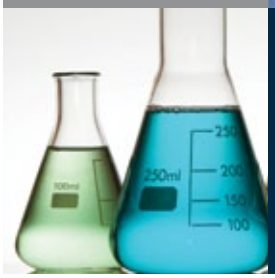
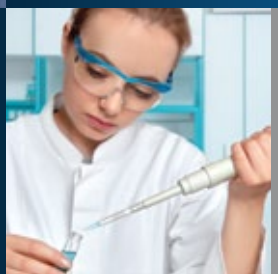
ACCREDITED TESTING
OF FOOD CONTACT MATERIALS





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ACCREDITED TESTING OF FOOD CONTACT MATERIALS:

- Overall migration into all food simulants: water, A, B, C, D1, D2, E, isooctane and 95% ethanol
- NIAS screenings: GC-MS/FID, LC-QToF-MS, Headspace-GC/MS, ICP-MS
- Specific migration of PIM Annex I substances (SMLs)
- Specific migration of PIM Annex II substances: Metals and Primary Aromatic Maines (PAAs)
- Solvents residual
- Sensory analysis acc. DIN 10955, EN 1230
- Color fastness, EN 646, EN 648, DIN 53160-1, -2
- Heavy metals content acc. EU 94/62 (Cr (VI) , Pb, Hg, Cd)
- PAHs, Phthalates, PAAs, Bisphenols, SCCP/MCCP/LCCP and other REACH substances
- Migration of certain elements EN 71-3, EN 71-9/10/11
- Restricted substances under REACH and RoHS Directive
- CRP, Child- Resistant Packaging testing acc. ISO 8317
- and many other

J.S. Hamilton Poland Sp. z o.o. is the laboratory that comprehensively bridge the consultancy services with a wide range of analytical services and techniques. Being the private and independent research laboratory, we are a partner for companies in the food, packaging, plastic, cosmetic, pharmaceutical and chemical industries, as well as for manufacturers and importers of toys and household goods. Our team of the experience Experts for years has ensured an independent assessment of the quality of controlled products.

The central laboratory in Gdynia and the network of specialized local laboratories have been offering a wide range of accredited physic-chemical, microbiological and sensory analyzes since 1949.

J.S. Hamilton is market leader in testing of food, cosmetics, as packaging for food, cosmetics and pharmaceuticals, as well as products and articles intended to be contacted with food (FCM).

J.S Hamilton's experts advise the appropriate and optimized configuration of FCM testing plan in order to ensure compliance with the relevant national, European and USA (FDA) safety regulations and the specific requirements of clients, organizations and retail chains.

ACCREDITATION:

J.S. HAMILTON POLAND Sp. z o.o.
Testing laboratory
PCA accreditation
acc. to PN-EN-ISO/IEC 17025:2005
Accreditation no. AB 079
Accreditation since: 15-10-1996

FOOD CONTACT MATERIALS AND FOOD SAFETY IN THE EU

Food contact materials (FCMs) are widely used in everyday life in the form of food packaging, dishes and utensils, tableware, repeated-use food containers, oven trays, cooking mats etc. When put into contact with food, the different materials may behave differently and transfer their constituents to the food. If transferred in large quantities, many chemicals might endanger human health, or change the food itself. Therefore, food contact materials are the subject to legally binding rules at EU level, currently laid down in the Regulation (EC)1935/2004 which aims at ensuring FCM safety but also the effective functioning of the internal market in FCMs raw materials and final products. The purpose of this framework legislation for FCMs is to ensure the effective functioning of the internal market for materials and articles intended to come into contact with food and secure a high level of protection of human health, as well as the interests of consumers.

(EC)1935/2004 gives general requirements that all FCMs must be manufactured in accordance with good manufacturing practice (GMP) so that they are safe and do not change the properties of food in unacceptable ways. As the general requirements for all FCMs set out under the Article 3 are linked to the general obligations of the GMP, separate rules of the GMP are laid down in Commission Regulation (EC)2023/2006. It also gives other rules, including those on labelling and on compliance documentation and traceability, and lays down the risk assessment process involving EFSA as part of the authorization process for substances.

