



# **Risk assessment and the choice of conformity assessment procedures in the EU**

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# Outline

- Legal Basis for Risk Assessment in the EU regulatory process
- Risk assessment as part of Impact Assessment
- Example of Risk Assessment for industrial products covered by New Legislative Framework

# Basis for EU legislation

- Precautionary principle
- Proportionality

## **Article 114(3) of the Treaty on the Functioning of the European Union (TFEU)**

“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”

## Article 2(2) of the WTO Agreement on Technical Barriers to Trade (TBT)

"[...] Technical regulations shall not be more trade restrictive than necessary to fulfil a legitimate objective, taking account of the risks that non-fulfilment would create. Such legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology or intended end-uses of products"

## **Article 5.1.2 of the WTO TBT Agreement – Conformity Assessment**

“[...] conformity assessment procedures shall not be more strict or be applied more strictly than is necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create”

# How to conduct risk assessment?

- **Article 114(3) TFEU – no guidance**
- **Case T-70/99-Alpharma** (judgment of the Court of First Instance of 11.9.2002 – on use of antibiotics as additives in feedingstuffs):

## Case T-70/99-Alpharma

- This case confirms **the need to conduct a risk assessment when regulating risks**
- “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”**



## **Alpharma, paras 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”

## Cont'd

“ 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 [...] ”

## Cont'd

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 [...]

# Examples:

- Regulatory authorities: categorization or classification (examples machinery, medical devices)
- Manufacturer: risk assessment and technical documentation
- Market Surveillance officers – Articles 19 and 20 of Regulation 765/2008 - accident reporting

# Impact Assessment–Drafting Legislation

## COMMISSION STAFF WORKING DOCUMENT Better Regulation Guidelines COM (2015) 215 final - Impact Assessment Guidelines

- **gathering and analysing evidence to support policy making**
- **informed decision-making**
- respecting the principles of subsidiarity and proportionality
- **What? - Commission initiatives that are likely to have significant economic, environmental or social impacts** (thus both legislative and non-legislative initiatives as well as delegated acts and implementing measures)

# Questions an Impact Assessment Should Answer

- *What is the problem and why is it a **problem**?*
- *Why should the EU act?*
- *What should be achieved?*
- *What are the various **options** to achieve the objectives?*
- *What are their economic, social and environmental **impacts** and who will be affected?*
- *How do the different options **compare** in terms of their effectiveness and efficiency (benefits and costs)?*
- *How will monitoring and subsequent retrospective evaluation be organised?*

# Impact Assessment

- Risk assessment and Risk management are part of IA
- Public consultation - 12-week internet-based public consultation - complemented by other approaches and tools in order to engage all relevant stakeholders and to target potential information gaps

# Drafting Legislation

When preparing legislative proposals, the Commission may rely on the opinion delivered by relevant:

- Scientific committees managed by DG Sante on:
  - **Consumer Products (SCCP)**
  - **Emerging and Newly Identified Health Risks (SCENIHR)**
  - **Health and Environmental Risks (SCHER)**
- Specialised agencies (e.g. EFSA (food), ECHA (chemicals), EMEA (pharmaceuticals))
- Other scientific expertise (e.g. studies by independent experts)



# Drafting Legislation - Cont'd

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

## **Drafting Legislation – Cont'd**

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.

# **Risk assessment in the context of legislation covered by NLF-New Approach**

Successful example of task sharing between:

- regulatory authority
- standardisers
- manufacturers
- market surveillance authorities

# Decision (EC) No. 768/2008

- Modernises conformity assessment modules
- Choice of **clear, transparent** and **coherent** conformity assessment procedures, restricting the possible variants
- Ensure **uniformity in the assessment** of conformity assessment bodies
- Ensure a **uniform high level of performance** of notified bodies throughout the EU

# Conformity Assessment

- **Menu of modules**, enabling the legislator to choose a procedure from the least to the most stringent, in **proportion to the level of risk involved and the level of safety required**
- ISO/CASCO Toolbox
- Procedures divided into **8 different modules** (from manufacturer's declaration to full quality assurance certification)
- Range of options set in Directives
- All procedures give equivalent results: **presumption of conformity**

