PANEL SESSION: RISK MANAGEMENT IN REGULATORY SYSTEMS
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Using risk management in regulatory systems:
the experience of the European Union

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I. Legal basis for risk assessment in the EU regulatory process

II. Risk assessment as part of impact assessment of legislative proposals

III. Focus on risk assessment in the area of technical harmonisation – The experience of the New Approach regulatory technique in the field of industrial products
• Risk-based approach is a key feature of EU legislation for the creation of the Internal Market and in the areas of protection of health, safety, environment, consumers, etc.
RISK ASSESSMENT
LEGAL BASIS (1)

• Article 114(3) of the Treaty on the Functioning of the European Union (TFEU) (ex Article 95(3) of the Treaty establishing the European Community (TEC)) provides the legal basis for EU Internal Market legislation:

“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) requires WTO members to adopt a risk-based approach to technical regulations:

“[…] 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** requires a risk-based approach to 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”
The TFEU does not explicitly state **how to conduct a risk assessment**

However, the interpretation of Article 114(3) TFEU (ex Article 95(3) TEC) as given by the European Court of Justice in relevant case law, in particular in the **case T-70/99-Alpharma** (judgment of the (then) Court of First Instance of 11.9.2002 – on use of antibiotics as additives in feedingstuffs) confirms **the need to conduct a risk assessment when regulating risks**
RISK ASSESSMENT
LEGAL BASIS (5)

• Alpharma, paras 162 and 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”
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”
RISK ASSESSMENT
LEGAL BASIS (7)

• Alpharma, paras 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 […]
• Alpharma, paras 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 European Commission conducts for legislative proposals and other major non-legislative policy initiatives 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 & RISK MANAGEMENT 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 response to the identified risk
  - appropriate
  - proportionate
  - effective
When preparing legislative proposals, the Commission may rely on the opinion delivered by relevant:

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

- regulatory authority
- manufacturers
- market surveillance authorities
- standardisers
RISK ASSESSMENT REQUIREMENTS ADDRESSED TO THE MANUFACTURER/SUPPLIER OF PRODUCTS

A. IN VIEW OF PLACING ON THE MARKET

• 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/SUPPLIER OF PRODUCTS

This normally implies that the manufacturer:

- carries out a risk assessment
  and
- documents results thereof in his technical file.
RISK ASSESSMENT REQUIREMENTS ADDRESSED TO THE MANUFACTURER/SUPPLIER OF PRODUCTS

Ex. of Directive 2006/42/EC on machinery - Annex I:

“The manufacturer must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment.”
RISK ASSESSMENT REQUIREMENTS ADDRESSED TO THE MANUFACTURER/SUPPLIER OF PRODUCTS

By the interactive process of risk assessment and risk reduction, the manufacturer shall:

- determine the limits of the machinery
- identify the hazards
- estimate the risks
- evaluate the risks
- eliminate the hazards or reduce the risks...."
RISK ASSESSMENT REQUIREMENTS ADDRESSED TO THE MANUFACTURER/SUPPLIER OF PRODUCTS

* Application of the “principles of safety integration” in the Machinery Directive and the Medical Devices Directives

* Coverage of:
  = “normal and reasonably foreseeable conditions of use ....” – Medical Devices Directives
  = “intended use and reasonably foreseeable misuse” – Machinery Directive

* Determination of protected persons
RISK ASSESSMENT REQUIREMENTS ADDRESSED TO THE MANUFACTURER/SUPPLIER OF PRODUCTS

B. OBLIGATIONS AFTER PLACING ON THE MARKET

Decision No. 768/2008 on a common framework for marketing of products, Annex I, Art. R2:

“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”
RISK ASSESSMENT REQUIREMENTS ADDRESSED TO THE MANUFACTURER/SUPPLIER OF PRODUCTS

Obligations to carry out corrective measures and to inform competent authorities

Similar obligations are stipulated in Article 5 of Directive 2001/95/EC on General Product Safety
RISK ASSESSMENT BY COMPETENT AUTHORITIES

Regulation (EC) No. 765/2008 setting out requirements for accreditation and market surveillance Articles 19, 20:

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.
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, where these are available.
RISK ASSESSMENT BY COMPETENT AUTHORITIES

* Directive 2001/95/EC on General Product Safety (GPSD) contains similar requirements

* Risk assessment guidelines for consumer products to be used by Market surveillance authorities for the implementation of the GPSD (OJ L 22, 26.1.2010, p.1)
European voluntary “harmonised standard” provide for the technical expression of protective legal requirements. They reflect an “anticipated risk assessment” by the Community of experts and form part of the state of the art.

Compliance with “harmonised standards” allows for a presumption of conformity with relevant legal requirements.
RISK ASSESSMENT OF MANUFACTURERS AND OF MARKET SURVEILLANCE AUTHORITIES

Manufacturer:
* Conformity Assessment
* Monitoring of marketed products

Products placed on the market
Corrective measures, e.g. withdrawal

Competent Authority
Market surveillance actions

Risk assessment
CONSEQUENCES FOR STANDARDISATION

Where European legislation relies on the support of European standards:

- standards should cover in a systematic way and in full compatibility with legislation all relevant hazards and take account of the Commission’s standardisation requests to the European standards organisations;

- solutions foreseen in standards should achieve a high level of protection
CONSEQUENCES FOR STANDARDISATION

• European standards organisations should make sure that standards are being adapted regularly taking account of the evolution of the state of the art

• In the process of elaboration/adaptation of harmonised standards due account should be taken of experience in the field and in particular from market surveillance authorities
CONSEQUENCES FOR STANDARDISATION

* Opinions issued by Scientific Committees, e.g. relating to:
  - ultraviolet radiation from sunbeds,
  - personal music players and hearing

should be duly considered in the standardisation process.


