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Embalaža – Zahteve za merjenje in overjanje štirih težkih kovin in drugih nevarnih snovi v embalaži ter njihov izpust v okolje - 2. del: Zahteve za merjenje in overjanje nevarnih snovi v embalaži ter njihov izpust v okolje

Packaging - Requirements for measuring and verifying the four heavy metals and other dangerous substances present in packaging, and their release into the environment - Part 2: Requirements for measuring and verifying dangerous substances present in packaging, and their release into the environment

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Verpackung - Anforderungen zur Messung und Feststellung der vier Schwermetalle und anderen gefährlichen Substanzen in Verpackungen und deren Freisetzung in die Umwelt - Teil 2: Anforderungen zur Messung und Feststellung von gefährlichen Substanzen in Verpackungen und deren Freisetzung in die Umwelt

Emballages - Exigences pour la mesure et la vérification des quatre métaux lourds et autres substances dangereuses présents dans l'emballage, et leur cession dans l'environnement - Partie 2: Exigences pour la mesure et la vérification des substances dangereuses présentes dans l'emballage, et leur cession dans l'environnement

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Foreword

This document (CEN/TR 13695-2:2004) has been prepared by Technical Committee CEN/TC 261 "Packaging", the secretariat of which is held by AFNOR.

This document supersedes CR 13695-2:2002.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directives, see informative Annex B, which is an integral part of this document.

This Technical Report forms one of a series of standards and reports prepared under Mandate M/200 rev.3 and the Second Standardisation Mandate M/317 given to CEN by the European Commission and the European Free Trade Association to support the European Parliament and Council Directive on Packaging and Packaging Waste [94/62/EC]. The procedure for applying this Technical Report in conjunction with the other mandated standards and reports is specified in EN 13427.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Report: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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Introduction

The European Commission gave a mandate to CEN for promoting the preparation of European Standards and CEN Reports in order to support the application of the Directive 94/62/EC of 20 December 1994, on Packaging and Packaging Waste, in particular to elaborate a CEN Report 'Requirements for measuring and verifying heavy metals and other dangerous substances present in packaging, and their release into the environment'.

NOTE The Directive 94/62/EC is amended by European Parliament and Council Directive 2004/12/EC of 11 February 2004

Part 1 of the CEN Report 'Requirements for measuring and verifying the four heavy metals present in packaging, and their release into the environment' has been previously released, (CR 13695-1) due to the priority given in Article 11(1) of the Directive to the four heavy metals explicitly mentioned: Lead, Cadmium, Mercury and Chromium VI.

This document is Part 2 to the CEN Report CR 13695 related to other dangerous substances. It refers to the end-of-life treatment of packaging by incineration or landfilling.

The task of the working group WG 8 'Heavy metals and other dangerous substances' had been attributed by a resolution of CEN TC 261/SC 4:

Have been considered for the development of this work:

- the existing European or national regulations (Directives);
- the CEN standardisation on waste TC 292;
- the OECD environment monograph series.

A detailed information on the regulatory context is given in Annex B; however this work is expected to be compatible with any further evolution of the related regulation, as it is independent of any specific case.

With regard to the number and diversity of substances, which may be considered as dangerous to the environment, there are no currently available general standardised methods for the systematic measurements of their presence in emissions, ash or leachate, when packaging or residues from management operations or packaging waste are incinerated or landfilled. The task of elaborating specific standardised methods for each substance and applicable in each practical case would be extremely complex and time consuming. This is the reason why a methodology to estimate or calculate these substances based on the use of Safety Data Sheets (according to Directive 91/155/EEC) has been developed.

A simple and efficient assessment method suitable for small and medium sized suppliers of packaging is proposed, based preferentially on an upstream approach (CR 13695-1, 8.1).

Guidelines are provided to identify and minimise dangerous substances and a methodology is proposed to assess the compliance with the requirements of the Directive.

1 Scope

This document specifies the methodology and procedure for determining the presence and minimisation of other dangerous substances in relation with Annex II Para 1 Indent 3 of Directive 94/62/EC. This document is intended to be of practical use, and to enable efficient application of the Directive 94/62/EC, even for small and medium sized companies in the packaging industry, providing them with a methodology for assessing compliance with the Directive.

This document cannot by itself provide presumption of conformity. The procedure for applying this document is contained in EN 13427.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 13193:2000, *Packaging – Packaging and the environment – Terminology*.

