nccr trade regulation
swiss national centre of competence in research

Introduction to Regulatory Action on Nanomaterials
European Union and Switzerland

Interdisciplinary Training for Young Scientists 2012
NRP 62 and NRP 64

2 November 2012, Murten

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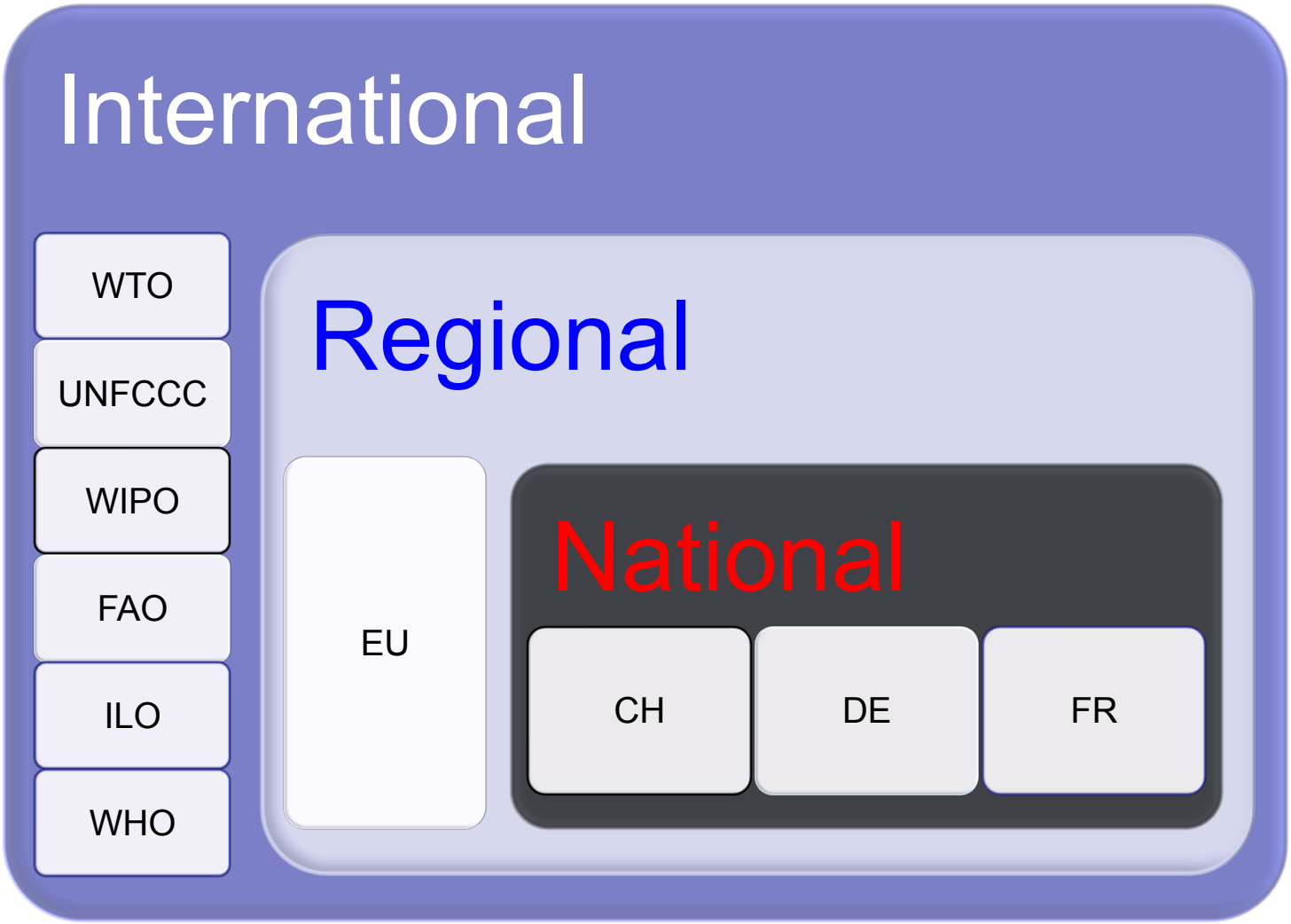
Overview

- Nanotechnology and Nanomaterials
  - National: Switzerland (CH)
  - Regional: European Union (EC)
  - International: Relevant WTO Provisions (TBT,SPS, GATT)
- Science and Regulatory Affairs



Terminology

- Binding (black letter law)
  - Directive (Biotech 98/44/EC)
  - Regulation (Verordnung) (REACH)
  - Decision
  - Law: CH: Gesetze (de), Lois (fr); Verordnung, Ordonnance
- Non binding
  - Recommendation
  - Opinion
- Principles
    - pacta sunt servanda (agreements must be kept)
    - estoppel, equity
    - precautionary principle
- Norms

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Nanotechnology

"Nanotechnology is the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale."

National Nanotechnology Initiative, USA (2001)

Zhai, L. et al. (2006) Patterned Superhydrophobic Surfaces: Toward a Synthetic Mimic of the Namib Desert Beetle. *Nano Letters*, **6**, 1213-7.

