

# Comply and Explain : A New Perspective on Nanosafety Regulatory Aspects and Legal Risks

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# I. A complex legal environment

Past, present and future of nanosafety regulatory aspects

# Overview of the main legal instruments dealing with nanomaterials issues

Directly	Indirectly
Food additives regulation	CLP Regulation
Active and intelligent materials food packaging regulation	RoHS directive
Plastic materials food packaging regulation	WEEE directive
Cosmetics Regulation	All occupational safety legislation
Food Information to Consumers Regulation	All product safety legislation
Foods for Specific Groups Regulations	All consumer information legislation
Biocidal Products Regulation	<b>Soft Law</b>
Novel Food Regulation	EU Code of conduct of 2008
Medical devices regulation	Recommendation of 18 October 2011 on the definition of nanomaterial
French nanoregister	
Danish nanoregister	
Belgian nanoregister	
Swedish nanoregister	
REACH (as from January 2020)	

# The Berlin Declaration on nanomaterials



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(DPL en)

12487/1/18  
REV 1

ENV 015  
RECH 304  
SAN 200  
CONSUM 203  
IND 253  
CHIME 62

## NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	'Berlin Declaration' on nanomaterials - Information from the German delegation, supported by the French and Luxembourg delegations

Delegations will find in the [Annex](#) an information note from the [German delegation](#), supported by the [French and Luxembourg delegations](#) on the above subject, to be dealt with under "Any other business" at the Council (Environment) meeting on 9 October 2018.

## BERLIN DECLARATION

### Conclusions and recommendations from the 12th International Nano-Authorities Dialogue (7 and 8 June 2018, Berlin)

The authorities in Germany, Liechtenstein, Luxembourg, Austria and Switzerland have been cooperating successfully for many years in the field of nanotechnology. The 12th International Nano-Authorities Dialogue took place in Berlin on 7 and 8 June 2018. At this meeting, conclusions on the current situation were drawn up and recommendations were made for dealing with this key technology up to the year 2025 (Roadmap 2025). This roadmap covers chemicals law, occupational health and safety, environmental protection and consumer protection.

# The Berlin Declaration on nanomaterials (cont.)

OECD Testing Programme of Manufactured Nanomaterials

*[...] needs identified for further activities in this field, most of which will have to be addressed at EU level. These needs include :*

Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU)

- the adaptation of test methods within the context of the OECD;
- a transversal definition of nanomaterials in all relevant regulatory contexts in the EU;
- the approach to be taken to the emerging topic of 'advanced materials';
- the continued support of research activities and SMEs in the field of nanomaterials;
- provisions to give the European Chemicals Agency (ECHA) a permanent mandate for the EU Nano-Observatory.

Horizon Europe

Multidisciplinary approach – Disruptive technologies convergence

**DELEGATION AGREEMENT ON  
THE EUROPEAN UNION OBSERVATORY FOR NANOMATERIALS AND THE  
EUROPEAN UNION CHEMICAL LEGISLATION FINDER**

## II. Comply and Explain

Shifting the compliance discourse from self-regulation to pro-active regulatory anticipation

# What does « Comply and Explain » mean ?

- No « comply or explain » existing in corporate governance and financial markets regulation
- No legal definition of the « comply and explain » approach
- Deep link with the CSR concept

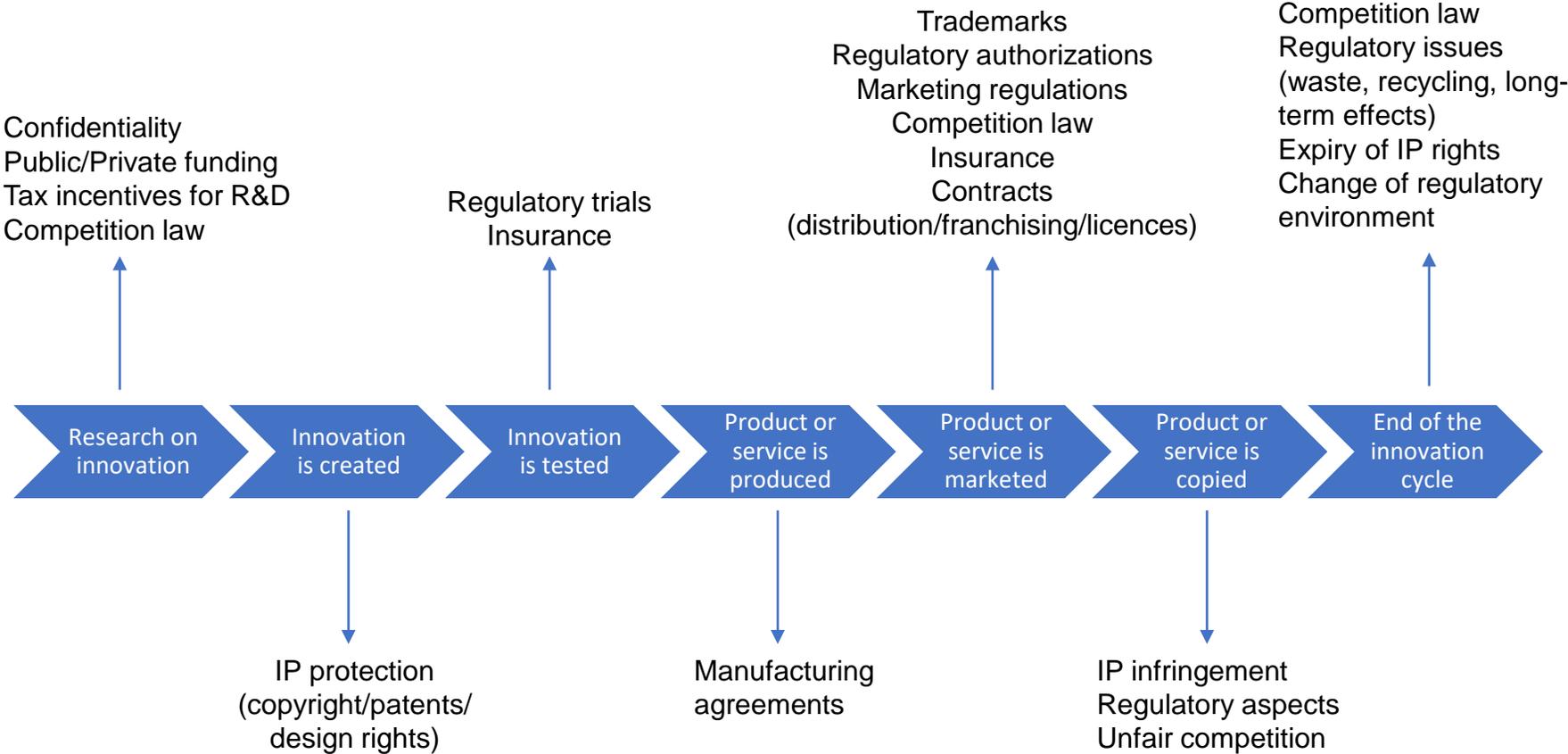
*Commission Communication on a renewed EU strategy for Corporate Social Responsibility (COM/2011/0681)*

