

Authorities anticipate innovation: Regulatory Preparedness concept

The European Commission's
science and knowledge service
Joint Research Centre

Agnieszka Mech

EC JRC, Dir. F Health, Consumer and Reference Materials, F.2 Consumer Products
Safety, Group: **Nano Governance**



European
Commission

The Joint Research Centre at a glance

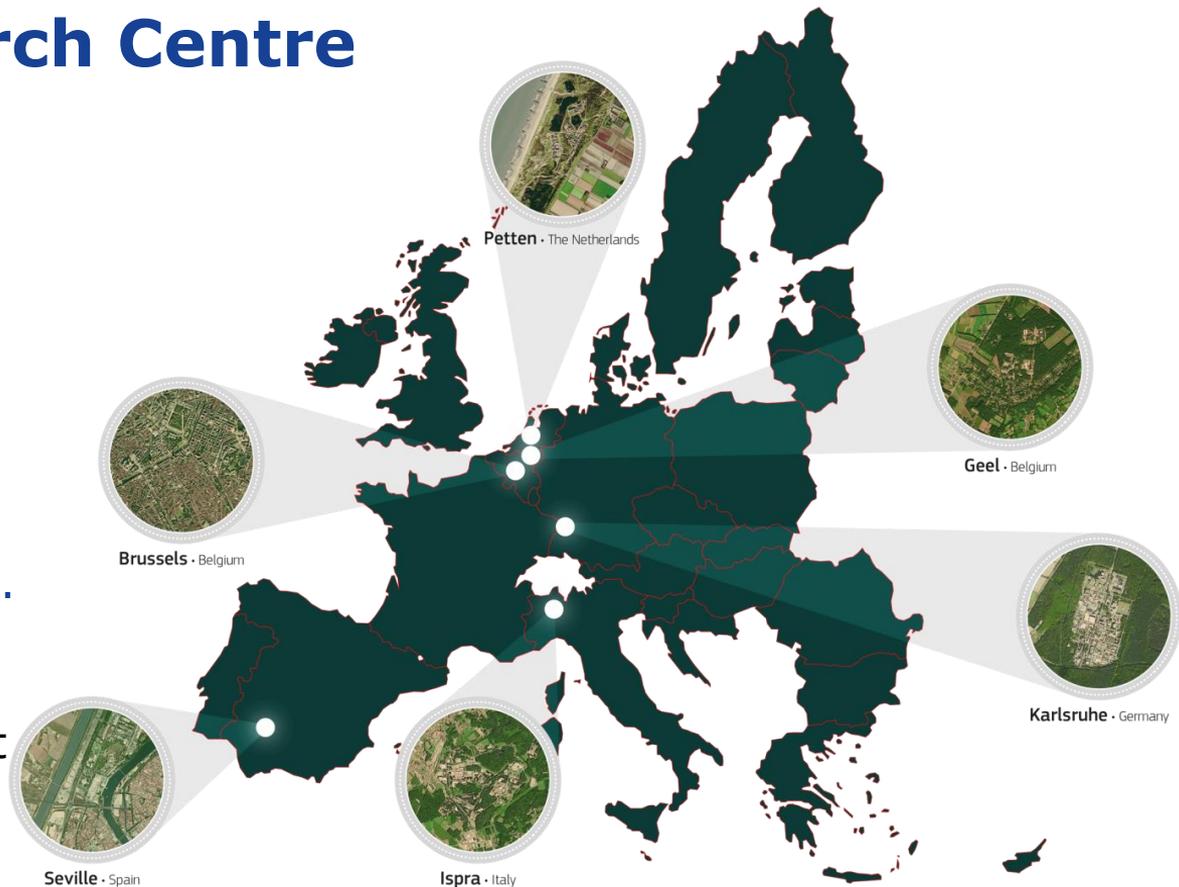
3000 staff

Almost 75% are scientists
and researchers.

Headquarters in Brussels
and research facilities
located in 5 Member States.

Mission

To provide scientific support
to the European policy
makers



**Dynamic pace of
innovation**



**Information on safety may lag
behind (static)**

How can regulators keep up with the pace of innovation?

**Innovation is moving
at a scarily fast pace.**

How can we ensure that they are in harmony?



