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**The role of smart and better regulation:  
Lessons from the Member States and beyond**  
*European Risk summit , 11-12 June 2013, Dublin Ireland*



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- Tukes in a nutshell
- Smart regulation: General aspects
- FI examples of Smart Regulation  
from enforcement points of view





## OUR MISSION



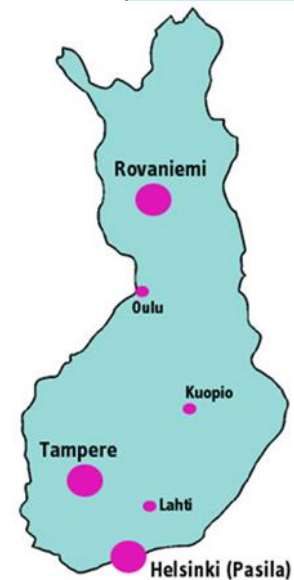
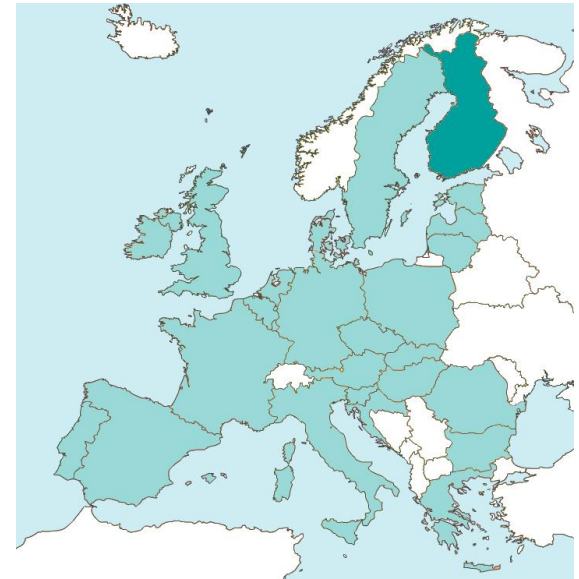
- We supervise products, services and production systems in our branches, and enforce the relevant legislation.

# WHAT IS TUKES?

- **National surveillance authority**
- **Multi-sector authority:** Tukes operates subject to the Ministry of Employment and the Economy and has 5 other steering ministries in their respective branches. Tukes oversees dozens of regulatory sectors.

=> "One-stop shopping" service idea

- **Roles:**
  - Surveillance
  - Communications
  - R & D
- **Staff 230**



# TUKES OPERATION CHART

<div>Customers</div> <div>Tukes</div>	PRODUCT MARKETS	SERVICE MARKETS	IN-SERVICE OPERATIONS
<b>PRODUCTS</b>	Electrical equipment and electronics Pressure equipment , chemical tanks and transportation Containers for dangerous goods Rescue service equipment, Construction products Articles of precious metals, Measuring instruments Fireworks and explosives, Gas appliances Chemicals, biocides, plant protection products Consumer products		
<b>INSTALLATIONS AND SERVICES</b>	Electrical equipment and lifts Rescue service installations Pressure equipment and pressurised systems Gas, oil and refrigeration installations Inspection, testing and installation services Consumer services		
<b>INDUSTRIAL PLANTS</b>	Pressurised systems Chemical plants and explosives factories Storages for chemicals and explosives Mining, gold panning and ore prospecting		

## Smart Regulation – General aspects



## WHAT IS SMART REGULATION?

- **No exact/standardized definition of SR**

Process approach: *Maximization of useful regulatory output/regulatory input ("Regulatory coefficient of performance")*

- **EU aspects** (*CION Communication on Smart Regulation 2010 et.al.*)

