European Commission

Enterprise and Industry

Conformity Assessment in Decision 768/2008

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	Covers both design and production. The manufacturer ensures himself the conformity of the products to the legislative requirements (no EC-type).
A1 Internal production control plus supervised product testing	Covers both design and production. 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:
A2 Internal production control plus supervised product checks at random intervals	Covers both design and production. A + product checks at random intervals carried out by a notified body or in-house accredited body:

The Modules (2)

Modules	Description
B EC-type examination	Covers design. It is always followed by other modules by which the conformity of the products to the approved EC-type is demonstrated. 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.

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	Covers production and follows module B. 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.
D1 Quality assurance of the production process	Covers both design and production. 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.

The Modules (5)

Modules	Description
E Conformity to EC-type based on product quality assurance	Covers production and follows module B. 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. 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
E1 Quality assurance of final product inspection and testing	Covers both design and production. 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. 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.

The Modules (6)

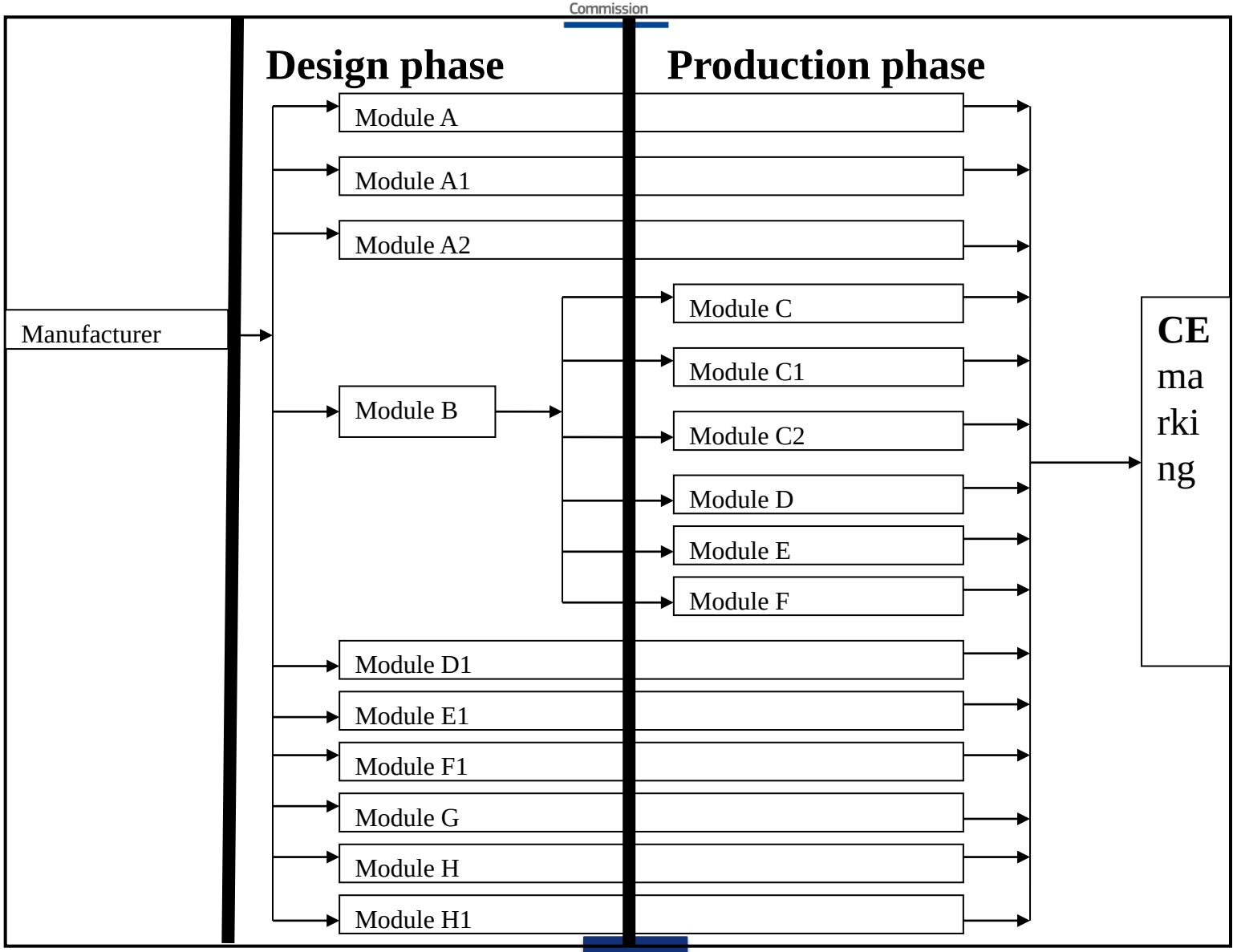
Modules	Description
F Conformity to EC-type based on product verification	Covers production and follows module B. The manufacturer ensures compliance of the manufactured products to approved EC-type. The notified body carries out product examinations (testing of every product or statistical checks) in order to control product conformity to EC-type. Module F is like C2 but the notified body carries out more detailed product checks.
F1 Conformity based on product verification	Covers both design and production. 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) Module F1 is like A2 but the notified body carries out more detailed product checks.

