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(concerning the Construction Products Directive - 89/106/EEC)

A HARMONISED APPROACH RELATING TO DANGEROUS SUBSTANCES UNDER THE CONSTRUCTION PRODUCTS DIRECTIVE

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Preface

Article 20 of the Construction Products Directive (89/106/EEC) states that the Standing Committee may, "at the request of its Chairman or a Member State, examine any question posed by the implementation and the practical application of this Directive".

In order to ensure as far as possible a common understanding between the Commission and the Member States as well as among the Member States themselves as to how the Directive will operate, the competent services of the Commission, assuming the chair and secretariat of the Standing Committee, may issue a series of ***Guidance Papers*** *dealing with specific matters related to the implementation, practical implementation and application of the Directive.*

These papers are not legal interpretations of the Directive.

They are not judicially binding and they do not modify or amend the Directive in any way. Where procedures are dealt with, this does not in principle exclude other procedures that may equally satisfy the Directive.

They will be primarily of interest and use to those involved in giving effect to the Directive, from a legal, technical and administrative standpoint.

They may be further elaborated, amended or withdrawn by the same procedure leading to their issue.

Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 Brussel - Belgium - Office: SC15;
Telephone: Switchboard 299.11.11. Fax: 296.10.65.
Construction@cec.eu.int http://europa.eu.int/comm/enterprise/construction/index.htm

A HARMONISED APPROACH RELATING TO DANGEROUS SUBSTANCES UNDER THE CONSTRUCTION PRODUCTS DIRECTIVE

1 Scope

1.1 This Guidance Paper is intended to describe a harmonised approach on addressing the problem of dangerous substances[1] and preparations[2], as well as radiation, when related to products falling under Council Directive 89/106/EEC[3] (hereafter referred to as the Construction Products Directive or CPD), as amended by Council Directive 93/68/EC[4]. It explains the extent to which the Directive applies to dangerous[5] substances and how technical specification writers (CEN/CENELEC and EOTA members) should take them into account to achieve harmonisation. Technical specifications shall provide all the relevant details for a given construction product and in particular the necessary information required for a producer to be able to complete the CE marking.

1.2 The Guidance Paper is aimed at those involved in the writing of technical specifications[6] (harmonised standards and European technical approvals), for consideration together with the respective mandates and provisions given therein, and manufacturers, regulators and enforcement authorities within the European Economic Area (EEA).

1.3 This Guidance Paper is limited to those aspects of the CPD essential requirement No.3 "Hygiene, health and the environment" that are linked to the presence of potentially dangerous substances in construction products. They do not consider those aspects of health, hygiene and environment that are related to the manufacture of products or their function (e.g. faulty disposal of wastewater). The Guidance Paper does not cover construction products in contact with water intended for human consumption.

1.4 None of the provisions of this Guidance Paper restricts Member States, with due regard to the Treaty, from maintaining laws, regulations, and administrative provisions[7] covering the use of products outside the scope of the CPD. As long as they conform with the provisions of the Treaty, e.g. voluntary schemes for the protection of the environment, which could provide an effective means for dealing with dangerous substances, they are not excluded by this Guidance Paper, although they too fall outside the scope of the CPD.

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[1] Substances mean chemical elements and their compounds in the natural state or obtained by any production process.

[2] Preparations mean mixtures or solutions composed of two or more substances.

[3] OJ No L 40, 11.2.1989

[4] OJ No L 220, 30.8.1993 Even if this Guidance Paper only mentions the original Directives/decisions (as in most cases), it is always the latest version/amendment that is referred to.

[5] In this Guidance Paper the term "dangerous substances" will be used as meaning substances, preparations and radioactive substances that may present a danger for man and the environment during normal use of construction products when installed in works.

[6] The Guidance Paper is also aimed at those who write guidelines for European technical approvals.

[7] In this Guidance Paper the term "national provision" will be used, meaning national law, regulation or administrative provision.

In practice it may be difficult to separate the substances related to the wider environmental risks from those affecting the immediate environment of works, and therefore a strict distinction of which risks fall inside or outside the scope of the CPD could be somewhat theoretical (see also paragraph 2.2 below).

