



Tentative governance by soft regulation – the case of nanotechnologies

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Soft regulation

Soft regulation: rules of conduct which in principle have no legally binding force, but which nevertheless have effects in regulatory practice to achieve certain policy goals (Senden 2004).

Examples: technical standards, codes of conduct, best practices

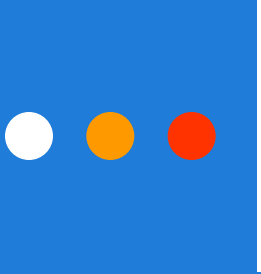


Central question

- How can soft regulation enhance responsible nanotechnological development?

Answers...

- Effectiveness problems
- Effectiveness enhancement (lessons)



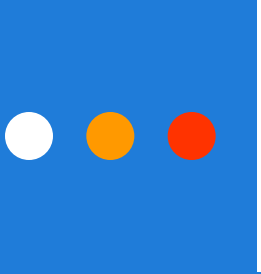
(Potential) effectiveness problems nano soft regulation

1. Voluntary self-reporting schemes
 2. Voluntary codes of conduct
 3. Voluntary nano reference values at the workplace
- implementation and compliance problems, questions on appropriateness regulatory tool



Effectiveness enhancement

- Framework of responsive regulation (Ayres and Braithwaite 1992; Baldwin & Black 2008; Dorbeck-Jung et al 2010)
- Unit of analysis: (multi-level) governance system (Hood et al 2001)
- Co-evolutionary institutional perspective



Effectiveness interrelated conditions (lessons)

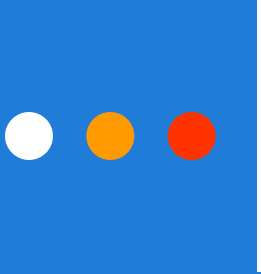
- Consistent & unambiguous regulation
- Strong binding force
- Strong interest in compliance
- Supportive implementation
- Knowledgeable oversight
- Responsive enforcement and adaptation



Exposure limits nano- materials NL

Regulatory system:

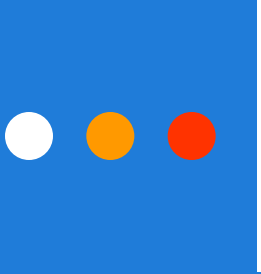
- EU directives and principles (precautionary and ALARA)
 - National legislation
 - International standards
 - Safety guidelines
 - Ministerial recommendation on nano reference values (NRVs)
- multi-level hard and soft regulation



Consistent and unambiguous regulation

- Regulatory system seems to be consistent
- However, parts are ambiguous (general duty to care, EU principles and Aug. 2010 Ministerial Recommendation on NRVs)

→ Improve unambiguity



Strong binding force soft regulation

- Confer binding force (Recommendation Dutch Minister on NRV's)
- Attribute quasi-legal status (harmonized standards)



Strong interest in compliance

- Reputational advantages
- Economic advantages
- Keeping the advantages of soft regulation

→ More insights into interests needed



Supportive implementation/compliance

- Strengthen interests in implementation
- Information distribution
- Provide guidelines
- Funding

→ Extent measures



Summary and conclusion

- Lessons
 - Next steps:
 - empirical research
 - translational research: taking social learning seriously
- NanoNext projects on governance arrangements, standardization, regulatory partnerships



The end

Thank you for your attention !!