June 21, 2011 (Tuesday) 55th EOQ Congress

KEMPINSKI HOTEL CORVINUS **Erzsébet tér 7-8, Budapest V.**

BALLROOM **Tuesday 9:00 – 10:30**

8.1. OPENING CEREMONY

9.00 Opening Ceremony

Zacharias Bilalis, European Commission, DG Enterprise and Industry, Brussels, Belgium**:**
European Quality Policy

Bilalis, Zacharias (Belgium)

Graduated as electrical engineer from the National Technical University of Athens and as telecommunications engineer from the "École Nationale Supérieure de Telecommunications" of Paris. He has worked as development engineer in the ICT area for Siemens in Munich, Germany.

Presently he is working in the unit dealing with the regulatory approach or the free circulation of goods and market surveillance of the Enterprise and Industry Directorate General at the European Commission.

European Quality policy

Unit C1: Regulatory approach for the free movement of goods and market surveillance

European Commission
Enterprise and Industry

Framework of a European Quality policy- 1

- **Quality assurance is "part of quality management focused on providing confidence that quality requirements will be fulfilled". Thus the term "quality assurance" excludes the notions of continuous improvement and customer satisfaction**
- **The legislator restricts himself to the part of "quality assurance" that relates only to legislative requirements while he is not allowed to dictate to manufacturers any policies for quality assurance in non-legislative areas and even more he cannot impose any provisions on the other sub-areas of quality management mentioned above**
- **However what matters is "quality itself" - A European quality policy must address the whole issue of "quality" as such, go beyond the limits of pure quality assurance and encompass the whole perimeter of quality management**

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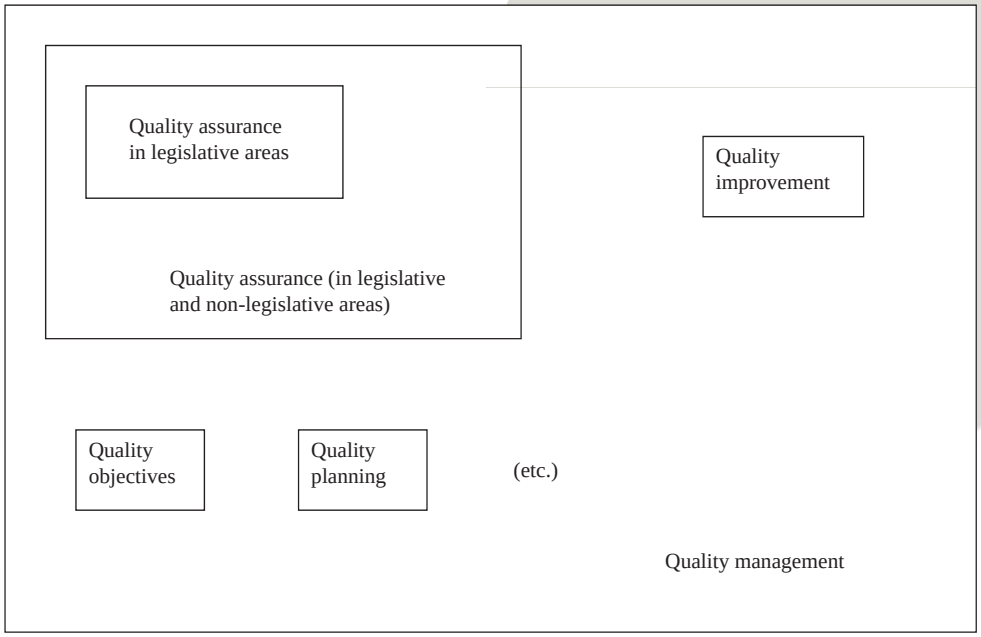
Framework of a European Quality policy- 2



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Objectives of European Quality policy

- **The European quality policy does not plan to widen Community legislative activity nor does it envision a more "interventionist" role for the Commission**

- **The Commission wants to act as a "facilitator", a catalyst for the projects and initiatives to be carried out in a decentralized manner, by fixing a reference point and by providing direction for thought and action**

- **A European quality policy must lead to**
  - **satisfied citizens, consumers and customers;**
  - **well trained, motivated and developed personnel;**
  - **efficiently managed companies;**
  - **respected environment;**
  - **well used resources;**
  - **strengthened employment on the basis of overall competitiveness, innovation and creativity.**

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Elements of European Quality policy -1

- Achieve greater coherence between Community policy and the instruments for quality management which are put in place at the Member States
- Taking quality issues into consideration while elaborating new legislation
- Promote the convergence on the national markets towards high quality objectives
- Rationalize the systems of marking, certification, labels, etc
  - importance must be paid to the overall quality performance of enterprises and not only to product certification schemes

