



# INTERNATIONAL CONFERENCE ON RISK ASSESSMENT AND MANAGEMENT

UNECE WP 6  
24-25 November 2009

Proportionality between risks and  
regulatory intervention:  
the experience of the European Union

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## RISK ASSESSMENT IN THE EU

- Focus on EU Internal Market legislation in the area of technical regulations aiming to ensure free circulation of goods
- Risk-based approach is a key feature of EU legislation for the creation of the Internal Market and in the areas protection of workers, health, environment, security, etc.



# RISK ASSESSMENT LEGAL BASIS (1)

- Article 95(3) of the Treaty establishing the European Community stipulates in the legal basis for the EU Internal Market :

“The Commission, in its proposals [...] concerning health, safety, environmental protection and consumer protection will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective”



## RISK ASSESSMENT LEGAL BASIS (2)

The EC Treaty does not explicitly state on how to conduct a risk assessment

However, the interpretation of Art. 95(3) of the EC-Treaty as given by the European Court of Justice by relevant case law, in particular in the case T-70/99-Alpharma, ECR II, 3495 confirms the need to conduct a risk assessment when regulating risks



## RISK ASSESSMENT LEGAL BASIS (3)

- Alpha, para 162 ff :  
“Risk assessment includes for [...] Community institutions, a twofold task [...] :
  - 1) determining what level of risk is deemed unacceptable and,
  - 2) conducting a scientific assessment of the risk”



## RISK ASSESSMENT LEGAL BASIS (4)

- Alpharma, para 175, 176 :  
“If it is not to adopt arbitrary measures which cannot in any circumstances be rendered legitimate by the precautionary principle, the competent public authority must ensure that any measures that it takes, even preventive measures, are based on as thorough a scientific risk assessment as possible”

➔ PROPORTIONALITY



## RISK ASSESSMENT LEGAL BASIS (5)

- Alparma, para 175, 176 :

The scientific risk assessment must enable the competent authority to ascertain, on the basis of the best available scientific data [...] whether matters have gone beyond the level of risk that it deems acceptable for society [...]



# RISK ASSESSMENT LEGAL BASIS (6)

- Alapharma, para 175, 176 :

A scientific risk assessment must also enable the competent authority to decide in relation to risk management, which measures appear to be appropriate and necessary to prevent the risk from materialising [...]





# DRAFTING LEGISLATION IMPACT ASSESSMENT

The Commission has taken the commitment to conduct for legislative proposals an Impact Assessment (IA) containing :

- analysis of the problems
- policy objectives and options
- likely economic, social and environmental impact

→ Risk assessment and risk management are a part of IA

Legislative proposals are accompanied by the IA report. IA is an aid to political decision-making. It provides transparency on the risk management related to the proposal.



# RISK ASSESSMENT DEFINITIONS

## RISK ASSESSMENT

The process of assessing (quantitatively or qualitatively) an adverse effect related to an activity, product or event and its probability

## RISK MANAGEMENT

The legislative (non) response to the identified risk

- appropriate
- proportionate
- effective



# DRAFTING LEGISLATION ASSESSING AND DEALING WITH RISK

- When preparing legislative proposals, the Commission may rely on the opinion delivered by relevant :
  - Scientific committees, i.e. Scientific Committee on Emerging and Newly Identified Health Risks, managed by DG Health & Consumers
  - Specialised agencies (EFSA, ECHA, EMSA...)
  - Other scientific expertise



## RISK ASSESSMENT BY THE LEGISLATOR

The decision whether or not a product represents a serious risk shall be based on an appropriate risk assessment which takes account of the nature of the hazard and the likelihood of its occurrence.



# DRAFTING LEGISLATION ASSESSING AND DEALING WITH RISK

- According to the scientific expertise received, the European Commission decides:
  - whether action is needed or not
  - If yes, the appropriate tool (Regulation, Directive, Decision, Communication, Guidelines, etc...) in order to deal and mitigate the risk
- When the choice falls over a tool of compulsory nature, the step of Impact Assessment shall be generally taken



# DRAFTING LEGISLATION GENERAL REQUIREMENTS

Hazards and risks of a cross-cutting nature are regulated in general horizontal legislation governing the placing of products on the Internal Market:

- General Product Safety Directive (2001/95/EC)
- Directive concerning liability for defective products (85/374/EEC)
- Decision on a common framework for the marketing of products (768/2008/EC)
- etc.



# DRAFTING LEGISLATION SPECIFIC REQUIREMENTS

Hazards and risks which may be present in given products are being regulated in relevant sector-specific legislation governing the placing of products on the Internal Market.

This refers to EU Directives relating to e.g. :

- electrical equipment
- medical devices
- machinery
- toys
- pressure equipment
- ...



## FURTHER INFORMATION

<http://ec.europa.eu/comm/enterprise/regulation/index.htm>

[http://ec.europa.eu/health/ph\\_risk/risk\\_en.htm](http://ec.europa.eu/health/ph_risk/risk_en.htm)

[http://ec.europa.eu/health/ph\\_risk/ev\\_20081113\\_en.htm](http://ec.europa.eu/health/ph_risk/ev_20081113_en.htm)

[http://ec.europa.eu/consumers/safety/rapex/index\\_en.htm](http://ec.europa.eu/consumers/safety/rapex/index_en.htm)

[http://ec.europa.eu/consumers/safety/prod\\_legis/index\\_en.htm](http://ec.europa.eu/consumers/safety/prod_legis/index_en.htm)

[http://europa.eu/legislation\\_summaries/consumers/consumer\\_safety/l32012\\_en.htm](http://europa.eu/legislation_summaries/consumers/consumer_safety/l32012_en.htm)

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0082:0128:EN:PDF>





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**THANK YOU!**