

New Machinery Directive 2006/42/EC

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Machinery Directive 2006/42/EC

Topics:

- **1. General introduction of European Directives** 機械指令簡介
- **2. Reasons of amendment and milestones for Machinery Directive** 修訂的理由及機械指令的沿革
- **3. Comparison MSD 2006/42/EC – MSD 98/37/EC with essential differences in the content** 新舊機械指令2006/42/EC 與 98/37/EC 的比較
- **4. Major differences in the Annexes of the New Machinery Directive 2006/42/EC** 新機械指令2006/42/EC 附件中之主要差異
- **5. Summery** 結論
- **6. FAQ – Frequently asked questions** 問與答

1. General introduction of European Directives



27 Member States
of the
European Union

In 2008

492.8Mio
Residents

23 Official
Languages

Main Currency:
EURO

Legislative:
European Parliament



General introduction of European Directives

History of European standardization

1957

Treaties of Rome
Market without borders and customs
Harmonization of all technical standards

1985

New Approach
Harmonization of all technical standards
Directives with fundamental requirements

1987

**Treaties of Rome became
European Act**
Article 100a(95) and 118a(137) important for machinery

European Act

Article 100a(95) and 118a(137) important for machinery

Article 100a(95)

Quality and safety requirements

Directives with fundamental requirements to the design, construct and equipment of machines

For example: MSD and LVD

Article 118a(137)