- Comply = follow the objectives of any regulatory requirement
  - Complying is not simply « implementing »
  - Need to understand the objectives
- Explain = increased transparency
  - Society's awareness about potential risks is greater than ever
  - If you do not communicate, others will do it for you !

# What would this new perspective be ?

- Nanosafety regulatory aspects must be taken into account from the very beginning (see Safe by Design)
- Development of Fab Labs and other multidisciplinary teams
- Need to have harmonised expertise
- Legal risks should be taken into account
  - Rise of class actions in most of the EU Member States
  - Trade wars will increase regulatory enforcement
  - Risks that potential hazards become reality
- Develop a « Compliance Scoreboard » to check the needs and priorities

# The legal trajectory of any innovation



# III. Case study : Can « Safe by Design » become a regulatory principle ?

Understanding how « Safe by Design » can shift from science to law

# Safe by Design under EU law

- No legal definition of the Safe by Design concept under EU law
- First appearance of the concept in the European Commission's Communication on future networks and the internet (SEC(2008)2507)

Paragraph 3.5 stating that « *it is clearly necessary to take steps now to make the internet of the future safe by design* »

- Second appearance of the concept in the Commission decision of 7 March 2013 on the safety requirements to be met by European standards for certain seats for children pursuant to Directive 2001/95/EC on general product safety

Annex – Section on « General Safety Requirements » : « [...] *products need to be safe by design as far as possible, and therefore labels and warnings must not replace safety by design* »

# Legal foundations of the Safe by Design concept

- In the field of environmental policy, article 191 (2) TFEU provides that the EU policy shall be based on the precautionary principle
- But the precautionary principle is not limited to protect the environment. Its scope is much wider and includes dangerous effects on human, animal or plant health – see the Commission Communication on the precautionary principle (COM (2000) 0001)
- Article 168 TFEU provides that a high level of human health protection shall be ensured
- Article 169 TFEU provides that a high level of consumer protection shall be ensured

# Safe by Design and occupational safety

## 1989 framework directive on workers health and safety

- 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 employers did actually review their prevention measures, consulted their employees and trained them adequately ?**

## 2001 General Product Safety Directive

- Definition of « safe product » (art. 2 (b) )

*Any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:*

- (i) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;*
- (ii) the effect on other products, where it is reasonably foreseeable that it will be used with other products;*
- (iii) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;*
- (iv) the categories of consumers at risk when using the product, in particular children and the elderly.*

- Obligation for producers to place only safe products on the market (art. 3.1)
- Quid over professional products that became consumer products: recital 10 of the directive provides that

*Products which are designed exclusively for professional use but have subsequently migrated to the consumer market should be subject to the requirements of this Directive because they can pose risks to consumer health and safety when used under reasonably foreseeable conditions.*

# Would it be possible to give a legal definition to « Safe by Design » ?

- Actually, yes
- « Privacy by design »: see Article 25.1 GDPR :

*Taking into account the state of the art, the cost of implementation and the nature, scope, context and purposes of processing as well as the risks of varying likelihood and severity for rights and freedoms of natural persons posed by the processing, the controller shall, both at the time of the determination of the means for processing and at the time of the processing itself, implement appropriate technical and organisational measures, such as pseudonymisation, which are designed to implement data-protection principles, such as data minimisation, in an effective manner and to integrate the necessary safeguards into the processing in order to meet the requirements of this Regulation and protect the rights of data subjects.*

- Does a « by-design » approach go against the principle of technological neutrality ?

# Safe by Design in the field of nanosafety

- Review of trainings, information and protective equipment for workers
- The development of safety by design would also imply more enforcement of the general product safety requirements – possible decisions of Commission in that field
- Safe by design would also become a marketing tool for compliant actors (advertising)
- Insurance and co-insurance issues: the lack of safety by design could result in the increase of insurance premiums or the exclusion from insurance coverage

# Thank you for your attention !

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The ULB logo consists of the letters 'ULB' in white, bold, sans-serif font, centered within a solid blue square.

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