

HOW TO ADDRESS EHS RISKS WITH NANOMATERIALS THROUGH THE EXISTING WORKERS AND CONSUMERS SAFETY LEGAL INSTRUMENTS ?

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The current EHS legal landscape and nanomaterials

Where are we today ?



Overview of the main legal instruments dealing with nanomaterials issues

| Directly | Indirectly |
|--|--------------------------------------|
| Food additives regulation | REACH |
| Active and intelligent materials food packaging regulation | CLP Regulation |
| Plastic materials food packaging regulation | RoHS directive |
| Cosmetics Regulation | WEEE directive |
| Food Information to Consumers Regulation | All occupational safety legislation |
| Foods for Specific Groups Regulations | All product safety legislation |
| Biocidal Products Regulation | All consumer information legislation |
| Novel Food Regulation | In the future ? |
| French nanoregister | Medical devices regulation |
| Danish nanoregister | Swedish nanoregister |
| Belgian nanoregister | German Consumer Goods Ordinance |

Avoiding the regulatory gap trick

Why « apparent » legal gaps do not decrease legal risks



There is no equation between a lack of targeted rules and a legal vacuum !

- Legal rules need a scope of application and rely on definitions to avoid confusion, conflicts with other existing rules and reach a certain degree of clarity
- There is no single legal definition under EU law of terms like « nanotechnology » or « nanomaterial »
- To this day, the legal instruments referring to nanotechnologies and nanomaterials are sector-based (except the national nanoregisters)
- Legal rules are always adopted at a given time under given circumstances (lawyers often underestimate the importance of preparatory works)
- Legal texts often pre-date the latest technological evolutions but their scope of application and their objectives are broad enough to cover these evolutions
- New risks identified or potential risks with nanomaterials actually oblige the addressees of EHS rules to check whether they comply with the objectives and principles of these texts (guidance documents from regulatory agencies are good indicators that new concerns must be addressed under « old » rules)



Which are the relevant legal instruments ?

A few examples taken from EHS legislation

The 1989 framework directive on workers health and safety

Revisiting the directive from a nanosafety perspective



Back to the roots of workers health and safety legislation

- Among the principles of prevention every employer has to comply with, article 6 (2) (e) of the directive identifies « *adapting to technological progress* »
- Technological progress is not defined but it has been so far undisputed that introducing the use of nanomaterials would be considered as a technological progress
- Article 6 (3) (c) further obliges employers to « *ensure that the planning and introduction of new technologies are the subject of consultation with the workers and/ or their representatives, as regards the consequences of the choice of equipment, the working conditions and the working environment for the safety and health of workers* » - See also the Belgian nanoregister
- Article 12 also obliges employers to train workers when a new technology is introduced
- But so far, how many employees did actually review their prevention measures, consulted their employees and trained them adequately ?
- Is the lack of scientific knowledge or measures a good defence ?

The 1998 Chemical Agents Directive

A cornerstone in the current nanosafety legal framework



Chemistry or alchemy of legal risks ?

- Again, technological progress must be closely monitored as recital 18 to the directives states that « *the employer must on a regular basis carry out evaluation and measurements and be aware of new developments in technology with a view to improving the protection of workers's safety and health* »
- Employers are obliged to determine whether hazardous chemical agents are present at the workplace
- Important role of Safety Data Sheets but when they are not needed, employers have to find information by themselves (online, by contacting ECHA or contacting their suppliers or the manufacturers)
- Again, is a lack of information a good defence ?

The 1985 Product Liability Directive

A robust piece of legislation or a 31 years old survivor of legislative reforms ?



