

Catalogue of services for safety and regulatory compliance testing

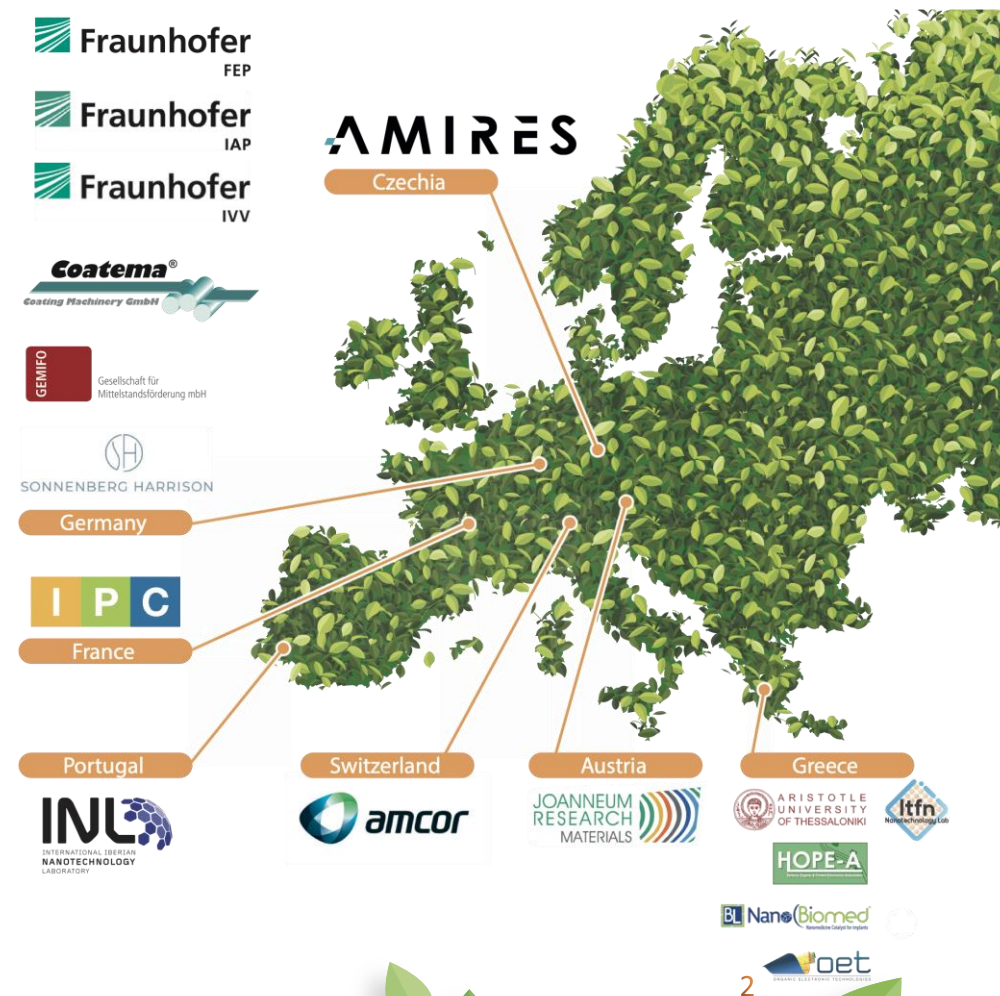


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Service Providers in FlexFunction2Sustain



Use Cases of the FlexFunction2Sustain project

FlexFunction2Sustain's technical facilities and the performances of novel nano-functionalised surfaces will be demonstrated and validated by Europe's leading companies within six industrial application scenarios. Application examples for the services related to the Use Cases are labelled with a code specific for each one (UC#)

Industrial Validation in 6 Use Cases

UC1



Biobased
Optical Films
for Labelling of
Consumer Goods
and Surface
Design

UC2



Marine
degradable
shampoo sachets

UC3



Selective and
switchable
water filter
membranes

UC4



Multifunctional
scratch resistant
surfaces in
automotive

UC5



Recyclable
mono-polymer
drink pouches

UC6



Sustainable
paper-based
food packaging

A full description of the six Use Cases can be found in the FlexFunction2Sustain Project Handbook, available at <https://flexfunction2sustain.eu>