Regulators and Innovation

Assessing applicability of the legislation

Product Specific Safety Assessment

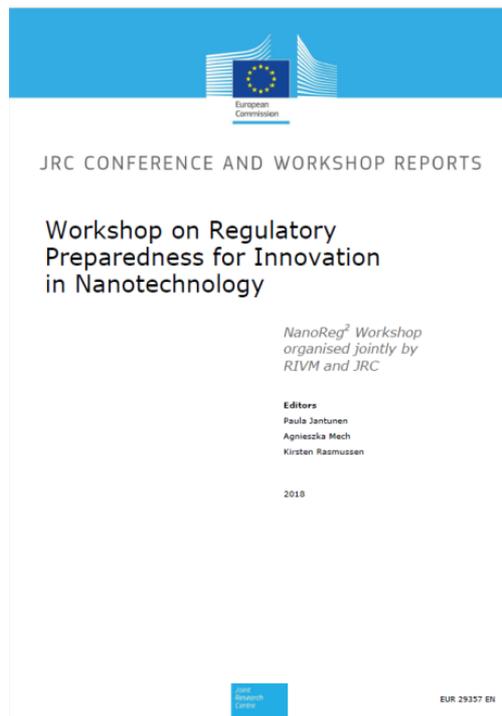
Research to promote methodology for SA

Update of the legislation and guidance

Knowledge on Innovation is a key

Workshop

How to minimise the gap between the pace of innovation and the development of nano-specific risk governance.



NanoImpact
Volume 14, February 2019, 100166



Frontier article

Perspective on how regulators can keep pace with innovation: Outcomes of a European Regulatory Preparedness Workshop on nanomaterials and nano-enabled products

Lya G. Soeteman-Hernández ^a ✉, Cindy Bekker ^a, Monique Groenewold ^a, Paula A. Jantunen ^b, Agnieszka Mech ^b, Kirsten Rasmussen ^b, Juan Riego Sintés ^b, Adriëne J.A.M. Sips ^a, Cornelle W. Noorlander ^a

First Workshop on Regulatory Preparedness for Innovation in Nanotechnology. EC JRC Ispra, 5-6 October 2017. EC JRC & RIVM

Regulatory Preparedness Aims

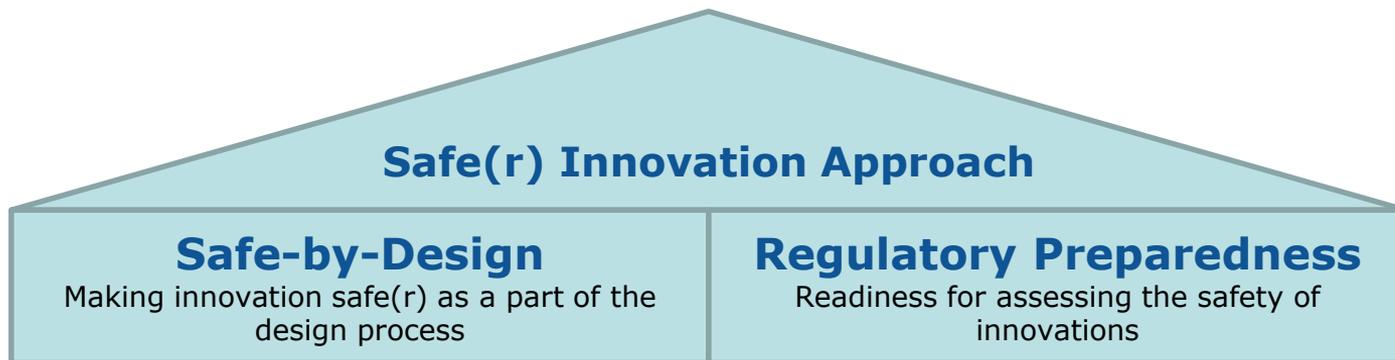
- to **improve the foresight** of regulators
- to facilitate the development of **adaptable (safety) legislation** that can keep up with the pace of knowledge generation and innovation



Why Regulatory Preparedness

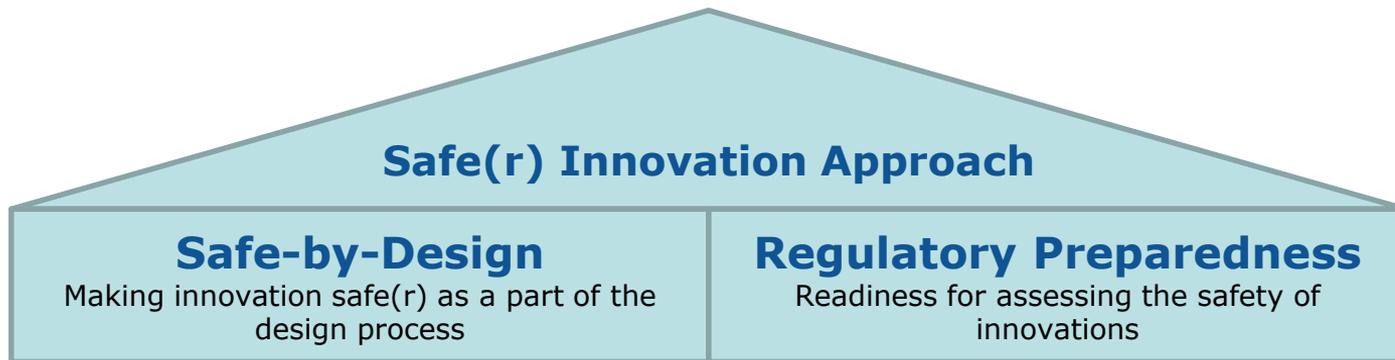
- To be able to keep up with the pace of technological change
- To ensure the human and environmental safety of innovative emerging technologies
- To reduce the regulatory uncertainty for innovative products