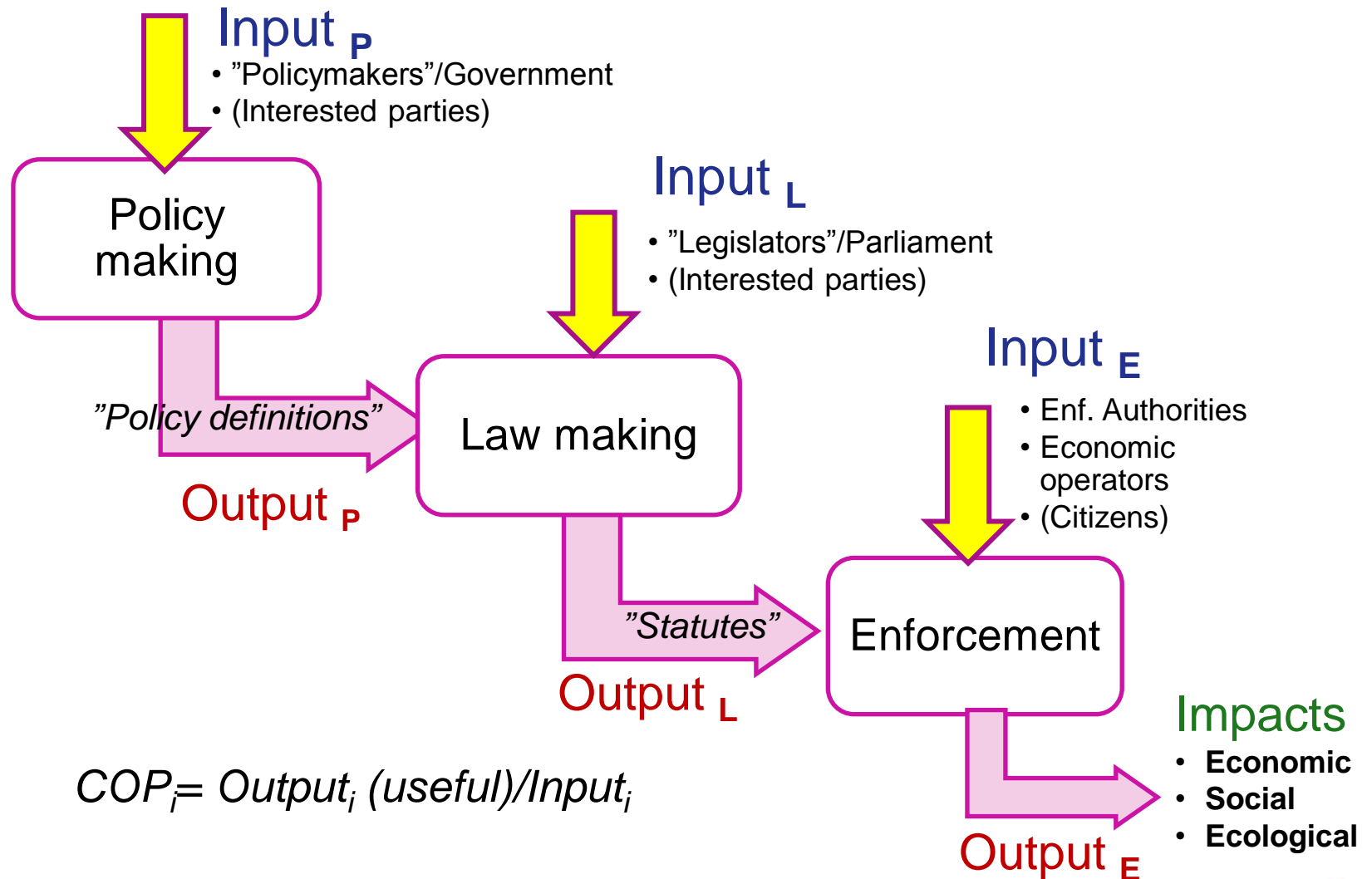
- smart EU regulation will support growth, maximise social and environmental benefits, while reducing burdens and costs.
- "limit the regulatory burden to what is strictly necessary"
- "quality throughout the policy cycle: from design and law making to implementation, enforcement, evaluation and revision
- "efficiency and effectiveness of legislation"

- **National/Member State aspects**

- "...both Community level and national level issue..."
- No difference in basic principles and practices
- Few statutes or enforcement practices that 'favour' the SMEs!