# Criteria for the choice of the relevant conformity assessment procedure

## General considerations:

- Proportionate and effective
  - economic infrastructure of the given sector (e.g. type and size of companies, complexity of product technology)
  - type and importance of production

## Criteria set in Decision 768/2008:

- Appropriate to the type of product
- Nature of risk involved and correlation of the procedure to the type and degree of risk
- When 3rd party involvement is mandatory - manufacturer must be given the choice between quality assurance and product certification modules

## ***Example on choice of SDoC***

# **Restriction of Hazardous Substances**

- the Impact assessment considered the risk involved with products
- then the benefits of SDoC vs. 3<sup>rd</sup> party assessment were considered in terms of mitigating the risks presented by the products in question, and the cost of each option
- the lightest possible conformity assessment procedure was chosen to reduce costs for manufacturers: SDoC

## ***Example – on choice of 3rd party CA***

### **Annex IV Machinery**

- distinction between machinery as a whole and machines which present more serious hazards (Annex IV machinery when harmonised standards are not used)
- for the first category only conformity assessment with internal inspection applies;
- for the more **hazardous machines** - either adequacy in respect of harmonised standards, EC type-examination of the machine, or full quality assurance
- simplified procedure for machinery which presents no inherent risk to safety and health



# **RISK ASSESSMENT REQUIREMENTS ADDRESSED TO THE MANUFACTURER**

Sectoral legislation covers the typical hazards/risks potentially present in relevant products by means of “essential requirements” aiming to ensure protection of health, safety, environment, etc...

- It is the obligation of manufacturers to establish the compliance of their products with relevant requirements of sectoral legislation (conformity assessment)

# **RISK ASSESSMENT REQUIREMENTS ADDRESSED TO THE MANUFACTURER Con't**

*OBLIGATIONS AFTER PLACING ON THE MARKET:*

Decision No. 768/2008

“Where deemed appropriate with regard to the risks presented by a product, manufacturers shall, ... carry out **sample testing** of marketed products, **investigate, and, if necessary, keep a register of complaints** of non-conforming products and product **recalls** and shall **keep distributors informed** of any such monitoring”

Obligations to carry out corrective measures and to inform competent authorities.

# RISK ASSESSMENT BY COMPETENT AUTHORITIES

Regulation (EC) No. 765/2008

**Market surveillance authorities** shall perform appropriate checks of products on the market on an **adequate scale** by means of documentary, physical and laboratory checks. They shall take account of the **established principles of risk assessment**, complaints and other information.

# RISK ASSESSMENT BY COMPETENT AUTHORITIES – CONT'D

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**.

In this context market surveillance authorities need to take account of the risk assessment inherent in harmonised standards.

## CONCLUSIONS

- EU experience shows that it is possible to attain a **high level of health, safety, environmental protection** whilst ensuring a **fair balance between pre-market and post-market controls**
- **Use Good Regulatory Practice principles and tools** (=> regulatory impact assessments) not only to determine the **need for regulation** but also in the **choice of conformity assessment procedures**
- Any type of conformity assessment procedure requires an **adequate level of post-market surveillance**
- Aim at an **efficient allocation of (private and public) resources** based on risk assessment and risk management considerations

# More information

- Better Regulation and Impact Assessment:
  - [http://ec.europa.eu/smart-regulation/index\\_en.htm](http://ec.europa.eu/smart-regulation/index_en.htm)
  - [http://ec.europa.eu/smart-regulation/impact/index\\_en.htm](http://ec.europa.eu/smart-regulation/impact/index_en.htm)
- Your Voice in Europe:
  - <http://ec.europa.eu/yourvoice>
- DG GROW – Free Movement of Goods:
  - [http://ec.europa.eu/growth/single-market/goods/index\\_en.htm](http://ec.europa.eu/growth/single-market/goods/index_en.htm)



# Thank you!