



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

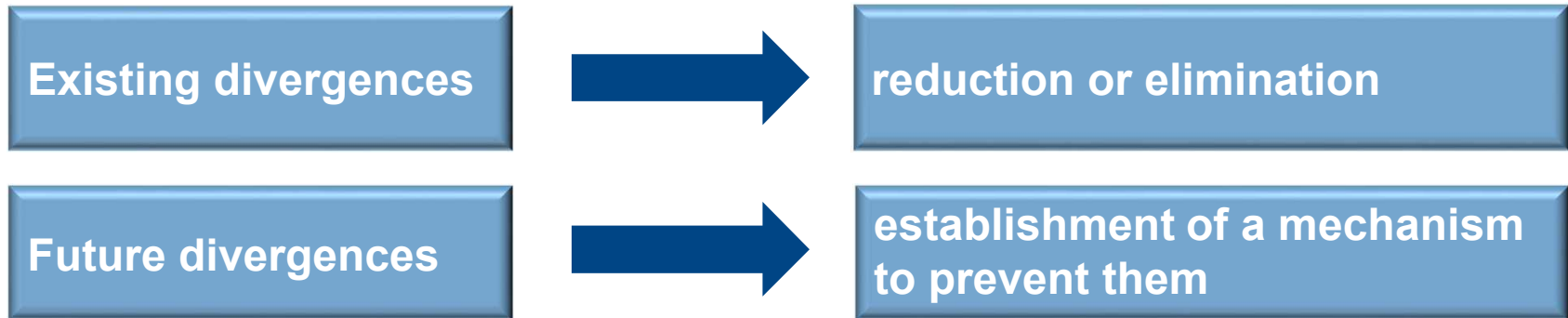
EP, INTA Hearing

Key Messages on Horizontal Regulatory Cooperation

- **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



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

- 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

- **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!

