



H2020-NMBP-HUBS-2019

FlexFunction2Sustain

Open Innovation Ecosystem for Sustainable Nano-functionalized Flexible Plastic and Paper Surfaces and Membranes

Starting date of the project: 01/04/2020
Duration: 48 months

= Deliverable D4.4 =

Catalogue of services for safety and regulatory compliance testing

Due date of deliverable: 30/September/2022
Actual submission date: 10/February/2023

WP and Lead Beneficiary: WP4, INL
Version: V1.0

Dissemination level		
PU	Public	X
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 862156

AUTHOR

Author	Institution	Contact (e-mail, phone)
P. Fuciños	INL	pablo.fucinos@inl.int
J. Savonitto	IPC	Julie.SAVONITTO@ct-ipc.com
E. Küçükpinar	FhG-IVV	Esra.kucukpinar@ivv.fraunhofer.de
S. Kassavetis	AUTH	skasa@physics.auth.gr
M.A. Berthet	IPC	Marie-Alix.BERTHET@ct-ipc.com
K. Tsimenidis	BL-NANO	ktsimenidis@bl-nanobiomed.com

DOCUMENT CONTROL

Document version	Date	Change
v0.1	05/12/2022	First Draft of the Working Document
v0.9	07/02/2023	First draft sent to the COORD and PM
v1.0	08/02/2023	Formatting

VALIDATION PROCESS

Reviewers	Validation date
WP leader	Pablo Fuciños 03/02/2023
Project Coordinator	Christian May 10/02/2023
Project Manager	Anastasia Grozdanova 08/02/2023
Exploitation and Innovation Manager	Robert Harrison N/A

DOCUMENT DATA

Keywords	Catalogue of services; safety assessment; compliance; technical facilities
Point of Contact	Name: Pablo Fuciños Partner: INL Address: International Iberian Nanotechnology Laboratory, Av. Mestre José Veiga s/n, 4715-330 Braga, Portugal Phone: + 351 253 140 112 - 2361 E-mail: pablo.fucinos@inl.int
Delivery date	10/02/2023

DISTRIBUTION LIST

Date	Issue	Recipients
10/02/2023	v1.0	EC Project Officer, all partners (via ownCloud)

DISCLAIMER

Any dissemination of results reflects only the authors' view and the European Commission, or the European Health and Digital Executive Agency (HaDEA) is not responsible for any use that may be made of the information Deliverable D4.4 contains.

Executive Summary

Deliverable D4.4 presents FlexFunction2Sustain “Catalogue of services for safety and regulatory compliance testing”. This catalogue describes technological support services provided by the FlexFunction2Sustain project partners for developing nano-functionalised plastic and paper-based flexible materials and membranes. The catalogue is based on the data of the methodologies provided to meet the performance verifications needs of the different industrial applications of the Case Studies of the project, as described on the FlexFunction2Sustain website (<https://flexfunction2sustain.eu/use-cases>) and on the FlexFunction2Sustain handbook (Deliverable D8.10).

The methodology for selecting the services included in the catalogue is based on the analysis of market needs, the available technical offer, the experience gained from the analysis and implementation of the Use Cases, and the available offer of partner OITB projects. The safety and compliance testing services described here will be integrated into the FlexFunction2Sustain Service Catalogue (Deliverable D6.4), in which different technical services will be combined to address complex industrial challenges related to the industrialisation of nano-functionalised plastic and paper-based flexible materials and membranes.

The catalogue presents the services available through the FlexFunction2Sustain facilities for safety and regulatory compliance (Facility Cluster 9) with the ambition to address the specific needs of developing new sustainable nano-functionalised materials and products. FlexFunction2Sustain targets highly regulated applications such as food processing and the use of nano-functionalised surfaces for healthcare applications, and potentially involving human body contact. Therefore, verification of safety and compliance with the relevant EU regulations for nanosafety (e.g., EU 2018/1881) and food contact (e.g., EU 10/2011, EC 450/2009) is essential. The services currently available through the Facility Cluster 9 are here described in detail and classified into the following categories:

- Assessment of food contact materials (FCM) and packaging
 - o Plastic food contact materials regulatory compliance
 - o Paper and paperboard food contact materials regulatory compliance
 - o Food contact material migration testing
 - o Off-flavours testing
 - o Food contact materials declaration of compliance
- Microbiological testing
- Toxicological and nano-safety assessment
 - o Nanoparticle characterisation
 - o Cytotoxicity
 - o Oxidative stress
 - o Biopersistence
 - o Environmental toxicology
 - o Advanced tissue models for nano-safety risk assessment

In addition, to extend the scope of our testing capabilities, an strategic partnership was established with key OITBs such as SAFE-N-MEDTECH (<https://safenmt.com>), and their technical offer relevant for nano-functionalised plastic and paper-based flexible materials and membranes was integrated into the FlexFunction2Sustain catalogue of safety and compliance services.