2 General principles

2.1 The scope of the CPD, and the link between the CPD and provisions on dangerous substances, can be characterised as follows :

a) Harmonisation introduced by the CPD in relation to dangerous substances falls under essential requirement No.3, Hygiene, Health and the Environment. The requirement is defined, in relation to works, by Annex 1 of the Directive as follows:

"The construction works must be designed and built in such a way that it will not be a threat to the hygiene or health of the occupants or neighbours, in particular as a result of any of the following:
- *the giving off of toxic gas,*
- *the presence of dangerous particles or gases in the air,*
- *the emission of dangerous radiation,*
- *pollution or poisoning of the water or soil,*
- *(...)*

b) The requirement is further defined and developed according to five specific aspects in the Communication of the Commission with regard to the interpretative documents[8] of Directive 89/106/EEC, namely:

Indoor environment;
Water supply;
Wastewater disposal;
Solid waste disposal;
Outdoor environment.

"Other directives relevant to hygiene, health or the environment, for example the protection of workers, must also be taken into account when elaborating technical specifications (...)"

c) In terms of requirements on construction products, the safe disposal of waste does not raise any issues relating to dangerous substances, as covered by this Guidance Paper. Interpretative Document No.3 develops the other relevant aspects above as follows:

[8] OJ No C 62, 28.2.1994, p. 1

Indoor environment: *"(...) The characteristics necessary for satisfactory performance (...) are listed below. Harmonised technical specifications are required to measure these characteristics or to calculate performance where technology permits. (...) Products are those for which emission of pollutants to the indoor air are possible (...). Product characteristics apply to all product families and systems:*

- emission of volatile organic compounds and release of other pollutants, taking account of the concentration of pollutants in the product where necessary,

- (...)

- *radioactive* emissions."

Water supply : *"Harmonised technical specifications are required to specify the following characteristics of construction products:*

a) Material in contact with water[9]

- migration of pollutants (...)"

Outdoor environment : *"(...) To conform with the scope of the Directive this document is restricted to works in use.*

For the other phases of the life cycle, as long as no Community legislation exists it is up to the Member States, with due observance of the Treaty, to take into account the scope of the Directive and, when they deem it necessary, to prescribe requirements affecting construction products in order to limit the deterioration of the environment.
(...)
The requirement is concerned with the protection of people and with the prevention of any impact on the immediate environment by pollution of the air, the soil and the water.
(...)
Technical specifications are required to define the following characteristics :
(...)
- release of pollutants to outdoor air, soil and water, taking account of the concentration of pollutants in the product, where necessary. (...)"

[9] A special European scheme will be elaborated for approval of construction products in contact with water intended for human consumption and therefore this Guidance Paper does not cover these products. Other products used for water supply, i.e. products not in contact with water intended for human consumption, are covered.

