Assessment of the French Notification System

Evaluation Report

Validation Workshop

Marco Camboni

30 June 2014

RPA
Risk & Policy Analysts

Overall Aim and Specific Objectives

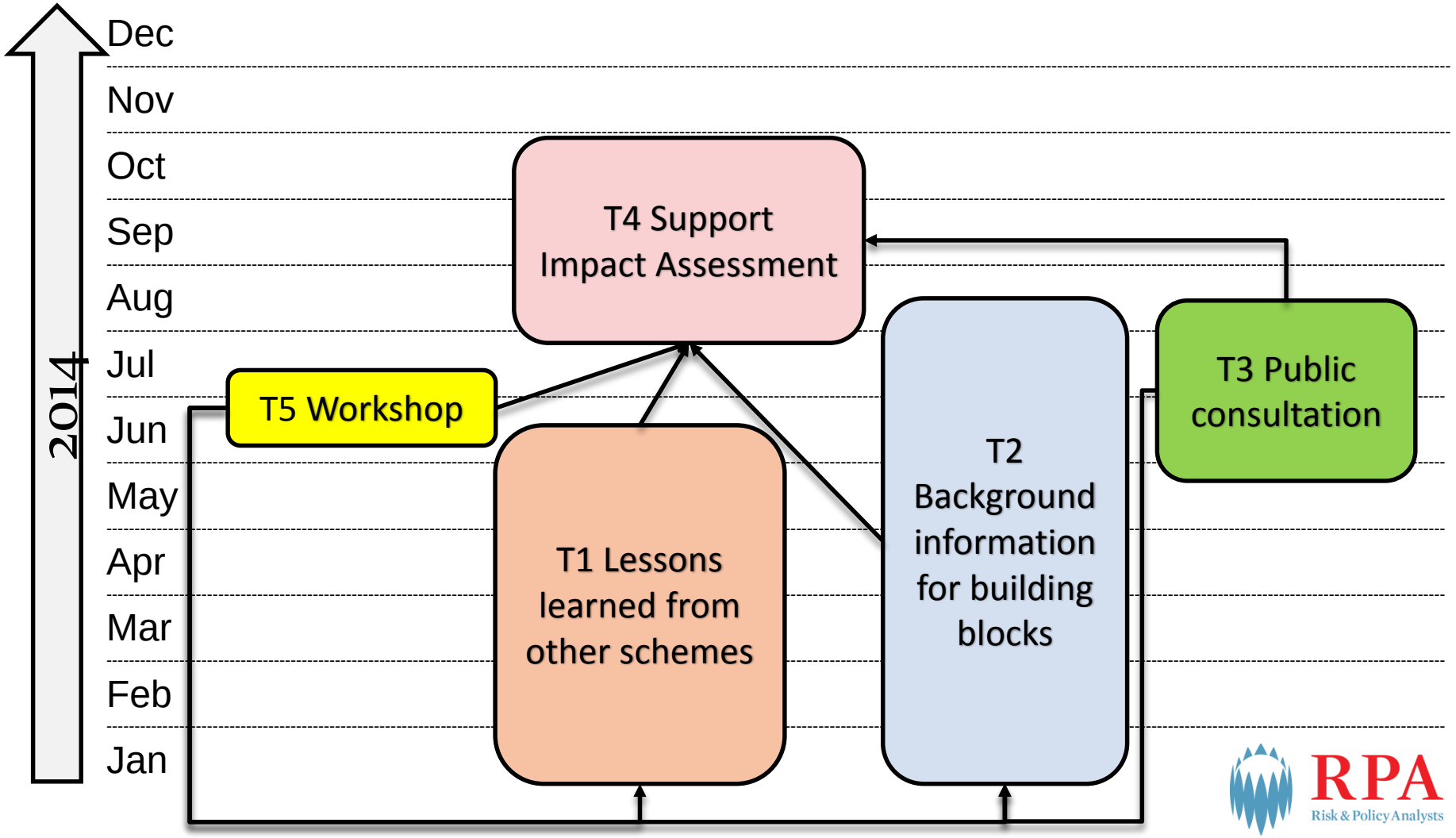
The overall aim of this study is to provide support to the European Commission in the preparation of an impact assessment to identify and develop the most adequate way to increase transparency and ensure regulatory oversight for nanomaterials.

Specific objectives:

- Gather relevant information on the experience from other nanomaterials register-like schemes;
- Provide information on health and safety, markets and research trends of nanomaterials for the better definition of the policy options to be assessed; and
- Support the impact assessment of the policy options.