The Catalogue of services for safety and regulatory compliance testing is subject to continuous updating to integrate new methodologies when they become available. This document represents that state of 06th February 2023.

Table of Contents

1. INTRODUCTION	5
1.1. CATALOGUE OF SERVICES FOR PERFORMANCE VERIFICATION IN APPLICATION IN THE CONTEXT OF FLEXFUNCTION2SUSTAIN PROJECT	5
1.2. OBJECTIVES OF THE DELIVERABLE	5
1.3. METHODOLOGY FOR PRODUCING THE CATALOGUE.....	5
1.3.1. EXAMPLE OF THE PROCESS FOR A SINGLE SERVICE	6
2. CATALOGUE OF SERVICES FOR SAFETY AND REGULATORY COMPLIANCE TESTING (PUBLIC DOCUMENT AVAILABLE ONLINE).....	9
2.1. CONTENTS OF THE CATALOGUE	9
2.2. USE CASES IN FLEXFUNCTION2SUSTAIN PROJECT	9
2.3. FULL CATALOGUE OF SERVICES FOR SAFETY AND REGULATORY COMPLIANCE TESTING.....	9
3. CONCLUSIONS.....	10
4. DEGREE OF PROGRESS	10
5. DISSEMINATION LEVEL.....	10
6. APPENDIX	11

1. Introduction

D4.4 presents a living digital deliverable, the Catalogue of services for safety and regulatory compliance testing detailing the technical capabilities of the FlexFunction2Sustain Facility Cluster 9 (Facilities for safety and regulatory compliance), which will be hosted on the FlexFunction2Sustain Project website (<https://flexfunction2sustain.eu>) and will be continuously updated as new services become available.

This section presents the context of the Catalogue of services for safety and regulatory compliance in the FlexFunction2Sustain project, the objectives sought with the release of the catalogue and, finally, the methodology used to prepare it.

1.1. Catalogue of Services for Performance Verification in Application in the context of FlexFunction2Sustain project

D4.4 "Catalogue of services for safety and regulatory compliance" is a public document of the FlexFunction2Sustain project, delivered in the context of WP4 "Facilities for Application Verification, Testing, Safety Assessment and Pre-Certification", Task 4.3 "Food and compliance test facilities and health safety testing facilities and pre-certification services".

This catalogue is part of a series of three service catalogues created in FlexFunction2Sustain WP4 which, in addition to the present D4.4, includes D4.1 "Catalogue of physicochemical and functional characterization services" and D4.2 "Catalogue of services for performance verification in application". All three together represent the technological offer of the Facilities for Characterisation and Quality Control in FlexFunction2Sustain. D4.4 is closely linked to two other deliverables, the FlexFunction2Sustain Project Handbook (Deliverable D8.10) and the FlexFunction2Sustain Service Catalogue (D6.4), whose implementation at the end of the project (M42) will benefit from the service catalogues developed in WP4 and from the lessons learned from the interaction between the Facilities for Characterisation and Quality Control the development of the Use Cases in WP5, and the clustering activities with other OITB projects.

1.2. Objectives of the deliverable

This service catalogue aims to provide a customer-friendly, clear, and comprehensive overview of the safety and compliance testing services available within the FlexFunction2Sustain Open Innovation Test Bed (OITB). The safety and compliance services described here are validated and aligned with customer needs through the industrial Use Cases of the FlexFunction2Sustain project. Furthermore, Pilot Case customers may receive discounted access to those services after successfully applying to the open calls for Pilot Case projects (<https://flexfunction2sustain.eu/open-calls>).

The Single Entry Point (SEP) company will actively promote and sell the performance verification services described herein as an integral part of innovation projects that will be conducted by the FlexFunction2Sustain OITB.