Safer Innovation



The Safe(r) Innovation Approach (SIA) aims at identifying and minimising the possible health and environmental risks of innovative materials, products, applications and processes in a timely manner in the course of the innovation process.

Safer Innovation



Concept

Inventory of tools



NanoReg2

Further development and testing

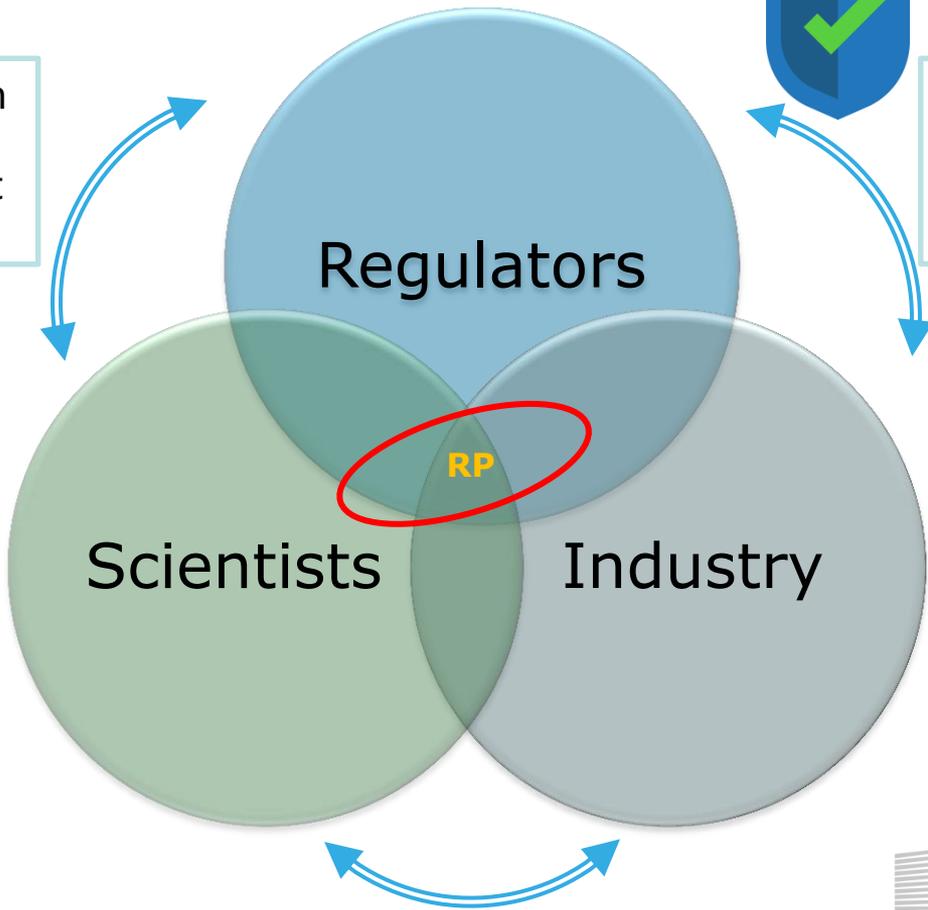
Towards a 'Safer Innovation Approach' for More Sustainable Nanomaterials and Nano-enabled Products: Overview of existing risk assessment tools and frameworks, and their applicability in industrial innovations



