

## **Frequently asked questions relating to the transition from the current Machinery Directive 98/37/EC to the revised Machinery Directive 2006/42/EC.**

### **1. Question:**



*Is there a transition period for application of Directive 2006/42/EC?*

#### **Answer :**

In general, there is no transition period, in the sense of a period during which both the current Machinery Directive and the new Machinery Directive are applicable (with one exception: there is a transition period until 29<sup>th</sup> June 2011 for the particular case of portable cartridge-operated fixing and other impact machinery).

However there is a period of adaptation, since the provisions of the Directive 2006/42/EC become applicable on 29<sup>th</sup> December 2009. During this period, all of the stakeholders concerned will be able to take the necessary steps to ensure a smooth transition from the current Directive to the new Directive.

### **2. Question:**

*Can manufacturers anticipate application of the new Machinery Directive?*

#### **Answer:**

Yes and no. Manufacturers can and should anticipate application of Directive 2006/42/EC from a practical and technical point of view, however, from a formal, legal point of view, the Directive cannot be applied before 29<sup>th</sup> December 2009:

- From the practical and technical point of view, manufacturers are encouraged to review their products without delay and adapt them as necessary to take account of the requirements of the new Directive. While machinery placed on the market before 29<sup>th</sup> December 2009 must continue to comply with Directive 98/37/EC, it can be assumed that a product that complies with the essential requirements of the new Machinery Directive continues to comply with the current Directive.
- From the formal, legal point of view, machinery can only be placed on the market with reference to Directive 2006/42/EC as from 29<sup>th</sup> December 2009.

### **3. Question:**

*When shall a manufacturer establish an EC Declaration of conformity according to Directive 2006/42/EC?*

#### **Answer:**

A manufacturer shall establish an EC Declaration of conformity according to Directive 2006/42/EC for products first placed on the market as from 29<sup>th</sup> December 2009.

In cases where the manufacturer cannot be certain on what date individual products will be first placed on the market, providing the products concerned comply with both the current and the new Directives, he may establish an EC Declaration of conformity referring to both Directive 98/37/EC and Directive 2006/42/EC. The reference to Directive 98/37/EC should be removed from the EC Declaration of conformity after the 29<sup>th</sup> December 2009.

#### **4. Question:**

*Can the current harmonised standards be used to comply with Directive 2006/42/EC?*

#### **Answer:**

Since there have been some modifications to the essential health and safety requirements set out in Annex I, it cannot be assumed that the current harmonised standards comply fully with Directive 2006/42/EC.

The European Commission is issuing a mandate to CEN and Cenelec to develop the necessary new standards and ensure that the current standards are checked against Directive 2006/42/EC and adapted as necessary. Furthermore, all harmonised standards must include a reference to the new Directive. The Commission intends to publish a list of harmonised standards supporting Directive 2006/42/EC before the Directive becomes applicable.

#### **5. Question:**

*When will manufacturers be able to use the new full quality assurance procedure for Annex IV machinery?*

#### **Answer:**

The Member States will first have to assess, appoint and notify Notified Bodies for the new full quality assurance procedure set out in Annex X of the new Directive. This can be done as soon as Directive 2006/42/EC has been transposed into national law.

As soon as Bodies have been notified for this procedure, they will be able to carry out the necessary audits and inspections and issue approvals of manufacturers' full quality assurance systems. However, products cannot be placed on the market on the basis of such approvals until Directive 2006/42/EC becomes applicable on 29<sup>th</sup> December 2009.

#### **6. Question:**

*Will the existing Notified Bodies be able to carry out EC type-examinations according to Directive 2006/42/EC?*

#### **Answer:**

Bodies that are notified to carry out EC type-examinations under Directive 98/37/EC will be able to continue to carry out EC type-examinations under Directive 2006/42/EC, providing their notification covers the product categories concerned.

For product categories included in Annex IV of Directive 2006/42/EC that are not listed in Annex IV of Directive 98/37/EC, the Member States will have to notify new Bodies or extend the scope of the notification of existing ones.

**7. Question:**

*Will EC type-examination certificates established according to Directive 98/37/EC remain valid for Directive 2006/42/EC?*

**Answer:**

Since there have been some modifications to the essential health and safety requirements set out in Annex I, it cannot be assumed that EC type-examination certificates issued according to Directive 98/37/EC remain valid for Directive 2006/42/EC. Furthermore, such certificates must be updated to refer to Directive 2006/42/EC..

Notified Bodies will thus have to review existing EC type-examination certificates to ensure that they remain valid in light of the requirements of the new Directive and update them to refer to Directive 2006/42/EC. Manufacturers are encouraged to request this review without delay in order to avoid a bottleneck in the months preceding December 2009.

Since Directive 2006/42/EC requires EC type-examination certificates to be reviewed every 5 years (see Annex IX, section 9.3), the 5-year period for existing certificates can be counted from the date on which they have been updated according to Directive 2006/42/EC.

**8. Question:**

*What will happen to products certified according to one of the procedures set out in Article 8 (2) (c) of Directive 98/37/EC (Receipt of technical file or Certificate of adequacy to harmonised standards)?*

**Answer:**

The procedures set out in Article 8 (2) (c) of Directive 98/37/EC will no longer exist under Directive 2006/42/EC. As from 29<sup>th</sup> December 2009, manufacturers of products placed on the market on the basis of these procedures will therefore have to apply one of the procedures set out in Article 12 (3) and (4) of Directive 2006/42/EC.

For products manufactured in accordance with harmonised standards that cover all the relevant health and safety requirements, the manufacturer will be able to certify the conformity of the product himself according to the procedure set out in Article 12 (3) (a) of the Directive.