

SCIENCE BASED POLICY MAKING

who does what?



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The JRC in the Commission



President José Manuel Barroso

27 Commission Members

... DG Environment

DG Climate Action

DG Agriculture and Rural Affairs

DG Mobility and Transport

DG Energy

Commissioner Geoghegan-Quinn
Research, Innovation and Science



Joint Research Centre (JRC)

DG Research and Innovation

JRC Director-General
Dominique Ristori



JRC's Mission and Role

... is to provide EU policies with independent, evidence-based scientific and technical support throughout the whole policy cycle.

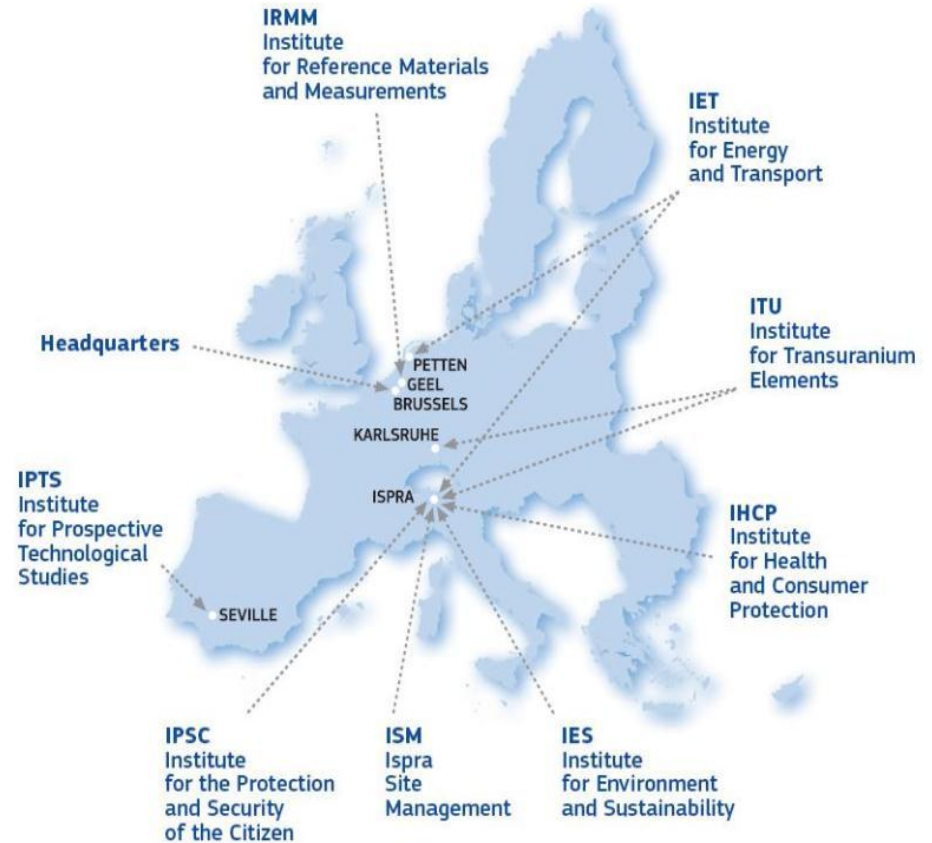
**Direct research:
JRC is the European Commission's in-house science service and the only DG executing direct research; providing science advice to EU policy.**



Serving society, stimulating innovation, supporting legislation

Quick facts:

- Established 1957
- 7 institutes in 5 countries
- 2,822 scientific and technical personnel
- Over 1400 scientific publications in 2012
- Budget: €356 million annually, plus €62 million earned income



JRC's structure

Key priorities

- Economic and Monetary Union (EMU)
- Internal market: growth, jobs and innovation
- Low-carbon economy and resource efficiency (environment, climate change, energy, transport)
- Agriculture and global food security
- Public health, safety and security
- Nuclear safety and security

Providing the needed scientific support to the Europe 2020 policy priorities.



Science-based policy?

Modern society presents us with an increasing demand to:

- understand uncertainty;
- estimate probability (if possible)
- ultimately, manage and reduce risks.

