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Challenges of Nanomaterial Regulation in Europe

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Nanomaterials

Cosmetics

Food / Food Contact

Biocides

Challenges for manufacturers (1)

- **Worker health protection**
  - First level: production of nanomaterial
    - **Awareness** of possible necessity of additional protection measures?
    - **Exposure** assessment?
    - **Communication** to downstream users?
  - Second level: formulation etc.
    - **Awareness** that nanomaterials are being handled?
    - **Awareness** of possible necessity of additional protection measures?
    - **Exposure** assessment?
    - **Communication** to downstream users?

		Exposure level			
		Low	Medium low	Medium high	High
Concern Category	Low	1	1	2	2
	Medium low	1	2	2	3
	Medium high	2	2	3	4
	High	3	3	4	4

Source: Guidance on the protection of the health and safety of workers from the potential risks related to nanomaterials at work (European Commission)

Challenges for manufacturers (2)

- **Registration under REACH**
  - **Annexes** not yet amended and not expected in time for 2018 deadline
  - **Guidance "**Nanomaterials in IUCLID 5" available but still a lot of open questions
    - Separate registration as nanomaterial or as form of bulk material?
    - Possibility of use of bulk material data?
    - …

- **National registers**
  - **France, Belgium and Denmark** have nanomaterial inventories but with different criteria for registration
  - **Switzerland, Norway** and (from 2018) **Sweden** product registers demand nanomaterial specific information

The challenge of nanomaterial definition - European legislation dealing with nanomaterials (1)

1. Nanomaterial definitions based on European Commission Recommendation (2011/696/EU)

Legislation	1 – 100 nm	50% -threshold (1-50%)	Aggregates/ Agglomerates	VSSA	Fullerene, Graphene, CNT	Natural, incidental, manufcatured	Additional criteria	Consequence
Biocidal Product Regulation (EU) No. 528/2012	Y	Y (N)	Y	N	Y	Y	/	- Indication (nano) - No simplified authorisation - Separarate risk assessment
Cosmetics Regulation (EC) No 1223/2009	Y	N	N	N	N	Manufactured only	-insoluble / biopersistent -nanostructured materials	- Indication (nano) - Data submission to Cosmetic Product Notification Portal (CPNP)
Regulation (EU) 1169/2011 on Food Information for Consumers and Novel Food Regulation (EU) 2015/2283 (entry into force: 01/2018)	Y	N	Y	N	N	Manufactured only	-nano specific properties -nanostructured materials	- Indication (nano) - EFSA: safety assessment - authorisation required

The challenge of nanomaterial definition - European legislation dealing with nanomaterials (2)

2. Nanomaterial definition **not** based on European Commission Recommendation

Legislation	Criteria	Consequence
Regulation (EC) No 1333/2008 on food additives	- no definition - case-by-case decision	- new entry in the Community list - Evaluation (EFSA)
Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food	- no definition - case-by-case decision	- Functional barrier concept not allowed
Regulation on Plastic Materials (10/2011/EC)	- nano specific properties - case-by-case decision	- Allowed nanomaterials and their respective use in Annex 1

3. Draft

Legislation	1 – 100 nm	50% - threshold (1-50%)	Aggregates/ Agglomerates	VSSA	Fullerene, Graphene, CNT	Natural, incidental, manufcatured	Additional criteria	Consequence
Proposal for a Regulation on Medical Devices 2012/0266 (COD)	Y	Y (N)	Y	N	Y	Y	/	- indication on device - risk class III

Conclusion

- Production / use of nanomaterials requires consideration of different aspects, e.g.
  - Worker health protection
  - Downstream user communication
  - Registration under REACH or in national inventories
  - Product specific legislation with differing definitions
- Although legislation and guidances are available, the exact requirements and obligations are often not clear, standardized methods are seldomly available
- Especially SMEs may suffer from the additional workload and costs

ANY QUESTIONS?

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