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Regulation of Nanomaterials Used in Food Contact Materials & Articles

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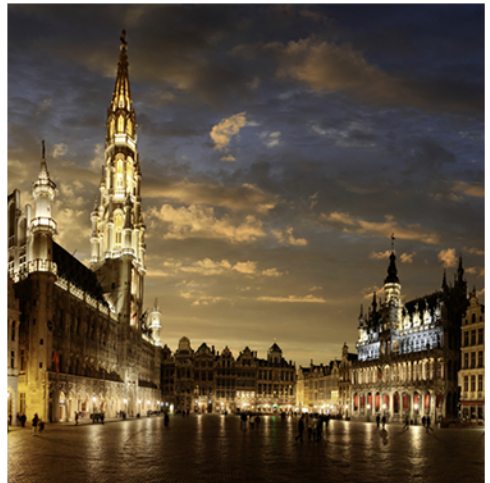
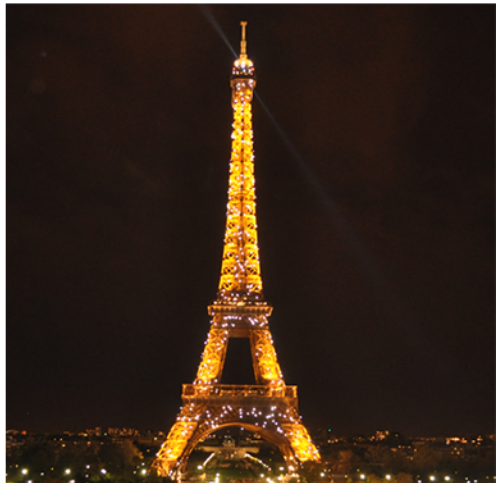
Rachida Semail, Partner
Keller and Heckman LLP
Brussels, Belgium Office
+32 (0) 2 645 5094
semail@khlaw.com

Presentation Overview

- How does the existing legislation regulate nanomaterials intended for use in food contact materials and articles?

- What are the challenges of industry?

Current EU Legislation

EU Horizontal Regulations

- Framework Food Contact Regulation (1935/2004)
  - Safety and inertness requirements
- GMP requirements (2023/2006)

EU Specific Regulations Containing Provisions on Nanomaterials (NM)

- Plastics Regulation (10/2011)
- Active and Intelligent Packaging Regulation (450/2009)

Specific Provisions on NMs in the Plastics Regulation

- Positive list system for monomers and additives used in plastics manufacture
- Substances in nanoform are currently permitted only if they have been risk-assessed as nano substances and cleared for use in FC plastics
- Nano substances (monomers and additives) do not benefit from any exemption under the functional barrier concept
- **NO DEFINITION in the Plastics Regulation**

EC Guidelines on Plastics

EC Recommended definition referred to in:

- **Union Guidance on Plastics Regulation**
  - https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_plastic-guidance_201110_en.pdf

- **Union Guidance on Declaration of Compliance**
  - https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_plastic-guidance_201110_reg_en.pdf

Plastics Regulation: Examples of Substances in Nano Form

FCM	CASRN	Substance name
87	—	Silicon dioxide, silanated
410	1332-58-7	Kaolin
411	1333-86-4	Carbon black
504	7631-86-9	Silicon dioxide
807	—	Titanium nitride, *nanoparticles*
1046	—	Zinc oxide, *nanoparticles*, coated with [3-(methacryloxy)propyl] trimethoxysilane (FCM No 788)
1050	—	Zinc oxide, *nanoparticles,* uncoated
1050	—	Zinc oxide, *nanoparticles*, for use as a transparent ultraviolet light absorber in unplasticized polymers at up to 2% by weight

Plastics Regulation: Examples of Substances in Nano Form

FCM	Substance name	Restrictions and specifications
87	Silicon dioxide, silanated	For synthetic amorphous silicon dioxide, silanated: primary particles of 1–100 nm which are aggregated to a size of 0.1–1 µm and may form agglomerates within the size distribution of 0.3 µm to the mm size.
807	Titanium nitride, nanoparticles	**No migration of titanium nitride nanoparticles** Only to be used in polyethylene terephthalate (PET) up to 20 mg/kg. In the PET, the agglomerates have a diameter of 100-500 nm consisting of primary titanium nitride nanoparticles; primary particles have a diameter of approximately 20 nm.