2.2 Three general principles can be drawn from the above:

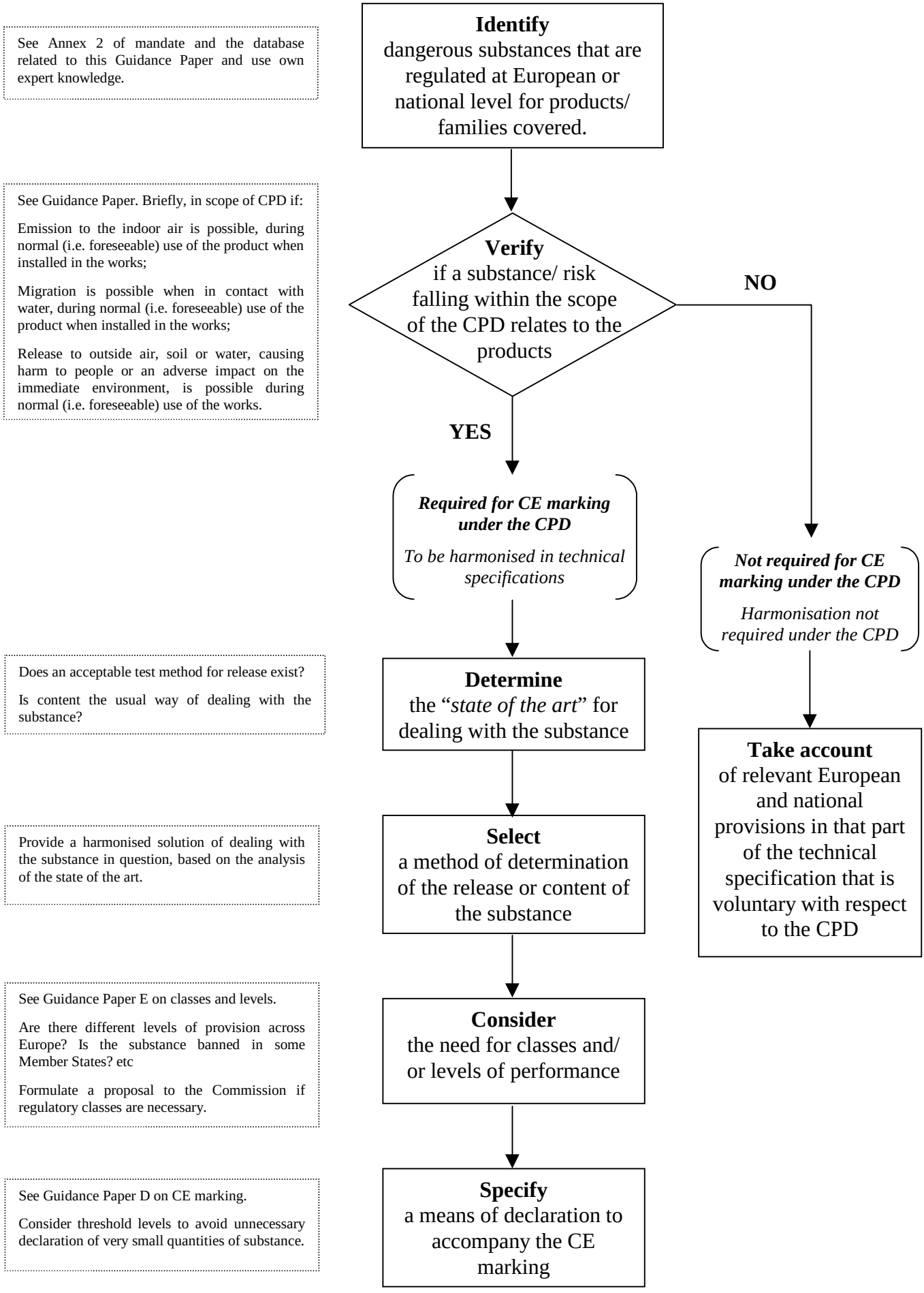
(i) Aside from the protection of people (occupants and neighbours), it is only the immediate environment that falls within the scope of the CPD. Wider environmental aspects, such as destruction of the ozone layer, are not covered. Although the term "immediate" is not defined in the interpretative documents, it can be taken to mean those parts of the environment that are influenced by direct effects of the products or works in question.

(ii) To conform with the scope of the CPD the harmonised approach relating to dangerous substances is limited to "works in use". Other phases in the life cycle of a product, i.e. its excavation or production stages, during the building process, during demolition, waste disposal, incineration or waste reuse (except where reuse is as a construction product in the sense of the CPD) are not considered for harmonisation under the CPD.

In addition, activities such as maintenance, replacement or other construction activities carried out during the normal life of a building might cause dangerous substances to arise from products already installed in the works. These activities are considered to be outside the scope of the CPD. It is the responsibility of the Member States to make procedural provisions if, on the basis of knowledge of the process or product involved, such activities are likely to lead to potentially harmful situations. Of course, any construction products used, for example for replacement, remain within the scope of the CPD.

(iii) The requirement on products is expressed either as emission or migration of dangerous substances or radiation, during normal (i.e. foreseeable) use. It is, therefore, when possible, the release of substances, that is the characteristic to be controlled. However, even if it is not the content of the dangerous substance itself in the product that should be controlled, this might be the only practicable solution (see also paragraph 3.13 below).

3. Guidance for technical specification writers – steps to be taken



Identify regulated dangerous substances of relevance for construction products

3.1 For the CE marking technical specification writers should identify all regulated dangerous substances given in the mandate and/or included in the database related to this Guidance Paper (see Annex 2), that during normal use are necessarily present in products, or a family of products covered by the technical specification. The substances that might be found in a construction product are either in the original constituents used or created in the process of manufacturing. It can be assumed that the specification writers have the best knowledge about this and thus are capable of identifying the substances. The most common substances mentioned in the mandates are asbestos, formaldehyde, cadmium, pentachlorophenol, radioactive substances and heavy metals (e.g. harmful through leaching).

3.2 The database of this Guidance Paper contains as complete a list as possible of dangerous substances of relevance for construction products, currently regulated either at Community level and/or at Member State level. In addition, only new or amended national provisions that will be notified by Member States in the framework of the Directive 98/34/EC[10] will be listed in the future. The Commission services have produced the database in collaboration with the Member States and it will be continuously updated with information on changes in existing provisions and about new ones. To make the information workable a database is the most appropriate tool for listing of substances and the related legislation and it is available for everyone on the Internet site[11] of the Commission.