* The existence of general risk assessment methods taking account of sectoral needs will allow less prescriptive outcomes in relation to product standards
THE EU CONFORMITY ASSESSMENT SYSTEM

THE NEW LEGISLATIVE FRAMEWORK (1)

Decision 768/2008

- **Modernise conformity assessment modules** initially set out in Council Decision 93/465/EEC, also in light of relevant ISO/IEC standards (17000 series) and guides

- **Choice of clear, transparent and coherent conformity assessment procedures**, restricting the possible variants

- **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
Decision 768/2008

- **Avoid creating unnecessary burdens for economic operators**
  ➞ choice of appropriate conformity assessment procedure based on a regulatory impact assessment (⇒ more detailed and coherent selection criteria)
  ➞ special attention to SMEs’ situation

- **Ensure uniformity in the assessment of conformity assessment bodies**
  (⇒ accreditation)

- **Ensure a uniform high level of performance of notified bodies**
  throughout the EU (⇒ strengthened supervision by Member States) and **consistency in the application of the modules** (⇒ coordination and cooperation mechanisms between notified bodies)
Criteria for the choice of the relevant procedure:

- Appropriate to the type of product
- nature and level of risk involved
- when 3rd party involvement is mandatory
  => Manufacturer must be given the choice between quality assurance and product certification modules
- 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
THE EU CONFORMITY ASSESSMENT SYSTEM

- Procedures divided into 8 different modules
- Modules range from manufacturer’s declaration to full quality assurance certification
- Range of options set in Directives
- All procedures give equivalent results: presumption of conformity
THE EU CONFORMITY ASSESSMENT SYSTEM

CONFORMITY ASSESSMENT MODULES

- A Internal production control
- B EC type examination
- C Conformity to type
- D Production quality assurance
- E Product quality assurance
- F Product verification
- G Unit verification
- H Full quality assurance
### CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>A. Internal production control)</strong></td>
<td>Manufacturer &gt; Keeps technical documentation at the disposal of national authorities</td>
</tr>
<tr>
<td><strong>B. (type examination)</strong></td>
<td>Manufacturer submits to notified body &gt; Technical documentation &gt; Supporting evidence for the adequacy of the technical design solution &gt; Specimen(s), representative of the production envisaged, as required</td>
</tr>
<tr>
<td><strong>Notified body</strong></td>
<td>&gt; Ascertains conformity with essential requirements &gt; Examines technical documentation and supporting evidence to assess adequacy of the technical design &gt; For specimen(s): carries out tests, if necessary &gt; Issues EC type-examination certificate</td>
</tr>
<tr>
<td><strong>C. (conformity to type)</strong></td>
<td>Manufacturer &gt; Declares conformity with essential requirements &gt; Affixes the required marking</td>
</tr>
<tr>
<td><strong>D. Production quality assurance</strong></td>
<td>EN ISO 9001:2000 Manufacturer &gt; Operates an approved quality system (QS) for design &gt; Submits technical documentation Notified Body &gt; Carries out surveillance of the QS</td>
</tr>
<tr>
<td><strong>E. Product quality assurance</strong></td>
<td>EN ISO 9001:2000 Manufacturer &gt; Declares conformity to essential requirements &gt; Affixes the required marking</td>
</tr>
<tr>
<td><strong>F. (product verification)</strong></td>
<td>Manufacturer &gt; Declares conformity to essential requirements &gt; Affixes the required marking</td>
</tr>
<tr>
<td><strong>G. Unit verification</strong></td>
<td>Notified Body &gt; Approves the QS &gt; Carries out surveillance of the QS</td>
</tr>
<tr>
<td><strong>H. (full quality assurance)</strong></td>
<td>Notified body &gt; Verifies conformity of design(1) &gt; Issues EC-design examination certificate(1)</td>
</tr>
<tr>
<td><strong>A1. Accredited in-house body</strong></td>
<td>or notified body &gt; Tests on specific aspects of the product (1)</td>
</tr>
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<td><strong>A2:</strong></td>
<td>&gt; Product checks at random intervals (1)</td>
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<td><strong>D1:</strong></td>
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</table>

**Notes:**
- (1) Indicates that the procedure is optional.
-_bold_ highlights key terms and concepts relevant to the conformity assessment procedures.
THE EU CONFORMITY ASSESSMENT SYSTEM
POST-MARKET CONTROLS

- Responsibility of Members States
- Public authority
- Organisation / Surveillance measures
- Minimum requirements
- Communication and Co-ordination
THE EU CONFORMITY ASSESSMENT SYSTEM

SHARED RESPONSIBILITIES

Manufacturers
PRE-MARKET ASSESSMENT

- Products must fulfil Essential Requirements
- Products need to be tested

Member States
POST-MARKET CONTROL

- Compliance with Essential Requirements
- Market surveillance authorities
USEFUL LINKS

• Better Regulation:

• Lisbon Strategy:

• Your Voice in Europe:
USEFUL LINKS

• DG Enterprise and Industry:

• DG Health and Consumers:
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THANK YOU