Impact Assessment of Further Regulation of Nanomaterials at a European Level

Gregory Moore

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KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

Disposition

- Background
- Information base
- Selection of baselines and regulatory options
- Cost estimates and benefit
- Conclusions
- Comments and questions

Background

- 2012
  - Second regulatory review on NM
  - German proposal to amend REACH
  - Swedish proposal to develop NM-legislation (2013)
- 2013
  - Hague conference, Danish informal WS
  - German proposal to amend REACH Annexes
  - MS agree to amend REACH Annexes as first step
  - German commentary, *Schwirn et al*., 2014
- 2013, 2014, 2015, …2016 ….?, DG-ENV -ENT/GROW

Background (2/2)

- How to make a proposal objective/acceptable?
  - ➢ Do an Impact Assessment!

- Methodology: EC Impact Assessment Guidelines

- The Contractor: RPA, Risk & Policy Analysis

- The aim of the IA study was to determine the qualitative and, where possible, quantitative impacts of two potential legislative options that would establish separate requirements for nanomaterials

Information base

- **Matrix (2014):** Impact Assessment of Relevant Regulatory Options for Nanomaterials in the Framework of REACH
- **RPA et al (2014):** Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials in the Market – Evaluation Report
- **BiPRO et al (2013):** Examination and Assessment of Consequences for Industry, Consumers, Human Health and the Environment of Possible Options for Changing the REACH Requirements for Nanomaterials
- **RPA (2012):** Impact Assessment of the REACH Implementation Project on Substance ID for Nanomaterials
- **French Notification System:** Authorities Analysis (2013, 2014), % total numbers of NM less than 1 tpa was 43 – 50%
- **German and Swedish regulatory proposals**
- **EU REACH Annex amendment:** “Non-paper” 2014

Baselines

Option 0A - “Status quo”

- Nanomaterials are currently regulated at EU level by the legislative framework formed by:
  - REACH Regulation (EC) No. 1907/2006
  - CLP Regulation (EC) No 1272/2008

Option 0B “Amendment of the REACH Annexes”