1.3. Methodology for producing the catalogue

The methodology for the selection of services is based on the analysis of market needs, the available technical offer in the OITB, and the experience gained from the analysis and implementation of the Use Cases. Additional testing capabilities were incorporated to the FlexFunction2Sustain Service portfolio by clustering with complementary OITB projects such as SAFE-N-MEDTECH. In brief, the Use Cases, Letters of Interest received during the application phase, and applications to the first Pilot Cases Open Call were analysed, and the information regarding the safety and compliance testing required to implement them was compiled into a document based on the different methodologies available at the FlexFunction2Sustain partners' facilities (Facility Cluster 9 Service Portfolio). The specifications of each of the potential services were then summarised to allow a quick interpretation of the technological capabilities available and to

make the catalogue more readily useful to potential users. For each of the services the following elements were elaborated:

- Service category
- Name of the service
- Functionalities provided
- Technical specifications and available facilities
- Examples of application in the Use Cases

After this first stage, the FlexFunction2Sustain partners providing Services for safety and compliance testing were asked to check the accuracy of the compiled information. Finally, all this information was uploaded to the FlexFunction2Sustain website. Figure 1 summarises the three stages followed to compile the catalogue.

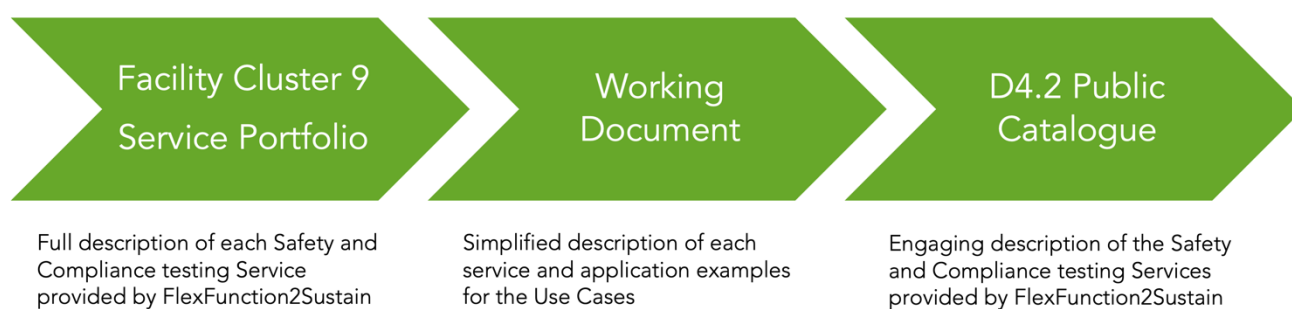


Figure 1. Steps for the development of the Catalogue of Services for safety and regulatory compliance testing

1.3.1. Example of the process for a single service

In the Facility Cluster 9 Portfolio of Services, the methodologies available for testing the migration of substances from food contact materials was described in the following tables:

Table 1. Methodology 1

Test Category	Assessment of food contact materials (FCM) and packaging
Test	Food contact material migration testing
Application	Assess the migration of substances from FCMs into food to ensure the safety
Partner (Service Provider)	IPC
Available equipment	ISO 9001 Food Testing Laboratory PerkinElmer Gas Chromatography with mass or FID detectors. Ovens and balances
Relevant standards	According to UE 10/2011
Sample dimensions (range)	--
Measuring range / conditions	Suitable for films and packages
Processing time per sample	Variable, depending on the application, up to 10 days
Processing capacity	Variable, depending on the sample type and application
HR profile - Technician - Engineer / graduate - Scientist	Technician
TRL	4-7
Invoicing model (€/sample or €/h)	€/sample

Table 2. Methodology 2

Test Category	Assessment of food contact materials (FCM) and packaging
Test	Food contact material migration testing
Application	Assess the migration of substances from FCMs into food to ensure the safety
Partner (Service Provider)	FHG-IVV
Available equipment	EN ISO 17025 Food Testing Laboratory
Relevant standards	According to UE 10/2011
Sample dimensions (range)	--
Measuring range / conditions	Suitable for films and packages
Processing time per sample	Variable, depending on the application, up to 10 days
Processing capacity	Variable, depending on the sample type and application
HR profile - Technician - Engineer / graduate - Scientist	Technician
TRL	4-7
Invoicing model (€/sample or €/h)	€/sample