Main Applications

Schmid & Riediker 2008

- Cleaning Products
- Cosmetics
- Food and Food Processing
- Milling Machines
- Paint
- Paper
- Pharmaceuticals
- Plastic
- Powder Production
- Printing and Packaging
- Sensors
- Microelectronics
- Surfaces
- Coating
- Textiles
- Watches
- Optics

Recommendation 2011/696/EU

[2011]OJ 275/38

18 October 2011

Preamble

(5) The definition of the term ‘nanomaterial’ should be based on available scientific knowledge.

Recommendation 2011/696/EU

Adopted Recommendation

2. ‘Nanomaterial means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm – 100 nm.

In specific cases and where warranted by concerns for the environment, health, safety or competiveness, the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%.

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but…

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Recommendation 2011/696/EU

Adopted Recommendation

3. By derogation from point 2, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.

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Recommendation 2011/696/EU

Adopted Recommendation

6. By December 2014, the definition set out in points 1 to 5 will be reviewed in the light of experience and of scientific and technological developments. The review should particularly focus on whether the number size distribution threshold of 50 % should be increased or decreased.

EU

- Lisbon Treaty
  - Treaty of the European Union
  - Treaty on the Functioning of the European Union
    - Institutions: Commission, Council of Ministers, European Council, European Parliament
- Regulatory body
  - European Chemicals Agency (ECHA)

Safety, Risk Assessment, Risk/Benefit Assessment

- Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)
- Scientific Committee on Consumer Safety (SCCS)
- European Food Safety Authority (EFSA)
- European Medicines Agency (EMA)

Europe / EC

- Communication on the Second Regulatory Review on Nanomaterials, COM(2012) 572, 3 October 2012
  - It describes the Commission's plans to improve EU law and its application to ensure their safe use (15 pages)
  - Staff Working Paper on types and uses of nanomaterials, including safety aspects

- **REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)**
- **Regulation (EC) No 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures**, OJ L353, 31.12.2008

- **Nanosciences and nanotechnologies: An Action Plan for Europe 2005-2009**

With nano provisions…

- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 Concerning the Making Available on the Market and Use of Biocidal Products, due to enter into force on 1 September 2013
- Regulation (EC) No 1223/2009 on cosmetic products, due to enter into force on 11 July 2013
- Regulation (EC) No 1169/2011 on the provision of food information to consumers, of November 22, 2011, due to enter into force on 13 December 2014

Standards & Cooperation

CEN/TC 352 Nanotechnology Committee

In 2010, CEN accepted Mandate M/461 *Standardization Mandate to CEN, CENELEC and ETSI for standardisation activities regarding nanotechnologies and nanomaterials.* Several ISO and CEN Technical Committees are involved of the execution of the mandate, the coordination of which has been allocated to CEN/TC 352 "Nanotechnologies".

ISO/TC 229 Nanotechnologies

Cooperation such as in the OECD or at UN-level, the Commission has started a regular dialogue with the United States in the context of the Transatlantic Economic Council (TEC), with a view to avoiding unnecessary divergences.

CEN – European Committee on Standardization

CENELEC – European Committee for Electrotechnical Standardization

ETSI - European Telecommunications Standards Institute

In its conclusions on “improving environmental policy instruments” of 20 December 2010[5], the Council invited the Commission to “evaluate the need for the development of specific measures for nanomaterials relating to risk assessment and management, information and monitoring, including the further development of a harmonized database for nanomaterials, while considering potential impacts”.

[5] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/envir/118646.pdf

COMMISSION STAFF WORKING PAPER - Types and uses of nanomaterials, including safety aspects, Brussels, 3.10.2012 SWD(2012) 288 final (111 pages)

Second Regulatory Review on Nanomaterials - COM(2012) 572 final

In line with SCENIHR's conclusion that nanomaterials are similar to normal substances in that some may be toxic and some may not, the Commission does not consider appropriate at present to change the rules for when a chemicals safety assessment is required. As regards registration thresholds and timelines for registration based on volume, the Commission considers REACH appropriate, subject to actions outlined in chapter 7 (Need for Better Accessible Information).

The Commission will

- create a web platform with references to all relevant information sources, including registries on a national or sector level, where they exist
- Harmonized data formats
- Improve exchange of information
- Launch an impact assessment to identify and develop the most adequate means to increase transparency and ensure regulatory oversight

CH

- **Action Plan on Synthetic Nanomaterials (9.4.2012)**
  - **Report 25 April 2012 (EDI, EVD, UVEK)**
    - On 25 April 2012 the Federal Council decided to continue the action plan until 2015.
  - **Safety Data Sheets**
    - **Guidelines for synthetic nanomaterials; April 2012, seco**

CH

- **814.01 Federal Act of 7 October 1983 on the Protection of the Environment (Environmental Protection Act, EPA)**
- **813.1 Federal Act of 15 December 2000 on Protection against Dangerous Substances and Preparations (Chemicals Act, ChemA)**
  - **813.11 Ordinance of 18 May 2005 on Protection against Dangerous Substances and Preparations (Chemicals Ordinance, ChemO)**