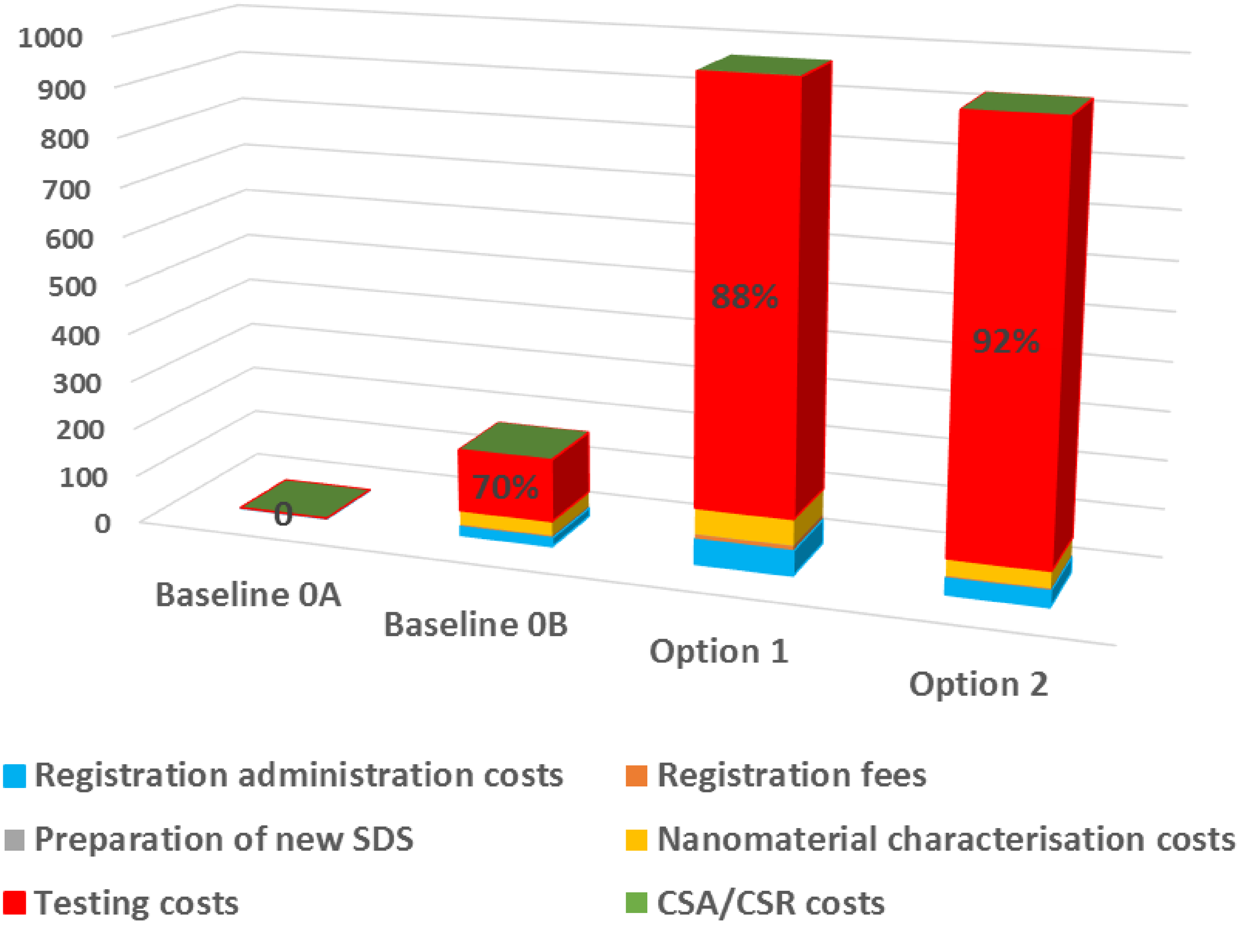
- assumed REACH Annexes have been amended
  - registration dossiers will provide information on the nanoform(s) of the substances only when the nanoform(s) are manufactured in quantities above 1 tpa.
  - information to be provided will be based on the tonnages of the nanoforms.
  - Tonnage bands unchanged **+** some more info **+** bulk when justified

Regulatory Options

The aim to ensure high level of protection to NM and functioning of internal market.

- EU NM definition legally binding
- REACH tonnage bands decreased
  - ❖ ≥10 kilograms → registered
  - ❖ ≥100 kilograms → complete CSR
- **Option 1** – “Nanomaterials as substances on their own”
  - ❖ Nanomaterials (substances on their own) registered individually
- **Option 2** – “Separate risk assessments within the same registration dossier”
  - ❖ Bulk and nanoforms are registered together

Cost estimates



Costs *cf.* benefits (health)

	Policy option 1	Policy option 2
Total marginal costs *cf* 0B	**€791.95M – €960M**	**€747.75M – €896M**
Total number of lethal cancers to be avoided	**235 – 285**	**222 – 266**

An illustration demonstrates that the total number of lethal cancer cases (over an undefined time) required to be avoided which would be equal to the financial cost of policy option 1 is 235-285, and option 2 is 222-266.

By comparison, cancer is predicted to kill about 1 359 100 Europeans in 2015.

Conclusions

- Cost estimates should be taken as illustrative of the order of magnitude of the actual costs
- Testing costs are the most important parameter (respectively, 88% for policy option 1 and 92% for policy option 2) to the final estimates
- Total marginal costs between €790 million and €960 million for policy option 1 and €750 million and €900 million for policy option 2
- If option 1 or 2 reduce 285 lethal cancer cases over time they can be economically justified.

❖ NB: Report will be published next week (www.kemi.se)

➢ There is a need for a regulatory tool for NM

➢ What is the next step?

Thank you!

Comments and questions