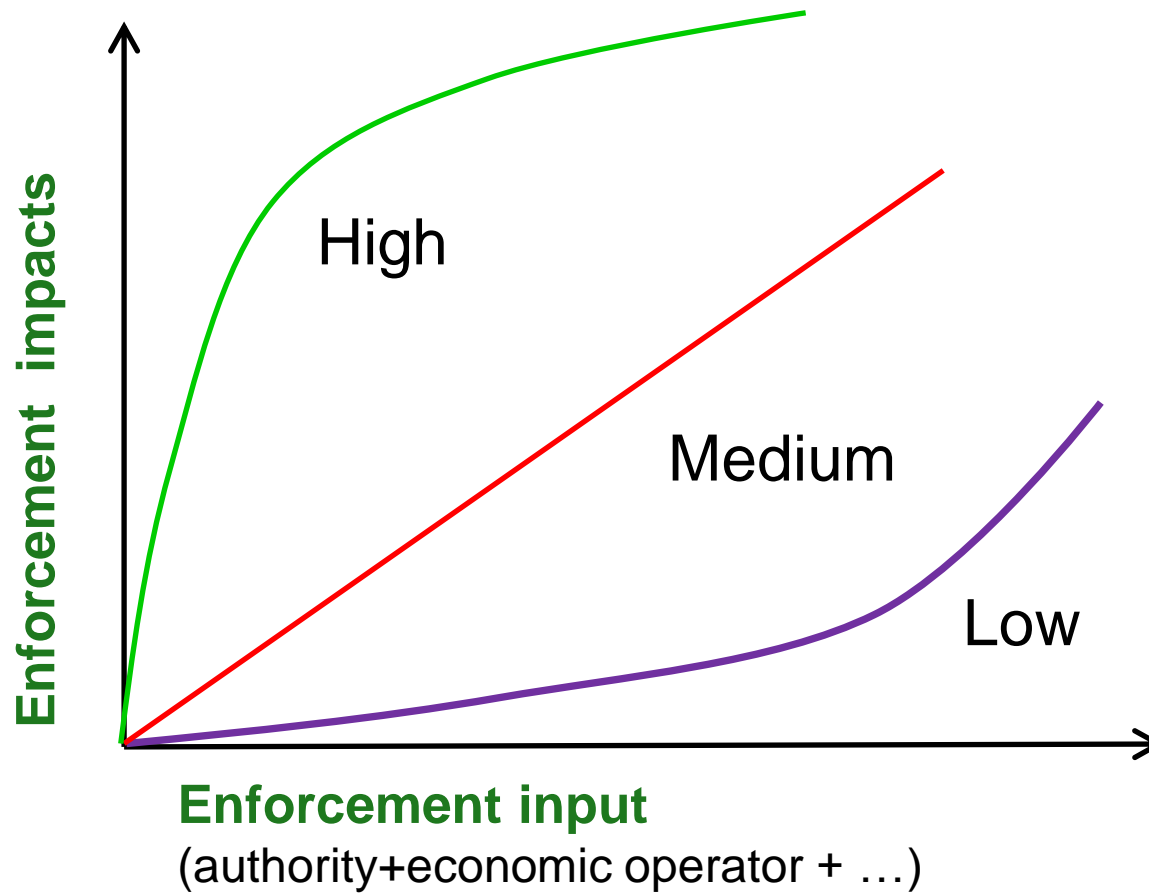
## Regulatory process - "from policy to practice"



## SMART REGULATION ASPECTS AT ENFORCEMENT STAGE

- Enforcement (incl. Implementation, supervision/surveillance) stage is critical as for gaining the targeted effects of regulation.
- Enforcement input should maximize the useful enforcement effects
- Identifying the link between enforcement output and societal impacts is important => a need for relevant impact indicators
- Enforcement input is a sum of authority enforcement, 'self-enforcement' by economic operators. The citizens/end customers have a role to play, too.
- Keys for high COP<sub>E</sub> and high effectiveness:
  - => an active 'self-enforcement'
  - ⇒ Risk based authority input (supervision, information/advice, R&D)
  - ⇒ Co-regulation/standardization