EN 13428, *Packaging – Requirements specific to manufacturing and composition – Prevention by source reduction*.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 13193:2000 and Article 3 of Directive 94/62/EC and the following apply.

3.1

substances

chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product, and any impurity deriving from the production process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition

NOTE A substance may be chemically very well defined (e.g. acetone) or a complex mixture of constituents of variable composition (e.g. aromatic distillates). For certain complex substances, some individual constituents have been identified

[Directive 67/548/EEC as amended by 2001/59/EC Annex VI, paragraph 1.7.1]

3.2

preparations

mixtures or solutions composed of two or more substances

[Directive 67/548/EEC]

3.3

safety data sheet

documentation provided by any person established within the community who is responsible for placing a dangerous substance or preparation on the market, whether the manufacturer, importer or distributor

NOTE The Directive requires that documentation to be provided to any recipient who is an industrial user of the substance or preparation and to contain the information required of the dangerous substance or preparation

[taken from Article 1(1) of Directive 91/155/EEC as amended by Directive 2001/58/EC]

CEN/TR 13695-2:2004 (E)**3.4****packaging component**

part of packaging that can be separated by hand or by using simple physical means

[EN 13193:2000]

3.5**packaging constituent**

part from which packaging or its components are made and which cannot be separated by hand or by using simple physical means

[EN 13193:2000]

4 The packaging and packaging waste Directive 94/62/EC requirements

4.1 The Packaging and Packaging Waste Directive 94/62/EC explains in the 21st recital of the preamble that:

"the presence of noxious metals and other substances in packaging should be limited in view of their environmental impact (in particular in the light of their likely presence in emissions or ash when packaging is incinerated or in leachate when packaging is landfilled)".

4.2 Article 1 of the Packaging and Packaging Waste Directive 94/62/EC requires the responsible body to:

"prevent any impact on the environment (...) or to reduce such impact, thus providing a high level of environmental protection".

4.3 Article 10 refers to Standardisation:

"in particular relating to <http://standards.iteh.ai>, the methods for measuring and verifying the presence of heavy metals and other dangerous substances in the packaging and their release into the environment from packaging and packaging waste".

4.4 Annex II, paragraph 1, requires that:

"packaging shall be designed, produced and commercialised in such a way as to permit its reuse or recovery, including recycling, and to minimise its impact on the environment when packaging waste or residues from packaging management operations are disposed of".

4.5 In addition Annex II, paragraph 1, requires that :

"packaging shall be so manufactured, that the presence of noxious and other hazardous substances and materials as constituents of the packaging material or of any of the packaging components is minimised with regard to their presence in emissions, ash or leachate when packaging or residues from management operations or packaging waste are incinerated or landfilled".

5 Subsequent Directives to be taken in account**5.1 The Incineration Directives**

Directives 94/67/EC and 2000/76/EC on the incineration of waste are regulating the Municipal Solid Waste (MSW) incinerators which are equipped to meet the technical and environmental requirements for emissions. The residues from incineration are also subject to regulations.

5.2 The Directive on the landfill of waste

More generally, Directive 1999/31/EC on the landfill of waste was adopted on 26 April 1999 (OJ of 16/07/1999), focused on a high level of environmental protection. New requirements have been introduced for the reduction of the landfilling of biodegradable waste. This Directive states also that:

- hazardous waste that fulfils defined criteria can only be assigned to landfill for hazardous waste;
- landfill for non-hazardous waste may be used for the disposal of municipal and non-hazardous waste;
- non-hazardous waste is defined as not being covered by the definition given in Article 1 (4) of Council Directive 91/689/EEC of 12 December 1991 on hazardous waste. They should not appear on the list annexed to the Commission Decision 2000/532/EC of 3 May 2000 amended by Commission Decision 2001/118/EC of 16 January 2001, or if so not have one or more of the properties listed in Annex III to Directive 91/689/EEC.

6 Summary of the present situation in industry

6.1 The working group has not been able to identify current examples where packaging materials or components of packaging produced in the EU present a risk to the environment due to the presence of dangerous substances in use or after use.

One reason is that substances that are dangerous to the environment might be dangerous in other respects as well, e.g. for the health and safety of consumers. In Article 2 of the Directive 94/62/EC, the importance of safety, the protection of health and the hygiene of the packed products are emphasised. A possible consequence of this may be that considerations related to health and safety have already had the effect of minimising or even eliminating the use of this kind of substances in packaging.