Main Actors

Knowledge acquisition
Translation Research
Methods development
Re-evaluation

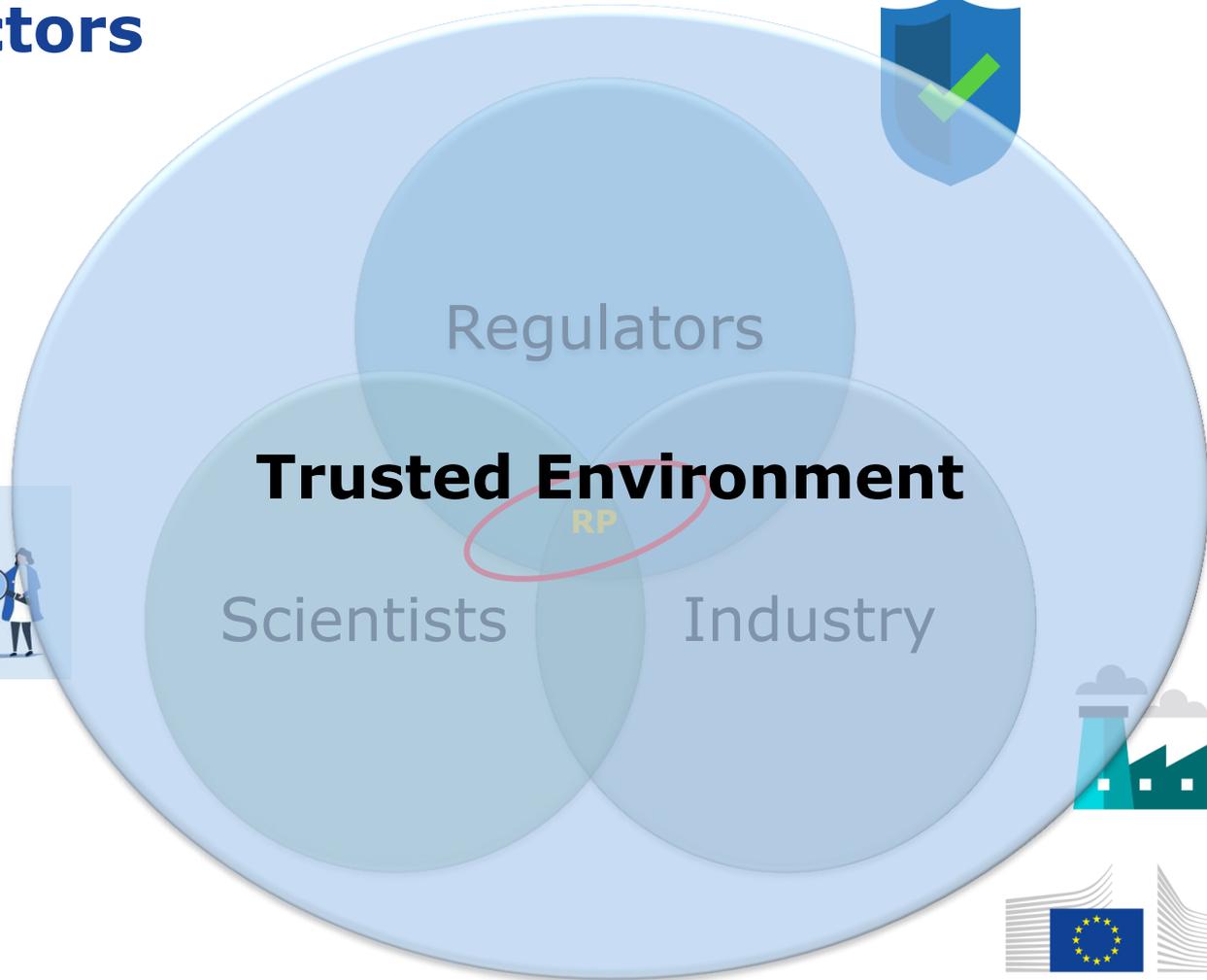
Information requirements
Guidance
Safety Assessment