Table 3. Methodology 3

Test Category	Assessment of food contact materials (FCM) and packaging
Test	Food contact material migration testing
Application	Assess the migration of substances from FCMs into food to ensure the safety
Partner (Service Provider)	INL
Available equipment	ISO 9001 Testing Laboratories NP 445 Food testing laboratory Agilent High Performance Liquid Chromatography with DAD and fluorescence detectors. Inductively coupled plasma mass spectrometry (ICP) Shimadzu ICPE-9000. <i>MigraCell</i> Standardized migration cells. Nanoparticle characterisation facilities including Scanning Electron Microscopy (SEM), Transmission Electron Microscopy (TEM), and X-ray diffraction (XRD)
Relevant standards	According to UE 10/2011 and Council of Europe 2021 Guidelines for "Paper and board used in food contact materials and articles"
Sample dimensions (range)	--
Measuring range / conditions	Suitable for films and packages
Processing time per sample	Variable, depending on the application, up to 10 days
Processing capacity	Variable, depending on the sample type and application
HR profile - Technician - Engineer / graduate - Scientist	Technician
TRL	4-7
Invoicing model (€/sample or €/h)	€/sample

The information in the above tables was then compiled and integrated into the public Catalogue of Services for safety and regulatory compliance testing and uploaded to the FlexFunction2Sustain website (an example is provided in Table 4).

Table 4. Description of the food contact material migration testing services in the FlexFunction2Sustain's Catalogue of Services for safety and regulatory compliance testing

Food contact material migration testing			
Functionalities	Equipment	Technical specifications	Application examples
Food contact material 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>	<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).</p>

2. Catalogue of Services for safety and regulatory compliance testing (public document available online)

The public version of the Catalogue of Services for safety and regulatory compliance testing is available on the FlexFunction2Sustain website in PDF format. The online catalogue includes the following sections:

- Use Cases of the FlexFunction2Sustain project
- Full catalogue of services for safety and regulatory compliance testing
- Services offered via SAFA-N-MEDTECH OITB

2.1. Contents of the Catalogue

The structure of the catalogue is briefly described in this section of the document to provide readers with a quick overview of the content (page 2 of the Annex).

2.2. Use Cases in FlexFunction2Sustain project

For users' reference, the six Use Cases of the project are presented as they were described in the FlexFunction2Sustain Handbook, with a short description, and identification of the linked industrial partner. Each Use Case has been labelled with a numerical code (UC1 to UC6), which will be used to identify them in the application examples for the services described in the catalogue (page 3 of the Annex).

2.3. Full catalogue of services for safety and regulatory compliance testing

This section describes the full range of safety and compliance testing solutions available in FlexFunction2Sustain to assess whether the nano-functionalised flexible surfaces are safe and comply with the existing regulations in order to be commercialised in the European Union. The main methodologies relevant to this market segment are made available to the industry through the FlexFunction2Sustain Open Innovation Test Bed (pages 4 to 15 of the Annex). In addition, p.16 shows an extended, complementary, service offer to assess the safety and compliance of functionalised plastic and paper-based flexible materials and membranes was made available through partnership with SAFE-N-MEDTECH (<https://safenmt.com>).

The individual safety and compliance assessment services available through this catalogue will be integrated into complete service offers, tailor-made for specific materials and products commissioned by the SEP customers, available through the FlexFunction2Sustain Service Catalogue (D6.4), to be released in M42.

3. Conclusions

Deliverable D4.4 presents the set of safety and regulatory compliance testing services available in the Facility Cluster 9 of the Open Innovation Test Bed project FlexFunction2Sustain. As a part of D4.4, a public catalogue of Services for safety and regulatory compliance testing for flexible materials has been produced and made available on the FlexFunction2Sustain website (<https://flexfunction2sustain.eu>). The methodology for setting up the catalogue is described for the example of "Food contact materials migration testing" techniques available in the consortium. Testing protocols for different customer requirements are defined and agreed on in the consortium. The catalogue of safety and regulatory compliance testing is subject to continuous updating to integrate new methodologies when they become available. This document represents that state of 06 February 2023.

4. Degree of progress

Deliverable 4.4 is fulfilled by 100 %. A public catalogue of safety and regulatory compliance testing services for flexible materials has been delivered and will be integrated into the Service Catalogue to be offered by the FlexFunction2Sustain OITB through the Single Entry Point (SEP). This service catalogue will be a living document, which will evolve together with the technological capabilities of FlexFunction2Sustain's partners and the needs of the project and future customers.

5. Dissemination level

Deliverable D4.4 "Catalogue of services for safety and regulatory compliance testing " is a public document, and version 1.0 is available for download in the project website (<https://flexfunction2sustain.eu>).

6. Appendix

The online Catalogue of Catalogue of services for safety and regulatory compliance testing is attached in this section.