6.2 With regard to the number and diversity of substances that may be considered as dangerous to the environment, simplified lists of such substances by relating to specific industrial sectors could be useful. Such lists would facilitate the identification of the substances dangerous to the environment, relevant for a given packaging supplier, especially for small and medium sized companies.

As a first step an enquiry was carried out in order to obtain detailed information on:

- which substances dangerous for the environment may be present in packaging or packaging components;
- their usual concentration or range of concentrations;
- their functional use in case of intentional introduction.

Feedback received from industry indicated that in practice the use of Safety Data Sheets instead of using simplified lists could be more helpful especially for small and medium sized companies to identify noxious or dangerous substances present in packaging.

7 Identification and minimisation of dangerous substances in packaging

7.1 General principle

The individual or organisation responsible for placing a specific packaging on the market shall be able to demonstrate that only the minimum adequate amount of any dangerous substance or preparation has been used in the packaging or packaging component, with regard to its presence in emissions, ash or leachate from landfills.

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7.2 Identification

7.2.1 The 'Upstream Approach' as the basic principle

A simple and efficient assessment method for the identification of dangerous substances in packaging and packaging materials, especially suitable for small and medium sized suppliers of packaging, is needed. This document proposes the 'upstream approach' as elaborated in CR 13695-1:2000, 8.1 for this purpose.

The upstream verification in the sense of EN ISO 9000:2000 should be traceable by means of information from the suppliers of raw materials or constituents. This document proposes – as a result of the above mentioned enquiry (see Clause 6) – the consultation of the relevant Safety Data Sheets which provide enough information to assess compliance with the Directive 94/62/EC.

7.2.2 The Identification procedure

7.2.2.1 For the purpose of the assessment procedure, 'dangerous substances' or 'noxious and other hazardous substances' are defined as:

- any substances classified as **dangerous to the environment** according to Directive 67/548/EEC (Dangerous Substances Directive) and its amendments **and classified with the symbol N and the corresponding indication of danger** (with the exception of lead, cadmium, mercury and chromium (VI) and their compounds already considered in CR 13695-1).

NOTE This is a general list of substances dangerous to the environment and cannot be taken as specifically relating to substances used in packaging.

7.2.2.2 For the purpose of identification the packaging manufacturer should consult the relevant Safety Data Sheets which he receives from his supplier. The Safety Data Sheets provide necessary information on dangerous substances or preparations and enable the packaging manufacturer to verify the presence of dangerous substances or preparations in his packaging (see 7.2.3.3).

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7.2.3 The use of Safety Data Sheets for determination of presence of dangerous substances and preparations

7.2.3.1 A Safety Data Sheet is documentation provided by any person established within the Community who is responsible for placing a dangerous substance or preparation on the market, whether the manufacturer, importer or distributor. The safety data sheet information is principally intended for use by professional users and shall enable them to take the necessary measures as regards the protection of health, safety and the environment at the place of work. The safety data sheet may be supplied on paper or electronically.

7.2.3.2 The safety data sheet contains 16 obligatory headings. Information on the composition of a preparation of dangerous substances is given in heading 2. Heading 12 (ecotoxicology) requires the description of the most important characteristic likely to have an effect on the environment due to the nature of the substance or preparation and likely methods of use. Information of the same kind shall be supplied for dangerous products arising from the degradation of substances or preparations.

7.2.3.3 For the purpose of identification and verifying the presence of substances or preparations dangerous to the environment (assigned with the symbol "N") the packaging manufacturer should receive from his supplier of dangerous substances or preparations a Safety Data Sheet according to Directive 91/155/EEC and its amendments (the present last amendment is Directive 2001/58/EC).

The heading 2 "composition/information on ingredients" should indicate the concentration or concentration range of substances presenting an environmental hazard within the meaning of Directive 67/548/EEC if they are present in concentrations equal to or greater than those laid down in the table set out in Article 3(3) of Directive 1999/45/EC (unless lower limits are given in Annex I to Directive 67/548/EEC or in Annexes II, III or V to Directive 1999/45/EC)".

The packaging manufacturers can calculate and so measure the presence of dangerous substances in his packaging on the basis of information associated with the packaging formulation and manufacturing process.

NOTE More detailed information on the current regulation of dangerous substances and preparations and on safety data sheets are given in Annex B and Annex C of this document.