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Assessment of food contact materials (FCM) and packaging

Plastic food contact materials regulatory compliance

Functionalities	Equipment & Facilities	Technical specifications / testing conditions	Application examples
Plastic food contact materials regulatory compliance	Laboratories accredited by EN ISO 17025, ISO 9001, or NP 4457	Assessment performed according to Regulation (EC) No 1935/2004, Commission Regulation (EU) No 10/2011, Commission Regulation (EC) No 450/2009, and Commission Regulation (EU) 2018/1881. FDA compliance may be assessed upon request.	<p>Comprehensive assessment of the safety and regulatory compliance of plastic FCMs according to relevant regulations and standards in the EU. This includes review of the material composition to determine the presence of harmful substances, their potential migration, and available toxicological data (UC5, UC6).</p> <p>FlexFunction2Sustain can provide guidance on how to improve the safety and compliance of packaging, including selection of more suitable materials, design of migration testing strategy, and support on the required documentation to meet regulations.</p>



FlexFunction2Sustain compliance assessment of plastic FCMs helps to protect consumers and reduce the risk of product recalls or other regulatory issues.

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Assessment of food contact materials (FCM) and packaging

Paper and paperboard food contact materials regulatory compliance

Functionalities	Equipment & Facilities	Technical specifications / testing conditions	Application examples
Paper and paperboard food contact materials regulatory compliance	Laboratories accredited by EN ISO 17025, ISO 9001, or NP 4457	<p>Regulations governing the use of paper and paperboard food contact materials are not harmonised in the EU and vary by regions, however basic requirements for compliance are defined by Regulation (EC) No 1935/2004.</p> <p>To ensure a compliance assessment as comprehensive as possible, assessment is performed according to the Council of Europe 2021 Guidelines for “Paper and board used in food contact materials and articles”.</p> <p>German BfR XXXVI, and other EU Member State legislation, or industry associations guidelines such as CEPI may be available upon request.</p>	<p>Ensure the safety and compliance of paper and paperboard food contact materials. Comprehensive assessment of the compositional data to ensure the packaging is manufactured using regulated substances, evaluation of the migration, and toxicological data (UC6).</p> <p>FlexFunction2Sustain can provide guidance on how to improve the safety and compliance of paper-based packaging, including optimise materials selection, design of migration testing strategy, and support on the required documentation to meet regulations.</p>



FlexFunction2Sustain can optimise compliance by implementing tailored strategies for products such as paper-FCMs beyond the scope of EU harmonised legislation.

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Assessment of food contact materials (FCM) and packaging

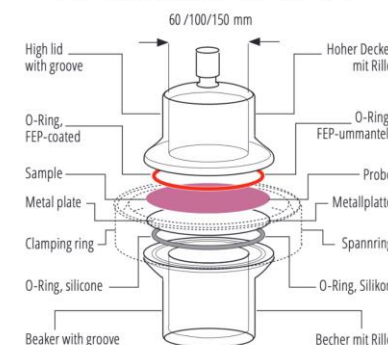
Food contact materials migration testing

Functionalities	Equipment & Facilities	Technical specifications / testing conditions	Application examples
Food contact materials migration testing	<p>Laboratories accredited by EN ISO 17025, ISO 9001, or NP 4457</p> <p>PerkinElmer Gas Chromatography with mass or FID detectors.</p> <p>Agilent High Performance Liquid Chromatography with DAD and fluorescence detectors.</p> <p>Inductively coupled plasma mass spectrometry (ICP) Shimadzu ICPE-9000.</p> <p><i>MigraCell</i> Standardized migration cells.</p> <p>Nanoparticle characterisation facilities including Scanning Electron Microscopy (SEM), Transmission Electron Microscopy (TEM), and X-ray diffraction (XRD)</p>	<p>Regulations governing the use of paper and paperboard food contact materials are not harmonised in the EU and vary by regions, however basic requirements for compliance are defined by Regulation (EC) No 1935/2004.</p> <p>To ensure a compliance assessment as comprehensive as possible, assessment is performed according to the Council of Europe 2021 Guidelines for “Paper and board used in food contact materials and articles”.</p> <p>German BfR XXXVI, and other EU Member State legislation, or industry associations guidelines such as CEPI may be available upon request.</p>	Assess the migration of substances from FCMs into food to ensure the safety of FCMs and packaging and to support toxicological risk assessments (UC5, UC6).



