

REACH:

Not a grab bag for scientists

KNCV / NVT / RIVM Symposium

“Does Science REACH policy?”

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Role of scientific information 1/4

➤ **Period before REACH proposal**

- ❑ Basis is experiences in the implementation of current EU chemicals legislation
 - Role of technical meetings
 - Agreed methodologies and formats (TGDs, EUSES)
 - MSs experts from competent authorities (CAs) and associated institutes
- ❑ Input MSs and Industry experts in 7 working groups
 - Testing, Registration, Evaluation
 - Risk Assessment
 - Very high concern substances
 - Classification & Labelling and industry inventory list
 - Risk management and authorization
 - Substances in articles
 - Information through supply chain

Role of scientific information 2/4

➤ **Preparation of REACH proposal**

- ❑ Closed EU inter service work; no involvement of external experts
- ❑ Draft REACH proposal: internet consultation
 - o Input received from stakeholders (over 7000 responses) including scientific institutes, individual experts, MSCAs
 - o Creating social support; Impact predominantly socio-economic consequences

Role of scientific information 3/4

➤ **Co-decision procedure:**

Negotiation process in Council

- o Ad-hoc consultation of MSCA experts by MS representatives
- o Draft council position regarding Annexes prepared by MSCA experts (under NL and LU Presidencies)

Negotiation process in European Parliament

- o Hearings of a.o. external experts
- o Lobbying, predominantly active groups (industry groups and NGOs: impact unpredictable)

➤ **Development of technical guidance (RIP projects)**

National experts involved

Role of scientific information 4/4

➤ **Implementation of REACH (in future)**

- ❑ Preparation of technical guidance, tools, methodologies
 - REACH implementation projects (RIP projects)
 - National experts, industry experts, etc. involved
- ❑ Implementation Agency's activities
 - Scientific opinions (SEAC'tee, RAC'tee)
 - Independent national experts
 - Policy opinions/decisions (MSC'tee)
 - Representatives of national CA's

Expertise behind the scene

➤ **REACH is based on scientific experiences gathered:**

- in evaluating notifications of new substances
- in drafting risk assessments of existing substances

➤ **Results implemented in REACH**

- Allowing evaluation based on standardised set of data
- Standardised evaluation procedures (TGD)
- Standardised evaluation tools (EASE, EUSES)
- Testing strategies
- Standardised exposure / emission scenarios
- Prerequisites for read-across / grouping
- Logic framework from collection of data, evaluation to conclusions

Summary

- **Involvement of scientific experts successful in developing harmonised basic thinking**
- **Role of scientists in preparing REACH limited to the technical Annexes and technical guidance**
- **Dominant role of scientists in implementation of REACH (preparing opinions on dossiers/substances)**
- **Scientific experts predominantly working in MSCAs (=National agencies)**

Why harmonisation /standardisation needed

Right of industry to expect legal security

So, legal conditions are needed:

- Guaranteed consistency in decision-making process
- Transparency in process and conclusions
- Controlled contribution of many evaluators
- Proportionality in decisions