3.3 The database is informative with the aim of providing support for specification writers, but cannot be considered exhaustive and it does not reproduce the full texts of the directives or other Community or national legislation to which it refers. In order to keep the information up to date Member States are requested to communicate any changes in their national provisions to the Commission. Member States should also, when possible, provide information about their existing methods of determination as well as limit values for the substances they regulate.

3.4 The listed substances in the database are supposed to be relevant for construction products covered by mandates issued under the CPD, but of course not all the substances and quoted legislation apply to every product. The fact that a substance is considered as dangerous does not automatically mean that the product that contains it is also dangerous. If there is a risk of release or content of the substance in the product, this is to be taken into account on solid scientific grounds (see also 3.13). The database lists about 115 substances or groups of substances that are of particular concern for EU/Member States.

3.5 Specification writers must carefully check the accuracy of the information in the database and the relevance for specific construction products since the provisions are often general and the restrictions or bans apply to all products placed on the market. The annex should not be regarded as a “black list” of substances that could not be used at all. It only gives information about the relevant legislation, without any assessment of the risks caused by the specific substances.

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[10] OJ No L 204, 21.7.1998, p. 37

[11] http://europa.eu.int/comm/enterprise/construction/internal/dangsub/dangmain.htm

Verify if a substance that fall within the scope of the CPD relates to the products

3.6 Section 2 of this Guidance Paper describes what is considered to be within the scope of the CPD, and therefore will form part of the CE marking (the exception being that the regulation of the substance is already harmonised at Community level). The dangerous substances are regulated in three different ways to ensure an adequate level of protection for man and the environment. These differences need to be identified by the specification writers because producers are responsible for knowing and complying with all relevant provisions for the products covered by the technical specification.

- Regulated at Community level - Producers always need to satisfy harmonised requirements and meet certain limit values (ranging from restriction to total ban) at Community level regardless of the kind of construction product they manufacture. Thus, it will not be necessary to provide this information with the CE marking, even if it is within the scope of the CPD. The general provisions on substances and the specific product legislation are complementary elements and the first have to be met irrespective of the latter. An example would be the content of all types of asbestos[12], which has been totally banned throughout the Community (however there will be a transitional period of five years).

- Regulated at Community level with national derogation - If the dangerous substances are the subject of harmonised legislation at Community level and national provisions have been allowed to derogate from this, there is a need to provide information with the CE marking since there are different levels of requirements. An example would be the content of cadmium[13] for which some Member States have stricter provisions while others follow the Community requirement.

- National provisions - If the dangerous substances are not the subject of harmonisation at Community level but fall within the scope of the CPD, and there are different levels of requirements and/or different determination methods between Member States, these differences in levels must be taken into account and the methods have to be harmonised. An example would be the release of formaldehyde, which should be declared with the CE marking and treated as described in paragraph 3.10.

3.7 Legislation on dangerous substances may also exist outside the scope of the CPD, either at Community level and/or at national level (as described in 3.6). Although outside the scope of the CPD and not part of the CE marking, technical specification writers should, where appropriate, take this legislation into account since a common approach in this area would be welcomed. Information about such legislation could e.g. for the harmonised standards be included in an informative annex. The technical specification need not repeat the text of the legislation but should make a cross-reference to it. This information will not be required to accompany the CE marking, unless the EC directive in question leads to CE marking in its own right.

Determine the "state of the art"

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12 Commission Directive 1999/77/EC, OJ No L 207, 6.8.1999, p. 18

13 Commission Directive 1999/51/EC, OJ No L 142, 5.6.1999, p. 22

3.8 Specification writers should determine the "state of the art"[14] for the dangerous substances, which have been identified according to the steps described above, regarding test methods or other methods of determination, taking note of descriptive solutions that may be justified.

3.9 The best judges of the present, generally accepted, "state of the art" for the products are the specification writers themselves. Specification writers should make a review of available test methods[15], whether national, European or international and the possibility of using or adapting methods developed by other technical committees or working groups should be thoroughly examined. Where current knowledge or appropriate methods of determination, for example for measuring the release of a substance, are lacking, a pragmatic approach like using the content should be taken, rather than starting to develop new test methods. More or less all substances can be dealt with by declaring either the release or the content.

Select a harmonised method of determination for each dangerous substance

3.10 A performance characteristic for a product relating to dangerous substances has to be taken into account by the technical specification writers. The characteristic should, in principal, be treated in the same manner as any other performance requirement listed in the mandates. That is, it should be subject to a harmonised method of determination, have a prescribed form of declaration to accompany the CE marking, and maintain the use of the "no performance determined" option. However, it is acknowledged that complete harmonisation in this area will not always be possible in the short-term, in which case technical specification writers should apply the "state of the art" principle referred to above.

