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**Joint Initiative on Standardisation — Action 5: Construction Products
Regulation — Dangerous substances assessment and declaration in hEN**

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Introduction

This document is a summary of the procedures to be followed when drafting clauses on the assessment and declaration of the performance of products for their release/emission of regulated dangerous substances.

The explanations were discussed by the experts of the Joint Initiative on Standardisation Action 5.

1 Scope

This document explains how to draft provisions related to the release/emission of regulated dangerous substances in harmonised standards. It also contains guidance on the actions to be taken to benefit from simplified procedures according to article 36(1) of the CPR, the bodies involved and the documents to be developed.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply

2.1

Construction Products Regulation (CPR)

Regulation (EU) No 305/2011 of the European Parliament and of the Council laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (CPD).

2.2

Regulation for implemented powers

Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

2.3

Regulation on the Classification, Labelling and Packaging of substances and mixtures (CLP)

Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

2.4

Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals and its amendments.

3 Identification of the situation of the harmonised standard

3.1 Relevant documents

The first action is to identify the relevant documents. The following documents should be considered:

- Product specific mandates, amendments to mandates and accepted standardisation requests for construction products including essential characteristics related to the release/emission of dangerous substances under the CPD/CPR;
- European standards and technical specifications to be applied for the assessment of content, emission and/or release of dangerous substances relevant for the substances and the products as defined in the previous document);
- Overview of substances covered by published and draft CEN/TC 351 European standards and technical specifications (CEN/TC 351 document 0724 and its updates).

3.2 Other documents to be considered

The following documents are not relevant but could be used as supportive information in case of doubts:

- Mandate M/366 development of horizontal standardised assessment methods for harmonised approaches relating to regulated dangerous substances under the construction products directive (CPD);
- Indicative list of regulated dangerous substances possibly associated with construction products under the CPD (CEN/TC 351 document 0403 and its updates).

3.3 Verification of the technical content

Regulatory and technical documents should be assessed and depending on the content of these documents CEN/TC will take different actions.

3.3.1 Regulatory documents

The mandate, amendment to mandate or accepted standardisation request applicable to the products shall be checked. Two situations can occur:

- The document includes the list of dangerous substances to be potentially declared for the products covered. This list will be the product reference list of dangerous substances to be considered in the next steps and it is the only situation allowing to continue the process without the need of additional actions involving the European Commission.
- The document includes a reference to dangerous substances, but it does not include the detailed list. In this case the recommendation is to request to the European Commission the development of the list. Until the reference list of dangerous substances is provided, the industry and stakeholders cannot go forward.
- The document does not include any reference to dangerous substances because it is not a relevant essential characteristic or because it was not developed yet (standardisation request required). In any case, the standard must not include a clause for dangerous substances in this situation.

3.3.2 Assessment methods

Assessment methods are required to properly address the release and emission of dangerous substances. The standardised assessment methods are usually test methods but could be other kind of assessments. If appropriate, additional European horizontal assessment methods should be developed. Table 1 describes the characteristics of the available assessment methods and the actions to be taken by the product CEN/TC.

The table refers to assessment methods published at European (usually in CEN) or at National level (usually national standardisation bodies).

Standardised assessment method is...					Action by the product CEN/TC
European	National	Horizontal	Product specific	Appropriate	
■		■		■	Method ready to be included in the harmonised standard.
■			■	■	Method ready to be included in the harmonised standard but horizontal method could be developed.
■		■			Request and support: <ul style="list-style-type: none"> — the robustness validation of the method; — the consideration of the products covered; — the consideration of the relevant regulated dangerous substances. And wait until the appropriate method is available
	■	■		■	Request and support the development of a European horizontal assessment method based on the National one
	■		■	■	Request and support the development of a European assessment method based on the National one (horizontal or by product) and wait until it is available
Any other combination					Request the development of a European assessment method for the relevant regulated substances and products.

Table 1 – Actions to be taken by CEN/TC depending on the availability of test methods

An assessment method is considered appropriate to be included in the harmonised standard if it fulfils all the following conditions:

- A precision statement is possible based on round robin testing and robustness validation (repeatability and reproducibility).
- It covers products within the scope of the standard;
- It is applicable to dangerous substances to be assessed (included in the product reference list of dangerous substances).

CEN/TC following the advice of their experts can decide that the assessment method is appropriate even if it does not fulfil some of the previous conditions.

3.4 Classification

The default declaration is a value for the declared substance but, considering the difficulties to manage the information, classes of performance could be developed.

CEN/TC are not permitted to develop classes of performance by themselves, but they can propose them to the European Commission. The official procedure is a Delegated act to be launched by the European Commission.

If European classes are available, manufacturers declaring the performance shall follow the classification.