FCM TYPES, ANNEX I OF (EC) 1935/2004:

- Active and intelligent materials and articles
- Adhesives
- Ceramics
- Cork
- Glass
- Ion-exchange resins
- Metal and alloys
- Paper and board
- Plastics
- Printing inks and colorants
- Regenerated cellulose
- Rubbers
- Silicones
- Textiles
- Varnishes and coatings
- Waxes
- Wood

The Framework Regulation sets up the general safety requirements applicable to all possible food contact materials and articles, and envisages a possibility for the adoption of specific safety requirements, national legislation or further harmonization at EU level, for seventeen FCMs listed in Annex I to Regulation (EC)1935/2004. So far, specific safety requirements on EU level have been adopted only for six FCMs (see table). These FCMs need to comply not only with the Framework and the GMP Regulations but also with their specific measures, which can contain detailed restrictions on the manufacture and use of FCM.

The most comprehensive specific EU measure is Regulation (EU) No 10/2011 on plastic materials and articles. It sets out rules on the composition of plastic FCMs, and establishes a Union List of substances that are permitted for use in the manufacture of plastic FCMs. The Regulation also specifies restrictions on the use of these substances and sets out the rules to determine the compliance of plastic materials and articles.

EU FCMS REQUIREMENTS OVERVIEW

General Regulations on FCM	
Regulation EC 1935/2004 (on the materials and articles intended to come into contact with food)	
Regulation EC 2023/2006 (on Good Manufacturing Practices)	
Specific Materials	
Ceramics	Directive 84/500/EEC
Epoxy Resins	Regulation (EC) 1895/2005
Regenerated Cellulose Film	Directive 2007/42/EC
Recycled Plastics Material	Regulation (EC) 282/2008
Active and Intelligent Packaging	Regulation (EC) 450/2009
Plastics	Regulation (EU) 10/2011
Specific Regulation	
Regulation (EU) 321/2011 (restricting the use of bisphenol A in polycarbonate infant feeding bottles)	
Regulation (EU) 284/2011 (import procedures for polyamide and melamine plastic kitchenware from China and Hong Kong	
Regulation (EC) 1895/2005 (restricting the use of certain epoxy resins)	
Directive 93/11/EEC (regulating the release of N-nitrosamines and N-nitrosatable substances from rubber teats and soothers)	

OVERALL & SPECIFIC MIGRATION

Food packaging can be a source of chemical food contaminants. The chemicals transfer from FCMs into food is called migration. The extent to which migration occurs depends on various factors: the physical and chemical properties of the migrant, of the packaging material and the food (e.g. fat content, acidity), temperature, storage, the packaging dimensions in proportion to the foodstuff volume (smaller size packaging has a larger surface to volume ratio).

The types of chemicals that can migrate from packaging into food are highly diverse and depend on the type of packaging material. For inert materials (stainless steel, ceramic, glass) only chemicals from the inside surface directly in contact with the foodstuff can migrate. Chemical diffusion either from the packaging material or from the outside (printing inks, adhesives) is not possible.

Non-inert materials, like paper and cardboards or plastics, can be a direct source of migrants. Chemicals may also migrate from the outside through the packaging. For instance the printed inks compounds applied on the surface of packaging material may migrate through paper into dry foods.

A special case of migration is SET-OFF migration, where the packaging back layer with the print on it can eventually create the actual contact with the other side. In this instance the migrant can transfer through due to the diffusion phenomena to the inside. The set-off migration occurs when printed film foil is stored in rolls, or when paper cups are stacked inside each other. The most comprehensive description and detailed migration testing rules is given by Plastic Regulation EU 10/2011. Safety assessment mechanism of plastic materials is based on use of migration limits. These limits specify the maximum amount allowance for the substances that is accepted to migrate to food. For the substances on the Union list the Regulation sets out Specific Migration Limits (SML). These are established by EFSA on the basis of toxicity data for each specific substance.

To ensure the overall quality of the plastic, the overall migration into the food of all substances together may not exceed the Overall Migration Limit (OML) of 60mg/kg food or 10 mg/dm2 of the contact material.

Although migration testing in the food prevails, migration is usually tested using 'food simulants'. These simulants are representative for a food category, e.g. Acetic acid 3 % is assigned for acidic foods and 50% Ethanol for milk and dairy products. Food simulants are used as substitutes for food due to the simplification of chemical analysis. Chemical detection and quantification requires specific analytical methods for each chemical of interest, specially developed for each food and food simulant type.

FOOD SIMULANTS ACC. (EU) 10/2011

- **A** Ethanol 10% (hydrophilic food)
- **B** Acetic acid 3% (hydrophilic food pH<4.5)
- **C** Ethanol 20% (alcoholic more lipophilic food)
- **D1** Ethanol 50% (lipophilic/alcoholic food; oil in water emulsion), milk products
- **D2** Vegetable oil; (lipophilic food; surface free fats) or alternative D2 food simulants Ethanol 95%, isooctane
- **E** poly (2,6-diphenyl-p-phenylene oxide) (dry food), Tenax®, MPPO

The migration testing is done under standardized time temperature conditions, representative for a certain food use, and covers the maximum shelf life of packed food including special thermal conditions treatment.