SET A MC 60 / MC 100 / MC 150

One-sided migration testing/ Einseitige Anwendung
Contact area/ Kontaktfläche = 0,5 / ~ 1,0 / ~ 2,0 dm²



MigraCell units for assessing migration levels in FCMs

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Assessment of food contact materials (FCM) and packaging

Off-Flavours testing

Functionalities	Equipment & Facilities	Technical specifications / testing conditions	Application examples
Sensory evaluation	Laboratories accredited by EN ISO 17025, ISO 9001, or NP 4457 Sensorial panel	Suitable for all types of FCMs Sensory analysis according to NF EN ISO 4120, NF ISO 13302	Ensure FCMs do not induce changes in the organoleptic properties of food as required by Regulation (EC) No. 1935/2004 (UC5, UC6).
Volatile Organic Compounds (VOCs) detection and measurement	PerkinElmer Gas Chromatography with mass or FID detectors and PerkinElmer Head-Space SPME	Suitable for all types of FCMs	

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Assessment of food contact materials (FCM) and packaging

Food contact materials Declaration of Compliance (DoC)

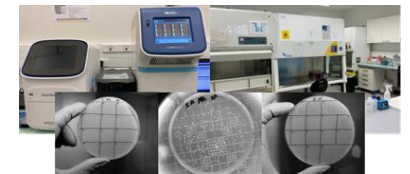
Functionalities	Equipment & Facilities	Technical specifications / testing conditions	Application examples
Support on DoC preparation	n/a	<p>Suitable for plastic and paper-based FCMs</p> <p>According to the applicable regulations or recommended guidelines (e.g., Commission Regulation (EU) No 10/2011 or Council of Europe 2021 Guidelines for “Paper and board used in food contact materials and articles”.</p>	Support manufacturing companies on the preparation of a DoC for demonstrating that their FCMs comply with the applicable regulations and specify the testing methodologies used to validate that they are safe for food contact.

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Microbiological testing

Microbiological testing

Functionalities	Equipment & Facilities	Technical specifications / testing conditions	Application examples
<p>Microbiological safety</p> <p>Support of antimicrobial or inertness claims</p>	BSL-2 microbiology laboratories	<p>Suitable for all types of materials upon consultation.</p> <p>Detection and quantification of microbial groups or specific microorganisms (e.g., yeast and moulds by ISO-21527, mesophiles by ISO-4833, total coliforms, faecal coliforms and E. coli by ISO-9308, L. monocytogenes by ISO-11290).</p> <p>Bioburden and sterility testing by ISO 11737.</p> <p>Rapid detection based on qPCR/LAMP upon request</p> <p>Antimicrobial testing of surfaces by ISO 21702 or ISO 18184 (other standards and microorganisms available upon request).</p>	<p>Test materials and products such as medical devices or food packaging to ensure they are safe and do not support microbial growth (UC2, UC3, UC4, UC5, UC6).</p> <p>Testing of FCMs to ensure they prevent microbial contamination ensuring the quality and shelf-life of food products (UC5, UC6).</p> <p>Ensure product performance according to the claims for antimicrobial materials (UC4, UC6).</p>



BSL-2 microbiology laboratory at INL

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Toxicological and nano-safety assessment