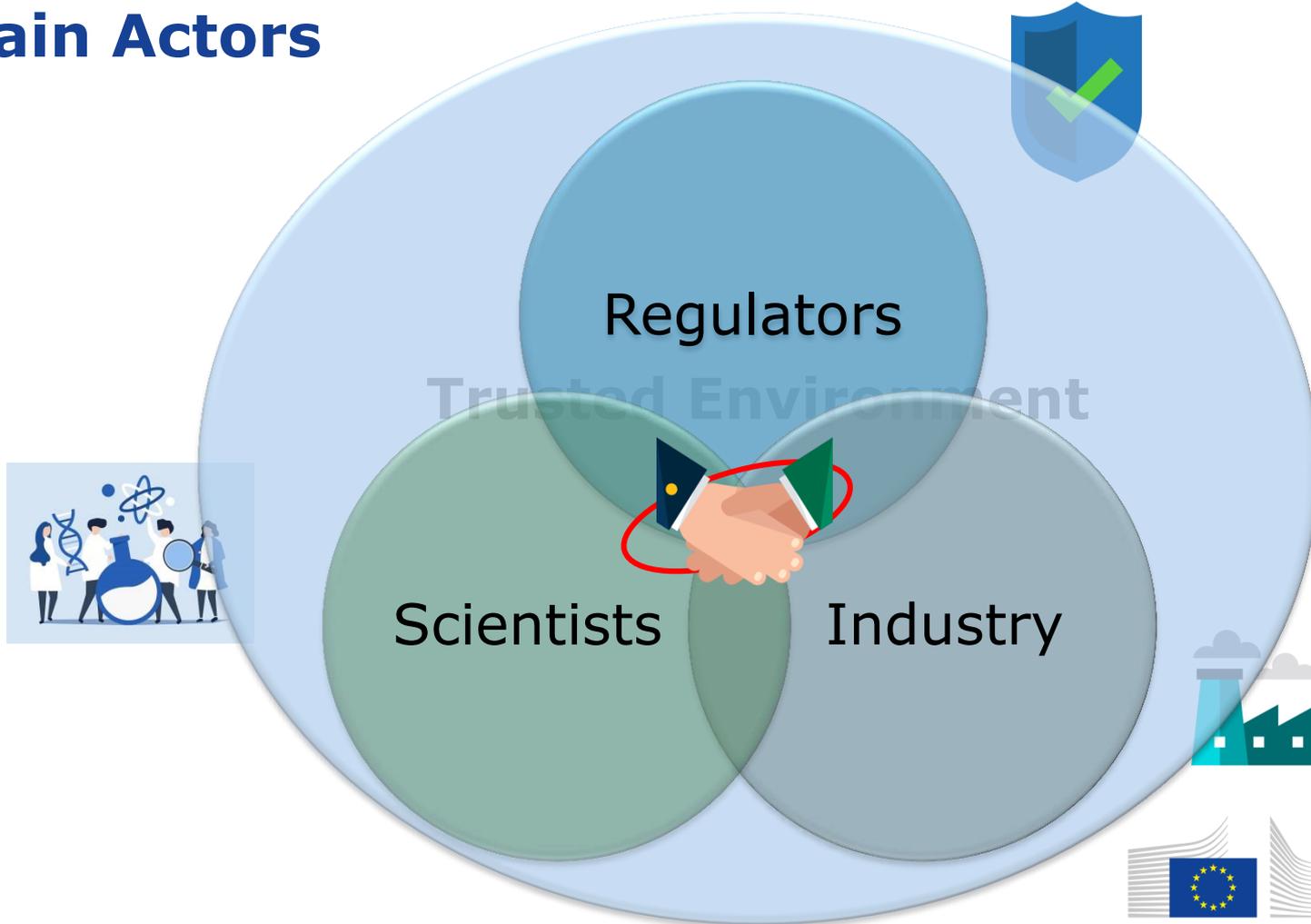
Translation Research
Scaling-up
Innovation
Patents
Data generation