To ensure the safety, quality and compliance of plastic materials adequate data of the composition of materials (intermediate) has to be communicated upfront via the manufacturing chain but not including the retail stage. For this purpose the 'Declaration of Compliance' (DoC) needs to be provided. The DoC is based on the supporting documentation which documents the reasoning on the safety of a plastic food contact material, and which must be provided to enforcement Authorities on their request. The supporting documentation also provides the important link to the manufacturer's responsibility under GMP (Regulation (EC) No 2023/2006).

NON-INTENTIONALLY ADDED SUBSTANCES

During the food contact materials life cycle unexpected and potentially harmful substances may migrate into the food products. The term NIAS was introduced for plastic FCMs in the legal context (EU) 10/2011. However, NIAS are not only limited to plastics but also occur in other non-plastic FCMs. Article 3(9) of EU 10/2011 defines NIAS as an impurity in the substances used or a reaction intermediate formed during the production process or decomposition or reaction product. Thus NIAS have various sources, it may be side products, breakdown products, and contaminants. Side products are often formed during the production of starting substances and all further manufacturing stages. Polymers, fibers as well as additives (e.g., antioxidants, UV-stabilizers) are often degraded during manufacture and use, thus leading to various different breakdown products. Starting substances often contain impurities or environmental contaminants which may remain in the final FCM. Processing and recycling high likely can also introduce many different contaminants in FCMs. Typical recycling-related NIAS are mineral oil hydrocarbons (MOHs), bisphenols, phthalates, and photoinitiators in recycled paper or flavor compounds, oligomers, and additives in recycled plastics.

According to the legislation, NIAS have to be assessed using scientifically recognized principles of risk assessment. Non-Intentionally Added Substances have to comply with the General Safety Requirements of Article 3 of Regulation (EC)1935/2004 and are subject to a risk assessment by the business operator in accordance with Article 19 of Regulation EU 10/2011.

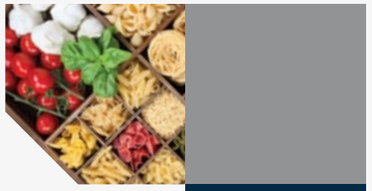
Sources:
https://www.foodpackagingforum.org;
https://ec.europa.eu

CONSULTANCY SERVICES

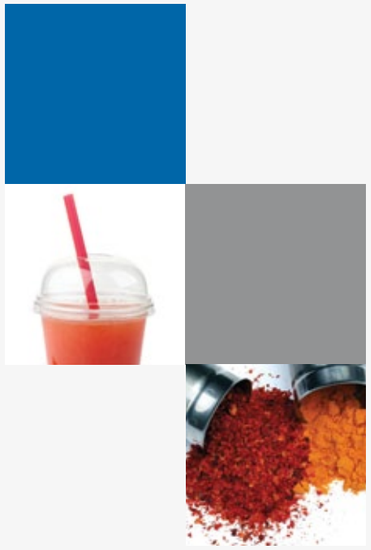
- Set-up of optimized testing plans for compliance verification of FCMs
- Documents review, DoCs for raw materials verification
- Compliance assessment based on EU 10/2011, Swiss Ordinance, BfR Recommendations
- Toxicological risk assessment e.g. by TTC-concept method
- Drafts of DoC (Declaration of Conformity) for final FCMs

PLASTIC MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD AND COSMETICS

- Overall and specific migration into all food simulants: water, A, B, C, D1, D2, E and D2 alternatives (isooctane and 95% Ethanol)
- Specific migration of:
  - Annex II: Primary Aromatic Amines (PAAs) and Metals taking into account the last amendment EU 2020/1245
  - Plasticizers, antioxidants, monomers and other additives acc. EU 10/2011 Annex I and Swiss Ordinance
  - Bisphenols and epoxy resin derivatives BADGE, BFDGE and NOGE in coated materials, plastics and adhesives
  - Mineral oils (MOSH/POSH & MOAH)
  - Oligomers
- NIAS screenings: GC-MS/FID, LC-QToF-MS, Headspace-GC/MS, ICP-MS
- Isocyanates content and migration (laminates with adhesives, printed materials)
- Set-off storage effect of printing inks and specific migration UV-initiators, acrylates, BHT, PAAs, etc.
- Solvents residual
- Sensory analysis acc. DIN 10955, EN 1230-1/ -2
- Colorfastness acc. EN 646, DIN 53160-1 / -2
- Gas transition rate: oxygen (OTR), water (VWTR), CO_2, N_2



J.S. HAMILTON OFFER FOR FCM ARTICLES AND PACKAGING MANUFACTURERS



METALS AND ALLOY

Specific release of metal ions testing based on „Metals and alloys used in food contact materials and articles, A practical guide for manufacturers and regulators" and Resolution CM/Res(2013)9 on metals and alloys used in food contact materials and articles, adopted by Council of Europe member states.