Decisions

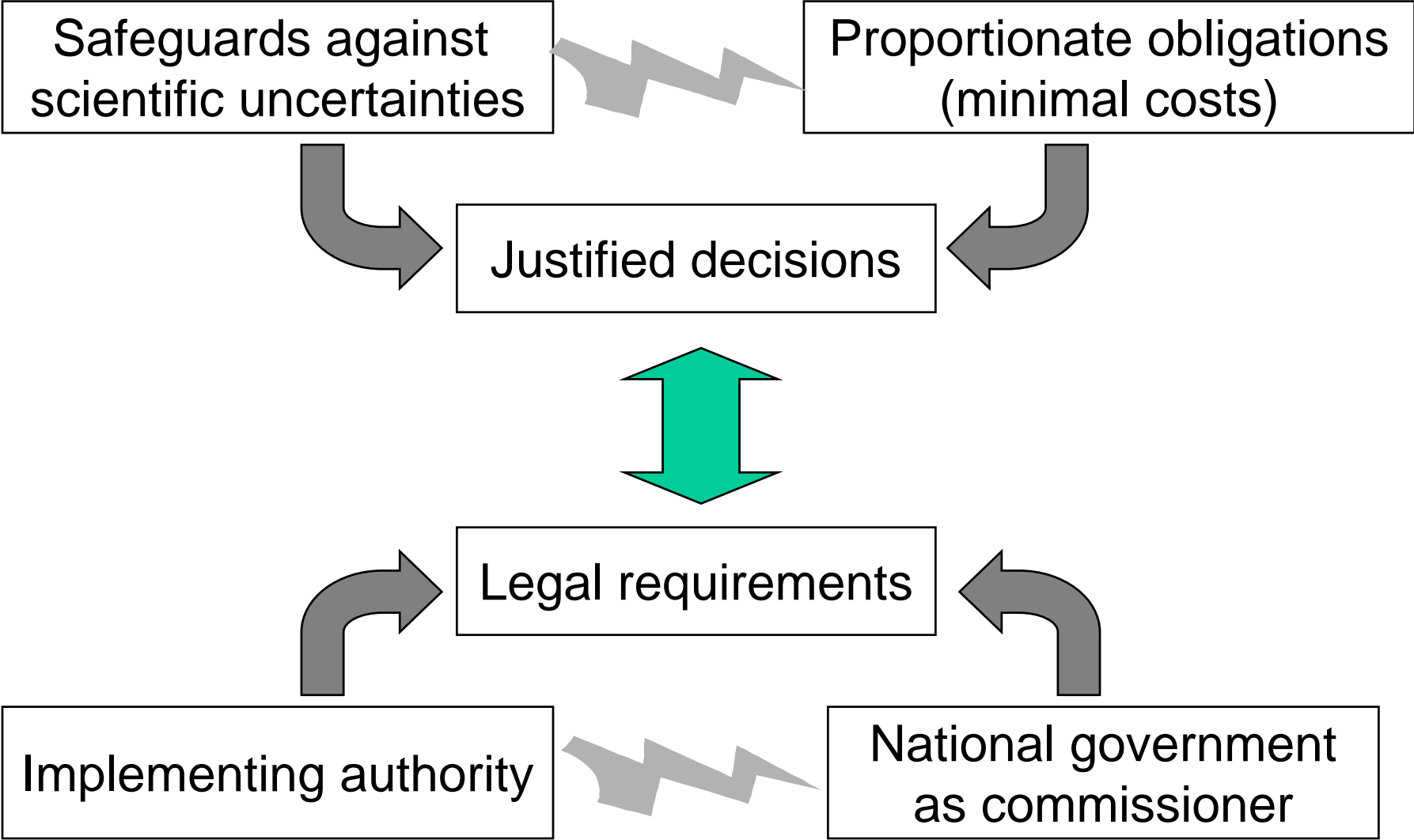
➤ **Decision-making process**

- Is a political laden process making use of scientific information
- is not a process fulfilling scientific preconditions
- makes use of scientific based motivation
- needs output, even with limited information
- Information need is determined by the subject

➤ **Characterisation of decision-making process**

- Tension between pragmatism / realism and scientific justification
- Tension between political interest and scientific independency
- Tension between legal requirements and flexibility

Tensions



Examples of tension

- **Scientific uncertainties may cause requests for additional information**
 - ❑ But where requests ends?

- **Precautionary principle may cause worst case approach to eliminate uncertainties**
 - ❑ But where precautionary starts?

My opinion on scientist's attitude

- **Be aware of the legal playing field:**
 - ❑ Feasible burden of proof to industry
 - ❑ Respect for opponent's view, even when more liberal (plausibility of arguments)

- **Use and improve assessment methods based on defined realistic data package**

- **Act with controlled “scientific curiosity”**
 - ❑ Scientists should be aware of interests of opponent
 - ❑ Explore other routes for getting missing data before requiring data
 - ❑ Consider urgency of information in relation to results of assessment
 - ❑ Be pragmatic (balanced approach based on level of concern)
 - ❑ Be flexible in applying legal requirements

Rule of thumb

Do you sleep well when not having that information?

Yes? don't ask!