See document JIS Action 5 – Delegated acts.

4 Assessment and declaration of dangerous substances

CEN/TC may define the way to assess and declare release/emission of a dangerous substance if all the following conditions are fulfilled:

- The substance is included in the product reference list of regulated dangerous substances (relevant mandate or standardisation request);
- A European appropriate assessment method is available for the relevant substance and product (see 3.3.2), discussions with CEN/TC 351 experts may be useful to decide if the method is appropriate;
- Declaration is a value or a European class according to the CPR requirements (classification available in a published delegated act or included in the relevant mandate, revised mandate or standardisation request).

If all the previous conditions are not fulfilled, the relevant clause in the standard cannot be developed and annex ZA cannot include any reference to it.

For these substances, experts from the industry should be able to classify them in one of the categories described in the following sub-clauses. The classification should be based on representative technical information, usually called a "technical dossier" to be sent to the European Commission as background document for the discussion of this topic in the relevant expert group.

4.1 Dangerous substances assessed

This clause applies to substances from the list of dangerous substances in the mandate or accepted standardisation request for which declaration of the performance follows the general principles of the CPR (testing, FPC, etc.).

Essential characteristics can be included in annex ZA of the harmonised standard including the applicable assessment method for the declaration of release/emission of these dangerous substances.

If European classes are available, manufacturers declaring the performance shall follow the classification.

The substances in this clause can be excluded from the technical dossier.

4.2 Dangerous substances to be declared without testing

This clause applies to substances from the list of dangerous substances in the mandate or standardisation request for which the performance is below certain limit with a significant certainty level under certain conditions.

Essential characteristics can be included in annex ZA of the harmonised standard including the applicable assessment method for the declaration of release/emission of these dangerous substances.

If European classes are available, manufacturers declaring the performance shall follow the classification but CEN/TC and experts from the industry can request to the European Commission the development of a delegated act to benefit from the provisions in article 36(1) of the CPR and allow them to declare the performance "without testing". This information must be justified from the technical point of view in the technical dossier. The basic information to be included is the following

- Products covered;

- Values to be declared;
- Statistical information on the performance;
- Criteria chosen to justify no need for assessment;
- Conditions and additional criteria to be fulfilled to benefit from the "without testing" approach (e.g. products manufactured using certain raw materials or process).

Experts from the European Commission and Member States will assess the proposal and, if accepted, the legal procedure will be initiated.

See document JIS Action 5 – Delegated acts.

Until the delegated act is published in the Official Journal of the European Union manufacturers cannot benefit from the "without testing" approach.

4.3 Dangerous substances not to be declared

4.3.1 CEN/TC dealing with a mandate and its amendments

Substances from the list of dangerous substances in the mandate for which the performance is not relevant.

The non-exhaustive list of situations for which substances are not declared are the following:

- The product does not contain the substance and it cannot be produced due to any physical or chemical reaction;
- The release/emission of the substances is below the detection limit of the applicable assessment method;
- Release/emission of the dangerous substance is not relevant for the intended use (e.g. release of regulated dangerous substances to indoor air for products installed outdoor).
- There is no relevant release/emission scenario during the life of the product.

CEN/TC should justify the reasons, referring to the technical dossier, in the answer to the mandate. The exclusion of regulated dangerous substances cannot be done until the answer to the mandate is approved by the European Commission (otherwise the citation in the Official Journal of the European Union could be blocked).

4.3.2 CEN/TC dealing with a standardisation request

Substances from the list of dangerous substances in the standardisation request for which the performance is not relevant should have been removed during the development of the standardisation request. If some of the substances are in the situations described in the list in clause 4.3.1 a new standardisation request should be developed to remove them from the list (otherwise the citation in the Official Journal of the European Union could be blocked).

See document JIS Action 5 – Procedure to develop a standardisation request.

5 REACH/CLP information

REACH/CLP and the CPR are complementary tools for health and consumer protection:

- REACH/CLP is a system created to identify and to empirically justify restrictions for specific chemicals and articles.
- CPR provides assessment methods and a format for product performance declarations.

If specific information is already available in the framework of REACH/CLP, no additional assessment under the framework of the CPR is needed.

According to the CPR, REACH/CLP information shall be provided together with the declaration of performance so there is no need to develop additional content dealing with REACH/CLP in the harmonised standards.

REACH/CLP require the delivery of information from products containing certain substances, as defined in the legal framework. The approach is different for

- substances and mixtures (combination of substances);
- articles.

Safety data sheets are required for some substances and mixtures, but some are only required to deliver REACH information. Articles only need to deliver REACH information to allow safe use of the article.

More information about the documents to be provided together with the declaration of performance are available in articles 31 to 33 of REACH.