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Developments in the EU – Impact on product safety – Conformity assessment and notified bodies

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Overview

- **Impact of Regulation 765/2008**
- **Impact of Decision 768/2008**
- **Discussion topics**
 - Conformity assessment modules
 - Requirements upon notified bodies
 - Revision of standards
- **Future perspectives**

Conformity assessment and notified bodies

- **Regulation 765/2008 – Accreditation**
 - Stronger co-ordination between Member States
 - Strengthening of accreditation
 - “peer evaluation”

Still unclear: Impact on notification

Conformity assessment and notified bodies

- **Regulation 765/2008 – Market surveillance**
 - Co-ordination of market surveillance activities
 - Involvement of customs authorities
 - Testing in the framework of market surveillance

Still unclear: Interaction with notified bodies

Conformity assessment and notified bodies

- **Decision 768/2008**

NONE ???

- Only a catalogue of measures for individual directives
- Will only start to take effect when the requirements have been implemented in individual product directives
- Effects will be subject to a discussion process

Conformity assessment and notified bodies

- **Conformity assessment procedures**
 - Harmonization of conformity assessment procedures – Transfer of the module decision
 - Maximum choice for manufacturers
 - Article 11 A for PPE
 - Module H

Conformity assessment and notified bodies

- **Requirements upon notified bodies**
 - Requirements concerning competence, organisation, independence
 - Obligation to participate in co-ordination activities
 - Recommendation for Use Sheets
 - Inter-laboratory testing
 - Obligation to participate in standardization

Conformity assessment and notified bodies

- **Application of standards**
 - Completeness of standards
 - Revision of standards

Conformity assessment and notified bodies

- **Revision of standards**
 - Obligation for manufacturers, notified bodies etc. following revision of standards
 - Limited validity of certificates
 - Withdrawal of certificates

Conformity assessment and notified bodies

- **Significance of Decision 768/2008**
 - Basis for solving general questions in future directives
 - Starting point to address other questions, too
 - Implementation in directives is essential

Conformity assessment and notified bodies

- **Conclusion / Future perspectives**

- The developments at EU level can contribute to the improvement of product safety
- Consistent continuation of the process is required, e.g. by revising / modifying directives
- Possible effects of the changes on conformity assessment procedures and product safety have yet to be examined
- Increased co-operation of all parties concerned constitutes the basis for further development

Thank you very much for your attention !