EC Guidelines on Plastics

- **Definition in the two guidelines in contradiction with Recital 23 of Plastics Regulation** which is worded so as to be understood as referring to substances engineered in nano form
- Questioned about this, the EC orally responded that « the EC services interpret the guidelines so as to be compliant with the intent of the Plastics Regulation »
  - Written nowhere
- **No legal clarity and certainty**

Specific Provisions on NMs in Active & Intelligent Packaging Regulation

- **Positive listing system** for substances responsible for the active/intelligent function
- Similar requirements to those in Plastics Regulation, i.e.,
  - No exemption possible based on functional barrier for substances in nano form
- **No definition of substance in nano form**
  - Just a reference to substances deliberately engineered to particle size

National Legislation on NM in FCMs

Dutch Regulation on Packaging & Utensils:

- Positive list system
- **No definition** of substances in nano form
- Listed substances may be used in nano form even though the listing does not identify them as such
  - ***Chapter 0****: Permitted substances consisting (partly) of nano particles may be used provided that the final product still complies with Article 3 (safety & inertness requirements) of the Framework Regulation*
- Non-listed substances cannot avail of the exemption of positive listing if they are in nano form (when notably migration is < 0.01 mg/kg)

National Legislation on NM in FCMS

Belgian coatings Order:

- No positive listing requirement
- Compositional criteria but exemption in place
- No exemption for substances in nano form

Challenges of Industry

- No specific regulatory definition on substances in nano form under the FC legislation

  => **No legal clarity and no legal certainty as to what should be petitioned or not**

- Operators do not exactly know on what basis they should make their own determination as to whether a substance is nano or not
- Member States may take a different interpretation of what should be nano

Challenges for Industry

- Per the EC recommended definition, a material is a NM when for **at least 50%** of the particles in the number size distribution, one or more external dimensions **falls in the 1 – 100 nm range**
- However, in some cases, **this 50% threshold may be replaced by a threshold between 1% and 50%**
- **Possible consequences**:
  - Different authorities may use different thresholds
    => Again, **this results in legal uncertainty**

Challenges for Industry

- EC is not considering taking any action with respect to FCMs to clarify the regulatory framework
- Operators are forced to submit petitions when the requirements of the recommended definition are met,
  - **even though they would have arguments demonstrating that the definition is not appropriate**
  - **or even though there would be scientific grounds/evidence showing that nanomaterials would not migrate into food**

Challenges for Industry

- The EC guidelines refer to the recommended definition of NM, which also covers substances naturally occuring in nano form
- **Some natural materials** have a plate-like structure solely with a thickness falling in the 1-100 nm range.
  - i.e., they only exist in nano form
- These substances might have been **used for several decades** and are also included **in the EU positive list of the Plastics Regulation,** without being identified as nano

Challenges for Industry

- Based on recital 23 of the Plastics Regulation, these substances are allowed as the Plastics Regulation only aims at specifically regulating substances engineered in nano form
- But this seems contradicted by the EC guidelines which considers as nano also substances naturally occurring in nano form

=> NO LEGAL CLARITY AND CERTAINTY

Challenges for Industry

- **EFSA is setting more stringent requirements on nano than on non-nano particles**
  - E.g., EFSA takes into account factors that are not considered (yet?) for non-nano particles, such as migration by abrasion effect, while this is not discussed in the Note for Guidance.

- **EFSA retains a case-by-case approach and thus its requirements vary from a petition to another**
  - this means that it is very difficult for industry to predict what data EFSA wants to see in support of the petition
  - Remember that a pre-discussion with EFSA's experts is not possible

Challenges for Industry

"The specific properties of nanomaterials may affect their **toxicokinetic and toxicology profiles**, but limited information is available in relation to these aspects. There are also **uncertainties stemming from the difficulty of characterizing, detecting and measuring nanomaterials in food and in biological matrices**, and from the **limited availability of toxicity data and test methods**. For these reasons, nanomaterials should be evaluated 'case-by-case'."

THANK YOU

Rachida Semail, Partner
Keller and Heckman LLP
Brussels, Belgium Office
+32 (0) 2 645 5094
semail@khlaw.com