Nano-safety assessment

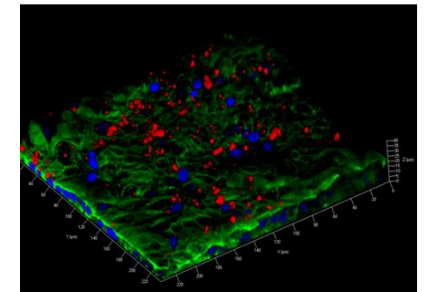
Functionalities	Equipment & Facilities	Technical specifications / testing conditions	Application examples
Nanoparticle characterisation	<p>FEI Titan G2 and FEI Titan G3 Cubed Themis TEM</p> <p>ThermoFisher Glacios Cryo-TEM</p> <p>FEI Quanta 650 FEG eSEM</p> <p>Horiba SZ-100Z DLS</p> <p>NanoSight NS300 NTA</p> <p>Witec Alpha 300R Confocal Raman</p> <p>Thermo Escalab 250 Xi XPS</p> <p>Please, see also the Catalogue of Physicochemical and Functional Characterization at https://flexfunction2sustain.eu</p>	<p>Suitable for organic and inorganic nanomaterials.</p> <p>Physical-chemical characterization of nanomaterials (e.g., size distribution, shape, and chemical composition) according to relevant standards such as ISO/TR 13014:2012 or OECD 2016 Guidelines on the Physical-Chemical Properties of Manufactured Nanomaterials.</p>	<p>Characterisation of nanomaterials in functional barriers (e.g., packaging materials) or active surfaces (e.g. antimicrobial) to support nanosafety risk assessment studies (UC4, UC5).</p>

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Toxicological and nano-safety assessment

Nano-safety assessment

Functionalities	Equipment & Facilities	Technical specifications / testing conditions	Application examples
Cytotoxicity	<p>BSL-2 cell culture and nanosafety laboratories</p> <p>Biophotonics and Bioimaging facilities including Advance Microscopy (Zeiss LSM 780 Confocal, Witec Alpha 300R Raman, Nikon Eclipse Ti-E Fluorescence, Nikon Ti-E TIRF/dSTORM for live cell imaging, and custom-developed combined Fluorescence/AFM).</p>	<p>Suitable for organic and inorganic nanomaterials in colloidal dispersion.</p> <p>In-vitro MTS assay for measuring the cytotoxic effect of nanoparticles according to ISO 19007:2018</p>	Assessing the potential toxic effect of raw nanomaterials and leachates from nanoparticle-containing materials on human cells



NPs internalisation in in-vitro cell models at INL's cell culture laboratory

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Toxicological and nano-safety assessment

Nano-safety assessment

Functionalities	Equipment & Facilities	Technical specifications / testing conditions	Application examples
Oxidative stress	<p>BSL-2 cell culture and nanosafety laboratories</p> <p>Biophotonics and Bioimaging facilities including Advance Microscopy (Zeiss LSM 780 Confocal, Witec Alpha 300R Raman, Nikon Eclipse Ti-E Fluorescence, Nikon Ti-E TIRF/dSTORM for live cell imaging, and custom-developed combined Fluorescence/AFM).</p>	<p>Suitable for organic and inorganic nanomaterials in colloidal dispersion.</p> <p>In-vitro, (CM-H2DCF-DA) assay for evaluating nanoparticle-induced intracellular reactive oxygen species (ROS) production according to ISO/TS 19006:2016.</p>	<p>Assessing the potential of nanomaterials to induce reactive oxygen species (ROS), which can damage cells and lead to cellular death, mutations, and other toxic effects. Support on nano-risk assessment.</p>

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Toxicological and nano-safety assessment

Nano-safety assessment

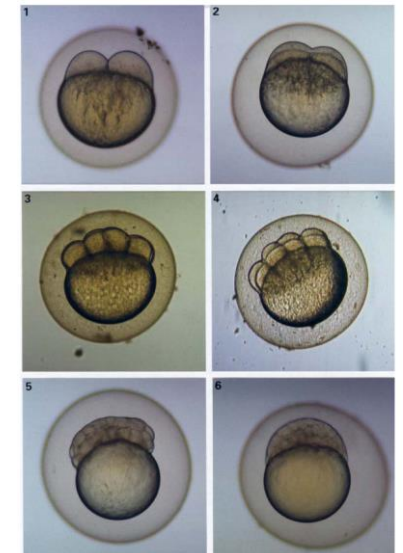
Functionalities	Equipment & Facilities	Technical specifications / testing conditions	Application examples
Biopersistence	<p>BSL-2 cell culture and nanosafety laboratories</p> <p>Biophotonics and Bioimaging facilities including Advance Microscopy (Zeiss LSM 780 Confocal, Witec Alpha 300R Raman, Nikon Eclipse Ti-E Fluorescence, Nikon Ti-E TIRF/dSTORM for live cell imaging, and custom-developed combined Fluorescence/AFM).</p>	<p>Suitable for organic and inorganic nanomaterials in colloidal dispersion.</p> <p>Simulated human digestion under the standardised INFOGEST protocol.</p>	<p>Assessing the potential of nanomaterials to induce reactive oxygen species (ROS), which can damage cells and lead to cellular death, mutations, and other toxic effects. Support on nano-risk assessment.</p> <p>Provide information on how nanomaterials intended for application in Food Contact Materials will behave in the human body after ingestion and support nano-safety assessment.</p>