Catalogue of services for safety and regulatory compliance testing

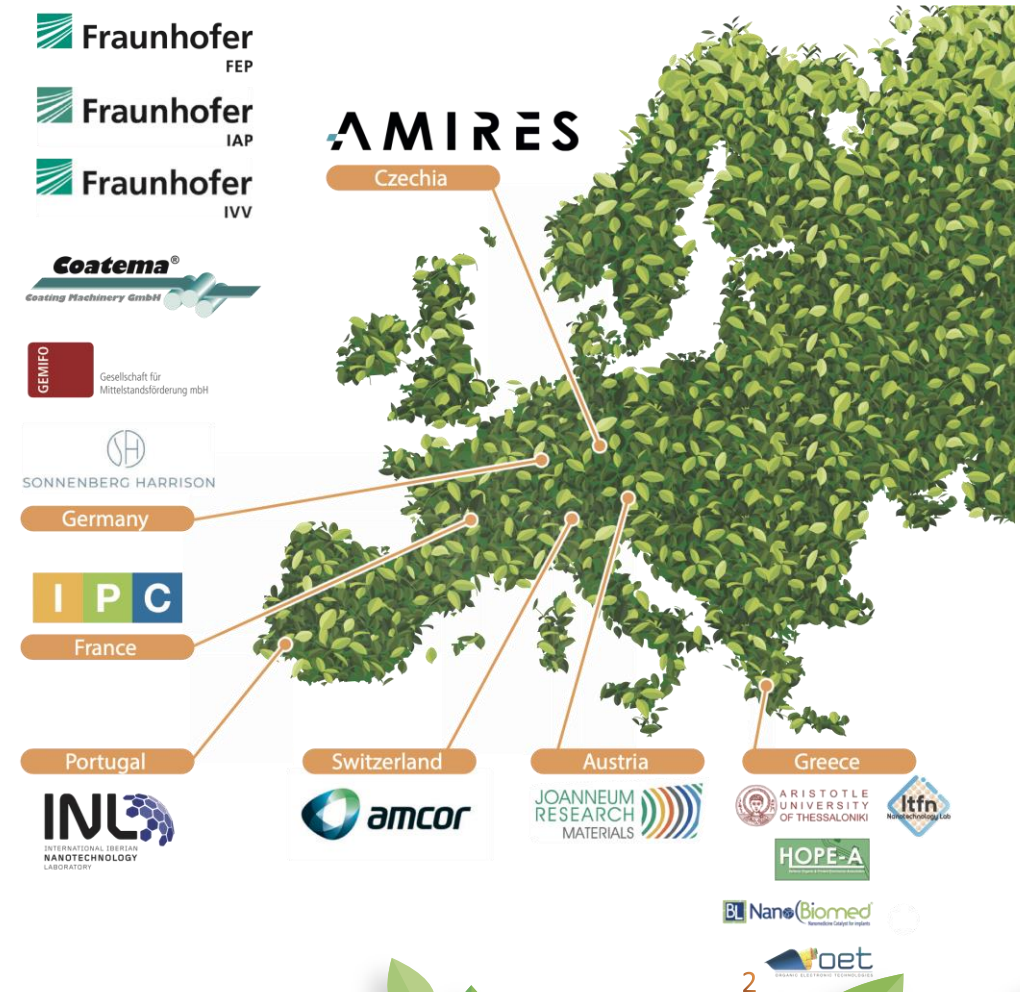


This project has received funding from the European Union's Horizon 2020 research and innovation programme under [grant agreement n°862156](#)

The catalogue at a glance

- Use Cases of the FlexFunction2Sustain project (p. 3)
- Catalogue of Services (p. 4)
 - Assessment of food contact materials (FCM) and packaging (pp. 4–8)
 - Plastic food contact materials regulatory compliance (p. 4)
 - Paper and paperboard food contact materials regulatory compliance (p. 5)
 - Food contact material migration testing (p. 6)
 - Off-flavours testing (p. 7)
 - Food contact materials declaration of compliance (p. 8)
 - Microbiological testing (p. 9)
 - Toxicological and nano-safety assessment (pp. 10–15)
 - Nanoparticle characterisation (p. 10)
 - Cytotoxicity (p. 11)
 - Oxidative stress (p. 12)
 - Biopersistence (p. 13)
 - Environmental toxicology (p. 14)
 - Advanced tissue models for nano-safety risk assessment (p. 15)
 - Services offered via the SAFE-N-MEDTECH OITB (p. 16)

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>

Catalogue of services for safety and regulatory compliance testing

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	<p>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.</p> <p>FDA compliance may be assessed upon request.</p>	<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.