3.11 As far as possible, available horizontal test methods should be used. If necessary, the harmonised product standard should complement the horizontal method by including provisions on sampling and preparation of specimens.

3.12 The characteristic of the product relating to dangerous substances should preferably be expressed in terms of the release, or emission, of the substance, or radiation. Where practicable, this is how the substance should be assessed, directly or indirectly, in performance terms and the result declared with the CE marking. But, as stated above, this depends on the "state of the art".

3.13 Descriptive solutions, such as limits on the content of the dangerous substance, where a clear relationship between content and release exists in end-use conditions, or the specification of a special surface treatment that prevents release, may be justified if it is not possible (no method), or very expensive, to determine the rate of release or emission of a dangerous substance. However, it is recognised that a relationship between content and release cannot be established for some substances and thus a declaration of content can be acceptable to accompany the CE marking. In particular

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[14] In this context, "state of the art" refers to the current level of knowledge that is generally accepted as being technically sound. It does not mean the most advanced technology.

[15] Where the "state of the art" consists of two or more methods of determination, the instructions given in the mandates for dealing with this type of situation must be followed.

this is applicable for substances and preparations for which there are restrictions on the marketing and use, as laid down in Council Directive 76/769/EEC[16].

3.14 Another descriptive solution would be to check the constituents since it can be assumed that a construction product does not contain or release dangerous substances if all the constituents used have been controlled in this aspect. Several producers of components and suppliers of raw materials may be involved in contributing to the final product. Only the producer who manufactures the specific construction product is responsible for the conformity of the product when it is placed on the market. The producer shall make sure that all applicable requirements on dangerous substances for the components and/or raw materials used have been fulfilled. To control this, the producer could use normal legal contracts between himself and the suppliers. The producer of the final construction product then need not do any further testing, unless the product is modified or the production process causes change.

3.15 Descriptive types of solution are better suited to well known construction products for which experience has been accumulated over a long period of time. The proposed solutions must take account of the intended use(s) of the product. Where entirely descriptive solutions are proposed, compliance with the technical specification will normally indicate that the product meets the required criteria and no further information is required to accompany the CE marking

Consider and define threshold levels and/or propose classes

3.16 Technical specifications must take account of the different required levels of protection existing either in Community legislation or in national provisions. The "zero content" or "substance banned" situations must be dealt with in the specifications when it falls within the scope of the CPD. An example would be the case of pentachlorophenol (PCP), where Community legislation allows it to be included in limited quantities in some products but where some Member States have stricter provisions. For relevant products a declaration on the content (or applicable class) of PCP in the product should accompany the CE marking.

3.17 Specification writers should, where appropriate, define thresholds[17] (or possibly classes) for the levels of emission of dangerous substances or on the content. For example threshold levels for radiation could be fixed in the specifications and if the determined value is below this level, the product is in compliance with the specification and the value does not have to be declared with the CE marking. However, if the determined value is higher than the level, the value needs to be declared. The threshold level could be set at what is considered to be effectively zero, which in this case could be the level of natural radioactivity that is unavoidable and causes no danger to the user of the works.

Specify a means of declaration to accompany the CE marking

3.18 Specification writers should specify a means of declaration to accompany the CE marking[18], if it is not considered to be covered by compliance with the technical

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16 OJ No L 262, 27.9.1976, p. 201

17 See the Guidance Paper E on levels and classes in the CPD for more information.

18 See the Guidance Paper D on CE marking under the CPD for more information.

specification directly, bearing in mind the option of “no performance determined”. The form of presentation of the determined values or a declaration on “zero content” required to accompany the CE marking must be given in the technical specification (see examples below). Technical specifications shall also clearly indicate which actions have to be undertaken by either the notified bodies or by the manufacturer, in relation to the requested level of attestation of conformity as laid down in the relevant Commission decision.

ANNEX 1

Examples

The following examples are indicative and only presented as an illustration of the principles given in this guidance paper. They shall not be regarded as discriminatory towards certain products or be seen as complete for the different dangerous substances of relevance for construction products. The examples do not give prejudice to specific technical specifications.

E.1 **Thermal insulation product** - The technical specification could deal with at least the following for a thermal insulation product (e.g. factory made mineral wool), applying the "state of the art".