RPA
Risk & Policy Analysts

Framework of the Study



RPA
Risk & Policy Analysts

Task 1: Lessons learned from other schemes Subtasks and Methodology

- **Overview of the Transparency Measures**: review of the legislative acts, IAs;
- **Assessment of the French Notification System (FNS):**
  - Review of the French decree and of the r-nano.fr website;
  - Review of the French public report published in November 2013;
  - Analysis of the list of notified substances published in the French public report;
  - Stakeholder meeting held in Paris on 10 March 2014;
  - Online survey on the administrative burden posed by the FNS and the CPNP;
  - Teleconferences with the French public authorities, industry associations and companies.

RPA
Risk & Policy Analysts

Overview of the Transparency Measures

Object of Notification

Belgium: **Substances manufactured at the nanoscale**, if placed on the market for professional users in more than 100 grams per year. **Mixtures** containing nanomaterials. **Articles and complex objects** containing nanomaterials, if the possibility of release cannot be excluded and if the release rate exceeds 0.1 percent of the initial mass contained in the article.

Denmark: **Mixtures and articles** that are intended for sale to the general public and which contain nanomaterials, where the nanomaterial itself is released under normal or reasonably foreseeable use of the mixture or article or where the nanomaterial itself is not released but substances in soluble form that are classified as CMRs or environmentally dangerous substances are released from the nanomaterial.

RPA
Risk & Policy Analysts

Overview of the Transparency Measures

Object of Notification

France: Substances manufactured at the nanoscale, on its own or contained in a mixture without being bound to it, or in material intended to release such a substance under normal or reasonably foreseeable conditions of use, must be notified if more than 100 grams are placed on the market for professional users per year.

CPNP: Cosmetic products and nanomaterials contained in cosmetic products, where a nanomaterial is defined as "*an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm*".

RPA
Risk & Policy Analysts

Overview of the Transparency Measures

Exemptions

Belgium: Nanomaterials covered by other legislation, pigments

Denmark: Mixture and articles covered by other legislation. Mixtures and articles in which the NM are nanoscale substances listed in Annex IV or V to REACH. Articles in which the nanomaterial is part of a fixed matrix, unless wear and tear, washing, breaking, and similar normal use of the article leads to the release of free nanomaterials; Articles, textiles and mixtures on which the nanomaterial is used as ink or added solely as a pigment; Articles of rubber, or rubber parts of articles, that contain the nanomaterials carbon black or silicon dioxide; Mixtures and articles produced or imported by individuals for their own, non-commercial use

RPA
Risk & Policy Analysts

Overview of the Transparency Measures

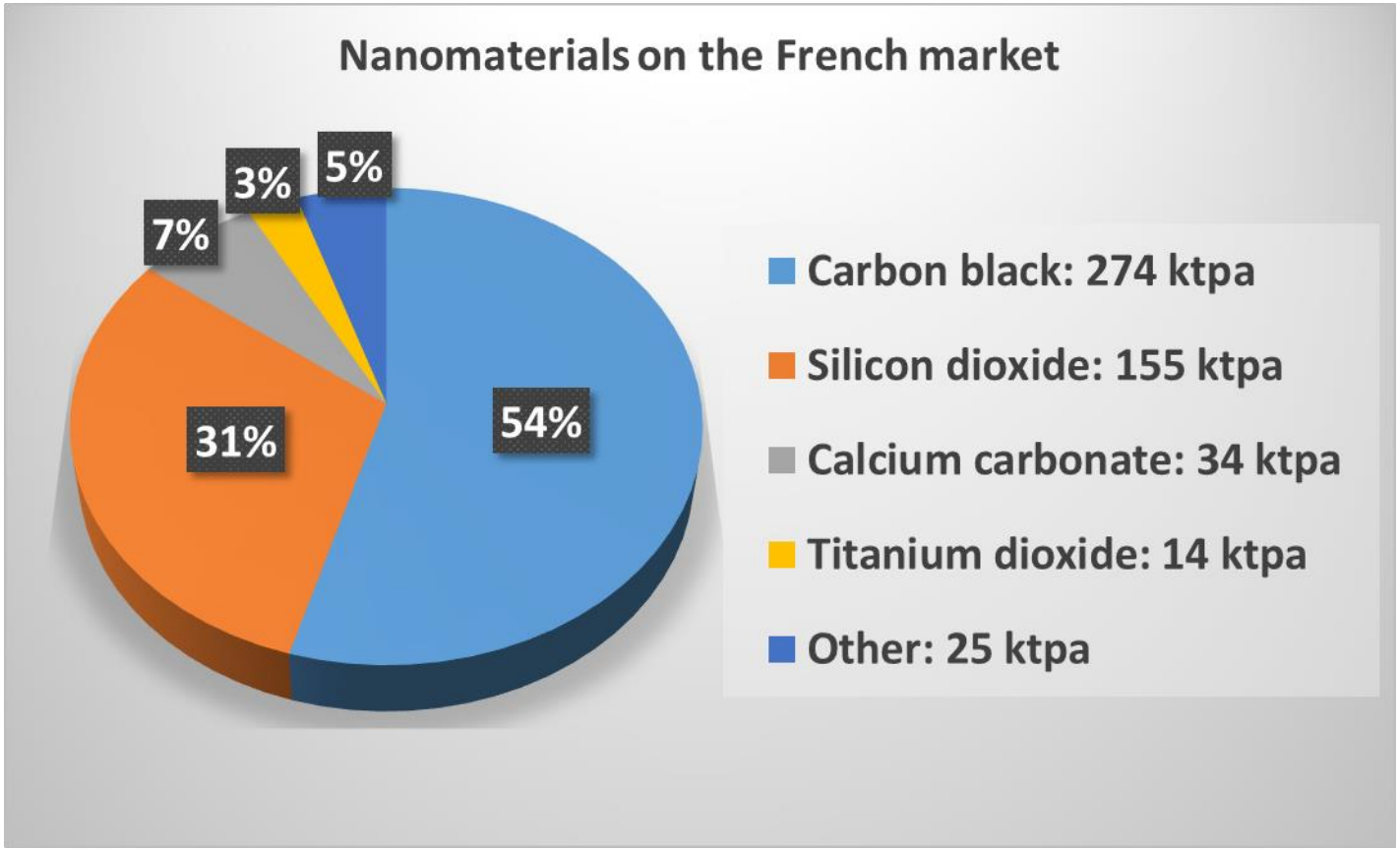
Norway: all chemical products (substances and mixtures) manufactured or imported in more than 100 kg per year and that are classified according to the CLP Regulation. Microbiological and biocidal products must always be reported to the Norwegian Product Register regardless of quantity. When a chemical product contains an intentionally added nanomaterial, this need to be identified in a note.