# Enforcement performance (schematic)

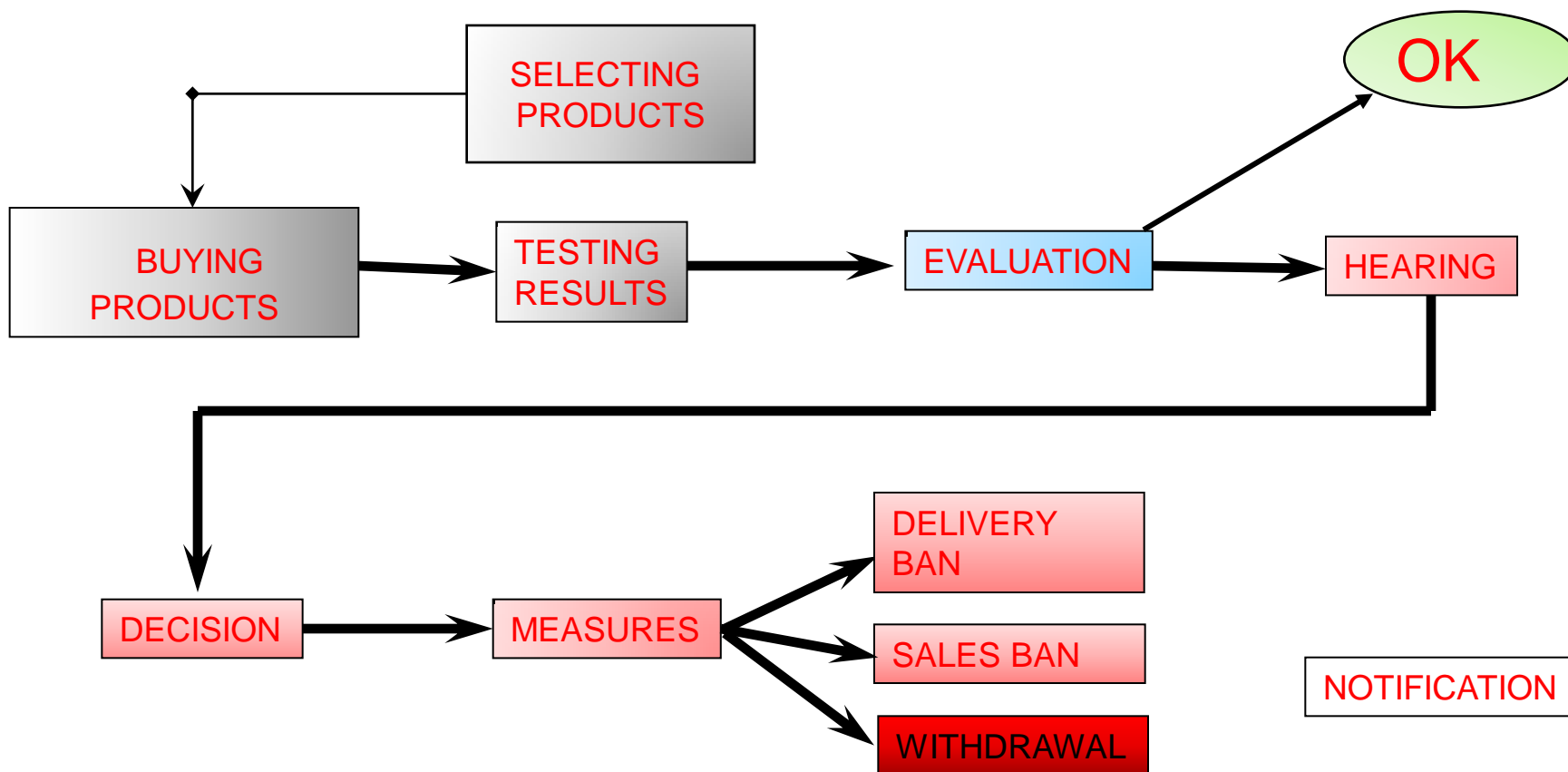


## FI examples of Smart Regulation from enforcement point of view

- Risk based market surveillance
- Risk based plant surveillance
- Impact indicators (safety&reliability)