Elements of European Quality policy -2

- Contribute to the development of quality on the Community market both on the supply and on the demand sides as a factor of economic integration and of internal and external industrial competitiveness
- Mobilize all public and private European players around the quality imperative, which will allow companies, and in particular SMEs, to respond better to the requirements of the various markets
- Demonstrate the advantages of adopting a system of quality management
- Promoting the use of quality methodologies (e.g. self assessment of enterprises), by means of Quality Plans

Elements of European Quality policy - 3

- Assist companies wishing to establish quality management structures.
- Improve the partnership relationship between customers and suppliers
- Support the research, development and demonstration of new methodologies of design, production, control, and organization which aim at the achievement of excellence in goods, services and companies
- Promote the integration of environmental aspects into the life cycle of products

Conclusions

- European Quality policy is directed towards companies, public authorities and consumers
- It aims to establish the overall framework for the development of the technical and political environment essential to the improvement of the quality of products and services, the competitiveness of European companies and the quality of life of the people of Europe.
- A European quality policy intends to develop a favorable environment in which enterprises achieve excellence in terms not only of conformity to regulatory requirements but also of their outputs and internal organisation for the benefit of the society as a whole.

Conformity Assessment in the New Legal Framework

Zacharias Bilalis

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Unit C1: Regulatory approach for the free circulation of goods

European Commission
Enterprise and Industry

Conformity Assessment

- Procedures divided into 8 different modules – which relate either to design or production control & concern suppliers and third parties
- 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

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The 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

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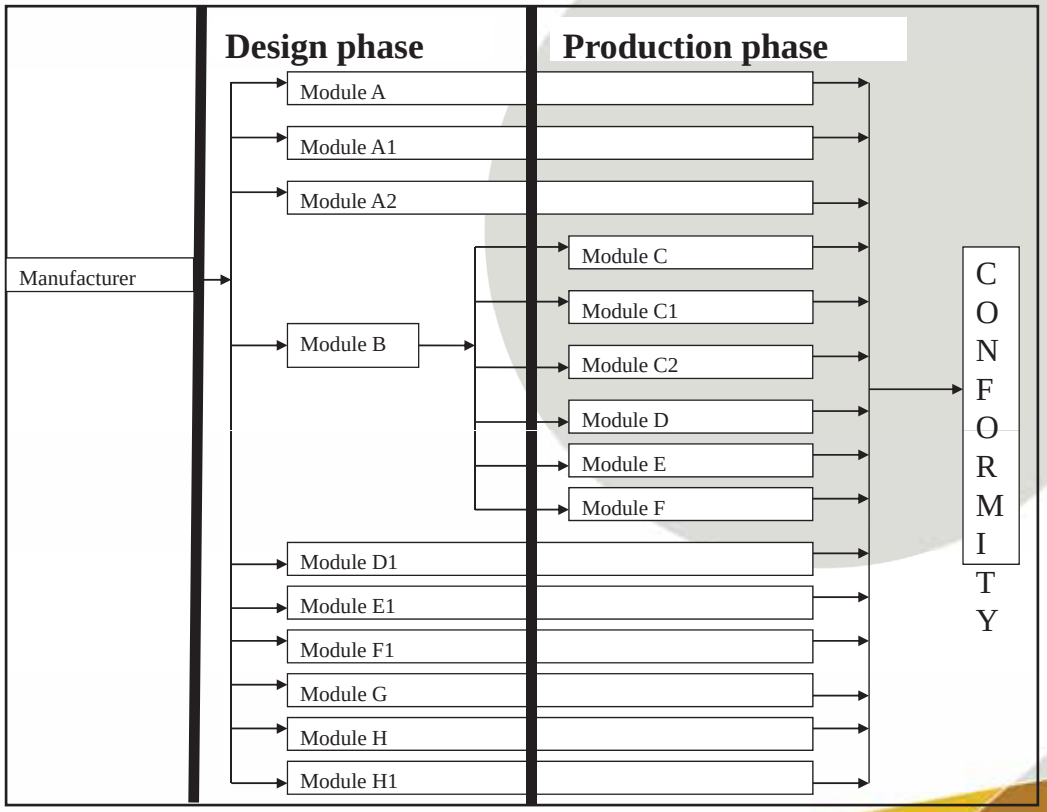