Scope of application and defences

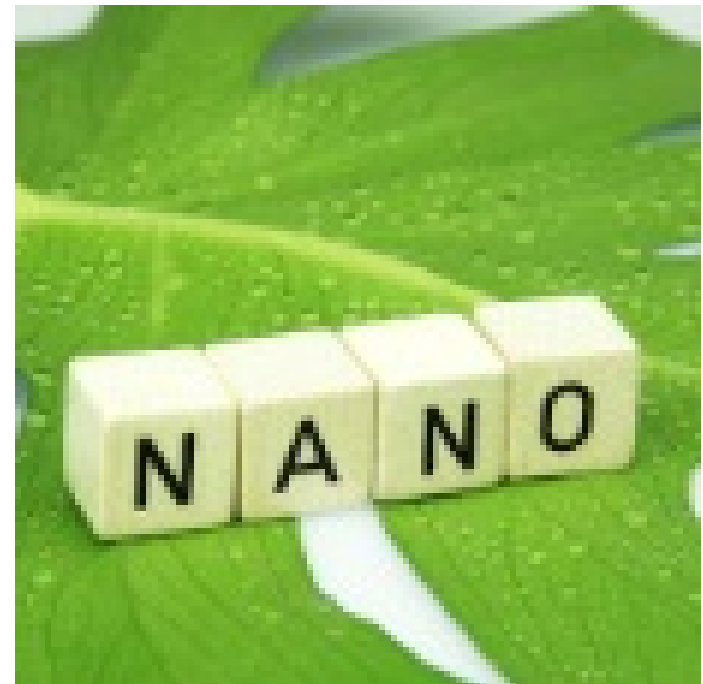
- Products mean « *product' means all movables even if incorporated into another movable or into an immovable. 'Product' includes electricity. »*
- Manufacturers or importers of nanomaterials, mixtures or articles containing nanomaterials fall within the scope of application of the directive
- A product is defective when it does not offer the safety a person is entitled to expect.
- To assess whether a product is defective, all circumstances are taken into account, including the product presentation, the reasonable use expected and when the product was put into circulation
- Several defences exist for the manufacturer/importer and two are of particular relevance in terms of nanosafety:
 - the defect is due to compliance with mandatory regulations issued by public authorities
 - the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the existence of the defect to be discovered

The interpretation of the scientific knowledge defence by the Court of Justice of the European Union

- *“It follows that, in order to have a defence under Article 7(e) of the Directive, the producer of a defective product must prove that the objective state of scientific and technical knowledge, **including the most advanced level of such knowledge**, at the time when the product in question was put into circulation was not such as to enable the existence of the defect to be discovered.” (ECJ Case C-300/95, *Commission v. UK*, 29 May 1997, §29)*
- Opinion of Advocate General Trstenjak in C-358/08 , *Aventis Pasteur SA v. OB*, 8 September 2009:
“The defence can therefore only partly remove the risk of holding back innovation which is inherent in no-fault liability for products. In this context, the 11th recital in the preamble to Directive 85/374 rightly points out that products age in the course of time, higher safety standards are developed and the state of science and technology progresses, so that it would not be reasonable to make the producer liable for an unlimited period for the defectiveness of his product.”

The 2005 Unfair commercial practices directive

Is « with nano » advertising harmless for companies and consumers ?



Can you freely advertise the (alleged) advantages of the inclusion of nanomaterials in your product ?

- Traders of products fall within the scope of application of the Unfair Commercial Practices Directives
- The directive does not apply to B2B commercial communications
- Products containing nanomaterials qualify as products
- The scope of the directive is without prejudice to EU and national rules relating to health and safety aspects of products
- Penalties are laid down in EU Member States legislation
- Would be qualified as unfair commercial practices, *inter alia*:
 - Misleading information about the nature of the nanomaterial;
 - Misleading information about, *inter alia*, the risks, benefits and specification of the nanomaterial;
 - Displaying a trust mark, quality mark or equivalent without having obtained the necessary authorization (common nanomaterials testings would fit the definition)
 - Non-compliance with approval, endorsement or authorization of a public or private body that the trader takes advantage of.

The rather unknown binding nature of codes of conduct

- Role of Code of Conducts about commitments for nanomaterials testings, safety, etc ...
- The Unfair Commercial Practices Directive considers as misleading commercial practices:
 - Non-compliance of the trader with a Code of Conduct by which the trader had undertaken to be bound and which contains firm commitments by the trader;
 - Claiming to be the signatory of a Code of Conduct when the trader is not;
 - Claiming that the Code of Conduct received an institutional endorsement when it does not have;
- We see more often advertisements for products such as car cleaning products, shoes, etc ... with a « with nano » indication on the advertisement.
- We can however wonder whether a « with nano » indication actually influences the average consumer and that, on the contrary, it does not creates distrust with him/her.

What can you do ?

Compliance = remediation ? Not only, it is also anticipation !



How to comply ?

- Check whether nanomaterials are used at the workplace and included in the products sold to the consumers
- Review your workers and consumers safety policy currently in place (if any) and verify if they address the question of the use of nanomaterials at the workplace and of the inclusion of nanomaterials in products.
- Identify the risks and their degree of uncertainty
- Inform your workers in due time, without causing any panic and rather favour transparency in order to keep or build mutual trust
- Build with your legal department and/or your lawyer a compliance programme which will take into account all nanosafety issues (identified or potential), in order to fulfil your legal obligations
- Try to align your policy on that of sister or mother companies (or the contrary if you are established in a country where regulations on nanosafety require(d) immediate actions)
- Review your advertising and, if you would like, label products.

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attention !***

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