GLASS AND CERAMICS

- Determination of lead (Pb) and cadmium (Cd) transferred (released) from ceramic articles which, in their finished state, are intended to come into contact with foodstuff, acc. Commission Directive 2005/31/EC of 29 April 2005 amending Council Directive 84/500/EEC.
- Glass: determination of the release of lead and cadmium from silicate surfaces other than ceramic ware.

Paper and cardboard products are the next in the row most important type of packaging. As with plastics they can be printed, glued and laminated with other materials. They are an alternative option to plastic packaging. The main source for the paper is processed cellulose and wood pulp. In addition, the paper contains a large amount of modifying additives. Contrary to plastics, no specific legal measures have been developed at European Union level. For this reason, manufacturers of products apply official recommendations to ensure safety. J. S Hamilton Poland makes it possible to meet all of the requirements contained in the recommendations.

- BFR XXXVI Paper and board for food contact
- Food Contact Guidelines for the Compliance of Paper & Board Materials And Articles - EU
- EDQM Paper and board used in food contact materials and articles - EU

PAPER AND CARDBOARD AS FCM

- Determination of the grammage, moisture content
- Dry matter in the Water Extract
- Heavy metals acc. EU 94/62, Metals in water extract
- Methanal (Formaldehyde), Pentachlorophenol (PCB), Glyoxal, Anthraquinone
- Primary Aromatic Amines (PAAs)
- Polychlorinated Biphenyls (PCB)
- Bisphenol A, Bisphenol S and other bisphenols
- Aromatic Ketones
- Phthalates
- Polycyclic Aromatic Hydrocarbons (PAHs)
- Mineral Oils (MOSH and MOAH) content and specific migration
- PFAS (perfluoroalkylated substances)
- NIAS screenings: GC-MS/FID, LC-QToF-MS, Headspace-GC/MS, ICP-MS
- Transfer of Antimicrobial Constituents
- Determination of the Fastness of Whitened Paper and Board, EN 648
- Colorfastness, EN 646
- Specific migration of printing inks compounds, like photo(UV)initiators, acrylates
- Extraction Tests According to the FDA Regulations, FDA Sec. 176.170
- Testing under Toys Directive (EN 71 standards) and RoHS

REACH AND OTHER REGULATIONS IN CONSUMER GOODS, TOYS, RECYCLED MATERIALS

- Heavy metals
- PAHs (polycyclic aromatic hydrocarbons), e.g. benzo[a] pyrene
- Phthalates
- PAAs and AZO dyes
- SCCP, MCCP, LCCP (Short / Medium / Long-Chain Chlorinated Paraffins)
- BPA (Bisphenol A), BPS (Bisphenol S) and other bisphenols
- Testing acc. to Toy Safety standard EN 71 series such as EN 71-3, EN 71-9/-10/-11, EN 71-12
- Testing of substances acc. RoHS Directive
- Testing against special requirements and specifications of you clients, e.g. retailers (RSLs, Toxic & Restricted Substances Lists

TESTING OF MATERIALS ACC. EUROPEAN PHARMACOPEIA (PH.EUR)

Testing of Polyolefins, PVC, PET, Rubber under GMP standard, e.g.:

- Appearance of solution, Absorbance
- Acidity / alkalinity
- Reducing Substances
- Extractable Al, Tl, Zn; Extractable heavy metals
- Sulfated ash; Plastic additives, Phenolic and non-phenolic antioxidants, Amides and stearates
- Penetrability

Testing is conducted according to method described in current edition of Ph.Eur. Monographs:

- (3.1.3) Polyolefins
- (3.1.4) Polyethylene without additives for containers for parenteral preparations and for ophthalmic preparation
- (3.1.5) Polyethylene with Additives for Containers for Parenteral Preparations and for Ophthalmic Preparations
- (3.1.6) Polypropylene for Containers and Closures for Parenteral Preparations and Ophthalmic Preparations
- (3.1.11) Material Based on NonPlasticised Poly (vinyl chloride) for Containers for Dry Dosage Forms for Oral Administration
- (3.1.15) Polyethylene Terephthalate for Containers for Preparations not for Parenteral Use
- (3.2.9) Rubber Closures for Containers for Aqueous Parenteral Preparations, for Powders and for Freeze-Dried Powders