CH

- 813.112.1 Ordinance of 18 May 2005 on Good Laboratory Practice (OGLP)
- 813.12 Ordinance of 18 May 2005 on the Placing on the Market and Handling of Biocidal Products (Ordinance on Biocidal Products, OBP)
- 814.81 Ordinance of 18 May 2005 on the Reduction of Risks relating to the Use of Certain Particularly Dangerous Substances, Preparations and Articles (Chemical Risk Reduction Ordinance, ORRChem)

CH

- Self-Supervisory (self-regulating) obligations in Switzerland's legislation on hazardous substances
- Self-Supervision: requires access to information

- In Switzerland chemicals must be placed on the market according to the Chemicals Act. However certain chemicals may be placed on the market according to the "Cassis de Dijon" Principle.

Art 26 EPA

1 The putting into circulation of substances for uses where, when handled correctly, they, their derivatives or waste may present a danger to the environment or indirectly endanger people is prohibited.

2 To this end, the manufacturer or importer is responsible for their own self-regulation.

3 The Federal Council issues regulations on the nature, extent and supervision of the self-regulation.

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Article 27 EPA

1. Anyone who puts substances into circulation must:

a. inform customers about their environment-related properties;

b. provide customers with instructions so that, when the substances are handled correctly, they do not present a danger to the environment or indirectly endanger people.

2. The Federal Council issues regulations on the nature, content and extent of the information given to customers.

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Article 5 ChemA

1. Any manufacturer who places substances or preparations on the market shall be responsible for ensuring that they do not endanger life or health. In particular, the manufacturer shall:

a. assess and classify substances and preparations according to their properties;

b. package and label them in accordance with the type of hazard concerned.

…

Article 5 ChemA

2. The Federal Council shall issue regulations concerning the nature, extent and review of self-regulation. In particular, it shall specify: a. test methods, the principles of Good Laboratory Practice (GLP) and the criteria for assessment and classification;

b. packaging and labelling requirements.

Article 6 ChemA

Having completed the appropriate self-regulation procedures, the manufacturer shall be entitled to place substances and preparations on the market without the prior consent of the authorities.

…

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Article 6 ChemA

…The following exceptions shall apply:

a. Notification is required if new substances are to be placed on the market as such or as a constituent of a preparation (Art. 9).

b. Authorisation is required if biocidal products or plant protection products are to be placed on the market (Art. 10 and 11)

Article 15 ChemA

Review of existing substances

1 The Federal Council shall issue regulations concerning the review and assessment of individual existing substances.

Article 15 ChemA

2 The notification authority may request manufacturers to carry out investigations or

tests or to provide documents relating to existing substances that:

a. in view of the quantities produced or placed on the market or in view of their dangerous character may pose a particular risk to life or health; or

b. are being reviewed in connection with international efforts and programmes.

Article 16 ChemA

- *1. The notification authority, in conjunction with the assessment authorities, shall identify possible hazards presented by substances or preparations (risk assessment). For this purpose, the notifier may be requested to provide additional information and, if necessary, to carry out further tests.*
- *…*

Article 16 ChemA

- *2. A risk assessment shall be required for:*
- *a. new substances (Art. 9);*
- *b. substances and preparations subject to authorisation (Art. 10 and 11); c. existing substances under review in accordance with Article 15 Paragraph 2b.*
- *...*

Article 16 ChemA

- *3. Having first consulted the notifier, the notification authority may, on the basis of the risk assessment, recommend or order that the notifier should take measures to reduce the risks.*
- …

Article 16 ChemA

- *4. If no measures can be taken to reduce the risks or if the risks cannot be sufficiently reduced by such measures, the authorities responsible shall take appropriate steps to amend the relevant legal regulations.*
- …

Article 16 Chem A

- *5. Risk assessments shall be reviewed and, if necessary, revised in the light of new findings. In addition, periodical reviews shall be carried out in the case of biocidal products and plant protection products.*

Article 17 Chem A

Subsequent information

The notifier shall be obliged to inform the notification authority without delay and if necessary to submit new documents if new findings should emerge relating to the substance or preparation concerned or if significant changes occur with regard to essential points such as properties, intended use, or the quantities produced or placed on the market.

Scope for Domestic Regulation

- Priority on Emerging International Regulations and Rules
- Domestic Regulation or Voluntary Standards – Transparency, Precautionary Principle
- Special Requirements for Foodstuff and Processing (Risk Assessment, Precautionary Principle; LCA)
- Potential of Equivalence and Mutual Recognition (CH-EC)
- Risk Communication (unregulated)

Relevant International Law

- Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)
- Agreement on Technical Barriers to Trade (TBT)
- Trade Related Aspects of Intellectual Property Agreement (TRIPS)
- GATT 1994
- SAICM, GHS, Stockholm, Rotterdam, Dubai, Basel
- Precautionary Principles or Approach (Customary Law)
- CH-EC FTA 1972
- CH-EC Mutual Recognition Agreement 1999
- Future CH-EC FTA in Agriculture (Food Standards)
- Future CH-EC Agreement on Chemicals (REACH)

Thank you!

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