The Modules (7)

Modules	Description
G Conformity based on unit verification	Covers both design and production. 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).

The Modules (8)

Modules	Description
H Conformity based on full quality assurance	Covers both design and production. 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.
H1 Conformity based on full quality assurance plus design examination	Covers both design and production. 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. Module H1 in comparison to module H provides in addition that the notified body carries out a more detailed examination of the product design. 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


European Commission
Design phase
Production phase
Manufacturer
Module A
Module A1
Module A2
Module B
Module C
Module C1
Module C2
Module D
Module E
Module F
Module D1
Module E1
Module F1
Module G
Module H
Module H1
CE marking

CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION

A. Internal production control)

Manufacturer

> Keeps technical documentation at the disposal of national authorities

A. Manufacturer
> Declares conformity with essential requirements
> Affixes the required marking

A1.
Accredited in-house body

or notified body
> Tests on specific aspects of the product (1)

A2:
>Product checks at random intervals (1)

B. (type examination)

Manufacturer submits to notified body
>Technical documentation
> Supporting evidence for the adequacy of the technical design solution
> Specimen(s), representative of the production envisaged, as required

Notified body
> 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

C. (conformity to type)

C.
Manufacturer
>Declares conformity with approved type
->Affixes required marking

C1:
Accredited in-house body

or notified body
> Tests on specific aspects of the product (1)

C2:
>Product checks at random intervals (1)

D. Production quality assurance

EN ISO 9001:2000
Manufacturer
> Operates an approved quality system (QS) for production and testing
> Declares conformity with approved type
> Affixes the required marking

D1:
Declares conformity to essential requirements
> Affixes required marking

Notified Body
>Approves the QS
>Carries out surveillance of the QS

E. Product quality assurance

EN ISO 9001:2000
Manufacturer
> Operates an approved quality system for inspection and testing
> Declares conformity with approved type,
> Affixes the required marking

E1:
Declares conformity to essential requirements
> Affixes required

Notified Body
>Approves the QS
>Carries out surveillance of the QS

F. (product verification)

Manufacturer
>Declares conformity with approved type
>Affixes the required marking

F1:
Declares conformity to essential requirements
> Affixes required marking

Notified Body
>Verifies conformity with essential requirements
> Issues certificate of conformity

G. Unit verification

Manufacturer
> Submits technical documentation

Manufacturer
>Submits product
> Declares conformity
> Affixes the required marking

Notified body
>Verifies conformity with essential requirements
> Issues certificate of conformity

H. (full quality assurance)

EN ISO 9001:2000
Manufacturer
> Operates an approved quality system (QS) for design
>submits technical documentation
Notified Body
> Carries out surveillance of the QS

H1
Notified body
> Verifies conformity of design(1)
> Issues EC-design examination certificate (1)

Manufacturer
> Operates an approved QS for production and testing
> Declares conformity
> Affixes the required marking

Notified body
> 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 sustem 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