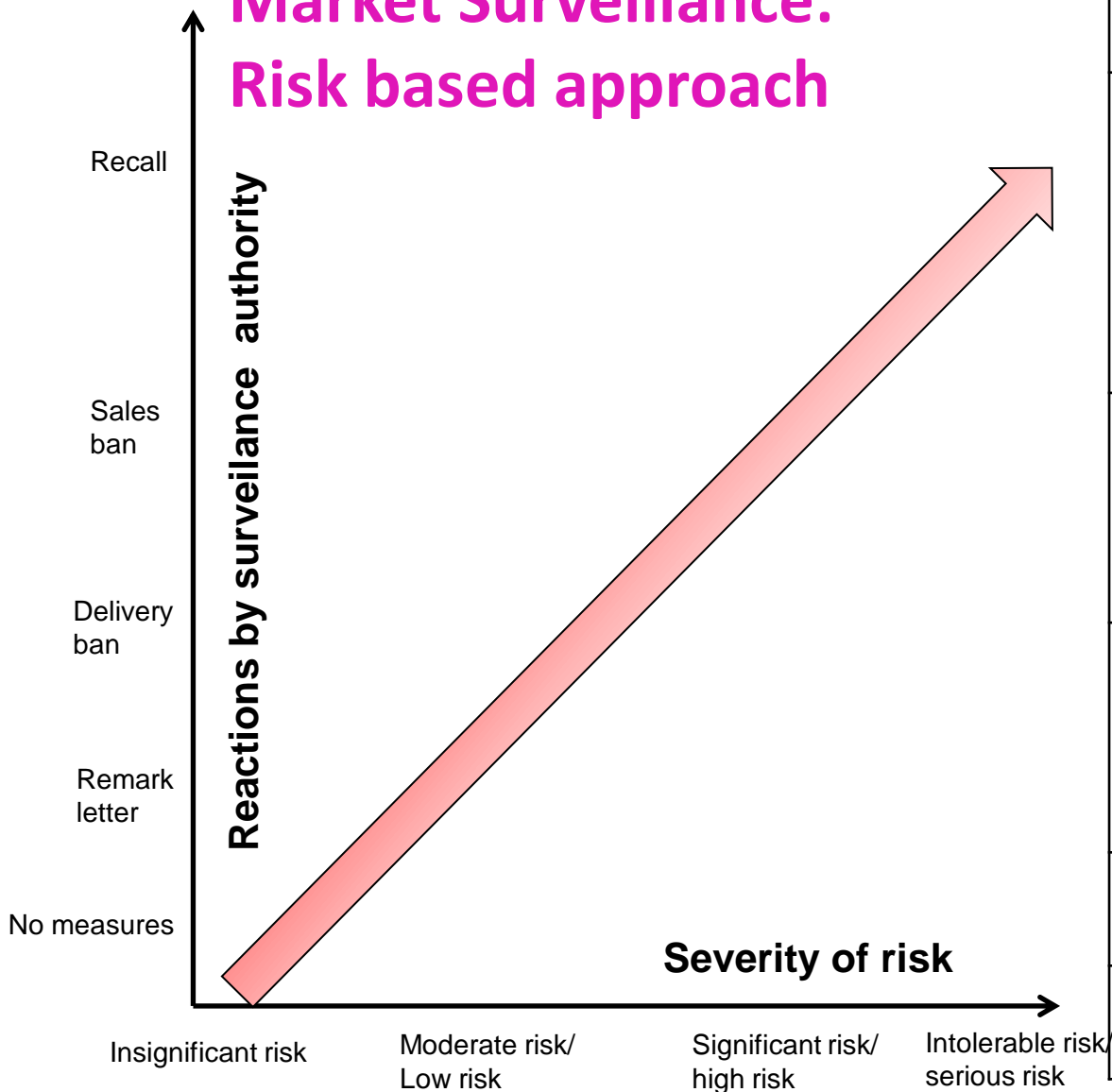


# Market surveillance procedure





# Market Surveillance: Risk based approach



Severity of risk/Deficiencies in conformity	Measures/reactions
Intolerable risk/ Immediate danger (serious risk)	To manufacturer/importer /distributor  1) Asking for clarification 2) Hearing 3) Decision Recall from the consumers or sales ban The selling of the product stopped immediately
Significant risk/deficiency which endangers the safety (high risk)	To manufacturer/importer /distributor 1) Asking for clarification 2) Hearing 3) Decision Recall from the consumers or sales ban
Moderate risk/deficiency which might endanger the safety	To manufacturer/importer /distributor 1) Asking for clarification 2) Hearing 3) Decision Recall from the consumers or sales ban or delivery ban
Minor risk/minor non compliance (low risk)	To manufacturer/importer /distributor a remark letter
Insignificant risk/ Compliance with the standard	No measures

# Supervision of the industrial handling and the storage of dangerous chemicals

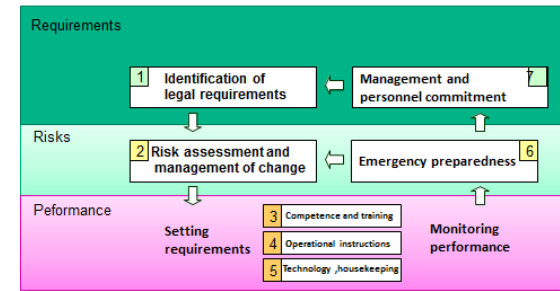
- The aim is to ensure that licensee takes precautions in advance to in order to prevent explosions, fires, releases of chemicals, operational errors, equipment failures or any other hazardous chemical related accidents, and to limit their effects and consequences
- The supervision based on EU [Seveso II](#) Directive (96/82/EC) and Finnish requirements concerning safe handling of hazardous chemicals