Catalogue of services for safety and regulatory compliance testing

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.

Catalogue of services for safety and regulatory compliance testing

Assessment of food contact materials (FCM) and packaging

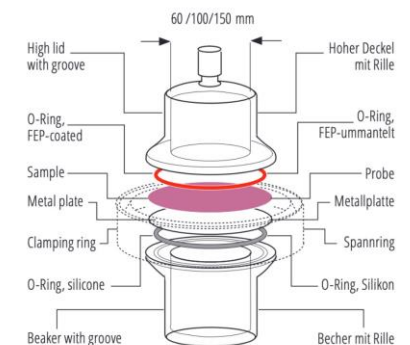
Food contact materials migration testing

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>	<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).</p>



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

Catalogue of services for safety and regulatory compliance testing

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	

Catalogue of services for safety and regulatory compliance testing

Assessment of food contact materials (FCM) and packaging

Food contact materials Declaration of Compliance (DoC)

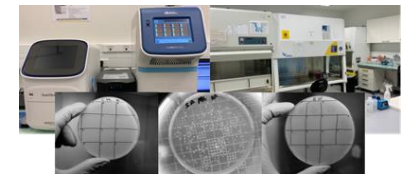
Functionalities	Equipment & Facilities	Technical specifications / testing conditions	Application examples
Support on DoC preparation	n/a	<p>Suitable for plastic and paper-based FCMs</p> <p>According to the applicable regulations or recommended guidelines (e.g., Commission Regulation (EU) No 10/2011 or 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.

Catalogue of services for safety and regulatory compliance testing

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>	<p>BSL-2 microbiology laboratories</p>	<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

Catalogue of services for safety and regulatory compliance testing

Toxicological and nano-safety assessment

Nano-safety assessment

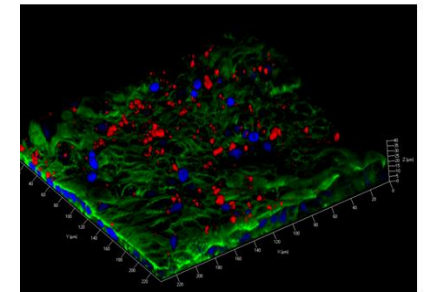
Functionalities	Equipment & Facilities	Technical specifications / testing conditions	Application examples
Nanoparticle characterisation	<p>FEI Titan G2 and FEI Titan G3 Cubed Themis TEM</p> <p>ThermoFisher Glacios Cryo-TEM</p> <p>FEI Quanta 650 FEG eSEM</p> <p>Horiba SZ-100Z DLS</p> <p>NanoSight NS300 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>

Catalogue of services for safety and regulatory compliance testing

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

Catalogue of services for safety and regulatory compliance testing

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>

Catalogue of services for safety and regulatory compliance testing

Toxicological and nano-safety assessment

Nano-safety assessment

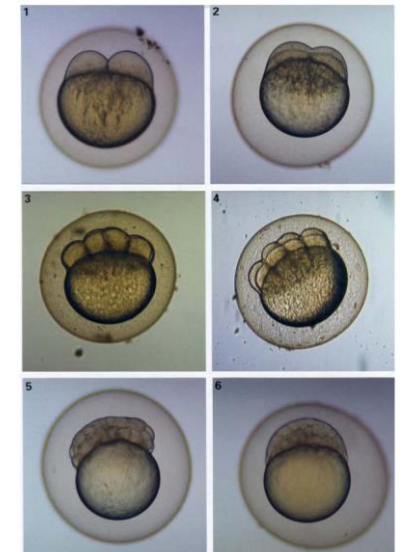
Functionalities	Equipment & Facilities	Technical specifications / testing conditions	Application examples
Biopersistence	<p>BSL-2 cell culture and nanosafety laboratories</p> <p>Biophotonics and Bioimaging facilities including Advance Microscopy (Zeiss LSM 780 Confocal, Witec Alpha 300R Raman, Nikon 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>

Catalogue of services for safety and regulatory compliance testing

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>	<p>Evaluate the potential environmental safety risk posed by the leaching of nanomaterials from surfaces coated with nanomaterials.</p>



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

Catalogue of services for safety and regulatory compliance testing

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

Catalogue of services for safety and regulatory compliance testing

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>