CHILD - RESISTANT PACKAGING TESTING ACC. ISO 8317

This applies to re-closable to packaging for pharmaceutical and chemical products, like detergents, disinfection agents, washing capsules, e-liquids and other substances and chemicals classified as:

- acutely toxic, category 1-3
- STOT - single exposure (effect on target organs), category 1
- STOT - repeated exposure (effect on target organs), category 1
- corrosive to skin, category 1
- containing 3% methanol and/or 1% dichloromethane
- posing a threat with toxic effect caused by aspiration, with exception of substances or mixtures marketed in aerosol containers or containers fitted with airtight aerosol-making devices
- external packaging for washing capsules, according to Regulation (EU) 1297/2014

The standard has a two part testing procedure. The first test is with up to 200 infants aged 42 to 51 months, the children must not be able to open the packaging, while a group of people aged 50 to 70 must be able to open the packaging without difficulty. Only packaging that has been considered child resistant in tests with infants as well as convenient for elderly people according to the standards will meet ISO 8317.

CERTIFICATION

Food SAFE – Certified Packaging & FCMs

Food contact materials (FCMs) are widely used in everyday life in the form of food packaging, dishes and utensils, tableware, food containers, etc. When put into contact with food, the different materials may behave differently and transfer their constituents to the food. If transferred in large quantities, many chemicals might endanger human health, or change the food itself.

In order to meet the increasing demands and governed expectations from the market (Consumers' preferences), J.S. Hamilton Poland has developed guidelines based on applicable law, including Regulation (EC) No 1935/2004, Regulation (EC) No 2023/2006, Directive 94/62/EC, Commission Regulation (EU) No 10/2011, Annex 10 of the FDHA Regulation on Materials and Articles intended to come into Contact with Food (SR 817.023.21) (Swiss Ordinance), BfR Recommendations on Food Contact Materials, Code of Federal Regulations 21, Food and Drugs, and other prescriptive requirements, supplemented by additional or modified requirements, as well as guidelines of various organizations depending on the respective use and type of material/article under review.

Producers, importers and exporters who want to stand out on the market can apply for the "Food SAFE, Certified Packaging & Food Contact Articles" certificate and obtain their individual quality mark.

Useful for Recycling

Environmental friendly materials and packaging have become very popular in recent years. It results directly from the emerging ecological trends, growing public awareness and market requirements. Such packaging can be an environmentally friendly alternative to standard products. The growing market demand for this type of products means, that many manufacturers focus on creating and improving materials with properties suitable for recycling.

To meet the changing market trends, the company J.S. Hamilton has developed guidelines using existing legal and normative acts, supplemented with additional or modified requirements, as well as guidelines of various organizations supporting the recycling of packaging waste.

Entrepreneurs who are producers, importers or exporters, wishing to distinguish their product, may apply for a certificate confirming the property "Useful for recycling" and obtain their individual mark of conformity.

Biodegradable and compostable

Environmental friendly materials and packaging have become very popular in recent years. It results directly from the emerging ecological trends, growing public awareness and market requirements. Such packaging can be an environmental friendly alternative to standard products. The growing market demand for such products causes many manufacturers to focus their attention on creating and improving biodegradable and compostable materials.

To meet the changing market trends, the Laboratory J.S. Hamilton has developed guidelines using existing legal and normative acts (harmonized with Directive 94/62 EC standards EN 13432, EN 14995 – assessing the composting capacity of plastics, as well as EN ISO 20200 and EN 14045 – determination of the degree of sample decomposition under simulated composting conditions on a laboratory scale), supplemented with additional or modified requirements.

Entrepreneurs who are producers, importers or exporters, wishing to distinguish their product, may apply for a certificate confirming the property "Biodegradable and compostable" in the "Industrial" or "Home" area, and obtain their individual mark of conformity.

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J.S. Hamilton laboratory is ...

- Market leader in testing of packaging for food, cosmetics and pharmaceuticals
- An independent research center offering knowledge and experience as well as a wide range of analytical methods
- A reliable partner of food, packaging and plastics processing industry
- Expert team ensuring impartial assessment of the quality, compliance and safety of products

We support the development of our partners and confirm their credibility, responsibility & innovation.

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