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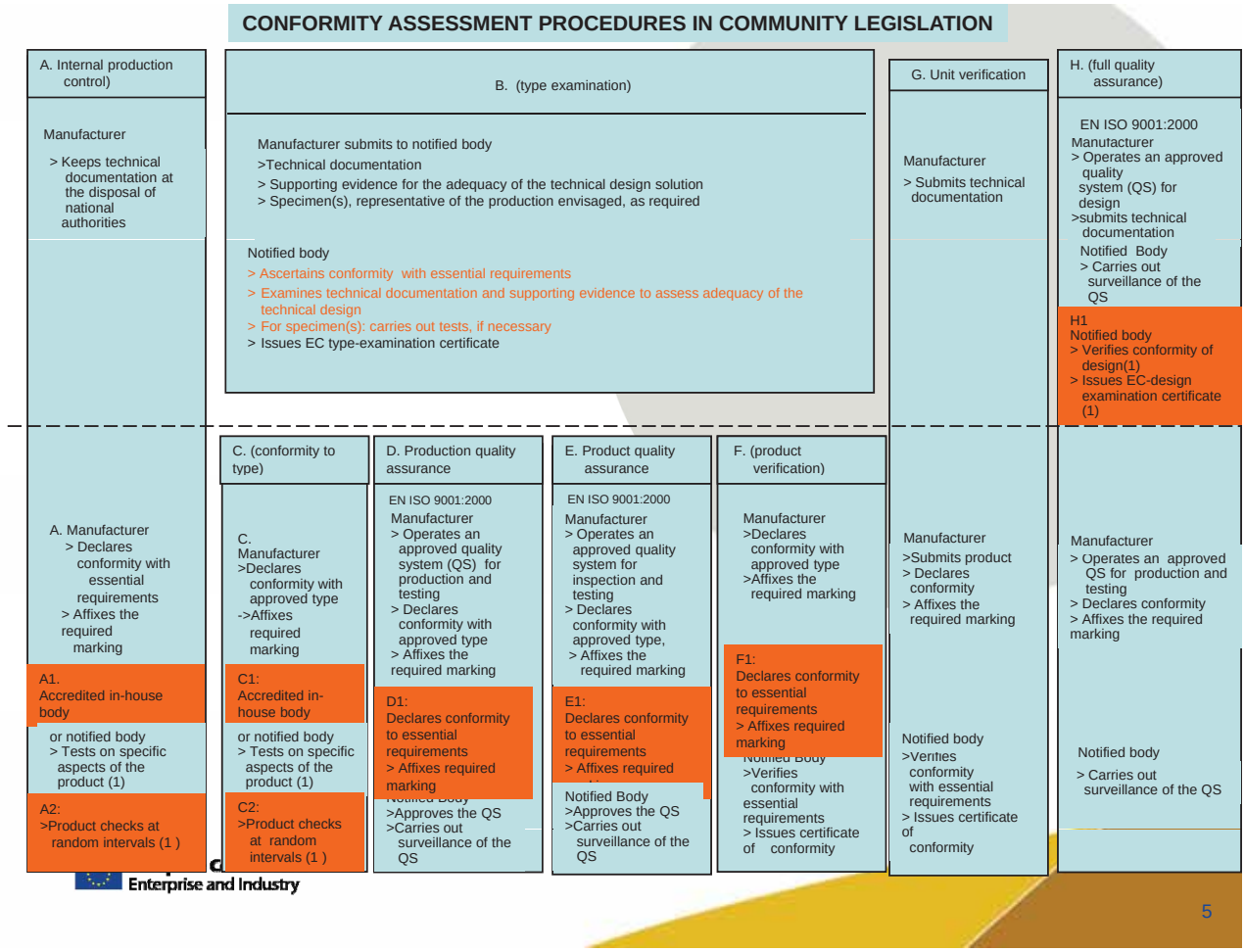

Conformity Assessment

- Modules give flexibility of Approach
- Manufacturer chooses

  → Remains responsible for products placed on the market

- All procedures lead to marking

- Choice product / QA certification

Notified Bodies

- Where the Directives delegate conformity assessment to third parties, these are undertaken by ‘Notified Bodies’
- Notified Bodies are officially ‘notified’ on the basis of set criteria EN ISO/IEC 17000…
- National authorities justify conformity via accreditation or other evidence

European standards

- ESOs – CEN / CENELEC / ETSI
- Developed following mandate from the Commission after opinion of 98/34 Committee
- Technical details set in harmonised European standards – performance based
- Standards (voluntary) give privileged route to conformity (reference in Official Journal European Union - OJEU)
- Less burdensome CA when following standards
- Products, tests, etc CA procedures, CABs