7.3 Release to the environment

7.3.1 The presence of dangerous substances in constituents of the packaging material, or in any of the packaging components, has to be minimised with regard to their presence in emissions, ash or leachate, when packaging or residues from management operations or packaging waste are incinerated or landfilled.

7.3.2 For the purpose of identification, only dangerous substances assigned with the symbol N that are likely to be released into the environment have to be considered.

7.3.3 With regard to the number and diversity of substances, which may be considered as dangerous to the environment, there are no currently available general standardised method for the systematic measurement of their presence in, emissions, ash or leachate, when packaging or residues from management operations or packaging waste are incinerated or landfilled.

The task of elaborating specific standardised methods for each substance and applicable in each practical case can be extremely complex.

Nevertheless, it can be possible in some cases to demonstrate with sound evidence that even when a substance dangerous to the environment is present in the constituents, there is no risk of it being ultimately released to the environment.

Examples can be dangerous substances of organic chemical nature, which are destroyed by very high temperatures or combustion processes. The risk of leaching into landfills can also be related to the chemical or physical nature of the material considered.

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7.4 Minimisation

7.4.1 If a constituent is identified to contain substances dangerous to the environment which are likely to be released into the environment, then the principle of using only a minimum adequate amount of these substances should be applied.

7.4.2 The principle of using the minimum adequate amount has to be established in relation to the functional performances or purposes of the substance being used.

The criteria listed in the EN 13428 standard, 'Packaging – Requirements specific to manufacturing and composition - Prevention by source reduction' shall be applicable to describe fitness for functional performance or purpose.

8 Basis for a proposed new standard for presuming compliance with Annex II, paragraph 1, indent 3 of Directive 94/62/EC

8.1 The principle

The individual or organisation responsible for placing a specific packaging on the market ('packaging supplier') shall be able to demonstrate that only the minimum adequate amount of any substance dangerous to the environment has been used as a constituent of the packaging material or any of the packaging components, with regard to its presence in emissions, ash or leachate from landfills. The steps taken in order to determine and demonstrate minimisation are explained below and are shown in the decision tree detailed in the informative Annex A.

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8.2 Determination of substances to be considered for minimisation

8.2.1 The packaging supplier shall first determine if any substance or preparation classified as dangerous to the environment and assigned with the symbol 'N' used in the manufacturing process of the packaging and/or packaging components is present in the packaging placed on the market. This determination shall be made using the Safety Data Sheets for the relevant substance or preparation as so classified in the EC Directives - Dangerous Substance Directive 67/548/EEC (and its amendments) and the Dangerous Preparation Directive 1999/45/EC.

If no such substances or preparations have been identified the procedure is concluded. In this case proceed to 8.3.1.

If such substances or preparations are present, proceed to 8.2.2.

8.2.2 The packaging supplier shall evaluate the possibility that any of the substances or preparations identified in 8.2.1 are likely to be present in emissions, ash or leachate resulting from incineration or landfilling of the packaging or the packaging components after it has been used for its purpose as a packaging.

- If the substances or preparations identified are not likely to be released in emissions, ash or leachate, the procedure is concluded. In this case consideration of the substances or preparations for minimisation is not applicable. Proceed to 8.3.1;
- if any substance or preparation identified is likely to be released in ash, emission or leachate, the packaging supplier has to demonstrate conformity with the minimisation requirement and shall proceed to Clause 8.3.2.

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8.3 Conformity with the minimisation requirement

8.3.1 If no substance or preparation as so classified as dangerous to the environment and assigned with the symbol 'N' has been identified and/or is unlikely to be present in emissions, ash or leachate, the packaging component conforms with the requirements of Annex II of the Directive 94/62/EC. A record of the data shall be retained.

8.3.2 If a substance or preparation dangerous to the environment and assigned with the symbol N has been identified according to the procedure described in 8.2, conformity with the minimisation requirement in Annex II of Directive 94/62/EC must be demonstrated.

For this purpose the packaging supplier shall:

- document the relevant substances identified in 8.2.1 and 8.2.2; and
- document that only the minimum adequate amount of the relevant substances has been used with regard to their functional purpose. For the assessment, the method and the performance criteria, described in EN 13428 standard 'Packaging - Requirements specific to manufacturing and composition - Prevention by source reduction' are applicable.

9 Conclusions

To assess compliance with the relevant requirements of the Directive 94/62/EC, guidelines are provided to identify and measure dangerous substances.