Information that has to accompany the CE marking because it falls within the scope of the CPD:
- release of formaldehyde *(to be tested, threshold levels could be used)*
- emission of radioactive substances *(to be tested, threshold levels could be used).*

Optional information that could be presented in an informative annex of the standard because it is considered to be outside the scope of the CPD:
- information about which countries regulate on release of fibres (could include descriptive specifications of acceptable methods of sealing or providing barriers to prevent emissions of particles and fibres and other substances from the surface or on design and installation)
- information about the handling of the product, e.g. related to worker safety, like Commission Directive 97/69/EC[19] adapting to technical progress for the 23rd time Council Directive 67/548/EEC[20] on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. This Directive lays down that certain man-made vitreous (silicate) fibres have carcinogenic effects and therefore an identification, classification and labelling of these fibres should be made. However, the classification as a carcinogen need not apply if it can be shown that the substance fulfils the conditions given in the Directive.

E.2 **Wood-based panel** - The following is a proposal for the product standard on wood-based panels in which it could be possible to make use of a level for the release of formaldehyde that effectively creates two classes (above and below a level). The class then has to be stated with the CE marking (the classes A and B are for example only):

"Where formaldehyde is added to the product as a part of the production procedure, the subsequent release of formaldehyde shall be assessed by testing to ENV 717-1 and the results shall be classified as follows:
A - emission of 0.1 ppm or less
B - emission of > 0.1 ppm
This requirement does not apply to products having naturally occurring levels of formaldehyde, which may be classified A without the need for testing.

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[19] OJ No L 343, 13.12.1997, p. 19
[20] OJ No 196, 16.8.1967, p. 1

Once initial classification has been obtained by testing to ENV 717-1, routine control of the production may be by any test method shown to correlate, for the product in question, with ENV 717-1."

E.3 **Radioactivity in construction products** – Radioactive substances occur naturally in many materials used also for construction products (e.g. aggregates and natural stone tiles) but radiation can also come from artificial sources (e.g. industrial by-products and incinerator residues) and contaminated materials. The concentration of different radionuclides should be measured (Bq/kg) and the "activity concentration index" calculated. The calculated value should be declared with the CE marking only when the value is above a threshold given in the specification. The threshold could for example be the same as the gamma dose present in the earth's crust, which would mean, "effectively zero" (some thresholds for natural radioactivity have been presented in a guidance developed by an expert group established under the terms of Article 31 of the Euratom Treaty). The risk for higher concentrations of radionuclides mainly exists when for example certain constituents are added to the products. The declared value will make it possible for regulators/designers to estimate the annual effective dose of radiation (mSv) and thus see if the regulatory requirements on the works can be met.

E.4 **Timber products (treated)** - A declaration about the content of pentachlorophenol (PCP) used in wood preservatives should accompany the CE marking because it falls within the scope of CPD and different levels of requirements exist.

- *EU legislation*: PCP shall not be used in a concentration equal to or greater than 0,1% by mass in substances or preparations placed on the market,

- *National derogation legislation*: e.g. Germany prohibits preparations containing more than 0,01% of pentachlorophenol and products treated with these preparations must not contain more than 5 mg/kg (parts per million – ppm). The Netherlands has completely prohibited the use of PCP in the treatment of wood and textiles.

E.5 **Flooring products and wall coverings** - measurement of emissions can be done, and thus a value can be declared by using ENV 13419 part 1-3 which gives a general harmonised method (part 1-2) for the determination of volatile organic compounds (VOC) from construction products. Part 3 ("Procedure for sampling, storage of samples and preparation of test specimens") of the standard contains annexes for different products and in the future more annexes will be included with the assistance of the product technical committees. Instead of developing specific product/material test methods for measuring emission, references should be made to this horizontal method.

However, the declared emission value might be meaningless since it seems that no Member State has regulations related to VOCs and no limit values have been set in national provisions. Nevertheless, on a voluntary basis due to market request, the information could be useful for different parties involved in the construction process when evaluating the impact certain products may have on the indoor air quality. It could also be a tool for promoting development of improved products.

ANNEX 2

The Commission services have set up a database with information about dangerous substances and applicable national and EU legislation. This way of presenting the information is aiming at making it as user friendly as possible and it also provides an easy tool to keep it up to date. The database is accessible through the Internet, i.e. the construction site (http://europa.eu.int/comm/enterprise/construction/internal/dangsub/dangmain.htm). This means that this Guidance Paper will contain a "living" annex, in the form of a database, which can easily be adapted to changes.

All interested parties are asked to continuously give their comments on the content of the database.