Operating industrial safety regulation

Minimum requirements to safety and health care at the workplace

For example: Directive 650 EWG

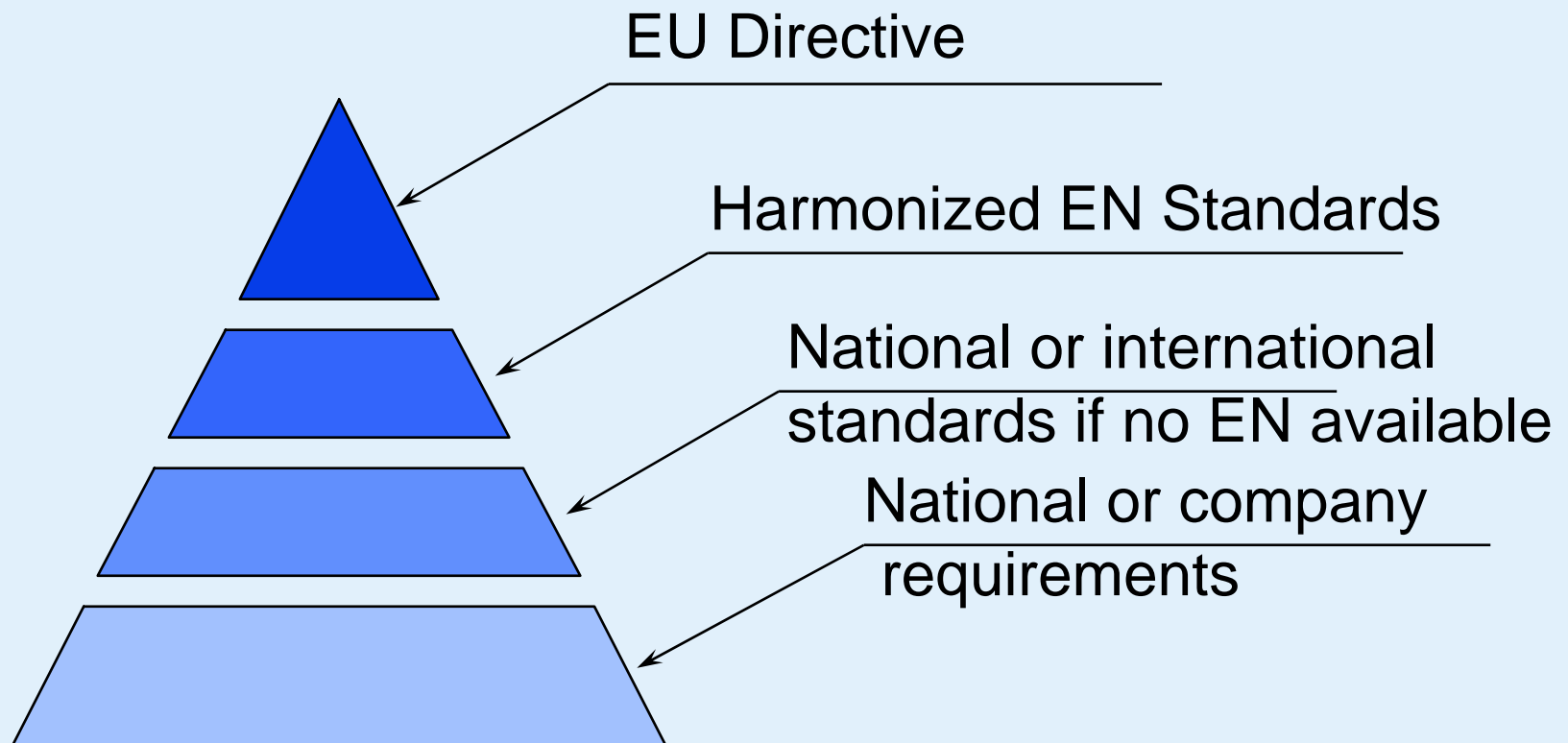
European Directives

Important EC Directives for machinery:

- Machinery Directive
- Low Voltage Directive
- EMC Directive
- ATEX Directive
- Acoustic Noise Directive
- Emission Directive
- and other Directives

See: <http://www.newapproach.org/directiveList.asp>

Directive, Standard



2. Reasons of amendment and milestones for Machinery Directive

Main purpose of Machinery Directive

- (2) “The social cost of large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction of machinery and proper installation and maintenance”**
- (3) ”Member States are responsible for ensuring the health and safety on their territory ...”**

Why the EU need a new Machinery Directive?

- **Meaning of the Directive :**
Freedom of movement of persons, services, capital and goods in the European Union
- **Therefore it is necessary to have harmonized directives valid for each member state of the EU**
(like LVD, TOY, PD, PPE...)
- **Commission got the task of revision of MSD**
Functionality, Practice Suitability, Effectiveness
- **For that reason so called: „Molitor-Report“**

Molitor – Report Recommendations

- Clarification of scope
 - Differentiation to Low Voltage Directive and Lifting Directive
 - Application on partly completed machinery
- Modification of procedures for assessing the conformity;
- Additional law simplifications;

Course of Proceedings of new MSD

- 17. May 2006

Formal postulation

- 09. June 2006

Published in the Official Journal of the European Union

- 29. June 2006

Entry into force of MSD 2006/42/EC

- 29. June 2008

Member States adopt and publish the provisions

- 29. December 2009

Implementation of MSD

No transition period

National Implementation - Germany

- Implementation by 9. Decree to GPSGV
- Time: June 29, 2008
- Application from Dec. 29, 2009 (No transition period)
- ZLS will do the designation for all applicants of Notified Body at the same time

3. Comparison MSD 2006/42/EC – MSD 98/37/EC with essential differences in the content

What is new, what was until now

2006/42

98/37

Instruction part Art 1 – 29 條文說明 條款1-29	Instruction part Art 1-16 條文說明 條款1-16
Annex I Essential requirements 附件一 基本健康與安全要求	Annex I Essential requirements 附件一 基本健康與安全要求
Annex II Declarations 附件一 宣告書	Annex II Declarations 附件一 宣告書
Annex III CE Marking 附件三 CE宣示	Annex III CE Conformity Mark. 附件三 CE符合標示



Annex IV:Categories of M. 附件 四: 機械種類	Annex IV:Types of M. 附件 四: 機械種類
Annex V:List of safety components 附件 五: 安全零組件	Annex V: EC Declaration of Conformity 附件 五: 安全零組件
Annex VI:Assembly instructi. partly completed Machinery 附件 六: 組裝說明書	Annex.VI: EC Type Examination 附件 六: 型式驗證
Annex VII: Technical file 附件 七: 技術文件	Annex VII: Minim. criteria NB 附件 七: 驗證單位最低準則
Annex VIII:Assessment of conformity-manufacture 附件 捌: 機械製造商藉由內檢所做之服符合性評估	Void 空白
Annex IX:EC Type Examinat. 附件 九: EC型式驗證	Annex IX: Correlation table 附件 九: 相關表格
Annex X: Full quality assurance 附件 十: 全面品質保證	
Annex XI: Minim. Criteria: NB 附件 十一: 會員國據以考量認可驗證機構之準則	
Annex XII: Correlation table 附件 十二: 相關表格	



