

A close-up photograph of a microscope's objective lenses and eyepiece, set against a blue background. The lenses are metallic and have some text on them, including "Plan" and "0.25".

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Food Contact Plastics 2010

Engineered nanomaterials in food contact applications - the regulatory landscape -

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OUTLINE

I. Application Possibilities for Nanomaterials in Food Contact

II. Nanomaterials Regulation in Food Contact Applications

1. Review of EU food contact legislation
2. Interpretation of existing rules
3. New regulatory developments

III. Ensuring Compliance

1. Due diligence, Declaration of Compliance and Record Keeping
2. Recommended industry strategy

Food Contact Application of Nanomaterials

- I. Opportunities in different **matrices**: paper, rubber, glass/ceramics etc.
- II. Applications in different **uses**: coatings, sensors (active and intelligent applications), processing aids etc.
- III. Existing **examples**
 1. Applications regulated with harmonized positive lists
 2. Applications regulated on Member States' level

The EU Food Contact Legislation

The Framework Regulation (EC) No. 1935/2004

- Applies to all food-contact materials, **including nanomaterials**
- Establishes general requirements (Art.3): safety, organoleptic properties, no deception of consumer
- Calls on the Commission to adopt specific measures for specific categories of materials (e.g. plastics, rubbers)
- Room for individual authorisations (recycling technologies ...)
- Establishes labelling, traceability, certification, and record-keeping requirements

The EU Food Contact Legislation

The GMP Regulation (EC) No 2023/2006

- Only covers food contact materials under the Framework Regulation
- Requires all business operators to establish, implement, and maintain effective systems for:
 - ✓ quality assurance
 - ✓ quality control and
 - ✓ documentation
- Objective: to meet Article 3 requirements of the Framework Regulation
- Annex with more specific rules (Presently: printing inks, and recycling)

The EU Food Contact Legislation

The Plastics Directive 2002/72/EC, as amended

- Under revision; recast (PIM) covers all amendments and other measures related to plastics
- Main Elements:
 - Positive lists of authorized monomers and additives, potentially with restrictions
 - Migration limits (OML, SML)
 - Declaration of compliance

Positive List Requirements for Plastics

- **Positive list of monomers, other starting materials and additives**
 - Only listed substances can be used, with some exceptions
 - ▶ **Does it cover their nano forms?**
 - Various materials are exempted from positive list requirements, subject to national law:
 - ✓ coatings, epoxy resins, adhesives, printing inks
 - ✓ colorants, solvents, aids to polymerization
 - ▶ **How to deal with nanomaterials in these applications?**

Nanomaterials in Food Contact Applications

- Nanotechnology: the ability to manufacture, manipulate and utilize nanometer-size (10^{-9} m) materials and structures with novel physico-chemical properties and functions
- Nanotechnologies may enable different consumer products in food contact applications providing novel functions
- Nanomaterials are subject to general requirements of current legislation (generally covered by scope, so far no regulatory distinction between conventional and nanomaterials)
- Potential new safety issues raised by nanotechnology
- Some specific requirements already introduced; further regulatory schemes in development

Crucial Steps to Address Nano:

- Based on a sufficient scientific understanding define proper descriptors which can serve as the basis of a definition
 - Establish suitable definition as the basis of any regulation
 - Develop and validate appropriate testing/detection
 - Define complete life cycle and determine exposure
 - Not yet known whether
new endpoints (such as *in vitro* oxidative stress) or
new target organs (such as *in vivo* genotox studies for the respiratory tract) or
new mechanisms (such as translocation) might need to be considered for toxicological test
- ▶ **Until defined: Case-by-case review**

Definition of “Nanomaterial”

- Fundamental issue for nano-industry; basis for any regulation
- No internationally agreed definition yet
- Clarification is needed on
 - size range and other relevant descriptors
 - physical and chemical properties particular to nanomaterials
 - thresholds
 - metrics to express thresholds
 - ...

Working Definitions

- March 2010 → **COM requests SCENIHR to adopt a Scientific Opinion** on the scientific basis for the definition of “nanomaterial”
- Deadline May 2010
- Terms of reference – Advice on “**essential elements**” for a science based working definition, defining these elements
- To assist in this task: ongoing REACH RIP-oN projects

RIP – oN Projects

Reach Implementation Projects on Nanomaterials (RIP-oN)

→ **3 main areas:**

1. RIP –oN1 Substance Identification
2. RIP –oN2 Information requirements
3. RIP –oN3 Chemicals Safety Assessment

RIP-oN 1 on Substance Identification (kick-off Oct 2009)

→ **4 case studies:**

- CNTs
- Nano-silver
- Nano-TiO₂
- Nano- CaCO₃

RIP –oN1: Progress on Substance Identification

➤ Special issues:

- ✓ Crystalline form as a descriptor?
- ✓ Doping?
- ✓ Surface treatment (up to 1% weight?)
- ✓ Are nanoforms distinct substances
 - Defined chemical composition and other main descriptors
 - UVCB