# Tukes's inspection model

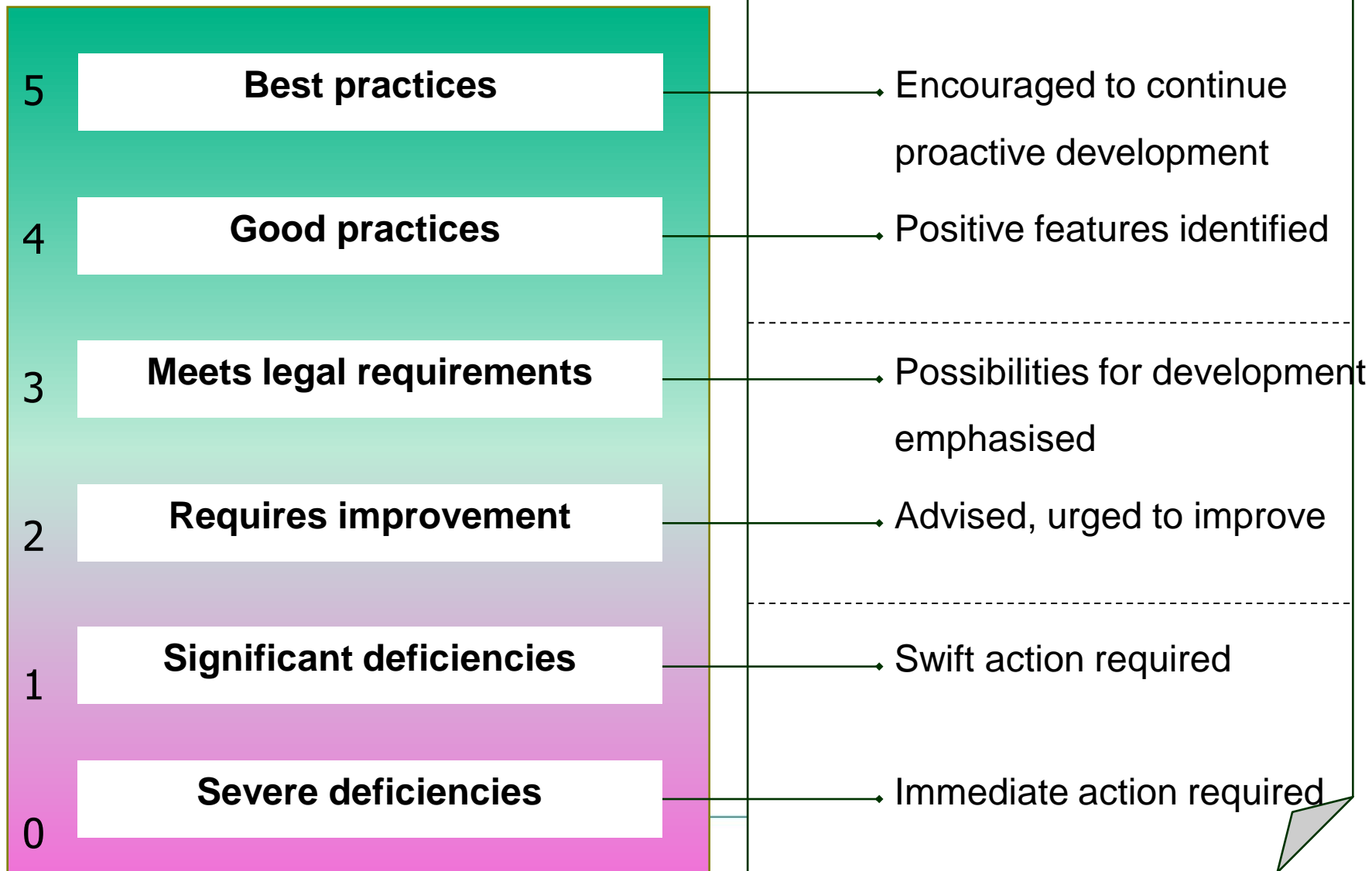
- 1) Awareness of regulatory requirements
- 2) Management and personnel commitment
- 3) Risk assessment and decision-making
- 4) Technical implementation and functionality
- 5) Instructions for and assessment of operations
- 6) Competence and training
- 7) Managing emergencies and deviations

Grades: 0 (severe deficiencies) – 5 (best practices)

-> total grade



# Inspection findings are classified to measure functionality of safety management system



# The inspection model has been used in a comparative study between some EU countries

(Kotisalo et al., 2010)

- Tukes carried out a comparative study within the EU
- Is the level of process safety in Finnish industry average in comparison with EU countries in general?
- Is the level of process safety within the same company better in some other EU countries than in Finland?