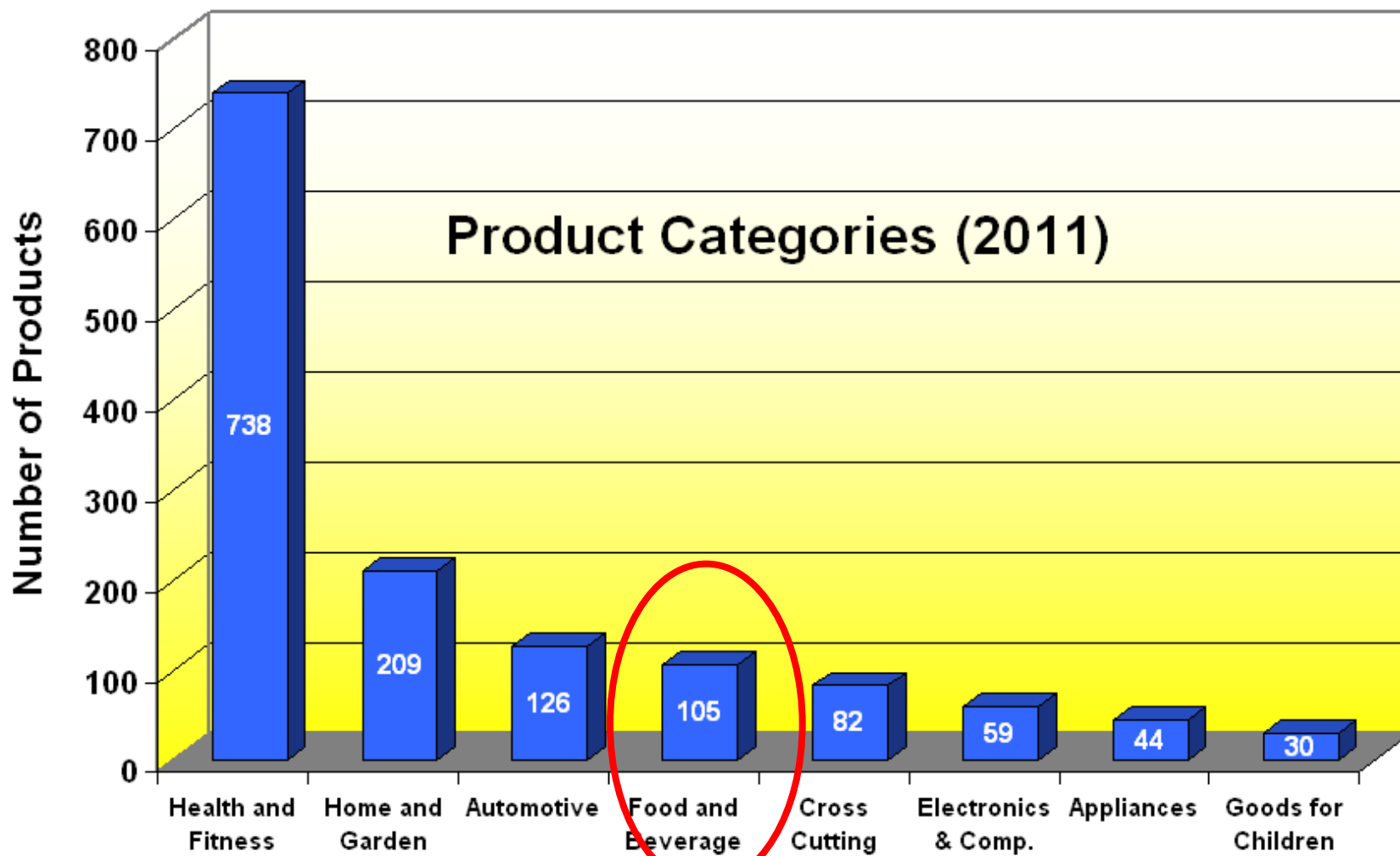
Which pushes us to ask ourselves:

- What information do we need/expect from science?
- What are the limits of science?
- What is its role in the face of uncertainty?

