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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

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

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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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This draft Technical Report is submitted to CEN members for Vote. It has been drawn up by the Technical Committee CEN/TC 261.

SIST-TP CEN/TR 13695-2:2019

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (FprCEN/TR 13695-2:2018) has been prepared by Technical Committee CEN/TC 261 “Packaging”, the secretariat of which is held by AFNOR.

This document is currently submitted to the Vote on TR.

This document will supersede CEN/TR 13695-2:2004.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

For Information on current regulation, see informative Annex B.

This document forms one of a series of standards and reports prepared under Mandate M/200 rev.3 and the Second Standardization 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 document in conjunction with the other mandated standards and reports is specified in EN 13427.

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SIST-TP CEN/TR 13695-2:2019

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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 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/TR / CR 13695 series 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.

The following elements were considered for the development of this work:

- the existing European or national regulations (Directives);
- the CEN standardization on waste (CEN/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 standardized 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 standardized 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 13695-1:2000, 8.1).

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

Since the publication of the previous edition of this document in 2004 a new chemicals regulation has been introduced within the community (REACH, Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals). Also, an adaptation to the Global Harmonized System (GHS) of Classification and Labelling of Chemicals has been made (CLP, Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures) repealing Directive 67/548/EEC (Dangerous Substances) and Directive 1999/45/EC (Dangerous Preparations). The REACH and CLP legislations now in force use different terminology and description of hazard statements compared to what is used in this document and in the connected standard EN 13428.

Due to the lack of mandate for a complete and joint update of the two documents reflecting the changed legislation, instead this document has been amended with minimum necessary explanatory text to be able to follow the assessment method. The amended document provides a “translation key” allowing for continued understanding and use of both FprCEN/TR 13695-2 and EN 13428.

Key differences relevant for the understanding and use of this document and EN 13428 are summarized in the table below. Throughout the report text ‘Notes’ are used to highlight differences in terminology, hazard descriptions and labelling criteria in the legislation now in force compared to what is used in FprCEN/TR 13695-2 and EN 13428.

Table 1 — Key differences in chemicals legislation, terminology and description of labelling criteria relevant for CEN/TR 13695-2 and EN 13428

CEN/TR 13695-2:2004 and EN 13428:2004	FprCEN/TR 13695-2:2018
Repealed Directives: Directive 67/548/EEC (Dangerous Substances) and Directive 1999/45/EC (Dangerous Preparations)	Replaced by: REACH, Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals) and CLP, Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
Term ‘Dangerous’	Replaced by term ‘Hazardous’
Term ‘Preparation’	Replaced by term ‘Mixture’
Criteria for identification of ‘noxious and other hazardous substances’: Any substances classified as dangerous to the environment and assigned with the symbol N and corresponding indication of danger ^a	Recommended interpretation: ‘Meet the criteria of labelling with the environmental hazard pictogram’
^a Classification criteria for labelling with the dangerous to the Environment pictogram.	

FprCEN/TR 13695-2:2018 (E)**1 Scope**

This document specifies the methodology and procedure for determining the presence and minimization 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 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 documents are referred to in the text in such a way that some or all of their content constitutes requirements 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*

CR 13695-1:2000, *Packaging - Requirements for measuring and verifying the four heavy metals and other dangerous substances present in packaging and their release into the environment - Part 1 : Requirements for measuring and verifying the four heavy metals present in packaging*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 13193:2000 and the following apply.

NOTE See the definitions in Article 3 of Directive 94/62/EC.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

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 1 to entry: 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.

[SOURCE: 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

[SOURCE: Directive 67/548/EEC]

Note 1 to entry: Regulation (EC) No 1907/2006 and Regulation (EC) No 1272/2008 (REACH and CLP) replacing Directive 67/548/EEC use the term mixtures.

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 1 to entry: 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.

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

3.4

packaging component

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

[SOURCE: EN 13193:2000, 3.1.1]

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

[SOURCE: EN 13193:2000, 3.1.2]

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 Standardization:

“in particular relating to (...), 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 commercialized in such a way as to permit its reuse or recovery, including recycling, and to minimize its impact on the environment when packaging waste or residues from packaging management operations are disposed of”.

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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 minimized 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 Directive 94/62/EC, the importance of safety, the protection of health and the hygiene of the packed products is emphasized. A possible consequence of this may be that considerations related to health and safety have already had the effect of minimizing 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 minimization of dangerous substances in packaging

7.1 General principle

The individual or organization 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.

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 9000:2015 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 1 This is a general list of substances dangerous to the environment and cannot be taken as specifically relating to substances used in packaging.

NOTE 2 N-classification as an indication for danger and criteria for labelling with Dangerous for the Environment pictogram does not exist in Regulation (EC) No 1907/2006 and Regulation (EC) No 1272/2008 (REACH and CLP) replacing 67/548/EEC. Recommended interpretation:

- any substances classified as hazardous to the environment and meeting the criteria of labelling with the environmental hazard pictogram according to Regulation (EC) No 1907/2006 and Regulation (EC) No 1272/2008 (REACH and CLP), (with the exception of lead, cadmium, mercury and chromium (VI) and their compounds already considered in CR 13695-1).

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).