

# 2006 SCREENING EXERCISE

- CONFORMITY ASSESSMENT:  
THE GLOBAL APPROACH  
TO TECHNICAL HARMONISATION

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# CONFIDENCE

- SAFETY/QUALITY OF PRODUCTS
  - COMPETENCE OF SUPPLIERS
- COMPETENCE OF THIRD PARTIES
- TRANSPARENCY OF PROCEDURES
- PROPER SAFEGUARD MECHANISMS
  - ENFORCEMENT/MARKET SURVEILLANCE

# NEW/GLOBAL APPROACHES

- COUNCIL RESOLUTION OF 7 MAY 1985
- COUNCIL RESOLUTION OF 13 DEC. 1989
  - COUNCIL DECISION OF 21 DEC. 1990
  - COUNCIL DECISION OF 22 JULY 1993

# GLOBAL APPROACH

**FOLLOWING PRINCIPLES OF THE NEW APPROACH, FIXES THE CRITERIA OF COMPETENCE FOR SUPPLIERS & THIRD PARTIES AND SETS OUT THE TRANSPARENCY MECHANISMS FOR CONFORMITY ASSESSMENT (MODULES, NOTIFICATION, ACCREDITATION & MARKING)**

# CONFORMITY ASSESSMENT

- **PROCEDURES FOR CONFORMITY OF PRODUCTS**
  - **CRITERIA FOR SUPPLIERS**
  - **CRITERIA FOR THIRD PARTIES**
- **PROCEDURES FOR CONFORMITY OF SUPPLIERS & THIRD PARTIES**
  - **MARKING**

# CONFORMITY ASSESSMENT PROCEDURES

- PROCEDURES DIVIDED INTO MODULES WHICH RELATE TO EITHER DESIGN OR PRODUCTION CONTROL & CONCERN SUPPLIERS AND THIRD PARTIES
  - 8 MODULES FROM SUPPLIER'S DECLARATION TO FULL QUALITY ASSURANCE CERTIFICATION

# THE MODULES

- A INTERNAL PROD. CONTROL
- B EC TYPE EXAMINATION
- C CONFORMITY TO TYPE
- D PROD. QA EN 9002
- E PRODUCT QA EN 9003
- F PRODUCT VERIFICATION
- G UNIT VERIFICATION
- H FULL QA EN 9001

DESIGN

<b>A. (Internal control of production)</b>
<p><b>Manufacturer</b> Keeps technical documentation at the disposal of national authorities</p> <p><b>Aa</b> Intervention of notified body</p>

<b>B. (type examination)</b>
<p><b>Manufacturer submits to notified body</b></p> <ul style="list-style-type: none"> <li>- Technical documentation</li> <li>- Type</li> </ul> <p><b>Notified body</b></p> <ul style="list-style-type: none"> <li>- Ascertains conformity with essential requirements</li> <li>- Carries out tests, if necessary</li> <li>- Issues EC type-examination certificate</li> </ul>

<b>G. (unit verification)</b>
<p><b>Manufacturer</b> - Submits technical documentation</p>

<b>H. (full quality assurance)</b>
<p>EN 29001 (*)</p> <p><b>Manufacturer</b> - Operates an approved quality system (QS) for design</p> <p><b>Notified body</b> - Carries out surveillance of the QS - Verifies conformity of the design (!) - Issues EC design examination certificate (!)</p>

PRODUCTION

<b>A.</b>
<p><b>Manufacturer</b> - Declares conformity with essential requirements - Affixes the CE mark</p> <p><b>Aa</b> <b>Notified body</b> - Tests on specific aspects of the product (!) - Product checks at random intervals (!)</p>

<b>C. (conformity to type)</b>
<p><b>Manufacturer</b> - Declares conformity with approved type - Affixes the CE mark</p> <p><b>Notified body</b> - Tests on specific aspects of the product (!) - Product checks at random intervals (!)</p>

<b>D. (production quality assurance)</b>
<p>EN 29002 (*)</p> <p><b>Manufacturer</b> - Operates an approved quality system (QS) for production and testing - Declares conformity with approved type - Affixes the CE mark</p> <p><b>Notified body</b> - Approves the QS - Carries out surveillance of the QS</p>

<b>E. (product quality assurance)</b>
<p>EN 29003 (*)</p> <p><b>Manufacturer</b> - Operates an approved quality system (QS) for inspection and testing - Declares conformity with approved type, or to essential requirements - Affixes the CE mark</p> <p><b>Notified body</b> - Approves the QS - Carries out surveillance of the QS</p>

<b>F. (product verification)</b>
<p><b>Manufacturer</b> - Declares conformity with approved type, or with essential requirements - Affixes the CE mark</p> <p><b>Notified body</b> - Verifies conformity - Issues certificate of conformity</p>

<b>Manufacturer</b> - Submits product - Declares conformity - Affixes the CE mark
<b>Notified body</b> - Verifies conformity with essential requirements - Issues certificate of conformity

<b>Manufacturer</b> - Operates an approved QS for production and testing - Declares conformity - Affixes the CE mark
<b>Notified body</b> - Carries out surveillance of the QS

(!) Supplementary requirements which may be used in specific directives

(\*) Renamed EN ISO 9001 (EN 29001), EN ISO 9002 (EN 29002) and EN ISO 9003 (EN 29003) in 1994 standards updating.



