

2006 SCREENING EXERCISE

- THE NEW APPROACH TO TECHNICAL HARMONISATION

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Legal issues linked to the Internal Market

OLD APPROACH HARMONISATION

- **VERY DETAILED SPECIFICATIONS**
 - **MIX OF NATIONAL TEXTS**
 - **LENGTHY APPROVAL PROCESS**
- **PUBLIC AUTHORITIES APPROVE**
 - **POLITICAL DECISIONS**

SINGLE EUROPEAN ACT

**INTERNAL MARKET TO BE COMPLETED BY
31 DECEMBER 1992**

**BY THE CREATION OF A TECHNICAL
ENVIRONMENT WHICH GIVES
THE NECESSARY LEVEL OF CONFIDENCE
FOR THE FREE PLACING ON THE MARKET
AND FREE CIRCULATION OF SAFE GOODS**

NEW APPROACH

ORIGINS

- **DIFFICULTIES OF OLD APPROACH**
- **ADOPTION OF 83/189 DIRECTIVE**
 - **CASSIS DE DIJON & BIOLOGISCHE PRODUCTEN**
 - **31 DECEMBER 1992**
- **NEED FOR NEW LEGISLATIVE TECHNIQUES**

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
- COUNCIL RESOLUTION OF 11 NOV. 2003

NEW APPROACH

GUIDING PRINCIPLES (1)

**LEGISLATION IS RESTRICTED TO
ESSENTIAL REQUIREMENTS WHILST
DETAILS REMAIN IN TECHNICAL
SPECIFICATIONS OR STANDARDS**

NEW APPROACH

GUIDING PRINCIPLES (2)

THE PRIVILEGED ROUTE TO THE MARKET IS THROUGH HARMONISED EUROPEAN STANDARDS ADOPTED BY THE CEN/CENELEC/ETSI ON MANDATE FROM THE COMMISSION AFTER OPINION OF 83/189 COMMITTEE

NEW APPROACH

GUIDING PRINCIPLES (3)

THE EUROPEAN STANDARDS REMAIN
VOLUNTARY BUT WHEN FOLLOWED GIVE
PRESUMPTION OF CONFORMITY
TO THE ESSENTIAL REQUIREMENTS

NEW APPROACH

GUIDING PRINCIPLES (4)

- **MANUFACTURERS WHO FOLLOW THE STANDARDS BENEFIT FROM LESS BURDENSOME CONFORMITY ASSESSMENT.**
- **OTHERS MUST DEMONSTRATE CONFORMITY THROUGH THIRD PARTY**
[NB: depends on level of risk in some directives]

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)

SCOPE

**BECAUSE OF THE RISK ORIENTED
NATURE OF THE ESSENTIAL
REQUIREMENTS, ALL NEW APPROACH
DIRECTIVES ARE VERY WIDE & COVER
SECTORS OR RISKS AS OPPOSED TO
INDIVIDUAL PRODUCTS**

ESSENTIAL REQUIREMENTS

- **BY DEFINITION THESE REQUIREMENTS ARE RESTRICTED TO ISSUES OF PUBLIC HEALTH AND SAFETY, ETC. SET OUT IN ARTICLE 36.**
- **RISK ORIENTED AND SET HIGH SAFETY LEVELS OF PROTECTION.**
- **NOT PRODUCT SPECIFICATION ORIENTED**

HARMONISED STANDARDS

- THESE SET OUT THE DETAILED TECHNICAL SPECIFICATIONS FOR THE PRODUCTS ACCORDING TO THE ESSENTIAL REQUIREMENTS.
- GENERAL REFERENCE BUT LISTS PUBLISHED IN THE O.J.E.C.

HARMONISED STANDARDS

- **CONFORMANCE TO HARMONISED STANDARDS GIVES PRESUMPTION OF CONFORMITY TO THE ESSENTIAL REQUIREMENTS**
- **BURDEN OF PROOF LIES WITH NATIONAL AUTHORITIES**

FREE CIRCULATION CLAUSE

- AS DIRECTIVES SET LEVELS OF PROTECTION, SO CLAUSE RELATES TO MARKETING AND INSTALLATION SETS ONE LEVEL OF SAFETY FOR ENTIRE UNION, SO HARMONISATION IS TOTAL AND MEMBER STATES MUST ENSURE MARKET SURVEILLANCE.

CONFORMITY ASSESSMENT

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

PRINCIPLES OF MODULES

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

CE MARKING

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

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

SAFEGUARD CLAUSES

- ALL NEW APPROACH DIRECTIVES HAVE A PRODUCT SAFEGUARD CLAUSE WHICH IMPOSES A COMMUNITY PROCEDURE FOR DANGEROUS PRODUCTS WHICH GET TO THE MARKET
- ANY POSITION WHICH COMES OUT OF THIS PROCEDURE IMPOSES ITSELF ON NATIONAL AUTHORITIES

SAFEGUARD CLAUSES

- ALL DIRECTIVES HAVE A SAFEGUARD CLAUSE FOR DEFICIENT HARMONISED STANDARDS OR BADLY IMPLEMENTED STANDARDS

- IN SUCH CASES THE COMMISSION MUST DECIDE TO WITHDRAW THEM FROM THE O.J.E.C. AND SET A NEW MANDATE

MARKET SURVEILLANCE

ALL MEMBER STATES MUST TAKE MEASURES TO ENSURE PROPER IMPLEMENTATION OF THE DIRECTIVES, INCLUDING SURVEILLANCE OF SUPPLIERS DECLARATIONS, NOTIFIED BODIES, ABUSIVE MARKING & HAVE MEANS OF OPERATING SAFEGUARDS (DECISIONS)