Main Actors



Main Actors

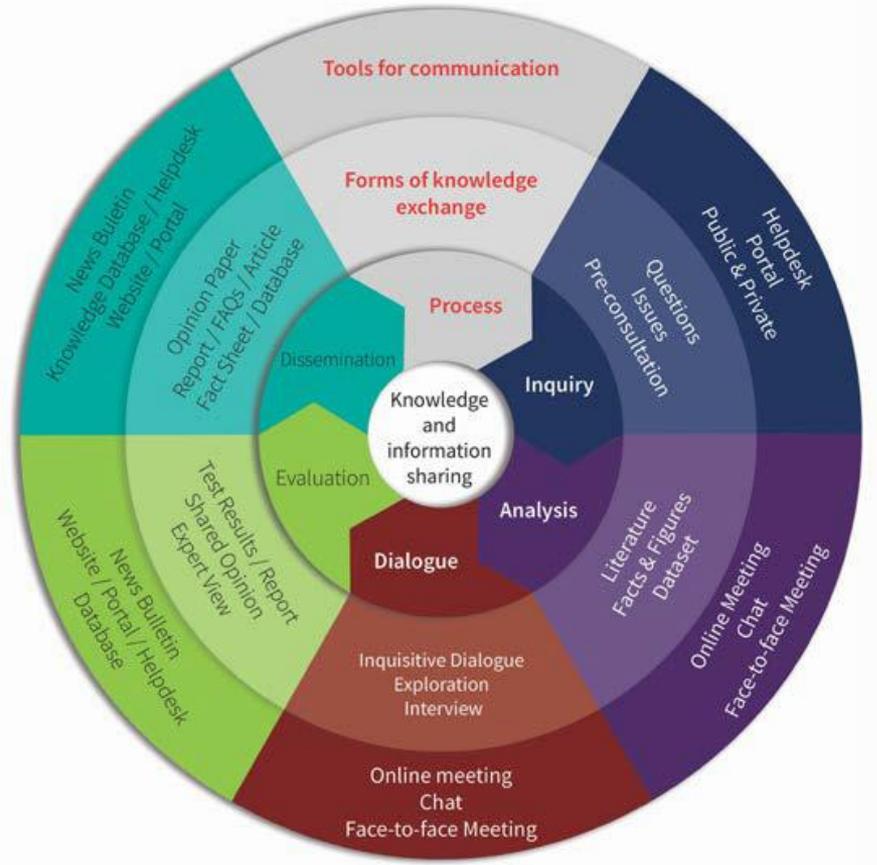


Trusted Environment

Physical or virtual environment

TE should stimulate **trust**, ensure **transparency** and **confidentiality**, and protect **intellectual property** and **organizational interests**

TE is seen as a Knowledge and Communication Platform



How to achieve Regulatory Preparedness?

Needs

- Access to information (open data, data exchange)
- Resources
- Tools for awareness
 - Horizon scanning
 - Trend watching
 - Funding research
- Registry of nano containing products
- Pre-market information requirements

Barriers

- Lack of trust in the dialog
- Lack of communication between main actors
- Lack of industrial declaration of MNM
- Lack of enforcement
- Rigid regulation
- Lack of methods

Actions

- Knowledge sharing platform (feed EUON)
- Founding small, more agile projects
- Overcoming methodological hurdles (in networks)
- Development of Methods and Guidance
- Soft regulation
- Hard regulation (revision)
- Early warning system (RAPEX)

Regulatory Preparedness Framework

A future proof
multifaceted

Vigilant, anticipatory, adaptive, and resilient RP system



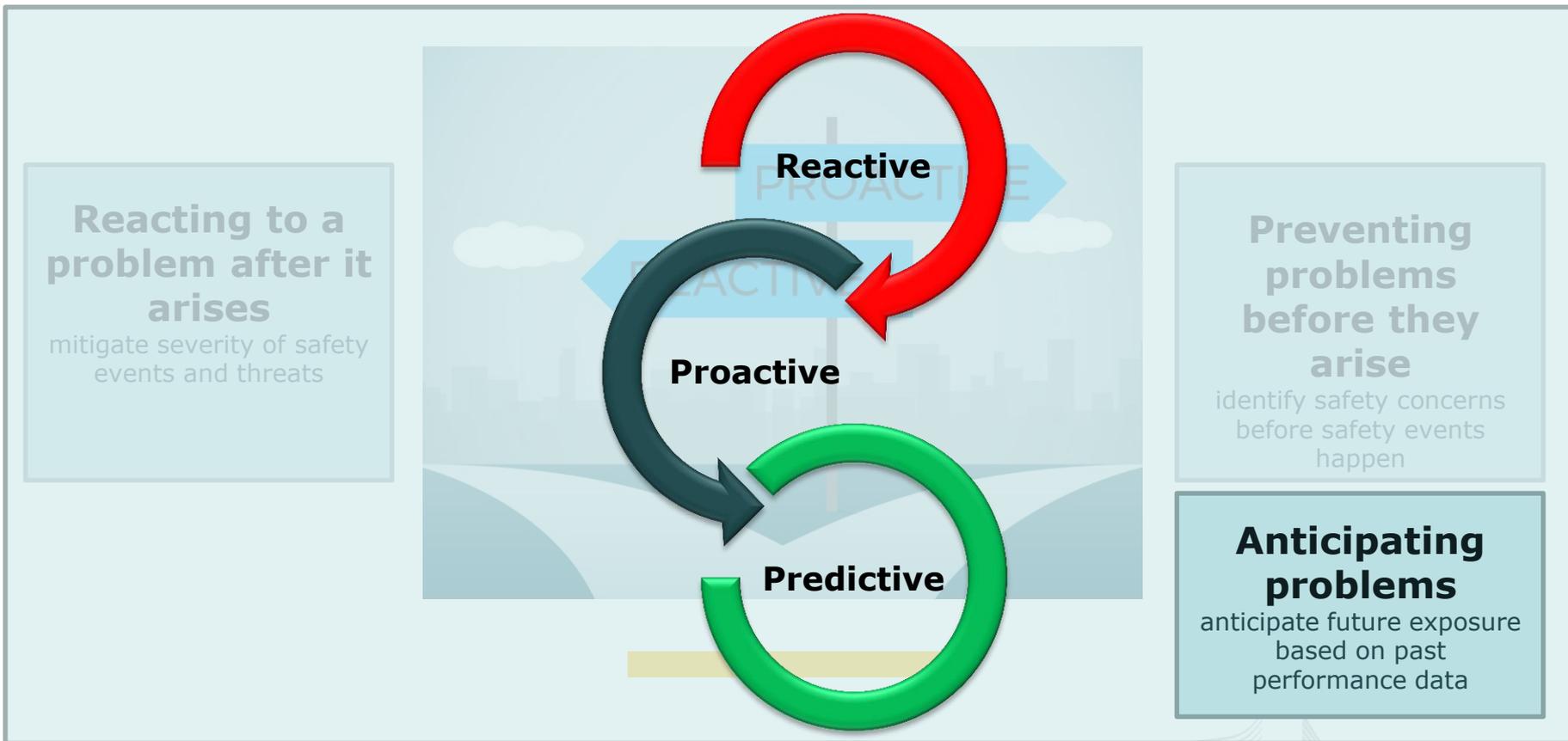
What it does:

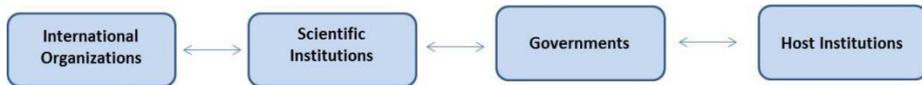
- Anticipates
- Interacts and engages

supports

- Implements

Regulators



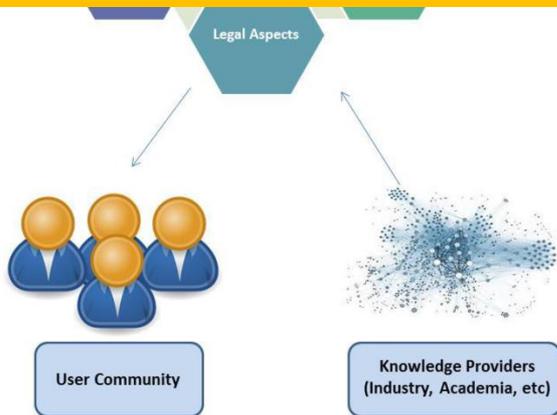


- Plan platform infrastructure
- Set legal and ethical frameworks
- Ensure long-term investment and support
- Set data and technical standards
- Provide data and service needs



Towards a system approach through a **Knowledge and Communication Platform**

Communication and Knowledge sharing are keys to success



OECD Coordination and support of international research data networks. *OECD Science, 21 Technology and Innovation OECD Policy Papers 51:1-46*

Nanomaterials in EU

EU only region in the world having provisions for **nanomaterials** and **nanotechnology** in its legislation

Specific provisions in:

- ✓ REACH
- ✓ Biocidal products
- ✓ Medical Devices
- ✓ Cosmetics
- ✓ Active and Intelligent Contact Materials
- ✓ Novel Foods
- ✓ Food Contact Materials
- ✓ Food Information to Consumers (impacts Food Additives)

Horizontal 'EC Recommendation on the definition of nanomaterial'

Towards Regulatory Preparedness. Examples

Knowledge and Communication Platforms: Trusted Environment

European Food Safety Authority's (EFSA) Emerging Risks Exchange Network (EREN)



Innovation Task Force (ITF) of the European Medicines Agency (EMA),

European Chemicals Agency (ECHA) Nanomaterial Expert Group (NMEG)



Towards Regulatory Preparedness. Examples

Knowledge Acquiring and Sharing

Knowledge for policy

Supporting policy with scientific evidence

We mobilise people and resources to create, curate and use knowledge to inform policy.

The JRC coordinates knowledge services (knowledge and competence centres) to process science-based evidence to inform policy-makers and to provide tools and services for all EU policy areas.