Essential improvements new MSD

- Clear description of scope;
- 清楚說明範圍
- Differentiation against other Directives
- 其它指令的差異
- Procedures for assessing the conformity
- 評估符合性程序
- Procedures for partly completed machinery
- 半成品機械的程序
- Essential requirements adjusted to state of the art
- 超出於最新技術

Strengthening of market surveillance

- Art.4 – Market surveillance (appointment of authorities; predictable misuse)

條款四:指定權責單位

- Art.9 – Specific measures for hazardous machinery

條款九: 相調和機械的特殊評估

- Art.10 – Challenging a harmonized standard

條款十: 調和標準的質疑

- Art.11 – Safeguard clause (withdraw from the market, restrict, prohibit)

條款十一: 安全防護條款

- Art.18 – Confidentiality (confidential treatment of warnings)



條款十八: 保密性

- Art.19 – Cooperation between Member States

條款十九: 會員國之間的合作



http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm

Reference	Country	Product Information	Risk	Measures
21 0351/08	Netherlands	<p>Category: Electrical appliances Product: Fryer Brand: Tefal Type/number of model: FR7009</p> <p>Description: Unknown.</p> <p>Country of origin: China</p> 	<p>Fire</p> <p>The product poses a risk of fire because once the appliance has been switched on and the voltage falls below 230V, the relay, which controls the power of the heating element, goes on and off more frequently than during periods of normal voltage. In this kind of situation, the silver contact points could self-destruct, thereby ending up in a locked position. This results in constant heating and a potential risk of overheating.</p> <p>20 incidents reported.</p> <p>This product does not comply with the Low Voltage Directive.</p>	Voluntary stop of sales, withdrawal from the market and information to consumers
22 0352/08	Portugal	<p>Category: Toys Product: Joke items Brand: Unknown Type/number of model: EAN 085754152410, Patent NO.ZL02237051.X, Ref.: MO1-B</p> <p>Description: The product resembles a remote control with a metal housing, small black buttons and a central button outlined in red which, when pressed, produces a series of electrical impulses. It is sold in cardboard packaging bearing images and instructions for the installation of the batteries (in English). The following warnings appear, also in the English language: - "warning: choking hazard - small parts; not for children under 14 years."; - "warning: use at your own risk, not recommended for children under 14, adults over 50 years old or persons under any medical conditions", and - "made in china".</p> <p>Country of origin: China</p> 	<p>Electric shock</p> <p>The product poses a risk of electric shock because it produces a series of electrical impulses when the central button is pressed. The electrical impulses are generated between the button pressed and the metal housing of the toy.</p> <p>Consequently, a flow of current is produced that passes through the hand of the user and is enclosed between the palm of the hand holding the toy and the finger pressing the central button (usually the thumb).</p> <p>This product does not comply with the Low Voltage Directive and the relevant European standard.</p>	Voluntary withdrawal from the market

Modifications in Detail

■ Art. 1, Scope

- Machinery 機械
- Interchangeable equipment 可更換設備
- Safety components 安全零組件
- Lifting accessories 昇降配件 **New**
- Chains, ropes and webbing 鍊條、繩索及帶子 **New**
- Removable mechanical transmission device 可移動機械傳動裝置
- Partly completed machinery 半成品機械 **New**

- An assembly, consisting of linked parts or components at least one of which moves;
- 相關零組件或零組件組合而成至少會有一項移動
- Joined together for a specific application;
- 組合是爲了特殊用途
- Fitted with or intended to be fitted with a drive system;
- 安裝組驅動系統
- Even missing the connection to source of energy
- 未連接動力
- Even the function is ready for use after it is mounted on a means of transport, or installed in a building or a structure
- 安裝在一個搬運設備建築物或結構上方可使用
- Even if part 1 and part 2 = machine
- 一項+二項方可使用
- Even if part 1 and part 2 = partly completed machine
- 一項+二項=部分完整機械