Example 1: Nanomaterials

Can we help fostering innovation?

NT Consumer products on the market

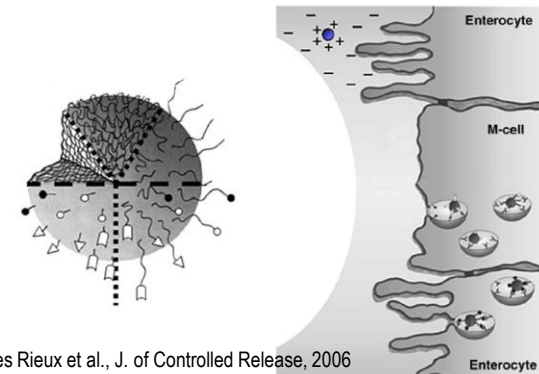
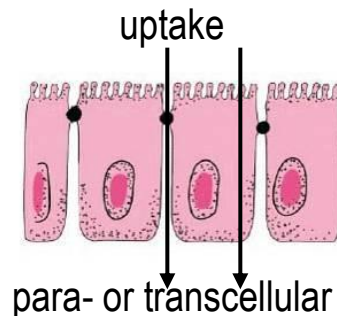
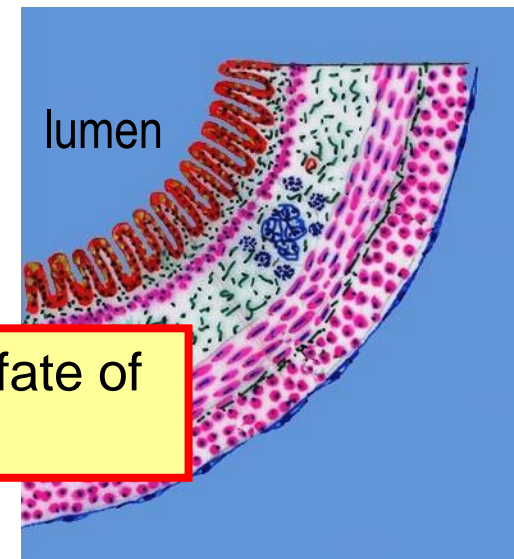


Fate of Nanomaterials in the GI-tract

- Transformation in the *lumen*
- Translocation through the *intestinal wall*
- Translocation to *target organs*
(liver, kidneys, lungs, spleen, ...)
- Biotransformation

Extremely limited data on biokinetics and fate of nanomaterials after oral exposure

intestine



Understanding the biological response

Nanomaterial properties

- Size and Shape
- State of Dispersion
- Physical and Chemical Properties
- Surface Area and Porosity
- Surface Properties



Effect

- Translocation from GI-tract to target organs
- Protein binding
- Cellular uptake
- Accumulation and retention
- Cell/tissue response



TOXICITY: Food Related Studies

- *Few* studies on oral administration
- Adequate *characterization* of nanomaterials *lacking*
- Only a *narrow range of effects* have been studied
- Reported oral toxicity studies *restricted to acute toxicity*
- *properties - toxicity* relationship not yet established
- Is current *toxicity testing adequate* to detect all aspects of potential toxicity?

**Solid hazard assessment helps ensuring that a new technology is safe
thereby facilitating new products reaching the market**

Example 2: Chemicals

**Could we use a paradigm shift
in toxicity assessment?**



Example 2: Chemicals

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a range of substan



Endocrine Disruptors

Protection Products

(c.2013) present a
specific scientific
endocrine disrupting

al Products

, the Commission shall
for the determination of

Example 2: Chemicals



EUROPEAN COMMISSION

Opinion the Scientific Committees in relation to knowledge gaps

For many chemicals, there is no good information on mode of action. Currently there is neither an agreed inventory of modes of action, nor a defined set of criteria on how to characterise or predict a mode of action for data-poor chemicals or how to group chemicals into assessment groups. Interactions²¹ of chemicals in mixtures are difficult to foresee, particularly for long-term effects. Research is needed to define criteria that predict potentiation or synergy.