➤ Main comments:

- ✓ Other descriptors: primary particle size and distribution, aspect ratio, surface chemistry
- ✓ Different surface treatment covered under UVCB approach

RIP-oN2-3 Projects

➤ **Commission's Call for tender on:**

- ✓ Specific advice on information requirements for nanomaterials– with representative case studies
- ✓ Specific advice on exposure assessment and Hazard/Risk Characterization for nanomaterials under REACH
 - Development of exposure scenarios
 - Evaluation of operational conditions and risk management/mitigation measures
 - Exposure estimation
 - Hazard and risk characterization
- ✓ Timing: 16 months from start of contract

Nanomaterials in EU Food Contact Legislation

- No explicit reference to nanomaterials – except in Regulation on A&I materials and in draft PIM (treated as CMRs)
- EFSA has published a favourable opinion on the direct application of a nanoparticles (TiN) in PET bottles. EFSA raised no toxicological concern based on lack of any detectable migration into food (no exposure; no risk)
- Commission still did not act on this opinion with a proper risk management decision to include TiN in the positive list of permitted food contact additives ...
- ... or provide explanation on lack of regulatory action

Nanomaterials in EU Food Contact Legislation

Recital 23 of draft PIM:

- *“New technologies engineer substances in particle sizes that exhibit chemical and physical properties that significantly differ from those at a larger scale, for example, nanoparticles. These different properties may lead to different toxicological properties and should be assessed on a **case-by-case basis** as regards their risk until more information is known about such new technology. Therefore it should be made clear that authorizations which are based on the risk assessment of the conventional particle size of a substance do not cover engineered nanoparticles.”* (emphasis added)
- Above Recital may exclude the use of the nanoform of any substance not specifically assessed

Nanomaterials in EU Food Contact Legislation

Article 9 of draft PIM on Specific Requirements:

- *“Unless explicitly mentioned in the specifications in Annex I, the use of a substance in nanoform shall not be authorized.”*
- Further, substances in nanoform are treated in the draft PIM the same way as CMRs when it comes to potential derogation from the positive list requirements (such as for substances behind a functional barrier)
- The **case-by-case assessment** recommended in the Recital is in conflict with the specifics of the positive list system (which allows the use of a substance by any manufacturer)
- The placing on the positive list of substances in nanoform following their individual risk assessment needs further considerations from the Authority

Ensuring Compliance for Nanomaterials in Food Contact Applications

- Define nanomaterial with all relevant descriptors for substance identification purposes
- Verify compliance with positive listings, if relevant, and other specific requirements (EU and national level)
- Ensure compliance with GMP
- Use all available elements (analytical data, scientific rationale) to demonstrate safety
- Adopt labelling, certification, traceability and record-keeping policies as required by legislation

Voluntary Industry Measures

- Due diligence - reasonable reliance on existing scientific knowledge
- Assist authorities with relevant information
 - ✓ Participate in EU integrated projects (by DG Research) such as NanoFutures
 - ✓ Submit REACH registration even before deadline and under 1MT
 - ✓ Submit data for Trade Association calls
 - ✓ Submit data for Member States' initiatives
- Increase public acceptance and confidence in the technology
- Consider the merits of collective voluntary actions, such as Code of Conduct to safeguard high level risk management standards

Record Keeping: Adopt Suitable Policies

- **Certification:** Establish a written declaration to
 - ✓ convey relevant information to customers
 - ✓ cover the specificities of the product related to nanotechnology with all relevant details
 - ✓ limit liability with appropriate communication

- **Keep records** of all relevant information substantiating:
 - ✓ compliance with positive list requirements
 - ✓ safety determinations
 - ✓ traceability information

...And if Something Goes Wrong?

- Unacceptably high migration results in food which is injurious to health and causes damage to consumers
- Possible Consequences:
 - ✓ Legal actions by consumers against food manufacturer and between food manufacturer and the packaging producers under contract law for damages
 - ✓ Recall (soft or hard) of injurious food products and/or packaging materials
 - ✓ Actions by enforcement authorities for non-compliance with Regulation 1935/2004; possibly adding new regulatory requirements
 - ✓ Negative impact on the brand/ need to reformulate product
 - ✓ Negative impact on the technology as such; loss in public confidence

Recommended Industry Strategy

- Characterize applied nanomaterials (size distribution, shape, surface treatment etc) and define processing conditions
- Ensure compliance with existing legislation, standards and relevant industry guidelines
- Keep record of due diligence efforts, risk assessments & monitoring of risks; continuously update knowledge
- Specify the added value of individual nanoparticles based products and distinguish them from existing applications in order to avoid generalization of the technology
- Engage in public dialogue
- Participate in “Voluntary Initiatives” supporting the safe use of nanomaterials
- Contribute to regulatory initiatives to establish proper governance for nanotechnologies

THANK YOU

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