

Enterprise and Industry

Conformity Assessment in Decision 768/2008

Unit C1: **Internal Market and
its International Dimension**



Conformity Assessment

- *Decision 768/2008, lays down the "horizontal menu" of conformity assessment modules and the ways procedures are built of modules.*
- *The sectoral legislator selects from the menu of conformity assessment modules/procedures the most appropriate ones for the concerned sector*
- *All procedures give equivalent results: presumption of conformity*
- *Some modules have variants*

The Modules (Overview)

- *A Internal production control*
- *B EC type examination*
- *C Conformity to type*
- *D Production quality assurance*
- *E Product quality assurance*
- *F Product verification*
- *G Unit verification*
- *H Full quality assurance*

The Modules (1)

Modules	Description
A Internal production control	<p>Covers both design and production.</p> <p>The manufacturer ensures himself the conformity of the products to the legislative requirements (no EC-type).</p>
A1 Internal production control plus supervised product testing	<p>Covers both design and production.</p> <p>A + tests on specific aspects of the product carried out by an in-house accredited body or under the responsibility of a notified body chosen by the manufacturer:</p>
A2 Internal production control plus supervised product checks at random intervals	<p>Covers both design and production.</p> <p>A + product checks at random intervals carried out by a notified body or in-house accredited body:</p>

The Modules (2)

Modules	Description
B EC-type examination	<p>Covers design.</p> <p>It is always followed by other modules by which the conformity of the products to the approved EC-type is demonstrated.</p> <p>A notified body examines the technical design of a product and verifies and attests that it meets the requirements of the legislative instrument that apply to it by issuing an EC-type examination certificate.</p>

The Modules (3)

Modules	Description
C Conformity to EC-type based on internal production control	Covers production and follows module B. The manufacturer ensures himself the conformity of the products to the approved EC-type.
C1 Conformity to EC-type based on internal production control plus supervised product testing	Covers production and follows module B. C + tests on specific aspects of the product carried out by an in-house accredited body or under the responsibility of a notified body chosen by the manufacturer
C2 Conformity to EC-type based on internal production control plus supervised product checks at random intervals	Covers production and follows module B. C + product checks at random intervals tests on specific aspects of the product carried out by a notified body or in-house accredited body:

The Modules (4)

Modules	Description
D Conformity to EC-type based on quality assurance of the production process	<p>Covers production and follows module B.</p> <p>The manufacturer operates a production (manufacturing part and inspection of final product) quality assurance system in order to ensure conformity to EC type. The notified body assesses the quality system.</p>
D1 Quality assurance of the production process	<p>Covers both design and production.</p> <p>The manufacturer operates a production (manufacturing part and inspection of final product) quality assurance system in order to ensure conformity to legislative requirements (no EC-type, used like D without module B). The notified body assesses the quality system.</p>

The Modules (5)

Modules	Description
<p>E</p> <p>Conformity to EC-type based on product quality assurance</p>	<p>Covers production and follows module B.</p> <p>The manufacturer operates a product quality (=production quality without the manufacturing part) assurance system in order to ensure conformity to EC type. A notified body assesses the quality system.</p> <p>The idea behind module E is similar to the one under module D: both are based on a quality system and follow module B. Their difference is that the quality system under module E aims to ensure the quality of the final product, while the quality system under module D (and D1 too) aims to ensure the quality of the whole production process (that includes the manufacturing part and the test of final product). E is thus similar to module D without the provisions relating to the manufacturing process</p>
<p>E1</p> <p>Quality assurance of final product inspection and testing</p>	<p>Covers both design and production.</p> <p>The manufacturer operates a product quality (=production quality without the manufacturing part) assurance system in order to ensure conformity to the legislative requirements (no EC-type, used like E without module B). The notified body assesses the quality system.</p> <p>The idea behind module E1 is similar to the one under module D1: both are based on a quality system. Their difference is that the quality system under module E1 aims to ensure the quality of the final product, while the quality system under module D1 aims to ensure the quality of the whole production process (that includes the manufacturing part and the test of final product). E1 is thus similar to module D1 without the provisions relating to the manufacturing process.</p>

The Modules (6)