Chemical mixtures

Toxicity and Assessment of Chemical Mixtures. Joint Opinion of the Scientific Committees (SCHER, SCENHIR and SCCS) adopted on 14th December 2011.

Example 2: Chemicals



EUROPEAN
COMMISSION

Brussels, 11.3.2013
COM(2013) 135 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

**on the animal testing and marketing ban and on the state of play in relation to
alternative methods in the field of cosmetics**

http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/animal_testing/com_at_2013_en.pdf

Example 2: Chemicals



Information Spectrum

knowledge

observation



information

paradigm
shift

information

Safety
Assessment
Paradigm

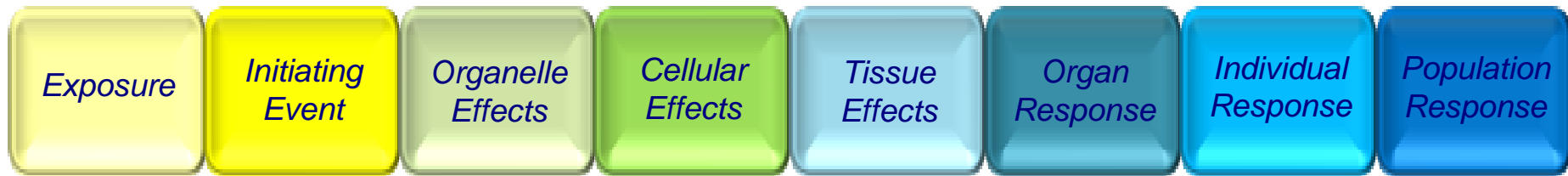
Observation
driven

Knowledge
driven

- Detect apical effects
- Measure to decide
- Data hungry
- Understand disease process
- Predict to decide
- Data efficient

Reductionism at the process level

- Understanding toxicological *mode of action*



- to rationally design *integrated prediction systems*
- fit for the purpose of *supporting safety decisions*

... facilitating a shift towards a knowledge-driven paradigm for chemical risk assessment

Example 2: Chemicals



Pragmatic fit for purpose – we could use a tool which ensures safety rather than giving us each detail