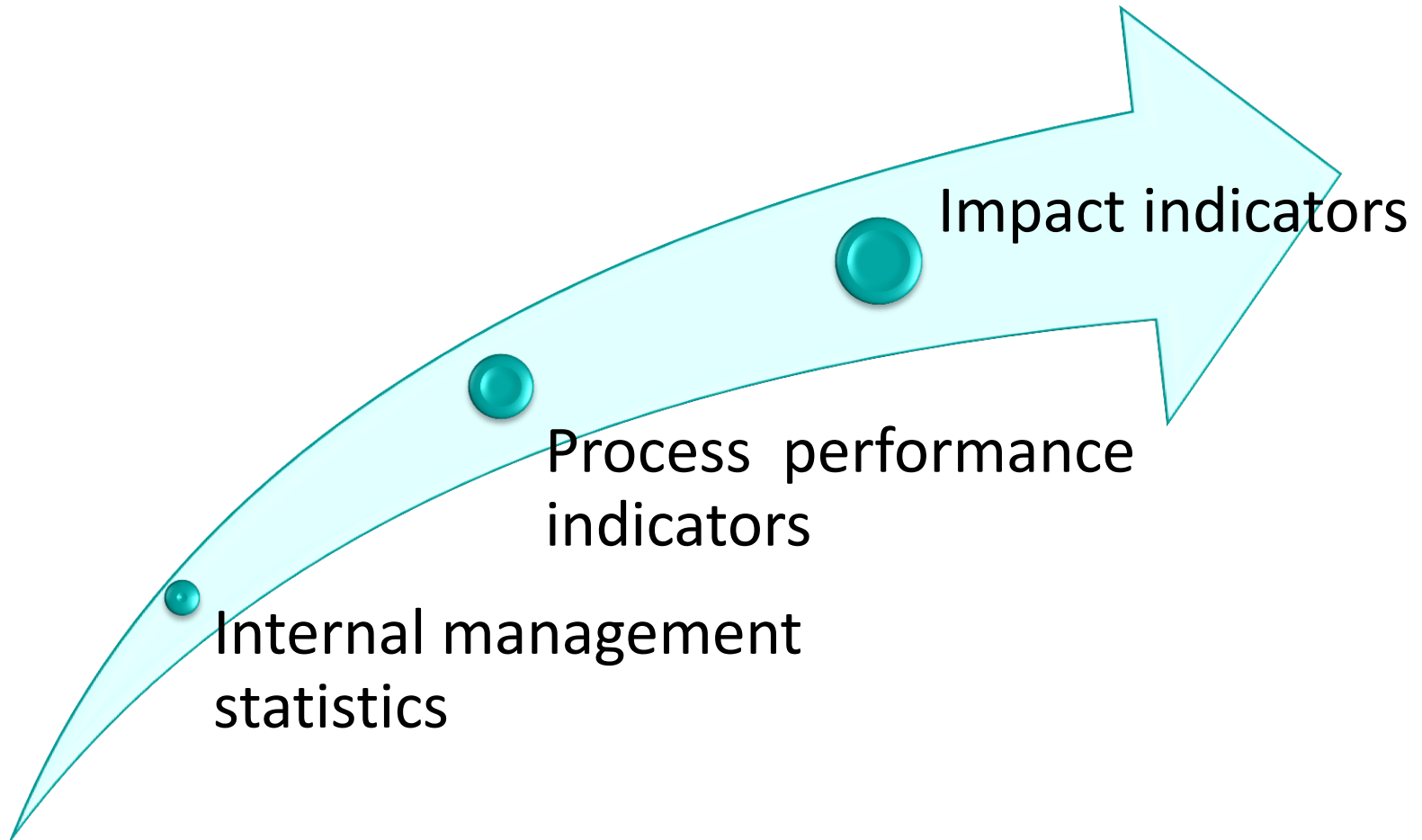
# Comparative study: Process safety level of two multinational companies that locate in different EU countries

Company A	Finland	The Netherlands	Germany
Recognition of the demands of legislation	3.5	3	4.25
Management and personnel commitment	3.5	4.25	3
Risk assessment and management of change	3.5	4.5	3.5
Technical requirements and condition of the equipment	3.5	4	3.5
Operating instructions	3.5	4.25	4
Competence and training	3.5	4.25	3.5
Emergency preparedness	3.0	4.25	3.5

Company B	Finland	Belgium	France
Recognition of the demands of legislation	4	3,5	4
Management and personnel commitment	3.5	3.5	3,5
Risk assessment and management of change	4	3.5	3.5
Technical requirements and condition of the equipment	3.5	3	3
Operating instructions	4	3	3
Competence and training	3	3	3
Emergency preparedness	4	3	3

(Kotisalo et al., 2010)

# Indicators for internal performance and impacts (safety and reliability)



## “Effectiveness” goals of Tukes (2012-2016)

***“The level of safety and reliability in the society improves”***

1. The number of accidents decreases
2. The level of safety-related practices of businesses and citizens improves
3. The technical safety and reliability of products, installations and industrial plants improve

## Examples of current impact indicators

- Number of deaths in Tukes' surveillance areas
- Number of serious chemical accidents (related to Seveso-directive)
- Number of accidents in process industry
- Number of fires in which the cause is related to electricity
- Number of deaths caused by fires started from electrical appliances
- Number of seriously inadequate electrical appliances in the market
- Proportion of industrial plants with inadequate safety level

Thank you!