All Events News Organisations Projects & Activities Resources

Search

AI Watch

Knowledge Centre for

Competence Centre on

Towards Regulatory Preparedness. Examples

Foresight, monitoring and Horizon scanning

European Commission

RESEARCH & INNOVATION

EU Login

Research and Innovation Observatory – Horizon 2020 Policy Support Facility

European Commission > Research & Innovation > RIO - H2020 PSF

Country analysis ▾ Policy Support Facility ▾ Library Statistics ▾

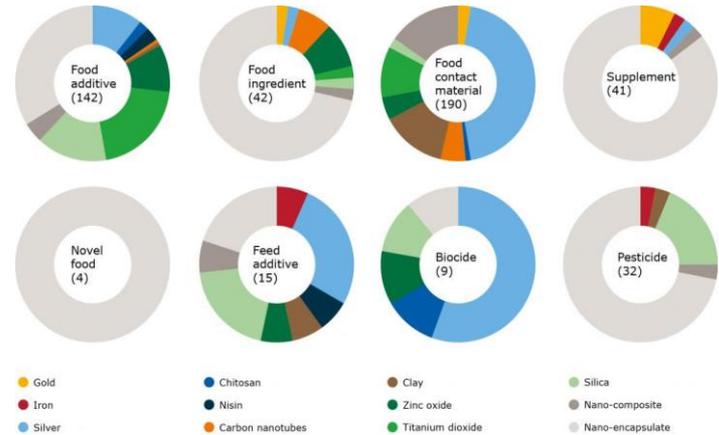
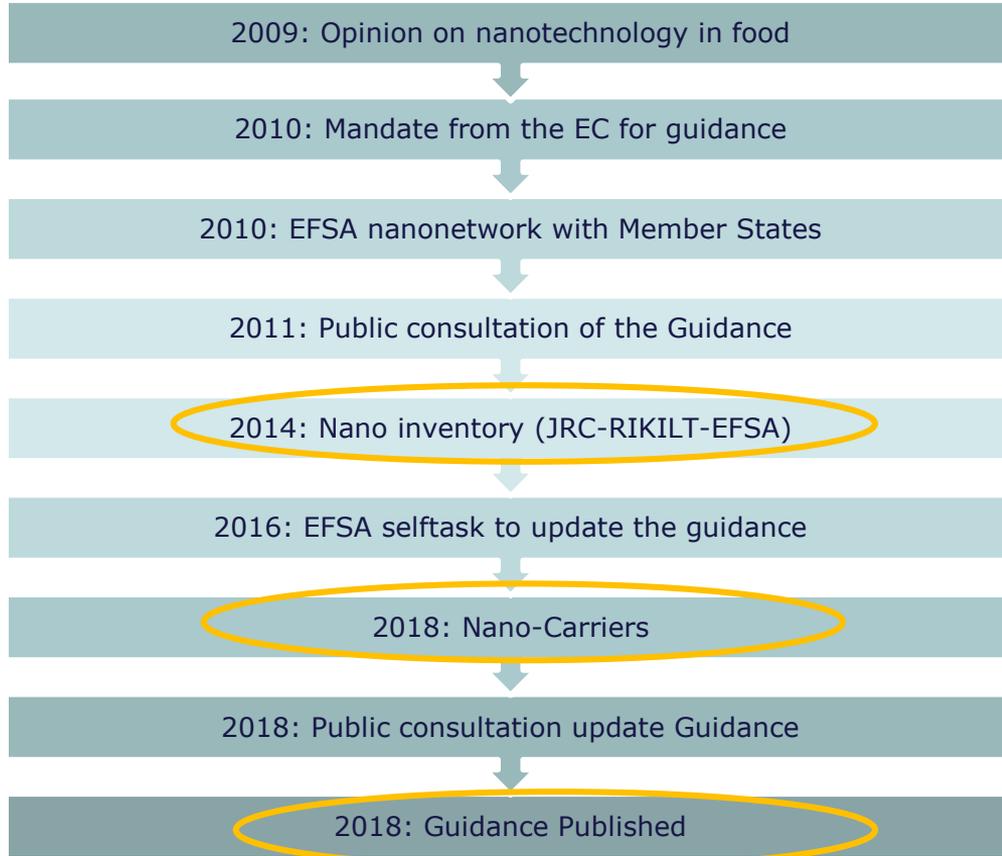
Thematic Analysis ▾ About ▾

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The RIO-PSF website is a reference and key source of information for European and national policy makers as well as other stakeholders in the field of R&I policy. It delivers analysis, insights, statistical data and best practices on designing, implementing and evaluating research and innovation policy at EU and national levels [More](#)

EFSA: example of being prepared



Summary

The goal is to make legislation and innovation dynamic, synchronised, and inclusive.

To achieve it we need Regulatory Preparedness

- Foresight
- Knowledge sharing and dialog
- Regulatory vigilance and resilience
- 'Holistic' or integrated innovation to include human, environmental safety and analytical elements from the start – Safe(r) by Design
- RP is a part of Risk Governance

Thanks!

Thanks to all contributors: JRC F.2, RIVM, TEMAS AG, INM-Leibniz and Public Impact (NL)



Any questions?

You can find me at Agnieszka.Mech@ec.europa.eu

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