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 & THURD 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 ECTYPE EXAMINATION
- C CONFORMITY TO TYPE
- D PROD. QA EN 9002
- E PRODUCT OA EN 9003
- F' PRODUCT VERIFICATION
- G UNIT VERIFICATION
- H FULL QA EN 9001

CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION

B. (type examination)

Manufacturer submits to notified body

- Technical documentation

- Type

A. (Internal control of

production)

Manufacturer

D

Keeps technical

the disposal of

national

documentation at

H. (full quality

Manufacturer

- Operates an

design

assurance)

EN 29001 (*)

approved quality

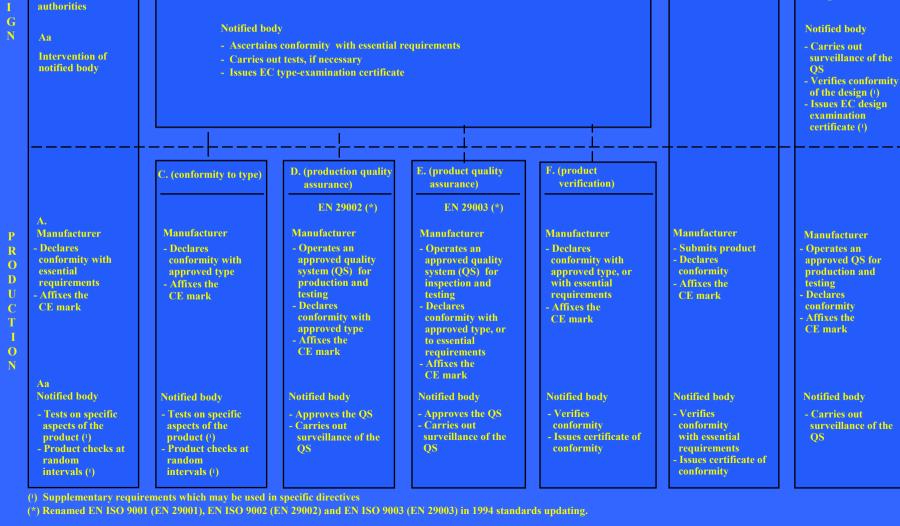
system (OS) for

G. (unit verification)

Manufacturer

- Submits technical

documentation



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 OLLOWS, 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

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

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

BASIC CRITERIA IN ANNEXES:

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

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 EYIDENCE

ACCREDITATION

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

NOTIFICATION SHOULD RELATE:

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

MUST WORK IN LESS BURDENSOME WAY

REPORT TO NATIONAL AUTHORITIES

PARTICIPATE IN EUROPEAN

CO-ORDINATIONS

THEY ARE THE CIVIL ARM OF THE

PUBLIC AUTHORITIES

ONLY MARKING OF CONFORMITY TO DIRECTIVES BASED ON MODULAR APPROACH

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

•AFFIXED BY SUPPLIER, HIS AUTHORISE REPRESENTATIVE, OR PERSON RESPONSIBLE FOR PLACING ON MARKE

•AFFIXED ON THE PRODUCT, OR ON PACKAGING, OR ACCOMPANYING DOCUMENTATION

ACCOMPANYING INFORMATION:

·IDENTIFICATION N° OF NOTIFIED BODY WHERE APPROPRIATE •PICTOGRAMME •CATEGORY OF USE

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