Example 3: GMOs

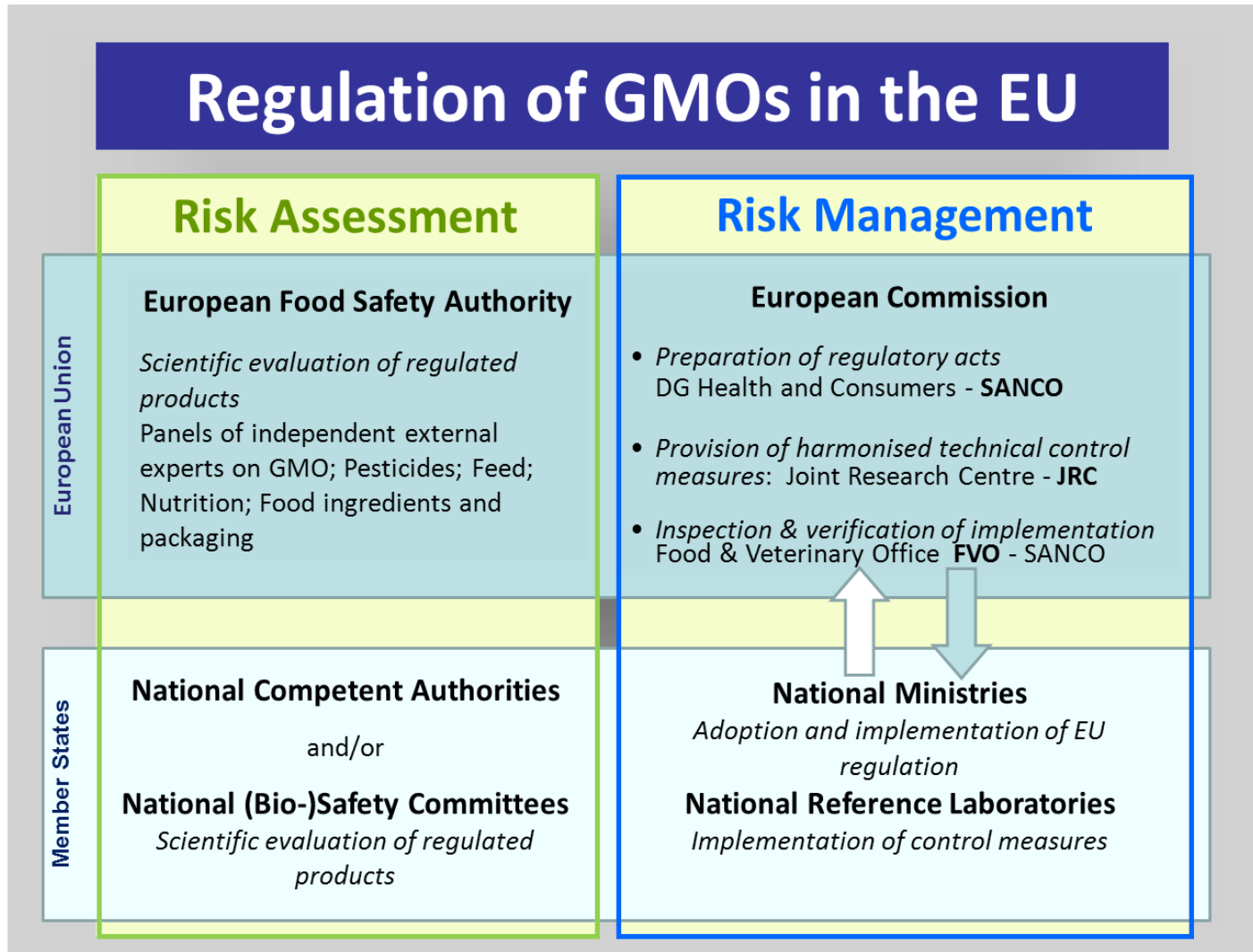
Who does what?



EU Legislation on GMOs – some key texts ...

- **Reg.(EC) No 1829/2003 on GM food & feed**
 - Mandatory approval and labelling of GM Food / Feed at more than 0.9% unavoidable contamination
 - requires standardised and reliable quantitative methods
 - **Principle: no method - no authorisation – no market access**
- **Reg. (EC) No 882/2004 on official compliance controls**
 - Lists EU-RLs for Food & Feed, and animal Health
 - Describes their tasks and the requirements they must meet
 - **Principle: establish level playing field**
- **Reg. (EU) No 619/2011 (Low Level Presence (LLP) of GMO)**
 - LLP of GMOs, elsewhere approved, may be tolerated in feed, pending the EU-approval, at "contamination" of up to 0.1%
 - **Principle: Take account of different approval processes**

Example 3: GMOs





Analysis: EU authorisation voting



10 countries vote against the EFSA scientific opinion more than 63% of the time.

Risk management is not the same as perception management...

...i.e. science is not the only element influencing risk-related decisions

Source: "Approvals of GMOs in the European Union". Report available from EuropaBio.



A strategic consideration

- **Every GMO policy needs reliable controls**
- The JRC provides validated, harmonised, state-of-the-art methods for GMO-analysis
 - New GMOs need new analytical methods
 - ✓ the JRC works on those and their validation
 - Economics and number of GMOs require efficiency
 - ✓ the JRC works on higher throughput methods
 - Internal (and global) market requires harmonised controls
 - ✓ the JRC offers proficiency testing, training and guidance
 - ✓ the JRC supports networking on GMO analysis

Conclusions:

- Rational policy making (increasingly) requires sound science advice, which is however only one of several factors in policy making
- Providing sound science advice can be costly and time-consuming, yet it is a fundamental base for informed, rational consideration of the options.
- Once the (political) decision is taken, science still has a task to provide instruments for implementation of risk management decisions.



*Serving society
Stimulating innovation
Supporting legislation*

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