



**TTIP: Regulatory Cooperation  
Mission (im)possible?**

**EP, INTA Hearing**

# Key Messages on Horizontal Regulatory Cooperation

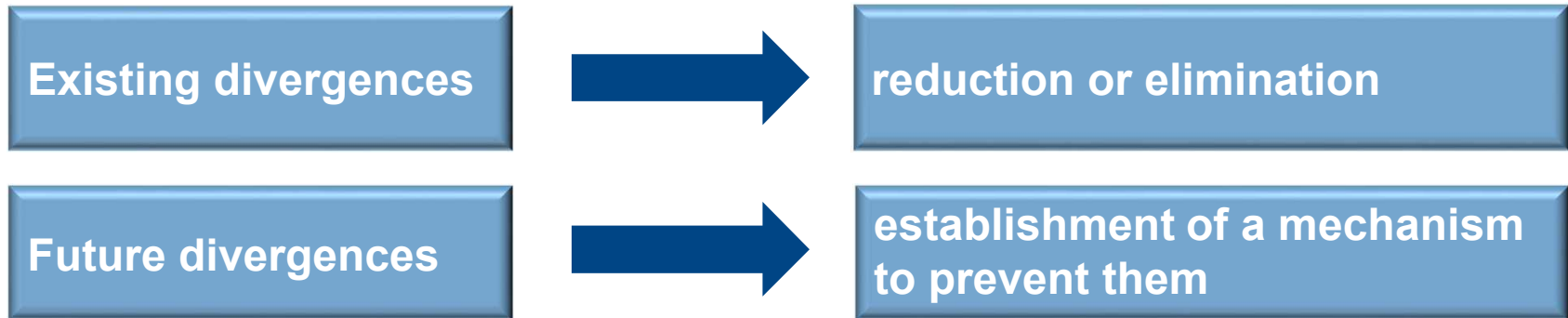
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- **Why** we need regulatory cooperation
  - (the transatlantic regulatory divide has increased over the last 20 years: duplicative testing, different conformity procedures, different standards and regulations)
- **How:**
  - Respecting **regulatory autonomy** (sovereignty)
  - **Obligation to cooperate** – not to achieve a result
  - Race to the bottom?
- **What:** scope



# Objectives

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Overcome „behind-the-border-barriers“ through:

- Avoidance of duplicative requirements
- Process to achieve:
  - Convergence
  - Mutual recognition (only possible if regulation is comparable in effectiveness)
  - Harmonisation



# Regulatory principles

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- Transparency
- Effectiveness and effectivity (impact assessment, cost-benefit analysis)
- Analysis of relevant alternatives
- Mimimize burdens and aim for simplicity
- Administrative and/or judicial review



# Good regulatory practice

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- **Mandatory consultation process:**
  - Timely announcement of draft regulation to counterpart
  - Solicit comments by counterpart
  - Address comments made by counterpart
- Identifying and sharing **common regulatory objectives**
- **Analysis of data:** comparing assumptions and methodologies
- Meaningful consultation of stakeholders





# Sectoral Regulatory Cooperation: The Case of Chemicals

## 1st Pillar:

### Existing regulation

Application of GHS  
(Classification and labelling of chemicals)

Sectoral proposals to exchange data between agencies

Prioritisation of chemicals for assessment

Avoidance of duplication through mutual recognition (GMP inspections)

## 2nd Pillar:

### The transatlantic divide

REACH versus TSCA

Mutual recognition not possible because laws are too divergent

## 3rd Pillar:

### Future regulation

Horizontal procedural mechanism

Early consultation and transatlantic impact assessment

Obligation to cooperate, no obligation to result (example: definition of nanotechnology)

Aim: achieve convergence while not lowering high standards



# Mission possible!

