NANoREG II

Development and implementation of Grouping and Safe-by-Design approaches within regulatory frameworks

James Baker

INERIS – French National Institute for Industrial & Environmental Risk Assessment

Coordinator Emeric Frejafon

3 years: 01-07-2015 to 30-06-2018

38 partners: Budget 15 M€
Overarching aim of NANoREG II

- Deliver dossier to ECHA
- 8 Themes for compliance
- Conformity with OECD TGs
- REACH evaluation

Impact of NANoREG

AIM - quality improvement, to guarantee the quality of data and develop read across

AIM - to achieve a reduction in data requirements (for approval) due to application of Safe by Design
## Safe innovation approach

### Value Chain of a product
- Basic research
- Materials processing
- Applied research
- Manufacturing (up-scaling)
- Transport
- Use
- Recycling / Waste treatment

### Industries Innovation Model (STAGE GATE)

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 1</td>
<td>Business Concept</td>
</tr>
<tr>
<td>Stage 2</td>
<td>Business Case/Plan</td>
</tr>
<tr>
<td>Stage 3</td>
<td>Experimental development</td>
</tr>
<tr>
<td>Stage 4</td>
<td>Testing &amp; Validation</td>
</tr>
<tr>
<td>Stage 5</td>
<td>Market Launch &amp; Full Production</td>
</tr>
</tbody>
</table>

### Safe Innovation Approach

<table>
<thead>
<tr>
<th>Safe by Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>FROM UNCERTAINTIES AND POTENTIAL RISKS TOWARDS CERTAINTY AND MANAGED RISKS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Uncertainty and risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>FROM SHARING EXPERTISE AND KNOWLEDGE WITH INNOVATORS TO IDENTIFY UNCERTAINTIES AND POTENTIAL RISKS TOWARDS GUIDANCE FOR REGISTRATION OR MARKET APPROVAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Regulatory Preparedness</th>
</tr>
</thead>
<tbody>
<tr>
<td>FROM SHARING EXPERTISE AND KNOWLEDGE WITH INNOVATORS TO IDENTIFY UNCERTAINTIES AND POTENTIAL RISKS TOWARDS GUIDANCE FOR REGISTRATION OR MARKET APPROVAL</td>
</tr>
</tbody>
</table>
Impact related to key NANoREG II deliverables

- Developing Safe-by-Design regulatory approaches (Safe Innovation Approach)

- Demonstrating the integration of Safe-by-Design methods, with Risk Management and Risk Mitigation

- Achieving approval of Methods, Tools and Data-sets for the manufacturing of inherently safe MNMs and safe products inspired by NMNs.

- Overcoming barriers for the Application of Safe-by-Design approaches as standard Industry practice
Impact on EU-US nano-EHS collaboration

Liaisons with international organizations
Task 5.2 lead JRC
Liaisons established with the OECD, ISO/CEN, WTO, EU-US R&D organizations for *coordinated actions* on harmonized templates, standards, regulations and precautionary measures

Cooperation with research centers and academic or public organizations outside EU
Task 5.6 Lead CNRS-CEREGE
Establishing cooperation with public laboratories or research centers with the objective of sharing knowledge on similar instruments under development. Several contacts have already made on grouping principles, SbD and ITS; Duke University linked to the North Carolina Research Triangle; Universities of Montreal and Quebec
END
Work plan

WP 1 Regulatory orientated activities

WP 2 Nanomaterial Value chains

WP 3 SbD approaches

WP 4 SbD Demonstration Industrial case studies

WP 5 Liaisons & Network

WP 6 Dissemination, Exploitation

WP 7 Management

Inputs from on-going Research & regulatory oriented projects

Outputs to regulatory and standardization activities To be implemented in industry

EU-US, Venice 12-13 March 2015