# PRINCIPLES OF THE MODULES

- A PROCEDURE COVERS DESIGN & PRODUCTION CONTROL
- ALL PROCEDURES GIVE EQUIVALENT RESULTS: CONFORMITY
  - COUNCIL CAN FIX A RANGE OF PROCEDURES IN A DIRECTIVE SETTING CONDITIONS FOR OPTIONS

# PRINCIPLES OF THE MODULES

COUNCIL FIXES RANGE ACCORDING  
TO PRODUCTS, RISKS, SECTOR STRUCTURE  
TYPE OF PRODUCTION, EXISTING  
INFRASTRUCTURES, RELATIONS WITH  
OTHER DIRECTIVES

# PRINCIPLES OF MODULES

- **WHEREVER POSSIBLE A CHOICE WILL BE LEFT BETWEEN PRODUCT & QA CERTIFICATION**
- **SUPPLIER MAKES THE CHOICE**

**ALL PROCEDURES LEAD TO CE MARKING**

# PRINCIPLES OF MODULES

WHATEVER PROCEDURE THE SUPPLIER  
FOLLOWS, HE REMAINS RESPONSIBLE FOR  
HIS PRODUCTS PLACED ON THE MARKET.

THE CONFORMITY PROCEDURE HELPS HIS  
DEFENCE IN PRODUCT LIABILITY  
BUT DOES NOT REPLACE IT  
(SEE 1985 PRODUCT LIABILITY DIRECTIVE)

# PRINCIPLES OF MODULES

**THE IMPLEMENTATION OF EACH  
DIRECTIVE IS BASED ON A  
BALANCE  
BETWEEN THE BURDEN OF  
THE CONFORMITY  
PROCEDURE  
& APPROPRIATE MARKET  
SURVEILLANCE MEASURES**

# NOTIFIED BODIES

WHERE THE DIRECTIVES DELEGATE CONFORMITY ASSESSMENT TO THIRD PARTIES, THESE ARE NOTIFIED BY NATIONAL AUTHORITIES TO THE COMMISSION & OTHER MEMBER STATES UNDER CERTAIN CONDITIONS

# NOTIFIED BODIES

- **CERTIFICATES OF CONFORMITY DELIVERED BY NOTIFIED BODIES MUST BE ACCEPTED BY ALL NATIONAL AUTHORITIES IN THE UNION**
- **SUPPLIERS MAY CHOOSE ANY NOTIFIED BODY IN THE UNION**

# NOTIFIED BODIES

## BASIC CRITERIA IN ANNEXES:

- INDEPENDENCE
- IMPARTIALITY
- PROFESSIONAL INTEGRITY
- TECHNICAL COMPETENCE
- LIABILITY INSURANCE



# NOTIFIED BODIES

- **CONFORMANCE WITH THE EN 45000/ISO 17000 STANDARDS GIVES PRESUMPTION OF CONFORMITY TO DIRECTIVES**
- **NATIONAL AUTHORITIES MUST BE ABLE TO JUSTIFY CONFORMITY THROUGH ACCREDITATION OR OTHER EVIDENCE**

# ACCREDITATION

**MEMBER STATES SHOULD DISPOSE OF:  
SINGLE NATIONAL INDEPENDENT,  
NON COMMERCIAL,  
ACCREDITATION NETWORK,  
MEMBER OF EA,  
& WHICH PARTICIPATES IN  
MLAs & PEER REVIEWS**

# NOTIFIED BODIES

**NOTIFICATION SHOULD RELATE:**

- **TO AT LEAST A FULL MODULE**
- **THE TECHNOLOGICAL KNOW-HOW**
- **THE CATEGORY OF PRODUCTS**

# NOTIFIED BODIES

- **MUST WORK IN LESS BURDENSOME WAY**
- **REPORT TO NATIONAL AUTHORITIES**
  - **PARTICIPATE IN EUROPEAN  
CO-ORDINATIONS**
- **THEY ARE THE CIVIL ARM OF THE  
PUBLIC AUTHORITIES**

# CE MARKING

- **ONLY MARKING OF CONFORMITY TO DIRECTIVES BASED ON MODULAR APPROACH**

- **MEANS CONFORMITY TO ALL DIRECTIVES APPLIED BY THE SUPPLIER (MATERIALISES HIS DECLARATION)**

# CE MARKING

- **AFFIXED BY SUPPLIER, HIS AUTHORISED REPRESENTATIVE, OR PERSON RESPONSIBLE FOR PLACING ON MARKET**
- **AFFIXED ON THE PRODUCT, OR ON PACKAGING, OR ACCOMPANYING DOCUMENTATION**

# CE MARKING

## ACCOMPANYING INFORMATION:

- IDENTIFICATION N° OF NOTIFIED BODY  
WHERE APPROPRIATE
  - PICTOGRAMME
  - CATEGORY OF USE

# CE MARKING

- **IS THE ONLY MARKING OF CONFORMITY TO DIRECTIVES**
  - **MEMBER STATES MUST TAKE MEASURES TO AVOID CONFUSION & UNDUE MARKING**
  - **MEMBER STATES MUST REFRAIN FROM ANY REFERENCE TO OTHER MARKINGS IN LEGISLATION**