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Environmental toxicology

Environmental toxicology

Functionalities	Equipment & Facilities	Technical specifications / testing conditions	Application examples
Environmental toxicology	<p>Eco-nanotoxicology laboratory, including Zebra fish facilities.</p> <p>Biophotonics and Bioimaging facilities including Advance Microscopy (Zeiss LSM 780 Confocal, Witec Alpha 300R Raman, Nikon Eclipse Ti-E Fluorescence, Nikon Ti-E TIRF/dSTORM for live cell imaging, and custom-developed combined Fluorescence/AFM).</p>	<p>Suitable for organic and inorganic nanomaterials in colloidal dispersion.</p> <p>Acute toxicity of nanomaterials on biotic systems using Zebra fish embryos according to OECD TG. 236.</p>	Evaluate the potential environmental safety risk posed by the leaching of nanomaterials from surfaces coated with nanomaterials.

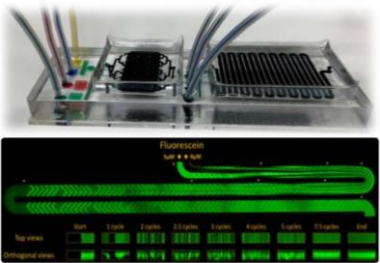


Zebrafish (*Danio rerio*) embryos at different development stages during Econanotoxicology assessment (Image from Braunbeck & Lammer 2005).

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Advanced tissue models for nano-safety risk assessment

Advanced tissue models			
Functionalities	Equipment & Facilities	Technical specifications / testing conditions	Application examples
Advanced tissue models	<p>BSL-2 cell culture and nanosafety laboratories.</p> <p>Biophotonics and Bioimaging facilities including Advance Microscopy (Zeiss LSM 780 Confocal, Witec Alpha 300R Raman, Nikon Eclipse Ti-E Fluorescence, Nikon Ti-E TIRF/dSTORM for live cell imaging, and custom-developed combined Fluorescence/AFM).</p>	<p>Suitable for organic and inorganic nanomaterials in colloidal dispersion.</p> <p>Nanomaterials toxicity testing on cell culture models tailored to the customer needs (gut, skin, lung...).</p>	<p>Study the interactions between nanomaterials and in-vitro cellular models of specific organs, predicting potential adverse effects on human health. Support on nano-risk assessment.</p>



Prototype of a gut-on-a-chip model of intestinal digestion at INL

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Services offered via the SAFE-N-MEDTECH OITB

Services offered via SAFE-N-MEDTECH

To extend the test service portfolio, FlexFunction2Sustain establishes links with other EU initiatives and associations.

Our partners at the SAFE-N-MEDTECH OITB can provide comprehensive testing for safety and exposure risk assessment of nano-materials and devices functionalised with nanomaterials, specially on those cases related to medical devices.

SAFE-N-MEDTECH service portfolio includes:

- Complete nanoparticle characterisation.
- In-silico predictive models for nano-risk assessment.
- In-vitro toxicology assessment, including cellular uptake, cytotoxicity, and genotoxicity.
- In-vivo models.

For additional details, please, see SAFE-N-MEDTECH catalogue of services at <https://safenmt.com>



SAFE-N-MEDTECH OITB
Safety Testing in the life cycle of
nanotechnology-enable Medical
Technologies for Health
<https://safenmt.com>