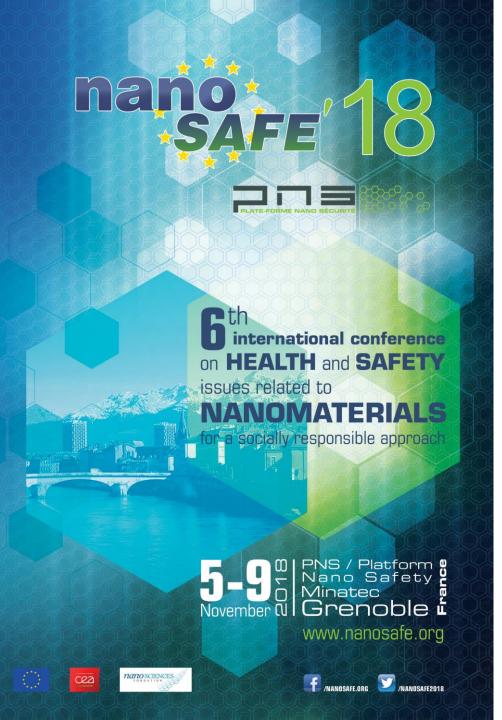
Session 6 Regulation / Standarization

Part I : Thursday 8 November 2018 From 2 p.m. to 3.30 p.m.





Regulation and standardization altogether ?

- Standardization precedes regulation and is piloted by standardization bodies
- Regulation is elaborated by institutions with political accountability
- Regulation is a generic word : covers, from a legal point of view, different types of legal instruments with legal effects (regulations, directives, decisions) and without legal effects (opinion, recommendation, guidelines) and hybrid legal instruments (some codes of conduct)
- Bridge between standardization and regulation is made from a legal perspective through the TRIS notification system



TRIS NOTIFICATION SYSTEM IN SHORT

Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services

Procedure implementing :

- A right to be informed
- A right to be heard

Standstill period of 3 months – Draft can be blocked from 12 months to 18 months if EU harmonisation on the way

Urgent procedure possible



¢ Country	Reference	ŧ	Reception 🔻 date	End of Standstill Date
Switzerland	<u>2017/9510/CH</u>	Draft Ordinance on Protection against Dangerous Substances and Preparations (ChemO); 16 pages; available in German and French (see attachment);	2017-10-05	2018-01-08
Switzerland	<u>2017/9511/CH</u>	Draft Ordinance on Biocidal Products (OBP); 16 pages; available in German, French and Italian (see attachment);	2017-10-05	2018-01-08
Switzerland	2017/9512/CH	Draft Ordinance on Fees with respect to chemical products (ChemGebV) ; 3 pages; available in German, French and Italian (see attachment);	2017-10-05	2018-01-08
Switzerland	<u>2017/9513/CH</u>	Draft Implementing Ordinance on Biocidal Products of the Federal Department of Home Affairs; 3 pages, available in German, French and Italian (see attach- ment)	2017-10-05	2018-01-08
Sweden Sweden	<u>2017/227/S</u>	Regulations amending the Swedish Chemicals Agency's regulations (KIFS 2017:5) on chemical products and biotechnological organisms	2017-06-07	2017-09-08
Estonia	2016/648/EE	Draft act amending the Tobacco Act	2016-12-13	2017-06-14
🔳 Germany	2016/333/D	Twenty-First Regulation amending the Consumer Goods Regulation	2016-07-05	2017-01-06
Switzerland	2015/9506/CH	- Ordinance on cosmetics (OC, unofficial translation)	2015-10-12	2016-01-13
Denmark	<u>2013/603/DK</u>	Draft Order on a register of mixtures and articles that contain nanomaterials as well as the requirement for manufacturers and importers to report to the register. Issued pursuant to Article 42 of the Chemicals Act.	2013-11-05	2014-05-06
Belgium	<u>2013/369/B</u>	Royal Decree on the market placement of substances manufactured at the nanoscale	2013-07-04	Closed

Showing entries 1 to 10 (from a total of 13 entries)

Previous Page Next page



Chair: Anthony BOCHON

14:00 - 14:15MESOCOSM TESTING AS A STANDARD FOR NON OCCUPATIONALA91873AMAND EXPOSURE DRIVEN RISK ASSESSMENT OF ENGINEERED
NANOMATERIALS?

MASION Armand

14:15 - 14:30A PROBLEM WITH ISO 16890: RATINGS CAN DEPEND ON TESTA91683PTAEROSOL CHOICE.

TRONVILLE Paolo

14:30 - 14:45RELIABILITY OF DETECTION OF NANOMATERIALS UNDER THE
A91501MMA91501MMTOXIC SUBSTANCES CONTROL ACT (TSCA) AND THE REACH.
MIETTINEN Mirella

14:45 - 15:00APPLICATION OF STANDARDIZATION FOR THE DESIGN OFA91844JLCNT-BASED PRODUCT PILOT LINES IN COMPLIANCE WITH EUREGULATION ON MACHINERY.

LOPEZ DE IPIÑA Jesus M.