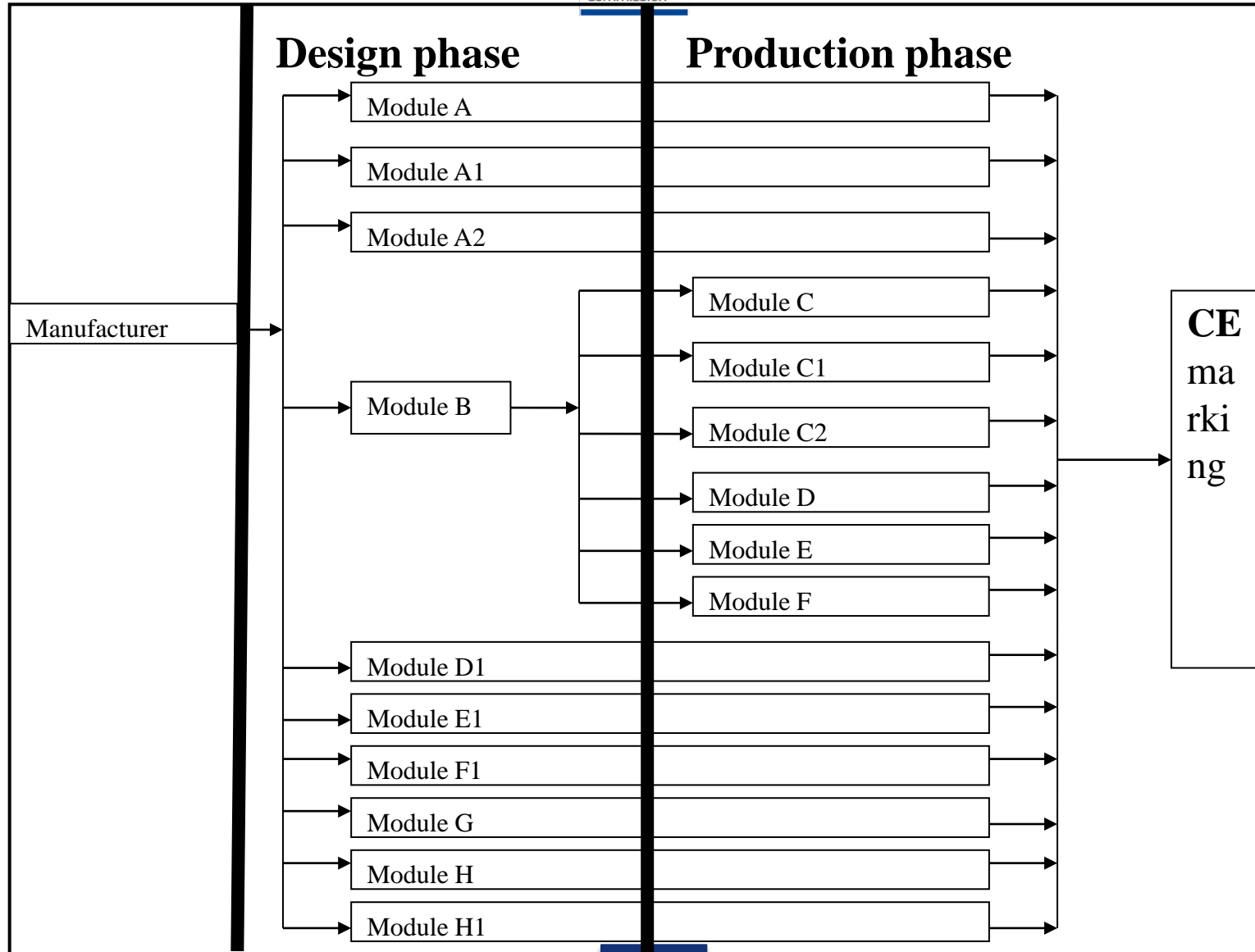
Modules	Description
F Conformity to EC-type based on product verification	<p>Covers production and follows module B.</p> <p>The manufacturer ensures compliance of the manufactured products to approved EC-type. The notified body carries out product examinations (testing of every product or statistical checks) in order to control product conformity to EC-type.</p> <p>Module F is like C2 but the notified body carries out more detailed product checks.</p>
F1 Conformity based on product verification	<p>Covers both design and production.</p> <p>The manufacturer ensures compliance of the manufactured products to the legislative requirements. The notified body carries out product examinations (testing of every product or statistical checks) in order to control product conformity to the legislative requirements (no EC-type, used like F without module B)</p> <p>Module F1 is like A2 but the notified body carries out more detailed product checks.</p>

The Modules (7)

Modules	Description
G Conformity based on unit verification	<p>Covers both design and production.</p> <p>The manufacturer ensures compliance of the manufactured products to the legislative requirements. The notified body verifies every individual product in order to ensure conformity to legislative requirements (no EC-type).</p>

The Modules (8)

Modules	Description
H Conformity based on full quality assurance	<p>Covers both design and production.</p> <p>The manufacturer operates a full quality assurance system in order to ensure conformity to legislative requirements (no EC-type). The notified body assesses the quality system.</p>
H1 Conformity based on full quality assurance plus design examination	<p>Covers both design and production.</p> <p>The manufacturer operates a full quality assurance system in order to ensure conformity to legislative requirements (no EC-type). The notified body assesses the quality system and the product design and issues an EC design examination certificate.</p> <p>Module H1 in comparison to module H provides in addition that the notified body carries out a more detailed examination of the product design.</p> <p>The EC-design examination certificate must not be confused with the EC-type examination certificate of module B that attests the conformity of a specimen “representative of the production envisaged”, so that the conformity of the products may be checked against this specimen. Under EC design examination certificate of module H1, there is no such specimen. EC design examination certificate attests that the conformity of the design of the product has been checked and certified by a notified body</p>





CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION

A. Internal production control)	B. (type examination)				G. Unit verification	H. (full quality assurance)
<p>Manufacturer</p> <ul style="list-style-type: none"> > Keeps technical documentation at the disposal of national authorities 	<p>Manufacturer submits to notified body</p> <ul style="list-style-type: none"> > Technical documentation > Supporting evidence for the adequacy of the technical design solution > Specimen(s), representative of the production envisaged, as required <p>Notified body</p> <ul style="list-style-type: none"> > Ascertains conformity with essential requirements > Examines technical documentation and supporting evidence to assess adequacy of the technical design > For specimen(s): carries out tests, if necessary > Issues EC type-examination certificate 				<p>Manufacturer</p> <ul style="list-style-type: none"> > Submits technical documentation 	<p>EN ISO 9001:2000 Manufacturer</p> <ul style="list-style-type: none"> > Operates an approved quality system (QS) for design > submits technical documentation <p>Notified Body</p> <ul style="list-style-type: none"> > Carries out surveillance of the QS <p>H1 Notified body</p> <ul style="list-style-type: none"> > Verifies conformity of design(1) > Issues EC-design examination certificate (1)
<p>A. Manufacturer</p> <ul style="list-style-type: none"> > Declares conformity with essential requirements > Affixes the required marking <p>A1. Accredited in-house body</p> <p>or notified body</p> <ul style="list-style-type: none"> > Tests on specific aspects of the product (1) <p>A2: >Product checks at random intervals (1)</p>	<p>C. (conformity to type)</p> <p>C. Manufacturer</p> <ul style="list-style-type: none"> > Declares conformity with approved type -> Affixes required marking <p>C1: Accredited in-house body</p> <p>or notified body</p> <ul style="list-style-type: none"> > Tests on specific aspects of the product (1) <p>C2: >Product checks at random intervals (1)</p>	<p>D. Production quality assurance</p> <p>EN ISO 9001:2000 Manufacturer</p> <ul style="list-style-type: none"> > Operates an approved quality system (QS) for production and testing > Declares conformity with approved type > Affixes the required marking <p>D1: Declares conformity to essential requirements</p> <ul style="list-style-type: none"> > Affixes required marking <p>Notified Body</p> <ul style="list-style-type: none"> > Approves the QS > Carries out surveillance of the QS 	<p>E. Product quality assurance</p> <p>EN ISO 9001:2000 Manufacturer</p> <ul style="list-style-type: none"> > Operates an approved quality system for inspection and testing > Declares conformity with approved type, > Affixes the required marking <p>E1: Declares conformity to essential requirements</p> <ul style="list-style-type: none"> > Affixes required marking <p>Notified Body</p> <ul style="list-style-type: none"> > Approves the QS > Carries out surveillance of the QS 	<p>F. (product verification)</p> <p>Manufacturer</p> <ul style="list-style-type: none"> > Declares conformity with approved type > Affixes the required marking <p>F1: Declares conformity to essential requirements</p> <ul style="list-style-type: none"> > Affixes required marking <p>Notified Body</p> <ul style="list-style-type: none"> > Verifies conformity with essential requirements > Issues certificate of conformity 	<p>Manufacturer</p> <ul style="list-style-type: none"> > Submits product > Declares conformity > Affixes the required marking <p>Notified body</p> <ul style="list-style-type: none"> > Verifies conformity with essential requirements > Issues certificate of conformity 	<p>Manufacturer</p> <ul style="list-style-type: none"> > Operates an approved QS for production and testing > Declares conformity > Affixes the required marking <p>Notified body</p> <ul style="list-style-type: none"> > Carries out surveillance of the QS

Conformity Assessment - Highlights

- *Modules give flexibility of Approach*
- *Manufacturer remains responsible for products placed on the market*
- *All procedures lead to CE marking*
- *Whenever possible sectoral legislator must give choice between product / Quality system certification*

Harmonised European standards

- *ESOs – CEN / CENELEC / ETSI*
- *Developed following mandate from the Commission*
- *Technical details set in Harmonised European standards – performance based, technology neutral*
- *Standards (voluntary) give privileged route to conformity (reference in Official Journal European Union - OJEU)*
- *Less burdensome Conformity Assessment when following Harmonised Standards*



Thank you for your attention!

Questions:

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Web adress

http://ec.europa.eu/enterprise/policies/single-market-goods/internal-market-for-products/index_en.htm