United Kingdom: pro-active survey by Defra and the Environment Agency of manufacturers of nanomaterials.

RPA
Risk & Policy Analysts

Analysis of the substances notified to the FNS in 2013

- Number of notifications finalised and validated: 3,409 from 933 notifiers;
- Total tonnage of NMs on the French market: **504 kt**;



RPA
Risk & Policy Analysts

Analysis of the substances notified to the FNS in 2013

- Number of substances notified to the FNS: **around 258**;
- If NMs are regarded as substances on their own and therefore to be registered individually under REACH, around 40-60% of the substances would not be triggered by REACH (because manufactured/imported in less than 1 tonne per year;
- If NMs are not considered substances on their own, 62% of the substances notified have already a full REACH registration dossier, with an other 32% likely to have one by 2018. Sixteen substances have been identified as polymers and thus outside the scope of REACH.

Some numbers:	
0.1 kg – 1 t (tonnage notified to the FNS)	43%
1 t - >1,000 t (tonnage notified to the FNS)	57%
Notified substances with a REACH dossier	62%
Notified substances without a REACH dossier	38%
Notified substances already on the market before 1981	80%

RPA
Risk & Policy Analysts

Analysis of the substances notified to the FNS in 2013

Code	Sector of Use	NMs
SU0	Other	147
SU10	Formulation of preparations and/or re-packaging	132
SU12	Manufacture of plastics products	70
SU1	Agriculture, forestry, fishery	60
SU24	Scientific research and development	32
SU19	Building and construction work	28
SU9	Manufacture of fine chemicals	27
SU11	Manufacture of rubber products	24
SU17	General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment	21

Over 150 pigments or dyes

RPA
Risk & Policy Analysts

Administrative burden, problems and criticisms

- Definition of nanomaterial and object of the notification;
- Communication of the information through the supply chain;
- Direct costs: €3,000 - €10,000 characterisation costs per substance, 2-3 work days per substance;
- Added value of the FNS over the current legislative framework (including the revision of the REACH Annexes);
- Confidentiality issues;
- Impacts on competitiveness and innovation.

Public authorities: €250,000 implementation costs + €30,000 operation costs

RPA
Risk & Policy Analysts

Use of the Information and Potential Benefits

- Available information to the general public;
- Availability of the information to industry;
- Availability of the information to the public authorities:
  - The FNS, the CPNP and the RAPEX system;
  - Epidemiological study;
  - Prioritisation of H&S research on some nanomaterials.

RPA
Risk & Policy Analysts

Thank you!

RPA
Risk & Policy Analysts